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American Society of Transplant Surgeons®

August 16, 2019

James Cowher, CAPT, USPHS
Division Director (Acting)
Division of Continuing Care Providers
Quality, Safety & Oversight Group; C2-18-03
7500 Security Boulevard
Baltimore, MD 21244

Dear Captain Cowher:

As President of the American Society of Transplant Surgeons (ASTS), I very much appreciate your July 22 response to ASTS' concerns about the new Interpretive Guidelines (IGs). We are extremely pleased that the IGs will be revised to clarify the supervision requirements for transplant surgeons working with fellows and residents¹ and to clarify the Transplant Center Director's responsibilities with regard to the training, oversight, and evaluation of nursing personnel. We also very much appreciate the deletion of new IG language prohibiting the ILDA from performing "infrequent" transplant-related activities and precluding the ILDA from being "associated with the transplant program even on a temporary or intermittent basis."

We remain concerned, however, that your July 22 correspondence appears to suggest that the revisions of the IGs that are being contemplated may require the ILDA to be assigned to another hospital department. We believe that the ILDA function is critical and is often best performed by dedicated personnel who are integrally and exclusively involved in transplantation. Assignment to another department would have the potential to limit the ILDA's time and dedication to the performance of ILDA responsibilities. We also remain concerned about the possibility that, even after revision, the IGs may retain the requirement that the ILDA interview all prospective donors before initial screening. We certainly acknowledge that regulations require that a living donor provide "informed consent" to the evaluation. However, pre-evaluation informed consent certainly can be instituted without slowing the process of living donation by requiring ILDAs to interview potential donors who may be ruled out as the result of blood and tissue or other screening testing. Because these types of ILDA restrictions and requirements would have the potential to impose substantial logistical and financial burdens on prospective donors, and to significantly disrupt the process of living donor transplantation, we believe that they are inconsistent with the objectives of the recent Executive Order on Advancing Kidney Health, which makes it clear that increasing both living and deceased donor transplantation is one of the Administration's major priorities.

¹ We note, however, that the IGs are to be revised to require that residents and fellows perform only those surgical tasks that they are authorized to perform under their hospital privileges. We understand that, in some institutions, because residents and fellows are in training, they may not formally have "staff privileges" as that term is usually used. For this reason, we recommend that the revised IGs simply require that the supervising surgeon be present for the critical portion of the procedure, in accordance with CMS payment policy.

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Executive Director

Daniel D. Garrett, CAE
daniel.garrett@asts.org

National Office

1401 S. Clark St.
Suite 1120
Arlington, VA 22202
703-414-7870
asts@asts.org
ASTS.org

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We are also concerned that the IG changes outlined in your correspondence will not be effective until they are formally published, especially since our prior conversation suggests that the revision process will be lengthy. Over the past month, we have heard from numerous transplant surgeons and others who are extremely concerned that the new IGs — as interpreted by the Office of Survey and Certification in a Q&A document that has been broadly circulated in the transplant community — require transplant centers to institute substantial operational changes, especially with respect to transplant surgeon supervision and ILDA responsibilities. We again request that CMS issue a letter to state surveyors that either instructs them to refrain from citing transplant programs for non-compliance with the IGs of concern or clarifies the IGs to incorporate the interpretations and revisions that will be made.²

We would be pleased to continue to work with you on other issues raised by the IGs, and hope that action can be taken soon to alleviate the widespread uncertainty that has arisen in the transplant community as the result of the new IGs and related Q&A.

Sincerely yours,

A handwritten signature in blue ink, appearing to read "L. Ratner", is positioned above the typed name.

Lloyd E. Ratner, MD, MPH
President
American Society of Transplant Surgeons

Cc. Daniel L. Schwartz, MD, MBA, Quality, Safety & Oversight Group, CCSQ/CMS

² See, e.g. We note that letters to survey agencies from the CMS Office of Survey and Certification have been issued in the past to clarify or revise the IGs <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/CMS1256876.html?DLPage=1&DLEntries=10&DLFilter=%202012-03-09&DLSort=3&DLSortDir=ascending>, which issued “interim guidance” to state surveyors that was inconsistent with the IGs.