



*Saving and improving lives with transplantation.*

**American Society of Transplant Surgeons**

Via e-mail

September 11, 2017

Thomas E. Price, MD  
Secretary of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Re: American Society of Transplant Surgeons Request for Regulatory Relief

Dear Secretary Price:

On behalf of the American Society of Transplant Surgeons, we applaud your initiative to minimize regulatory burdens on physicians that interfere with the efficient and effective delivery of high quality care. Along these lines, we strongly believe that this initiative should address the current duplicative regulation of transplant centers (TCs) by both the Centers for Medicare and Medicaid Services (CMS) and the Organ Procurement and Transplantation Network (OPTN) under the auspices of the Health Resources and Services Administration (HRSA). This letter sets forth an overview of the problem, a proposed framework for addressing it, and proposed next steps.

## **I. Overview**

### **A. In General**

For the past several years, the transplant community has been facing a steadily mounting burden of oversight that is now threatening the creative and vibrant spirit that has marked the field since its inception, like the frog in the old adage sitting in slowly heating water until it finds itself boiling. We recognize the complexity of our enterprise and embrace the challenge of caring for our patients with compassion and expertise. We also welcome the opportunity to seek ever-improving results in a safe and reliable patient care system. We are proud to publicly demonstrate our outcomes and our ever-improving processes to ensure patient safety and fairness to all who need a transplant. However, despite the culture of pride and innovation that permeates our community, individual infractions by a small number of transplant programs have led to an overwhelming burden of oversight on transplantation and transplantation-related care.

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Under current law, both the OPTN and CMS impose both process and outcomes requirements on TCs. The CMS and OPTN outcomes requirements differ, and for that reason the TCs identified for review by the OPTN and those identified as out of compliance with Medicare approval requirements differ. In addition, the OPTN and CMS impose different process requirements on transplant centers, and their methods of ensuring compliance with several of the common requirements differ. A crosswalk of CMS and OPTN requirements available on the OPTN website suggests that, together, there are approximately 123 requirements (a number that we believe to be underestimated), approximately 30% of which are reviewed by both CMS and the OPTN. The remaining requirements relate principally to Quality Assurance & Performance Improvement (QAPI) and multi-disciplinary team requirements imposed by CMS but not the OPTN, differing review processes for pediatric and adult programs, differing volume (clinical experience) requirements, and differing waitlist management and notification requirements. Both the CMS and the OPTN regulatory processes require extensive review of medical records. This duplication of regulatory requirements is costly both for TCs and for the federal government (and its paid private contractors), and unnecessarily distracts time and attention from patient care. Preparation for a CMS or OPTN survey is a months-long process requiring hundreds of FTE hours as well as considerable physical resources. Both surveys require an egregious waste of paper, when it could all likely be done electronically. Moreover, both sets of requirements are overly prescriptive and interfere with the patient-physician relationship and with physician judgment in the context of complex clinical decision-making.

The imposition of these extraordinarily burdensome regulatory requirements is particularly inappropriate in light of the extremely demanding outcomes requirements imposed by both the OPTN and CMS. Both CMS and the OPTN impose strict patient and graft one-year survival requirements that dissuade TCs from accepting “suboptimal” organs. Post-transplant organ graft and patient survival expectations are set significantly higher for transplantation than other diseases like cancer, which has a 66.9% five-year survival rate. As the chart below illustrates, transplantation truly has excellent outcomes and ideally should be made available to a greater number of recipients.<sup>1</sup>

Organ	One-Year		Three-Year		Five-Year	
	2017 Report	2014 Report*	2017 Report	2014 Report*	2017 Report	2014 Report*
Heart	91%	89%	85%	82%	78%	75%
Intestine	81	80	67	63	58	53
Kidney	97	96	93	92	86	86
Liver	91	89	83	81	75	74
Lung (Single and Double)	87	85	69	66	55	51
Pancreas	92	93	88	89	80	81
Heart-Lung	80	73	59	54	51	45
Kidney-Pancreas	98	96	95	92	88	87

<sup>1</sup> Bently, “2017 US Organ and Tissue Transplant Cost Estimates and Discussion,” Milliman Research Report, 2017. <http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf>. By comparison the US 5-Year Relative Survival for all cancers is 66.9% according to the National Cancer Institute SEER Cancer Statistics Review. ([https://seer.cancer.gov/archive/csr/1975\\_2013/results\\_single/sect\\_01\\_table.05\\_2pgs.pdf](https://seer.cancer.gov/archive/csr/1975_2013/results_single/sect_01_table.05_2pgs.pdf))

In light of the excellent outcomes achieved by TCs, it is unclear to us why such extraordinarily onerous “process” requirements are considered necessary by not only one government agency, but two.

## **B. Some Examples**

The overlapping (and sometimes conflicting) morass of TC regulatory requirements imposed by both CMS and the OPTN are ripe for simplification and streamlining. Not only are these requirements duplicative, they are also extraordinarily detailed. For example:

- The OPTN regulatory requirements include 230 pages of policy, 180 pages of Bylaws, and 65 pages of Evaluation Plan. <sup>2</sup>
- CMS regulatory requirements includes 85 pages of the Federal Register, 107 pages of the Survey and Certification Interpretive Guidelines, 50 pages of Survey and Certification Interpretive Guideline Changes, 49 pages of Quality Assessment and Performance Improvement (QAPI) Program requirements, 103 pages of updated Interpretive Guidelines (pending revisions May 2016), and numerous additional updates and clarifications. <sup>3</sup>
- **Organ and Vessel Tracking**
  - The time out and verification process has been cumbersome. Requirements in this area have been characterized by variation in surveyor preference between the OPTN and CMS and by each agency’s practice of changing its own regulatory requirements, in an asynchronous manner over time. Forms developed by the OPTN do not meet the

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<sup>2</sup> [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf)

[https://optn.transplant.hrsa.gov/media/1201/optn\\_bylaws.pdf](https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf)

[https://optn.transplant.hrsa.gov/media/1202/evaluation\\_plan.pdf](https://optn.transplant.hrsa.gov/media/1202/evaluation_plan.pdf).

<sup>3</sup> See, e.g.

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/downloads/Transplantfinal.pdf>;

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-25.pdf>;

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-09.pdf>;

<https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf>

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-10.pdf>

requirements of CMS surveyors, and CMS and OPTN surveyors have imposed different requirements regarding electronic documentation in the Electronic Medical Record (EMR) versus paper copy and signatures.

- **Patient Education and Consent to Proceed**
  - It is critical that patients and living donors are well informed of the risks, benefits, and alternatives to participation in the various phases of transplant and donation. However, regulations call these encounters “Informed Consent” which create unnecessary concern from the patient and confusion with legal and risk departments within a hospital. The OPTN consent requirements are incredibly prescriptive yet they do not provide a templated form for use. TCs find themselves constantly updating the forms to include small language changes, only to then be cited for missing something miniscule. Meeting these informed consent requirements has resulted in extremely lengthy documents and encounters to “cover all bases,” which are overwhelming to both recipients and potential donors, and which add significant physician time.
  
- **Time Requirements and Disparate Timeframes**
  - The OPTN and CMS are on separate timelines for completing onsite and offsite surveys. Often TCs encounter both teams within a given year, resulting in 3-5 days of interruption for each visit. OPTN surveys are scheduled and CMS surveys are unscheduled. These agencies do not coordinate TC survey schedules, which has resulted in disruption of TC hospital and clinical operations. Survey readiness, even when scheduled, also necessitates significant TC financial and resource commitment. In addition, significant team time is required to implement plans of correction, education, and auditing after the visit. Surveys are useful tools when they result in process improvements; however, typically these surveys result in more administrative work, redundant documentation, and team time away from clinical care. In one large center, over 60 staff are occupied full time at the expense of patient care and other duties the week of the CMS survey.
  
- **Clinical Micromanagement**
  - Process oversight extends to the micromanagement of educational materials provided to patients and specific documentation requirements of the role of social workers and others in the overall care of patients in multiple locations. For example, the transplant nephrologist must document the results of the psychiatric assessment *even when* the consultation report of the psychiatrist is part of the patient’s chart.
  
- **ABO Verification**
  - A single highly publicized misallocation of a heart by blood type led to a process of verification of blood types prior to transplantation that has grown into a morass of checklists and forms, which are dated and timed and avidly reviewed by surveyors for spelling errors and marks in the wrong box. Up to 63 points of failure have been identified in form completions and design. Compliance with this regulation has led to a substantial number of new administrative positions to oversee the work of the clinicians and evaluate form completion and requirements. While well intentioned, these processes do not contribute to patient safety, only paperwork and administrative burden.

### **C. Statutory Authority**

Despite the extraordinary level of detailed oversight imposed by both CMS and the OPTN, neither Medicare certification nor OPTN TC review processes are clearly or unequivocally required by statute. Section 1881(b)(1) of the Social Security Act (the “Act”) gives the Secretary authority to prescribe regulations for payment for renal transplantation services; however, there does not appear to be any specific statutory authority mandating certification of renal transplant programs, and no provision of the Act of which we are aware mandates the establishment of any type of specialized certification requirements for other forms of transplantation. In fact, CMS only adopted specific certification regulations for TCs in March of 2007, as the result of earlier public and Congressional concerns raised in response to certain highly publicized lapses by a handful of TCs. Before that time, CMS relied entirely on the OPTN to oversee TCs, since Section 1138 (a)(1)(B) of the Social Security Act, enacted in 1986, requires Medicare and Medicaid participating hospitals that perform organ transplants to be members of and abide by the rules and requirements of the OPTN. CMS relied on its general rulemaking authority to publish rules and regulations “necessary for the efficient administration of the functions” of the Medicare Program to adopt the final TC certification regulations, which reflects the lack of specific statutory authority to establish TC certification requirements independent of OPTN membership criteria.

The OPTN was established by the National Organ Transplant Act (NOTA) (PUBLIC LAW 98-507-OCT. 19, 1984), and Section 372(b)(2) of NOTA sets forth with specificity the responsibilities of the OPTN. None of these explicitly requires the OPTN to establish quality requirements for TCs; however, NOTA does indicate that the OPTN has the responsibility to establish its own membership standards,<sup>4</sup> and it appears that this is the sole statutory basis for the OPTN’s extensive oversight of TCs. While it may be argued that comprehensive oversight of TCs by the OPTN was necessary when the OPTN was the only body charged with ensuring that TCs maintained quality standards, since the adoption of Medicare certification standards, that is no longer the case.

## **II. A Proposed Framework to Reduce TC Regulatory Burden**

### **A. Principles to Guide TC Regulatory Reform**

Because TC regulatory requirements are imposed by two separate and independent agencies within HHS and because the requirements imposed by both agencies are detailed and complex, administrative simplification in this arena may prove challenging. For this reason, the administrative simplification process should be guided by clear and easily understood basic principles, the objective of which is to preserve transplant quality and patient protections, while simplifying and streamlining oversight. Specifically, we strongly believe that the regulatory review process should result in:

- One set of TC oversight regulations and regulatory interpretation;
- One set of TC outcomes measures intended to maximize transplantation rates;
- One combined survey conducted as necessary based on a single set of survey triggers; and
- One set of consequences for noncompliance.

We refer to these objectives as the “Reform Principles.”

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<sup>4</sup> 42 USC §274(b)(2)(B)

## B. Operationalizing the Reform Principles

The Reform Principles could be operationalized in any number of ways. As discussed above, currently the OPTN and CMS oversee and monitor both outcomes and process. However, it may be possible to apply the Reform Principles by providing one of the two agencies with the authority to establish outcomes requirements while the other establishes process requirements, or, following historical areas of special competence, the OPTN might be given primary responsibility for establishing the requirements for activities and processes that occur outside the four walls of the TC (e.g., organ retrieval, allocation and distribution, patient ranking on the waitlist, and ensuring the fairness of waitlist processes), while CMS retains primary authority to establish rules related to TC activities, including QAPI (an area in which CMS and its contractor have established special experience and expertise).

However, in our experience, each of the two agencies has considerable expertise that the other does not, and the ideal regulatory framework would involve close collaboration of CMS and the OPTN/HRSA to establish a single integrated regulatory framework and oversight process. For this reason, we urge the Secretary to consider a TC regulatory framework with the following characteristics:

- Approval of New TCs: Currently, CMS does not regulate TCs until they become operational, and the job of approving new centers falls to the OPTN. We believe that this allocation of responsibility is appropriate and that, while the OPTN requirements for new centers should be reviewed and streamlined to the extent practicable, the OPTN should retain the responsibility for initial TC approval.
- Organ Retrieval and Allocation, Waitlist Management, and Related Data Management: Likewise, the OPTN has considerable expertise in the area of waitlist management and oversight, and has comprehensive processes in place to ensure that waitlist rules are not subject to “gaming.” In addition, the OPTN routinely engages in considerable data collection to ensure compliance with organ allocation and distribution policies. In operationalizing the Reform Principles, we urge the Secretary to direct the OPTN/HRSA to review its current standards related to these and other areas that take place outside the “four walls” of the TC, but to retain OPTN/HRSA sole oversight authority in these areas. To the extent that on-site surveys must be conducted to ensure compliance with such waitlist, allocation or other rules, the survey should be conducted as part of a unified OPTN/HRSA/CMS survey (discussed below).
- Establishment of Interagency Committee: We urge the Secretary to appoint an interagency committee (“Interagency Committee”) composed of representatives appointed by CMS, HRSA, and the OPTN, to operationalize the Reform Principles and to enforce compliance. The tasks of the Interagency Committee should include at least the following:
  - Unified Outcomes Requirements: Under current rules, TCs’ one-year outcomes, as reported and risk adjusted by the Scientific Registry of Transplant Recipients (a HRSA contractor), are assessed by CMS and by the OPTN using different statistical standards, resulting in the “flagging” of different centers and different times by the two agencies. We urge the Secretary to direct CMS and the OPTN/HRSA to establish a single set of TC outcomes standards and to modify Medicare certification regulations and/or OPTN Bylaws and policies as necessary to adopt the agreed outcomes standards.

- Streamlined Process Requirements Focused on Transparency and Due Process: TCs are among the only, if not the only, type of provider, other than Organ Procurement Organizations (OPOs) that are required to comply with both outcomes requirements and comprehensive process requirements as a condition of participation in the Medicare Program. Each TC publicly reports its individual patient and organ survival statistics, and, under current Medicare certification standards, a TC that reports lower than expected patient and graft survival for two years fails to meet Medicare certification standards. We do not believe that TCs that maintain high outcomes standards also should be subject to comprehensive process requirements related to various aspects of clinical care. Since outcomes standards are generally viewed as out-of-reach for many types of providers, Medicare certification requirements generally focus on compliance with processes thought to contribute to positive outcomes. In the absence of outcomes standards that are definable and enforceable, the imposition of process requirements is viewed as the “best that can be done.” Where, as in the case of TCs, outcomes standards are available and applied on a continual basis, why should CMS or OPTN also impose comprehensive and detailed process requirements related to various aspects of clinical care? On the other hand, there are certain transparency and due process standards that all TCs should maintain regardless of the outcomes they achieve. We believe that it is in these areas that process requirements and oversight surveys should focus:
  - ✓ Patient rights
  - ✓ Core safety measures
  - ✓ QAPI programs
  - ✓ Care of living donors
  
- Non-Prescriptive Interpretive Guidelines: Currently, much of the burden of compliance with both CMS and OPTN regulatory requirements arises not because of the basic CMS regulations and OPTN Bylaws or policies, but because of the overly prescriptive manner in which these requirements are applied by surveyors from the two agencies. The Interpretive Guidelines used by surveyors under contract with CMS are currently over 100 pages in length, and an equally long revision is currently on hold as the result of substantial objections from the TC community.<sup>5</sup> Likewise OPTN surveyors utilize a comparable 65 page document, the OPTN Evaluation Plan, in conducting OPTN surveys, of approximately equal length. We urge the Secretary to direct the Interagency Committee to develop a single interpretive document to be used by those conducting surveys of compliance with those relatively limited process requirements that are retained, and that, in developing this document, the Interagency Committee should be requested to use the following guidelines:
  - ✓ The Interagency Committee should develop Interpretive Guidelines with the clear objective of minimizing administrative burden. Care should be taken to ensure that the Interpretive Guidelines stay within the scope of limited process requirements.

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<sup>5</sup> See current Interpretive Guidelines at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter08-25.pdf> and proposed revision at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-10.pdf>.

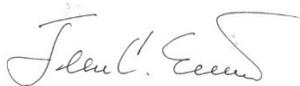
- ✓ The Interpretive Guidelines should be developed with input from the transplant community.
- ✓ When CMS and the OPTN both have current interpretive documents relating to the same basic requirement, the least prescriptive guideline should be adopted as the model.
- ✓ To the extent that TCs are expected to utilize a particular form or process, a model document should be provided to the transplant community.
- Triggers for Oversight Survey: Oversight surveys should be performed in a coordinated fashion and should involve surveyors from both CMS and the OPTN, working together. Surveys should be performed under well-defined circumstances, such as:
  - ✓ Failure to meet outcomes thresholds
  - ✓ Major sentinel events
  - ✓ Failure to comply with OPTN rules regarding listing and allocation practices
- Consequences of Failure to Comply with Process/Meet Outcomes Standards: The Interagency Committee should merge the OPTN and CMS plan of correction/mitigating circumstances processes; review of TC performance should be conducted jointly by the OPTN/SRTR and CMS; and the process should draw upon the expertise of the OPTN Membership and Professional Standards Committee (MPSC).

### III. Next Steps

The reforms outlined above likely would require modification of the CMS Conditions of Participation for TC and OPTN Policies (and possibly Bylaws). It is also possible that the task of streamlining the TC review process should be included in the scope of services set forth in the Request for Proposals to be issued by HRSA for the OPTN contract, which we understand will be released this Fall.

We would be delighted to meet with CMS, OPTN, and HRSA representatives to discuss the next steps in developing a unified, streamlined, and effective TC oversight process. If we can provide any further information regarding our concerns or proposed framework for addressing the overregulation of TCs, please do not hesitate to contact Kim Gifford, ASTS Executive Director, at [kim.gifford@asts.org](mailto:kim.gifford@asts.org) or 703-414-7870.

Sincerely yours,



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