ASTS
American Society of Transplant Surgeons

April 22, 2016

Thomas Hamilton
Director, Certification and Survey Group
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Mr. Hamilton:

On behalf of the American Society of Transplant Surgeons (ASTS), I very much appreciate your willingness to review our comments on the new Interpretive Guidelines (IGs) for Transplant Centers (TCs). We understand that the new IGs were scheduled to go into effect April 18; however, as discussed below, we are hopeful that certain changes still can be made on a moving forward basis. In the interim, we request that CMS place the revised IGs on hold, pending further discussion.

Preliminarily, though, we must express our disappointment that CMS moved forward to revise the IGs substantially without consultation with ASTS or others in the transplant community. As you know, the prior IGs were the result of extensive collaborative efforts between CMS and the professional community—collaborative efforts that, we believe, resulted in significant improvements. In addition, since the inception of the program, ASTS and CMS have collaborated closely on a number of other projects, including efforts related to CMS's Focused QAPI surveys, the mitigating circumstances criteria and processes, and other critical components of CMS's survey and certification functions as they apply to TCs. We would have hoped that any revisions of the IGs to be put in place likewise would have been undertaken in partnership with ASTS and the rest of the professional community. Had the IG revisions been undertaken through an open and collaborative process, it is unlikely that the final product would raise the significant concerns set forth below.

As it is, however, we must raise serious objections to the adoption of the revised IGs. The new IGs not only have the potential to substantially raise costs and inappropriately reduce TCs' flexibility to meet constantly changing clinical and administrative demands, but also will interfere with our ability to provide the highest quality personalized care to our patients.

At this stage, we have not yet had an opportunity to formulate an exhaustive list of the new IGs' deficiencies; however, we have identified a number of major concerns, as described in further detail below.

- **The TC outcomes requirements set forth in the regulations are misstated in the new IGs. (Tags X035 and X045).**

The new IGs do not correctly state the outcomes requirements that TCs must meet to obtain and retain certification.

- **The new IG (X114) requirements with respect to surgeon presence are inconsistent with clinical standards recently adopted by the American College of Surgeons (ACS).**

The governing regulations require that a Transplant Center (TC) ensure that "transplantation surgery is performed by, or under the direct supervision of, a qualified transplant surgeon." The new IGs (Tag X114) interpret this requirement to mean:

> "Direct supervision" means that the transplant surgeon who is supervising the transplantation surgery is physically present in the operating room at all times during the surgery, from verification through closure.

This interpretation is not consistent with sound surgical practice or professional standards. In fact, the new IG language is directly inconsistent with the recent ACS statement on this issue (copy attached), which requires that the operating surgeon be "in the operating suite or immediately available for the entire surgical procedure" (Emphasis added). In the case of overlapping operations (which happen frequently in transplantation), the ACS statement has clear language about completion of the "key or critical elements" by the primary attending surgeon. Wound closure, for example, is specifically named as not part of the "critical elements" in some cases. It is entirely inappropriate for CMS to dictate surgical practice in a manner that is directly inconsistent with professional standards. [1]

- **The new IGs include requirements with respect to waitlist management that virtually all TCs likely will fail to meet.**

The revised IGs raise a number of concerns with regard to waitlist processes and procedures. The most serious of these appears to be raised by Tag X083:

> Transplant programs are required to keep their waiting lists up to date to ensure that **all** active waitlist patients are ready for organ offers and transplantation based on their current clinical presentation (underline added).

While this is no doubt a laudatory goal, strict application of this standard is unreasonable, especially since many waitlisted transplant recipients are not in TCs' immediate geographic area and frequent return visits to TCs solely to check waitlisted patients' health status is both impracticable and wasteful.

[1] Similarly, the new IGs interpret the requirement for the transplant physician to be "immediately available" to provide transplantation services when an organ is offered to preclude a surgeon from living more than 60 minutes away, even if s/he routinely stayed on site or at an immediately accessible location when on call.

In short, strict application of this IG likely would result in citations of noncompliance of virtually all transplant centers.

In addition, the revised IGs appear to impose a number of additional problematic requirements with regard to waitlist management, including, for example, requiring approval of waitlist decisions by a "selection committee" which is not required by the regulations or by OPTN requirements (Tag X053); requiring waitlist decisions to be made based on the determination of the "multi-disciplinary team" (Tag X055), despite the language in the regulations suggesting that multi-disciplinary team involvement is not required in the pre-transplant phase; language suggesting that a TC's making an exception to its waitlist policy should be listed as a deficiency (Tag X055); language encouraging surveyors to second guess whether particular patients should continue to be included on a waiting list (Tag X055) ("During the review of the transplant candidate's medical records, confirm that it is still appropriate for the individual to receive a transplant…."); language requiring medical records to be maintained even if a patient is not actually examined for inclusion on the waitlist (Tag X087); and language specifying what information must be provided to those who do not meet the waitlist criteria regarding actions they could take to be included. In addition, Tag X165 could be read to require in depth discussions with patients who are on the waiting list and bypassed for a particular organ, due to clinical considerations. In short, the new IGs impose requirements on waitlist decisions that are outside the scope of the regulations and that hold the potential to substantially increase the difficulty of already-delicate waitlist decisions.

- **The new IGs appear to include extensive and ambiguous new QAPI requirements that have the potential to divert TCs' attention from quality improvements that truly benefit patient care.**

While we agree with CMS that a well-designed and consistently implemented QAPI program is critical to ensuring high quality care, we believe that the new IGs' QAPI requirements have the potential to increase bureaucracy without improving quality. For example, while we recognize that it is critical for TCs' QAPI programs to be integrated into the hospital's QAPI program, we believe it inappropriate for CMS to dictate specific lines of communication of quality reporting within the hospital structure (e.g., dictating when and under what circumstances a hospital's board of directors should become involved in the TC's QAPI process).

Even more importantly, the new IGs' QAPI requirements appear to require a root cause analysis of events that fall outside the TC's control. For example, the QAPI IG (X103) states:

> Transplant programs should clearly define the methods that will be utilized to conduct a "thorough analysis" for any adverse event (e.g., death, harm, no harm, or process deviation events) that may affect a transplant candidate/recipient and potential LD (Emphasis added).

Thus, as written, the IGs would require a TC to conduct a root cause analysis if a living donor were hit by a truck prior to the surgery or if a candidate on the waiting list were to die of complications of ESRD before a suitable organ were found. Moreover, no time limit is placed on the TC's obligation to conduct a root cause analysis in the event of the death of a transplant recipient, raising the question of whether the IGs implicitly obligate the TC to monitor a recipient's health status indefinitely. We respectfully suggest that limited QAPI resources could be better spent identifying and addressing clinical issues within the TC's immediate control.

- **<u>The IGs impose unreasonable and counterproductive obstacles to living donor transplants and paired donor transplants.</u>**

For example, the IGs (X058) state:

> In the event of a paired-exchange or LD/transplant recipient swap process, the transplant program accepting the LD organ for their transplant candidate must review the pre-transplant evaluation for the potential LD. The program must document review and approval of the medical and psychosocial evaluation prior to donation.

This IG places the TC performing the transplant in the position of functioning as a "watchdog" overseeing compliance of the donor TC's program. TCs are neither trained nor equipped for this purpose: Such oversight functions are more appropriately performed by the OPTN or CMS. (See also X126, requiring a recipient's transplant program to have a copy of the Medicare approval letter of the TC providing LD care and requiring the recipient TC to "check the website of the donor institution to assure that its Medicare certification remains current.")

- **<u>The new IGs unnecessarily interfere with clinical decision-making, patient-physician relationships, and TC operational flexibility</u>**.

The new IGs are almost 100 pages in length and dictate everything from the precise content of TCs' policies and procedures to the nature and timing of required discussions between potential recipients and the transplant team. For example, the IGs specify the content of psychosocial evaluation (X053); dictate precisely what clinical information must be shared with those rejected from inclusion on the waiting list (X087); specify what constitutes an adequate training program for nursing and other clinical personnel (X112); include restrictions on the use of traveling and pool nurses; specify the level of supervision needed for social work students; and dictate whether surgeon verification of blood type needs to be in a separate note or included in the patient's clinical record. The new IGs purport to require multiple conversations with a patient regarding the suitability of an organ for the patient's particular needs and dictate the precise content of those discussions, potentially unnecessarily increasing potential recipients' and donors' anxiety and confusion. Moreover, the new IGs impose requirements for multi-disciplinary team involvement that are not included in the regulations (including a requirement that social services and nutrition counseling be supplied to all transplant patients and LDs, even though the regulations only require that these services be "made available"), and impose requirements related to multi-disciplinary team involvement in the pre-transplant phase, which are not supported by the regulations.

At the same time, the IGs include virtually unintelligible instructions on how the regulatory requirements are to be applied to centers that include both pediatric and adult programs, and include ambiguous instructions on how the Medicare certification requirements are to be applied to "inactive" programs.

Because ASTS was not involved in the process of formulating the revised IGs, it is unclear to us precisely what problems or concerns the revised IGs were intended to address. We suggest that this be the starting point for discussions. Working together, it would be possible to address CMS' objectives without subjecting TCs to the level of micromanagement reflected in the new IGs. For all these reasons,

we request that CMS place application of the new IGs on hold while these and other issues raised by these revisions are reviewed in further depth.

Sincerely yours,

Charles M. Miller, MD
ASTS President