American Society of Transplant Surgeons

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February 8, 2012

Mario Checchia
Contract Specialist
Health Resources and Services Administration
5600 Fishers Lane, Room 13A-43
Rockville, MD 20857

Re: Solicitation Number: RFI-HHSH2012-DCS1: Request for Information Concerning the Contract for the Operation of the Organ Procurement and Transplantation Network (OPTN)

Dear Mr. Checcia,

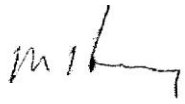
On behalf of the American Society of Transplant Surgeons (ASTS), I am writing to you with regard to the Health Resources and Services Administration (HRSA) Request for Information (RFI) soliciting public comments on a future proposal to operate the Organ Procurement and Transplantation Network (OPTN) (Solicitation Number: RFI-HHSH2012-DCS1) . The ASTS is comprised of over 1900 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.

The RFI solicits comments about whether any changes should be made to the statement of work (SOW) to enhance or improve existing processes and operations of the OPTN. More specifically, HRSA is seeking comments on the effectiveness of the scope of the current contract in supporting the operation of the OPTN and in meeting the needs of the patients that are served by the system; whether certain new provisions should be added to the OPTN SOW; and on whether or not the operation of the OPTN would be improved if certain tasks or elements of tasks were done by entities under subcontract with the prime OPTN contractor.

ASTS is pleased to offer the enclosed comments and observations with respect to the RFI. We look forward to continuing to work with HRSA to improve OPTN's effectiveness and efficiency to allow the contractor to better meet its statutory goal of increasing the number of organ donors and the number of available organs for transplantation through research and through identification, dissemination and implementation of best practices.

ASTS stands ready to provide additional input as needed and invites you to contact ASTS Executive Director, Kim Gifford, via email, *kim.gifford@asts.org*, or phone, 703-414-7870, if we can be of further assistance.

Sincerely,



Mitchell L. Henry, MD
President

I. Effectiveness of the Current OPTN Contract

We believe that the OPTN is severely underfunded in light of the significant growth in OPTN responsibilities and activities in recent years. Over the years, the duties and responsibilities of the OPTN in the regulation of transplantation have grown exponentially, to a large extent through the addition of unfunded mandates such as oversight of living donor transplantation and increased emphasis on patient safety issues. Currently, federal funding of the OPTN covers only approximately ten percent of the current contractor's operating costs and the remaining ninety percent of OPTN expenses are covered through a group of registration fees, which in sum amount to over $700 per newly added transplant candidate. These registration fees, which have increased 31% since 2005, have important financial implications for transplant centers and patients. Under these circumstances, we believe that HRSA should conduct an in-depth review of the current scope of work, and eliminate or fund separately those activities that are not central to the OPTN's statutory functions. New or expanded functions and activities should not be added unless a funding source is identified, and activities that duplicate those of other agencies or private entities should be eliminated.

We urge HRSA to take a fresh look at the OPTN SOW and to focus OPTN activities on its statutory mandate. The National Organ Transplant Act (NOTA) sets forth the responsibilities of the OPTN as follows:

- Establish in one location or through regional centers-(i) a national list of individuals who need organs, and (ii) a national system… to match organs and individuals included in the list;
- Maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list;

- Assist organ procurement organizations in the distribution of organs which cannot be placed within the service areas of the organizations;
- Adopt and use standards of quality for the acquisition and transportation of donated organs;
- Prepare and distribute samples of blood sera . . . to facilitate matching;
- Coordinate the transportation of organs from OPOs to transplant centers;
- Provide information to physicians and other health professionals regarding organ donation; and
- Collect, analyze, and publish data concerning organ donation and transplants.

We suggest that HRSA refocus the OPTN SOW on the OPTN's statutory responsibilities to the extent practicable. We note that the $3.5 million appropriated by Congress for the OPTN was determined based on this statutory statement of work. We believe that, to the extent that the OPTN is required to conduct additional activities, such activities should be included in a separate contract and should be separately funded at a level sufficient to cover the additional costs involved.

We further recommend that HRSA review and revise the provisions of the OPTN contract relating to the funding of the OPTN. Since the overwhelming majority of the OPTN contractor's revenues are derived from registration fees, the OPTN has a strong economic incentive to maximize the number of potential recipients added to the waiting list. This has the inevitable consequence of reducing the efficiency of the OPTN. We urge HRSA to consider alternatives that are better designed to maximize OPTN efficiency and to align the OPTN's incentives with those of the transplant community and patients. As an example, a component of the registration fees could be made available to the OPTN only if and when a listed candidate receives an organ.

The costs of performing any activity unrelated to the core functions set forth in the statute should not be funded by fees levied on patients but by other revenue sources that are more transparent and provide incentives for efficiency.

We believe that considerable additional efficiency could be achieved through streamlining the OPTN Board and staff and we strongly encourage HRSA to include provisions related to efficient Board and staff operations in the new contract. The board composition sets forth a mechanism that precludes more than 50% representation from transplant surgeons and physicians. It also allows for 25% representation from transplant candidates, recipients, living donors, donor families and the public at large. While this board structure allows for diversity of thought, it is not necessarily aligned with the statutory goals of increasing the number of organs donors and the number of available organs for transplantation through research and through identification, dissemination and implementation of best practices. Nor does it ensure that policy decisions will best serve the medical needs of patients. Instead, the process makes too little use of physician and medical society input at the "front end" of policy goal-setting and development, which markedly increases costs, results in unnecessarily lengthy delays in the formulation and implementation of policy revisions, and complicates committee deliberations by obfuscating critical clinical issues.

A solution to this form of ineffective policymaking lies within the Rockville Policy Development Discussions document (Rockville Agreement) dated April 9, 2010. Representatives from ASTS, AST, NATCO, OPTN/UNOS and HRSA developed a new process for incorporating clinical input into developing policies with the potential to direct or prescribe medical care. There was agreement that early involvement of the Societies was an important advance that would allow policies to be developed in a timelier manner that would foster acceptance by the

transplant community at large. This process was piloted with the Joint Societies Working Group (JSWG) to review living donor requirements. Many lessons were learned through this process to provide for greater efficiency moving forward. ASTS suggests that the Rockville Agreement be restored and enforced, including the requirement for quarterly conference calls to review the current and planned policy agenda and determine when a JSWG should be convened.

By restoring and enforcing the Rockville Agreement, OPTN could ensure that policies with the potential to impact patient medical care would follow best practices. It is critical to reinstate the primary role of transplant professionals in the development of policy yet retain an appropriate mechanism for lay input.

The new contract should address Information Technology (IT) issues in considerable detail. The current contract does not provide sufficient resources dedicated specifically to IT; yet, almost all of the OPTN core functions are dependent on the quality and reliability of the OPTN's IT capabilities. The OPTN continues to invest large amounts of time and resources into developing policies that are subsequently stalled before implementation because they cannot be incorporated into the IT systems in a timely manner.

The lack of appropriate financial support for IT has driven the current OPTN to develop and launch for-profit subsidiaries to develop the necessary software and systems, which it also appears to be utilizing for non-OPTN purposes. We believe that the government should own the IT software that is developed for national organ allocation purposes, and that any use of such software for non-OPTN purposes should be subject to license fees that offset other OPTN costs and reduce registration fees. Additionally, the primary contractor, or subcontractor, must be held to a standard that requires the implementation of new organ allocation policies into the IT system within a prescribed amount of time after board approval.

Finally, we are concerned that there is currently a lack of transparency and separation between UNOS and the OPTN: It is unclear which of the various UNOS functions are related to the operation of the OPTN and which are related to separate contracts and private UNOS endeavors. Moreover, since $92 (12.6%) of each registration fee paid by transplant centers is related to membership in UNOS, rather than for membership in the OPTN, we urge HRSA to insist on greater transparency to transplant providers and patients in the new OPTN contract and to include contract provisions that clearly specify the role, responsibilities and expertise of all staff.

II. Proposed Areas of New or Expanded OPTN Responsibility

The RFI solicits comments on whether the OPTN scope of work should be extended into a number of new or expanded areas, in particular:

- Kidney Paired Donation
- Public involvement in OPTN policy-making
- Policy compliance and monitoring for recipient and living donor safety and disease transmission
- Role in educating the community and public on safety and disease transmission information
- Expand research capacity to inform policy development
- Increase ability of data system to improve organ allocation

Of these potential areas for new or expanded responsibility, it is our opinion that no additional provisions should be included without additional resources. We have provided input on the six areas for potential new or expanded provisions listed in the RFI and note the absence of vascularized composite allografts (VCA) from this list. Given HRSA's proposal to place

VCA under the purview of OPTN, we believe this is worthy of comment. The inclusion of VCA under the auspices of OPTN will provide common safety standards consistent with the existing practice of organ transplantation. The public transparency through this mechanism is necessary for the field in terms of the development of an effective and efficient allocation policy that provides maximum benefit to patients and society. However, to develop and implement the systems required to facilitate VCA allocation on a national level will require additional resources beyond the current SOW.

1. **Kidney Paired Donation**: There is a consensus conference scheduled to be held in Herndon, VA, on March 29-30, 2012. We propose that HRSA delay any change to the OPTN role in Kidney Paired Donation until the conference proceedings are published.
2. **Public involvement in the OPTN policy-making process**: In our view, the current public comment system already significantly hampers the efficient operation of the OPTN. Each new OPTN policy is subject to public comment, and each of the relevant OPTN committees and staff dedicate substantial time to responding individually to each comment submitted by the "public", often in response to mass mailings by advocacy groups with narrow agendas. This process has typically resulted in delays of 15 months or more in the revision or adoption of OPTN policies (not even factoring in the delays added by IT backlogs) which could and should be adopted much more quickly, in the interests of transplant recipients and donors. In addition, the current OPTN Board includes members of the public who generally are not—and cannot be expected to be—expert in the highly medical and technical areas addressed by many OPTN policies. Further expansion of public involvement in OPTN policymaking would be counterproductive. In fact, we would urge HRSA to consider including in the new OPTN

scope of work a requirement that it review its processes for soliciting and incorporating public input into its policies, and direct the OPTN to modify those processes to increase the efficiency of OPTN policymaking to specifically incorporate the provisions of the Rockville agreement.

3. **Policy compliance and monitoring for transplant recipient and living donor safety and disease transmissions**: We do not believe that the OPTN involvement in policy compliance and monitoring should be expanded. Instead, the OPTN role in this area should be re-evaluated and restructured to avoid duplication of functions between the OPTN and the Centers for Medicare & Medicaid Services (CMS) in this area. Since the last OPTN contract was negotiated and executed, CMS has fully operationalized an entirely new and separate system for assuring recipient and living donor safety, through Medicare certification of transplant centers. Duplicative OPTN and CMS requirements are burdensome to programs and such duplication should be eliminated. For example, CMS approval could serve as the pathway for OPTN membership: Currently, a program has to be an OPTN member first to apply to CMS. A more unified process would alleviate the time gap between the two processes. We strongly support performance evaluation and consequences for programs that under-perform, but believe that OPTN and CMS should unify and harmonize the program evaluation process to the extent possible.
4. **Role in educating the transplant community and the public on safety and disease transmission information gained through the OPTN**: We do not believe that there is a pressing need to increase the role of the OPTN in educating members of the public or the community on the safety of organ transplantation or on issues related to disease

transmission. There are a myriad of sources of information on the safety of organ transplantation, and there is no need to expand the OPTN's role in the dissemination of this information, much of which is already disseminated through professional medical organizations (such as ASTS) and through other organizations dedicated to the advancement of transplantation.

5. **Expand research capacity to support informed OPTN policy development**: There is a need for objective evaluation of OPTN policies and performance by an outside entity. We believe that it would be duplicative and unnecessarily wasteful to increase the OPTN's research capacity to perform policy development. The SRTR currently provides this capacity quite satisfactorily and we believe that the SRTR should continue to be charged with the responsibility to do so. In light of the limited resources available to the OPTN, we believe that such duplication should be avoided. The OPTN should not be responsible for assessing its own performance.
6. **Increase ability of the OPTN's data system to quickly utilize advancements in IT to improve the organ allocation system**: As previously discussed, ASTS believes this should be a high priority within the new SOW. We strongly believe that it is critical for the OPTN to increase the ability of its data system to improve organ allocation and be responsive to board-approved changes in allocation policy. Information Technology (IT) system improvements are desperately needed in order for the OPTN to perform its core responsibility of establishing a workable and efficient system for organ allocation. In our view, the OPTN's current performance with regard to this critical function is unacceptable. Modifications of organ allocation policy that were adopted several years ago still have not been incorporated into the OPTN organ allocation data systems, which

directly and negatively impacts those potential organ recipients intended to benefit from the policy revisions. Updating the data system is so critical that we believe the new OPTN contract should require the OPTN to implement new policy into the IT system within a certain amount of time after the policy is approved. We believe that it is not unreasonable for the new contract to require the OPTN to incorporate new organ allocation policy into implemented OPTN data systems within 90-120 days after policy approval. Also, as stated above, we feel that the IT systems developed to fulfill the requirements of the OPTN contract should belong to the government. In the event that the contractor changed, this would enable a smooth transition and reduce the likelihood of disruption of this critical national system.

III. Proposed Tasks That Could Be Subcontracted

Outside expertise should be brought in to update the OPTN IT system, and this expertise is needed on an ongoing basis: Based on current performance, it does not appear that the current OPTN contractor has the expertise to perform this function efficiently and in a timely manner. For this reason, we urge HRSA to consider including in the next OPTN contract a provision requiring the OPTN to delegate this function to an IT subcontractor, based on the results of competitive bidding. Separately, we feel that some of the work of the OPTN Membership and Professional Standards Committee could be completed by a subcontractor.