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**American Society of Transplant Surgeons®**

Submitted via email: [hrsacomments@hrsa.gov](mailto:hrsacomments@hrsa.gov)

**Re: Administrative Streamlining and Burden Reduction RFI**

**Specific RFI Section:** These comments relate to RFI Section B (HSB)

The American Society of Transplant Surgeons appreciates HRSA's issuance of an RFI soliciting public comments on how to achieve administrative streamlining and burden reduction in HRSA programs. We note that the only proposed initiative related to the reduction of administrative burden for those programs within HRSA's Healthcare Systems Bureau (HSB) is an initiative related to the administration of the Hill Burton Program. As noted in the RFI, HRSA's HSB also exercises extensive authority over the regulation of solid organ transplantation programs, and, in our view, HRSA could play a pivotal role in reducing the administrative burden for transplant centers (TCs), which are subject to extensive, duplicative, and sometimes inconsistent regulation by the Centers for Medicare and Medicaid Services (CMS) and HRSA, through the activities of the Organ Procurement and Transplantation Network (OPTN). We request that HRSA include this issue in its administrative relief agenda.

Late last year, we submitted to both CMS and HRSA a request for administrative relief from the duplicative and overly prescriptive requirements imposed on TCs. Our correspondence includes an approach under which TCs would be subject to a single set of regulations, a single set of outcomes requirements, a single unified survey, and a single set of sanctions.<sup>1</sup> (Attachment A)

*Request: We urge HRSA to work with CMS to institute the unified approach outlined in the attached correspondence.*

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<sup>1</sup> ASTS' request for relief of the administrative burdens imposed by duplicative and overly prescriptive regulation of TCs, including our proposal for a unified regulatory scheme, were submitted to HRSA in conjunction with our comments on the OPTN's scope of work. (Attachment B) In those comments, we requested that HRSA include in the OPTN's scope of work a new task requiring the OPTN contractor work with HRSA and CMS to eliminate duplicative and overly restrictive regulation of transplant centers. Unfortunately, that additional task was not included in the final OPTN scope of work issued earlier this year.

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**American Transplant Congress**

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**I. Request for Reconciliation of OPTN Policies related to TC Operations and CMS Conditions of Participation (CoPs) that Overlap, as a First Step in Relieving Administrative Burdens on TCs.**

The National Organ Transplant Act (NOTA) and the Final Rule implementing NOTA (42 CFR §121) (the Final Rule) envision an extremely limited role for HRSA and the OPTN in overseeing the quality of the services provided by TCs. In fact, the OPTN’s statutory tasks, as delineated in NOTA, do not include the kind of comprehensive, detailed and intrusive OPTN oversight of TC operations that is in place today. While NOTA requires the OPTN to “adopt and use standards of quality for the acquisition and transportation of donated organs,”<sup>2</sup> it does not include among the OPTN’s statutory tasks the adoption of quality standards for the transplantation of donated organs. The only statutory authority for OPTN oversight over TCs is language that gives the OPTN authority to establish membership criteria.<sup>3</sup>

However, the Final Rule significantly restricts the OPTN’s authority to establish membership criteria for TCs. Specifically, 42 CFR §121.3(b) **requires** the OPTN to “admit **and retain**” transplant hospitals that participate in Medicare or Medicaid as OPTN members. Likewise, §121.9(a) of the Final Regulation indicates that, to be eligible to receive organs for transplantation (i.e., to be a “designated transplant program”), a non-federal program must either participate in the Medicare program or meet a list of particular requirements as set forth in OPTN policies.<sup>4</sup> The Final Rule, therefore, clearly does not anticipate duplicative regulation of TCs by both CMS and the OPTN, but rather anticipates the OPTN’s reliance on CMS operational standards for TCs.

Since the submission of our initial request for administrative relief and accompanying proposal, a number of developments have occurred. Most importantly, we have met both with you and with CMS officials to discuss the current administrative burden placed on TCs. At this stage, it appears that, as a first step, there is some willingness on the part of both agencies to review requirements that overlap and to eliminate disparities.

***Request:** We request that, as a first step in implementing the unified TC regulatory process described in the ASTS correspondence, CMS and OPTN place a high priority on identifying overlapping areas of TC oversight and work with the transplant community to reconcile conflicting and overly prescriptive requirements.*

**II. Request for Further Reform of OPTN Oversight Process to Conform to Requirements in the Final Rule.**

Both CMS and OPTN have separate and uncoordinated processes for enforcing each of their respective TC regulatory requirements. The Final Rule does anticipate the OPTN’s exercise of some oversight responsibilities over TCs in connection with the

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<sup>2</sup> 42 USC Section 274 (b)(2)(E)

<sup>3</sup> 42 USC Section 274(b)(2)(B).

<sup>4</sup> It follows from these provisions of the Final Rule that the OPTN does not have the authority to expel a Medicare-participating TC from membership or to revoke its “designated transplant center” status, unless HRSA has decided to impose sanctions under 42 CFR §121.10

imposition of sanctions under §121.10: The Final Rule, at 42 CFR §121.10(b)(1), requires the OPTN to design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for the purpose of, among other things, “conducting ongoing and periodic reviews and evaluations of each member.... transplant hospital for compliance with the [Final Rule] and OPTN policies.” However, not all policies are subject to oversight and sanctions process authorized by §121.10: The Final Rule specifically requires that HRSA publicly identify those OPTN policies that are subject to sanctions under the OPTN oversight process. Specifically, 42 CFR §121.4 (c), relating to OPTN policies, states:

The Secretary will publish lists of OPTN policies in the FEDERAL REGISTER, indicating which ones are enforceable under § 121.10 or subject to potential sanctions of section 1138 of the Social Security Act.

It is only violations of policies specifically designated by HRSA that can result in revocation of a TC’s status as a designated transplant program or can terminate the transplant program’s Medicare or Medicaid reimbursement. 42 CFR §121.10 (c). HRSA is required to publish lists of OPTN policies in the Federal Register, indicating which ones are enforceable under Section 121.10 or subject to sanctions under the Social Security Act. See 42 CFR §121.4( c).

***Request.** We request that HRSA review the multitude of OPTN policies related to TC performance and operations that are subject to OPTN/MPSC oversight and identify a limited number of policies whose violation may result in loss of “designated hospital” or Medicare participation status, as required by the Section 410.4 (c) of the Final Rule.*

### **III. Request for Collaborative OPTN Oversight Process.**

We note that both HRSA and the OPTN appear to be attempting to move toward a less adversarial model of TC oversight. Section 3.6 of the final OPTN Scope of Work anticipates a less threatening oversight process involving greater self-disclosure and a less adversarial relationship between the OPTN and member TCs. The Membership and Professional Standards Committee (MPSC) of the OPTN recently put forward OPTN Bylaws changes, the objective of which ostensibly is to create a less formal and less onerous process of TC evaluation. These Bylaws changes substantially change the OPTN review and oversight processes for TCs.

It is significant then that the new OPTN scope of work, which will become effective later this year, provides that, within one month of the designation of the Contracting Officer Representative (COR), the OPTN is required to submit to HRSA a document outlining TC oversight processes that are consistent with these Bylaws changes. The document required under Section 3.6 must meet the following requirements:

- a) Standard: The document includes a description of data and processes the Contractor use to monitor compliance with NOTA, the OPTN final rule, OPTN Bylaws and policy, and other applicable Federal laws.
- b) Standard: The document includes frequency of OPTN member monitoring.

c) Standard: The document provides guidance to OPTN members on criteria used to monitor and evaluate compliance to NOTA, OPTN final rule, OPTN Bylaws and policies.

d) Standard: The document includes specific criteria to assess member data submissions for completeness, accuracy, and timeliness consistent with the requirements of the OPTN final rule.

e) Standard: The document includes guidance to members for performance improvement, including development of corrective action plans, processes for participating in collaborative performance improvement structures, and guidance on the potential imposition of sanctions by the OPTN per the OPTN Bylaws and final rule, and potential imposition of federal sanctions by the Secretary.

***Request:** We request that, in formulating the document required by Section 3.6., HRSA instruct the OPTN to minimize TCs' administrative burden and to coordinate review processes, plan of correction requirements, and review criteria with those used by CMS to the extent practicable.*

ASTS appreciates the opportunity to comment on the RFI. If you have any questions regarding these comments, please do not hesitate to contact ASTS Executive Director Kim Gifford at [kim.gifford@asts.org](mailto:kim.gifford@asts.org) or 703-414-7870.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dixon Kaufman". The signature is fluid and cursive, with a large initial "D" and "K".

Dixon B. Kaufman, MD, PhD  
President  
ASTS