American Society of Transplant Surgeons®

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Via E-Mail

June 25, 2019

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Dear Dr. Schwartz and Mr. Cowher:

On behalf of the American Society of Transplant Surgeons (ASTS), I am writing to follow up on our call of June 18 regarding the new Interpretive Guidelines ("IGs") for Transplant Centers. As we discussed, while we applaud CMS' efforts to simplify and streamline the IGs, a number of the provisions of the new IGs have raised concerns among ASTS members. We very much appreciate the time that you spent discussing these concerns with us and your openness to considering our views on these important issues.

We thought that it might be useful for us to provide to you proposed modifications of the IG language that we believe would alleviate our members' concerns in a manner that is consistent with CMS' views, as expressed during our call. Our suggested modifications of the IG language are provided on Attachment A. Language proposed for deletion is ~~stricken~~ and new proposed language is in *italic* typeface. We hope that these suggestions accurately reflect our discussions with you and are consistent with CMS' interpretations of the governing regulations.

Implementation of the IG provisions of concern would require Transplant Centers to institute substantial operational changes. For example, the requirement for Independent Living Donor Advocate (ILDA) pre-evaluation interviews with potential living donors has the potential to significantly disrupt the current work flow for living donor teams; the

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provision precluding any ILDA involvement with transplant activities implicates ILDA staffing; and the requirement for “skin-to-skin” supervision of fellows and residents would interfere with current teaching practices. For this reason, we request that CMS direct state survey agencies to suspend enforcement of the IGs that we have discussed pending consideration of ASTS’ concerns and that we plan to meet again by phone in two weeks to discuss the status of these IGs.

We look forward to working with you to address other issues that may arise with regard to the new IGs and the new transplant center certification process and hope that we can be of assistance in facilitating communication between CMS and the transplant community. If you have any questions or if we can be of any further assistance, please do not hesitate to contact ASTS Advocacy Manager Jennifer Nelson-Dowdy at Jennifer.Nelson-Dowdy@asts.org.

Sincerely yours,

Lloyd E. Ratner, MD, MPH
ASTS President

Cc: Valerie Caldwell-Johnson, Transplant Team

Attachment A

Direct Supervision by Transplant Surgeon

Applicable Regulation:

The Transplant Center (TC) certification regulations provide that the Transplant Director is responsible for, among other things:

> Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).[1]

42 CFR §482.98(a)(3).

Interpretive Guideline Suggested Change:

> If a fellow or a resident participates in a surgery, the attending transplant surgeon must remain in the operating room or be physically present in the operating suite *to the same extent as required for other teaching physicians in the hospital*. *Generally, this requires that the attending surgeon be present for the key/critical portions of the surgical procedure*.

Rationale:

We understand that CMS' intent is to ensure that the same supervision requirements are applied for transplantation as for other surgical specialties. Medicare payment rules applicable to teaching physicians as well as the standard definition of direct supervision in the surgical context – which has been accepted by CMS--requires that the supervising physician be present during the key/critical portions of the surgical procedure.

[1] Section 482.98(b) does not provide any definition of direct supervision, but rather requires only that a primary transplant surgeon have the appropriate training and experience to provide transplant services and that s/he be immediately available to provide transplant services when an organ is offered for transplantation.

Independent Living Donor Advocate (ILDA) Independence

Applicable Regulation:

The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

42 CFR §482.98(d)(1)

IG Suggested Change:

> Because of the conflict of interest which would be created for an advocate to perform ~~any~~ transplant activities *other than those related to the ILDA role on a routine basis*, ~~even on an infrequent basis~~, the ILDA or ILDAT must not ~~be associated with the transplant program in any capacity even on a temporary or intermittent~~ *routinely engage in transplant-related activities other than those related to carrying out the responsibilities described at §482.98(d)(3) and accompanying Tags. Interview the ILDA or ILDAT to ensure that ILDA activities are focused exclusively on representing and advising the donor; protecting and promoting the interests of the donor; and respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion. In particular, ensure that the ILDA or an ILDA team member does not also serve as a member of a transplant recipient team.*

Rationale:

ASTS completely agrees that an ILDA and all ILDA team members must be free of conflict of interest and that this function should not be performed by those who also routinely serve on transplant recipient teams. At the same time, it is critical that the ILDA function be performed by trained individuals with substantial knowledge of the transplant procedure, process, benefits, and risks. Such knowledge cannot be obtained without substantial and ongoing association with the transplant team. We believe that precluding an ILDA (or ILDAT member) from routinely performing transplant-related activities other than those that advance the interests of living donors is consistent with the regulatory language and strikes an appropriate balance between the need for independence and the need for ILDAs to be trained professionals with significant knowledge of the transplant process.

Living Donor Pre-Evaluation ILDA Interview and Other Living Donor Pre-Evaluation Requirements

Applicable Regulation:

Standard: Independent Living Donor Advocate or Living Donor Advocate Team. The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.

42 CFR §482.98(d)

§482.98(d) IG Suggested Change:

> Every potential living donor must be assigned to and have an interview with an Independent Living Donor Advocate (ILDA) or an Independent Living Donor Advocate Team (ILDAT) ~~prior to the initiation of the~~ *during the* evaluation *phase* and continuing to and through the discharge phase.

Standard Transplant Center Survey Protocol Suggested Change (Task 4.V):

> 'The medical record must include evidence that the Independent Living Donor Advocate (ILDA) was made available to the living donor, to include the name and contact information of the ILDA. Every living donor must be assigned and have an interview with the ILDA or ILDA team ~~prior to the initiation of~~ *during the* evaluation *phase* and throughout the donation phase."

***

Applicable Regulation:

Standard: Informed consent for living donors.

> Transplant centers must implement written living donor informed consent policies that inform the prospective living donor of all aspects of, and potential outcomes from, living donation. Transplant centers must ensure that the prospective living donor is fully informed about the following

***

> (2) The evaluation process;

***

> (5) The potential medical or psychosocial risks to the donor;

(6) The national and transplant center-specific outcomes for beneficiaries, and the national and center-specific outcomes for living donors, as data are available.

IG Suggested Changes:

Guideline §482.102(b)(2)

The informed consent process ensures that the donor understands what the evaluation process entails ~~prior to its initiation~~. ~~Prior to~~ *When* a donor candidate ~~making~~ *makes* a decision to ~~undergo~~ *proceed with* an evaluation for donation, they must understand what the process demands, patient and transplant program responsibilities, what determination(s) can be made as the result of an evaluation, and what factors could determine their non-candidacy for donation. The evaluation process is ongoing, beginning at the time ~~an individual is identified as a possible candidate~~ *of the evaluation for* donation and continues until donation. Routine re-assessments, as determined by the program's protocols must be conducted to ensure continued suitability for donation

Guideline §482.102(b)(5)

There are general risks applicable to all organ transplants and there are risks specific to each organ type. The transplant program must address both categories of risk with the potential donor ~~*prior to his/her decision to proceed with*~~ *during* the evaluation process. The informed consent discussion should include information regarding the fact that long term medical implications of organ donation have not been fully identified.

Guideline §482.102(b)(6)

~~Prior to undergoing~~ *During* an evaluation, the transplant program informs the potential donor of the location of the SRTR website and explains how the website may be used by the potential recipient to periodically review the transplant data pertaining to the program performance. The potential ~~recipient~~ *donor* should also be provided with a contact at the transplant program whom he/she may contact for any additional questions or assistance with the use of the website. There are currently no national or center specific outcomes for living donors calculated by the SRTR.

Applicable Regulation:

If a transplant center performs living donor transplants, the center also must have written donor management policies for the donor evaluation, donation, and discharge phases of living organ donation

42 CFR §482.94

IG Suggested Change:

Guideline §482.94

Living Donor Care Phases:

• Evaluation Phase: *Begins at the potential donor's first visit to the Transplant Center following any preliminary blood, tissue or similar screening and ends at* ~~from first presentation by the potential donor~~ the time he/she enters the OR for the donation surgery.

Rationale:

As indicated during our call, it is standard procedure for potential living donors to undergo rudimentary screening before the decision is made about whether or not to schedule evaluation. Potential living donors may reside great distances away from potential recipients, and the requirements for a pre-evaluation interview with an ILDA and the other pre-evaluation requirements imposed by the new IGs have the potential to substantially delay the living donor matching process and result in unnecessary inconvenience and expense for living donors. In addition, as the result of screening, many potential donors are essentially eliminated from consideration, and the imposition of pre-evaluation requirements of the kind reflected in the new IGs has the potential to result in substantial loss of time and increase in expenditures for Transplant Centers—expenses that are ultimately paid by the Medicare program, which provides cost-based payment for organ acquisition costs. Finally, the governing regulations do not recognize a "Pre-evaluation" phase for living donors.

Transplant Director Responsibilities

Applicable Regulation:

§482.98(a) Standard: Director of a Transplant Center.

> The transplant center must be under the general supervision of a qualified transplant surgeon or a qualified physician-director. . . The director is responsible for planning, organizing, conducting, and directing the transplant center and must devote sufficient time to carry out these responsibilities, which include but are not limited to the following:
>
> 1) Coordinating with the hospital in which the transplant center is located to ensure adequate training of nursing staff and clinical transplant coordinators in the care of transplant patients and living donors.

IG Suggested Change:

> **Guideline §482.98(a)(1)**
>
> **.** .. . Evidence of coordination should include:
>
> 1. The transplant director has participated in the development of training and orientation plans for nurses who work or will work with transplant recipients and living donors; *and*
>
> 2. The transplant director offers ongoing training opportunities for nursing staff. ~~; and~~
>
> ~~3. The transplant director provides feedback to the Nursing Department on the clinical competency of those nursing staff working with transplant recipients or living donors~~

Rationale:

In some institutions, nursing staff may be employed by a different entity or Human Resources rules lines may preclude a Transplant Director from providing direct input on nursing staff. In addition, this provision of the IG appears to be outside the scope of the governing regulation, which only addresses the Transplant Director's responsibility with regard to training and orientation for nursing staff working with transplant recipients and living donors.