November 21, 2011

Donald M. Berwick, MD, MMP
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (HHS)
200 Independence Avenue
Washington, DC 20201

Re: Living Donor Services Occurring in Transplant Programs Other than that of the Organ Recipient: Requirements and Interim Surveyor Guidance

Dear Dr. Berwick:

On behalf of the American Society of Transplant Surgeons (ASTS) and American Society of Transplantation (AST), we are writing to express our serious concerns regarding a Memorandum issued on September 30, 2011 to State Survey Agency Directors setting forth new CMS requirements and interim surveyor guidance relating to living donor services occurring in transplant programs other than that of the organ recipient (the "Memorandum").

Background

The Memorandum states that, if services for a living donor are provided by a transplant center (the "donor transplant center") other than the transplant center that performs the recipient procedure (the "recipient transplant center"), the services to the living donor are considered to be provided by the recipient transplant center under contract or arrangement. The Memorandum essentially makes the recipient transplant center responsible for ensuring that the donor transplant center meets certain Medicare conditions of participation. In addition, the Memorandum:

- requires that the recipient transplant center enter into a contract with the donor transplant center that gives the recipient center the right to review and monitor the donor center's policies and procedures;

- requires the recipient transplant center to monitor and evaluate the living donor services provided by the donor center as part of the recipient center's quality assessment program (including adverse events); and,

- requires the recipient transplant center to ensure that the donor transplant center is adequately addressing any areas of Medicare non-compliance.

In other words, the Memorandum appears to make the recipient center the guarantor of the quality of services provided by the donor center.

Summary of Substantive Concerns

We do not believe that it is appropriate for transplant centers to be held responsible for the activities or regulatory compliance of independent centers that may be geographically distant and with which they may have only sporadic contact. CMS has established a comprehensive system for the survey, certification, and re-certification of transplant centers, including outcome requirements that are uniquely demanding and process requirements that are detailed and resource-intensive. The purpose of these requirements is to ensure that transplant centers in this country provide high quality services upon which Medicare beneficiaries and other members of the public can rely. Recipient transplant centers are no less entitled to rely on the thoroughness of the Medicare certification process than are other members of the public. Holding current CMS certification must mean that a transplant center meets minimum Medicare requirements: If it does not, it is the Medicare program—not the recipient transplant center—that shoulders the responsibility.

We also note that UNOS/OPTN policy 3.12.6 requires that a donor center be approved for living donor recovery by the OPTN. In light of both CMS and UNOS requirements for living donor recovery, we believe that a recipient center should not be required to independently monitor compliance any more than a recipient transplant center is responsible for ensuring that a Medicare-certified and OPTN-approved OPO is compliant with its regulatory obligations.

We are especially concerned that the new requirement regarding disclosure of adverse events between centers represents a threat to the entire quality process, since such disclosures would remove the legal protection of peer review and quality statutes. The elimination of the protection afforded by peer review and quality standards has the potential to significantly deter paired kidney exchanges and to impact the openness and effectiveness of quality assurance processes at both donor and recipient centers.

Procedural Concerns

The Memorandum imposes new substantive requirements on transplant centers that extend beyond the requirements imposed by the transplant center certification regulations, without compliance with notice and comment rulemaking procedures. The new requirements outlined in the Memorandum purport to be authorized by 42 CFR Section 482.12(e), which outlines requirements for contracted services "in a hospital." This section of the regulations provides simply:

> (e) *Standard: Contracted services.* The governing body must be responsible for services furnished <u>in the hospital</u> whether or not they are furnished under contracts. . . .

(Emphasis added.) By contrast, the Memorandum addresses services that are not performed "in the [recipient] hospital" and, for this reason, 42 CFR Section 482.12 would appear to be inapplicable.

Moreover, these requirements go well beyond those imposed by the transplant center certification regulations. While the transplant center certification regulations impose numerous requirements related to living donors, they do not suggest or imply that a transplant center is to be held responsible for services that it does not provide directly to living donors, nor was this issue addressed in the extensive commentary in the preamble that accompanied adoption of the final transplant center certification regulations. Under these circumstances, we do not believe that these new requirements can be imposed on transplant centers without compliance with notice and comment rulemaking procedures.

Specific Objections

In addition to requiring the recipient transplant center to obtain a copy of the donor program's Medicare approval letter -- a requirement with which we agree-- the Memorandum imposes the following requirements:

Requirement 1. Requires the recipient transplant center to have an agreement with the donor center that gives the recipient center a role in reviewing the donor center's policies and procedures and in monitoring and evaluating the donor center's services.

> *While we do agree that a recipient transplant center should have an agreement with the living donor transplant program, we believe that this requirement should be construed very broadly. For example, many transplant centers participate, by written agreement, with paired kidney donor registries. Two hospitals may only exchange organs once under such an arrangement. We encourage CMS to consider participating in a paired kidney donor registry to fulfill the requirement for a written contract or agreement. Certainly recipient centers that have ongoing relationships with another transplant center for all or most of their donor services, such as a pediatric hospital with an adult transplant center, should be required to have a contract or legal arrangement with the donor center.*
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> *Although requiring a contract is not unreasonable, the requirement that one transplant center review the policies and procedures of another and monitor compliance with those policies and procedures is unnecessary, so long as the donor transplant center is CMS-certified and is a member in good standing of the OPTN.. The recipient center should be entitled to rely on the federal survey and certification process and the OPTN regulatory system.*

Requirement 3. Requires the recipient transplant center to obtain donor medical records and review these records in advance of transplant to ensure that the donor center complies with CoPs relating to medical and psychosocial evaluation of the donor; the living donor advocate; informed consent; and verification of recipient/donor blood and other clinical compatibility.

We do not disagree with the requirement to review and retain the donor medical records, however, it is the responsibility of the donor team at the CMS and OPTN approved donor transplant center to ensure that the donor has been cared for in a compliant manner, not the responsibility of the recipient center. Again, we point to the OPO model, it is not the recipient center's responsibility to review the deceased donor's medical record for regulatory compliance. Additionally, we question the requirement to verify donor and recipient blood type and other vital data as this is contrary to the proposed changes to reduce burdens on providers published in the Federal Register/Volume 76, No. 205/Monday, October 24, 2011. This proposal (out for public comment through December 23, 2011) calls for the removal of certain blood type verification requirements by transplant centers set forth in §482.92. The proposal labels the current requirement as redundant and burdensome and anticipates the elimination of the provision at §482.92(a) will benefit all parties involved in the practice of organ transplantation. Therefore, we do not understand why the interim guidance puts forward a requirement that CMS is proposing to eliminate.

Requirement 4. Requires the recipient transplant center to monitor and evaluate the living donor services (i.e., pre-, during and post-donation) contract as part of the recipient center's Quality Assessment and Performance Improvement (QAPI) program including the review of any adverse events.

CMS Conditions of Participation for Transplant Centers require a robust QAPI program for certification; it is redundant, at best, to require recipient centers, particular for a single exchange, to monitor and evaluate the living donor services. For centers with a more ongoing relationship (such pediatric recipient centers with all adult living donor services provided by another center), providing donor quality indicators periodically may be reasonable.

We are very concerned about the disclosure of Adverse Events to another institution. This requirement represents a serious threat to the legal protection provided to hospitals under state peer review and quality acts. Adverse events related to organ donation are reported to and subject to peer review by UNOS/OPTN as well as reported to the Joint Commission and subject the provisions of the CMS general hospital COPs.

Requirement 5. Requires the recipient transplant center to have a written process to ensure that the living donor transplant program that is under contract is addressing its own areas of Medicare non-compliance based on a CMS survey or the transplant program's knowledge of the minimum requirements of the CoPs.

We also disagree with this requirement; we find no basis in the COPs to require such disclosure between centers. The requirement to address non-compliance is between CMS and the donor transplant center. We do agree, however, that the contractual

relationship between the donor and recipient centers should require the donor center to report to the recipient center the loss of CMS certification or UNOS/OPTN membership.

Administrative Burden

Finally, we believe that these requirements unnecessarily and significantly increase the administrative burden on transplant centers in a manner that is directly inconsistent with Executive Order 13563, "Improving Regulation and Regulatory Review" released January 18, 2011. Similar to CMS' own findings regarding the redundant efforts of OPOs and transplant centers in organ recovery ABO validation (CMS-3244-P), we believe that this guidance adds little in the way of patient benefit and adds cost for both CMS and transplant centers. At a time when the CMS is moving aggressively to reduce the administrative burdens on the health care providers, we do not believe that the imposition of these new requirements is warranted.

Conclusion

We do not believe it is appropriate for transplant centers to be held responsible for the regulatory compliance of CMS certified centers especially where, as here, assuring compliance may impact the confidentiality (and therefore effectiveness) of quality assurance processes. Moreover, we believe that the requirements that are set forth in the Memorandum exceed the scope of the transplant center certification requirements and are inconsistent with this Administration's initiative to reduce administrative burdens on health care providers.

Sincerely,

Mitchell L. Henry, MD
ASTS President
ASTS National Office
2461 S. Clark Street, Suite 640
Arlington, VA 22202
PH: 703 414-1609
Email: *kim.gifford@asts.org*

Robert S. Gaston, MD
AST President
AST National Office
15000 Commerce Parkway, Suite C
Mt. Laurel, NJ 08054
PH: 856 642-4438
Email: *snelson@ahint.com*

Cc: Thomas Hamilton
Director, Survey and Certification Group

Karen Tritz
Technical Director, Survey and Certification Group