ASTS
American Society of Transplant Surgeons®

Saving and improving lives with transplantation.

October 4, 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:

On behalf of the American Society of Transplant Surgeons (ASTS), I am writing to thank you for the opportunity to comment on the proposed revisions of the Interpretive Guidelines (IGs). Our comments and proposed changes are set forth on the attached document.

While some of our proposed language changes are relatively minor, we would like to call your attention to a number of IGs that we believe continue to be highly problematic. First, the revised version of the IGs continues to require that the attending transplant surgeon "must remain in the operating room or be physically present in the operating suite." While this language mirrors the language in the 2008 IGs, in light of the confusion that has arisen as the result of prior CMS communications that clearly required the supervising surgeon to remain in the operating room/suite "skin to skin," retention of the 2008 language will not allay the transplant community's concerns at this point. Since the new IGs became public (along with the Q&A imposing a "skin to skin" supervisory responsibility on transplant surgeons), the ASTS has fielded numerous calls from transplant surgeons, administrators, and in-house counsel expressing concern that transplant fellows and residents appear to be subject to unique supervision requirements that are not imposed in other surgical specialty areas. We believe that it is critical that CMS specifically dispel this impression.

In addition, the revised language states:

> The supervision requirements are consistent and implemented in conjunction with the hospital surgical privileges at §482.51(a)(4). Therefore, when a resident or fellow participates in transplantation surgery, the level of supervision for each procedure would be specified in their surgical privileges.

In fact, residents and fellows that are performing services in a training capacity generally are not accorded "surgical privileges" by their hospitals and the cross reference to §482.51(a)(4) is inappropriate: That subparagraph of the hospital CoPs addresses staff privileges granted to "practitioners" (e.g. physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, etc). We are suggesting language related to residents and fellows that we believe to be consistent with the regulations and with CMS' intent and urge you to adopt it.

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Second, we note that the revised IGs require a transplant hospital to "ensure" that a living donor recovery hospital is in compliance with applicable rules, which is inconsistent with current policy. It is imperative that the recovering center and not the transplanting center be responsible for ensuring compliance. As Kidney Paired Donation (KPD) programs continue to grow, it has become clear that we cannot ask transplant centers to police compliance of distant donor centers. To do so will significantly impede the growth of KPD programs that have the potential to help achieve the objectives of the Administration's current initiative with respect to kidney health.

Third, the revised IGs would still require a living donor to have an interview with an ILDA "prior to the evaluation. . ." We continue to urge CMS to refrain from implementing this requirement. Since numerous prospective donors never become actual donors, requiring an ILDA interview prior to evaluation will unnecessarily tax the ILDA resources of living donor transplant programs. In addition, we also request that the revised IGs clarify what is required for the ILDA to be considered "independent" by adopting the proposed revised language that is attached.

We hope that these comments and suggestions are helpful. 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 or on (571) 447-5447.

Sincerely yours,

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

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

Organ Transplant Programs
Draft for Comments – Do Not Distribute

Definitions and Clarifications

Transplantation/Donation Phases—

Transplant Recipient Phases:

- Transplant Phase: Begins when the potential candidate is admitted to the transplant hospital for transplantation and continues through the completion of the transplantation surgery and inpatient post-operative recovery from surgery. If a patient is admitted for a procedure or condition other than transplantation, the transplant Phase begins when the patient consents to transplantation.
- Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from inpatient stay that includes that transplant procedure.

Living Donor Care Phases:

- Evaluation Phase: Begins with the potential donor consents to undergo evaluation for donation and continues until the time the donor is admitted to the transplant hospital for donation.
- Donation Phase: Begins when the potential candidate is admitted to the transplant hospital for donation and continues through the completion of the donation surgery and inpatient post-operative recovery from surgery.
- Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from the inpatient stay that includes the donation procedure.

X-051

§482.90 Condition of Participation: Patient and Living Donor Selection.
The transplant center must use written patient selection criteria in determining a patient's suitability for placement on the waiting list or a patient's suitability for transplantation. If a center performs living donor transplants, the center also must use written donor selection criteria in determining the suitability of candidates for donation.

Guideline §482.90
Transplant programs are required to develop their own selection criteria to determine suitability for organ transplantation and living donation. There must be evidence that the written selection criteria are followed for the selection of transplant candidates to be placed on the transplant waitlist and, if applicable, potential living donors. Any deviations from the written selection criteria must be documented in the medical record.

X-056

§482.90(a)(4) A transplant center must provide a copy of its patient selection criteria to a transplant patient, or a dialysis facility, as requested by a patient or a dialysis facility.

Guideline 482.90(a)(4)
See 482.90(a)(4)

X-074

§482.92(b) Standard: Living Donor Transplantation.
If a center performs living donor transplants, the transplanting surgeon and another licensed healthcare professional at the center must verify that the living donor's blood type and other vital data are compatible with transplantation of the intended recipient immediately before the removal of the donor organ(s) and, if applicable, prior to the removal of the beneficiary's organ(s).

Guideline §482.92(b)
See above discussion at X073 regarding surgeon and other health care professional verification.

Verification that the living donor blood type and other vital data are compatible with the intended recipient must occur onsite, after the donor arrival in the operating room but prior to the induction of general anesthesia.

The verification must be completed by the donor organ recovery surgeon and another licensed healthcare professional. The program should identify in it's protocols which categories of health care professional(s) may do the second verification.

Verification by the transplant surgeon and another licensed healthcare professional must be documented. The documentation must include signatures and corresponding date and time of the verification. To ensure that verification is completed immediately before the removal of the donor organ(s), documentation must include the time of donor arrival into the operating room, time of organ verification and time general anesthesia was started.

Verification of correct organ for the correct recipient and verification that the blood type and other vital data are compatible with the potential recipient must occur immediately before the removal of the living donor organ(s).

If the donor organ recovery surgeon is also the transplanting surgeon, verification prior to removal of the living donor organ(s) and verification prior to transplantation must occur separately.

In a paired exchange, the recovering surgeon must verify the living donor's blood type and other vital data are compatible with the potential recipient and this must occur immediately before the removal of the living donor organ(s).

X-081

§482.94 Condition of Participation: Patient and Living Donor Management.
Transplant centers must have written patient management policies for the transplant and discharge phases of transplantation. 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.

Guideline §482.94
Transplantation and Living Donor Care Phases are generally defined as:

Transplantation Care Phases:

- Transplant Phase: Begins when the potential candidate is admitted to the transplant hospital for transplantation and continues through the completion of the transplantation surgery and inpatient post-operative recovery from surgery. If a patient is admitted for a procedure or condition other than transplantation, the transplant Phase begins when the patient consents to transplantation.

- Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from inpatient stay that includes that transplant procedure.

Living Donor Care Phases:

- Evaluation Phase: Begins with the potential donor consents to undergo evaluation for donation and continues until the time the donor is admitted to the transplant hospital for donation.
- Donation Phase: Begins when the potential candidate is admitted to the hospital for donation and continues through the completion of the donation surgery and inpatient post-operative recovery from surgery.
- Discharge Phase: Begins once the multidisciplinary team initiates discharge planning and continues through to the discharge from the inpatient stay that includes the donation procedure.

Some transplant programs perform living donor services under arrangement with other hospitals. In these cases, the transplant program retains all responsibility for compliance with management of the living donor. The transplant program must communicate the donor management activities that are required as a part of the living donor organ recovery to the hospital under the arrangement and ensure that the activities are completed appropriately.

If donor recovery takes place at a CMS-approved transplant hospital, that hospital needs to have policies and procedures in place that describe the transfer and acceptance of the donor organ.

X-082

§482.94(a) Standard: Patient and Living Donor Care.
The transplant center's patient and donor management policies must ensure that:
(1) Each transplant patient is under the care of a multidisciplinary patient care team coordinated by a physician throughout the transplant and discharge phases of transplantation; and
(2) If a center performs living donor transplants, each living donor is under the care of a multidisciplinary patient care team coordinated by a physician throughout the donor evaluation, donation, and discharge phases of donation.

Guideline §482.94(a)
A multidisciplinary care plan includes ongoing assessments to identify any new patient needs and/or to determine if any currently identified patient's needs have changed. A multidisciplinary team must be identified for each patient at the time the evaluation for wait listing begins. This multidisciplinary team participates in the patient care planning from evaluation through transplantation. At the time of the initial evaluation, each member of the team participates in the evaluation of the patient. It may not be necessary for all team disciplines to see the patient again until transplant is imminent unless there are identified needs. Following the transplant, each discipline must, as appropriate: 1) reassess the recipient following the surgery; 2) see the recipient as often as indicated by identified issues; and 3) see the recipient prior to discharge.

X-090

§482.94(c)(3) In the case of patients admitted for organ transplants, transplant centers must maintain written records of:
(i) Multidisciplinary patient care planning during the transplant period; and

Guideline §482.94(c)(3)
[guideline under 482.94(c)(3) was moved to 482.94(a)]

X-091

§482.94(c)(ii) Multidisciplinary discharge planning for post-transplant care.

Guideline §482.94(c)(ii)

Discharge planning beginsonce the multidisciplinary team initiates discharge planning . Each member of the dedicated multidisciplinary team must be involved in assessing the needs of the

patient in preparation for discharge from the hospital. Areas of assessment for discharge planning include medical, psychosocial and financial.

The recipient's medical record must contain documentation that the dedicated multidisciplinary team participated in the development of the discharge plan to address the individual needs of the recipient.

Components of a multidisciplinary discharge plan may include, but are not limited to:

- A description of the recommended follow-up appointments and the practitioners expected to perform the follow-ups (such as the transplant program, a local physician, or both);
- Contact numbers of transplant program staff that can be contacted for questions;
- The clinical signs and symptoms indicative of a potential complication from transplantation that would necessitate a call to the doctor;
- A transplant recipient/living donor specific nutrition plan, as applicable;
- A plan for addressing psychosocial issues (for example available supports, adaptation to stress of transplant, etc.);
- Activity restrictions and limitations (for example driving after taking pain medication);
- Need for coordination of other health services (for example physical or occupational therapies, home care, etc.) and assistance in securing these health services;
- Medication and administration, including the transplant recipient's schedule for taking medication and the process to obtain the medication; and
- Any assistance required to access transplant-related local medical care, equipment or support.

X-112

§482.98(a)(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.

Guideline §482.98(a)(1)

Care of transplant patients and living donors is unique and complex, requiring clarification of roles and responsibilities and appropriate training for nursing staff and clinical transplant coordinators. The director of the transplant center is responsible for coordination with the hospital's Nursing Department to determine the appropriate depth and type of orientation and training that will be provided to nursing staff that care for the transplant patients.

Evidence of coordination should include:

1. The transplant director has participated in the development of training and orientation plans for nurses, by providing input to training for nursing staff who work or will work with transplant recipients and living donors.
2. ~~The transplant director ongoing training opportunities for nursing~~

X-114

§482.98(a)(3) Ensuring that transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon in accordance with §482.98(b).

Guideline §482.98(a)(3)
A transplant surgeon must be credentialed by the hospital in which the transplant program is located to perform transplant surgeries.

If a fellow or a resident who is working in a training (learning) capacity participates in a surgery the activities of the fellow or resident and the level of attending surgeon supervision required are specified in written protocols adopted by the hospital in conjunction with its residency training program. The level of supervision required for transplant residents and fellows is consistent with the level of supervision required for residents and fellows in other surgical specialty areas.

X-121

§482.98(d) 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.

Guideline §482.98 (d)
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 acceptance of a donor for donation and continuing to and through the discharge phase.

X122

§482.98(d)(1) The living donor advocate or living donor advocate team must not be involved in transplantation activities on a routine basis.

Guideline §482.98(d)(1)
A transplant center must identify either an **independent** living donor advocate (ILDA) or an **independent** living donor advocate team (ILDAT) to ensure protection of the rights of living donors and prospective living donors. The living donor advocate or living donor advocate team must not be a member of the recipient's multi-disciplinary team and may not be involved in the transplant program's recipient transplantation activities on a routine basis.

"Routine" basis means a regular, ongoing basis.

It is expected that the ILDA's or ILDAT's focus is primarily assessing and advocating for the

living donor's needs and concerns. The transplant program must create a structure for the donor advocate or advocate team that allows independent evaluation and avoidance of conflict of interest. It is however, crucial that the ILDA is aware of the chain of command and communicates with the appropriate member(s) of the transplant team if and when any issues are identified.

These individuals may be in-house hospital staff members who perform other duties in addition to their living donor advocate responsibilities.

We do not specify requirements for a donor advocate's background, education, or training or the donor advocate team's composition. Instead, we specify their duties and the skills they must be able to demonstrate in 482.98(d)(2) and 482.98(d)(3).

X-125

§482.98(e) Standard: Transplant Team.
The transplant center must identify a multi-disciplinary transplant team and describe the responsibilities of each member of the team. The team must be composed of individuals with the appropriate qualifications, training, and experience in the relevant areas of medicine, nursing, nutrition, social services, transplant coordination, and pharmacology.

Guideline §482.98(e)
The team will include an individual with expertise in transplant pharmacotherapy, which may include a pharmacist.

X-153

§482.102(a)(3) Alternative treatments;

Guideline §482.102(a)(3)
Each potential recipient's options for treatment will vary based on organ type and individual medical condition(s). It is expected that discussions related to alternative treatments occur during evaluation for transplantion.

These discussions should be begin broad in focus and narrow in focus as options change or become available.

The discussions of alternative treatments should be reviewed any time the candidate has significant changes in their medical condition including changes that increase or limit options available.

X-155

§482.102(a)(5) National and transplant center-specific outcomes, from the most recent SRTR center-specific report, including (but not limited to) the transplant center's observed and expected 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all Medicare outcome requirements not being met by the transplant center;

Guideline §482.102(a)(5)
Prior to a recipient's inclusion on the waitlist, the transplant program informs the potential recipient 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's performance. This information allows the patient to make an informed decision about listing with the program.

X-162

§482.102(b)(3) The surgical procedure, including post-operative treatment;

Guideline §482.102(b)(3)
Discussions by the surgeon who performs the donor procedure with the potential donor candidate would include:

- What is the surgical procedure to be performed?
- What are the risks of the surgery?
- How is the surgery expected to improve the potential donor's health or quality of life?
- How long will the potential donor be hospitalized?
- What is the expected recovery period?
- When normal daily activities generally may be resumed?

X-163

§482.102(b)(4) The availability of alternative treatments for the transplant beneficiary;

Guideline §482.102(b)(4)
The potential donor must be made aware of potential alternative treatments that are available for the potential recipient, which may include the possibility of a deceased donor transplant.

X-165

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

Guideline §482.102(b)(6)

Prior to undergoing an evaluation During the evaluation process, 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.
There are currently no national or center specific outcomes for living donors calculated by the SRTR.

X-186

§482.104(a)(cont'd) … A kidney transplant center must have written policies and procedures for ongoing communications with dialysis patients' local dialysis facilities.

Guideline §482.104(a)(cont'd)
Transplant programs must have policies in place on how information is shared with dialysis facilities for patients currently receiving dialysis. Transplant programs must have bi-directional communication with the dialysis facility about any waiting list status changes or changes in patient condition or status. There will be communication periodically between the two entities, however, the frequency is determined by patient status changes and the policies of the transplant program.