



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

Via email: David.Wright@cms.hhs.gov

July 13, 2018

Mr. David Wright
Director, Quality and Safety Oversight Group (QSOG)
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Mr. Wright:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to thank you and your colleagues for meeting with us on June 21, 2018. We very much appreciate having the opportunity to discuss with you the burdens imposed by duplicative regulation of Transplant Centers (TCs) by both the Organ Procurement and Transplantation Network (OPTN) (under the authority of the Health Resources and Services Administration (HRSA)) and the Centers for Medicare and Medicaid Services (CMS). We also appreciate the prior and ongoing efforts made by CMS and HRSA to coordinate regulatory oversight over TCs.

We understand from correspondence that we recently received from CMS Administrator Seema Verma that you will be briefing her office on the issues we discussed. At our June 21 meeting, we had agreed that it would be useful to conduct a joint CMS/HRSA review of those areas of TC operations that are subject to both CMS and OPTN oversight and to focus on simplifying and eliminating inconsistencies in those areas. We look forward to working with you on this project.

As a first step, after our meeting with you, we reviewed the OPTN Bylaws and policies against the TC Conditions of Participation (CoPs). In general terms, the OPTN has adopted bylaws or policies that overlap with many of the TC CoPs to at least some extent. The areas where CMS has specific requirements that do not appear to have been addressed in any detail by the OPTN are:

- Quality Assurance and Performance Improvement Programs (QAPI)(42 CFR § 482.96)
- Pediatric program requirements (42 CFR § 482.76)
- Clinical management of patients on the waitlist (42 CFR § 482.94(b));
- Special TC requirements for kidney transplant programs (e.g. having access to dialysis) (42 CFR §482.104)
- Multi-disciplinary team involvement in clinical care of transplant recipients (certain provisions of 42 CFR §482.94).

President

Dixon B. Kaufman, MD, PhD
University of Wisconsin

President-Elect

Lloyd E. Ratner, MD, MPH
Columbia University

Secretary

A. Osama Gaber, MD
Houston Methodist Hospital

Treasurer

William C. Chapman, MD
Washington University

Immediate Past President

Jean C. Emond, MD
Columbia University Medical Center

Past President

Timothy L. Pruett, MD
University of Minnesota

Councilors-at-Large

Peter L. Abt, MD
Wendy J. Grant, MD
Randall S. Sung, MD
Talia B. Baker, MD
Jonathan P. Fryer, MD
Alan I. Reed, MD, MBA
Michael J. Englesbe, MD
Julie K. Heimbach, MD
Debra L. Sudan, MD
Georgeine Smith, MS, MHS, PA-C

Executive Director

Kimberly A. Gifford, MBA
kim.gifford@asts.org

National Office

2461 S. Clark St.
Suite 640
Arlington, VA 22202
703-414-7870
asts@asts.org
ASTS.org

American Transplant Congress

June 1–5, 2019
Boston, Massachusetts

The primary area that is subject to in-depth regulation by the OPTN but not by CMS relates to organ allocation.

Since it appears that there are many areas involving joint oversight by both CMS/and HRSA, we would propose that the process of reviewing overlapping requirements focus on those areas of greatest direct concern to patients. In our view, these include informed consent, living donor protection, ABO verification, and outcomes/clinical experience requirements.¹

We understand from our meetings both with you and your colleagues and with HRSA that CMS and HRSA officials meet regularly to share information with regard to TC regulation. We strongly believe that transplant community input into these meetings would make a significant contribution to less duplicative and more effective oversight of TCs. We urge your team and your HRSA counterparts to involve the transplant community to the maximum extent practicable in reviewing, simplifying and eliminating inconsistencies in areas of joint concern to both agencies.

We look forward to hearing from you with respect to next steps. In the interim, if you have any questions or concerns, please do not hesitate to contact Kim Gifford, ASTS' Executive Director, at kim.gifford@ASTS.org.

Thank you for your time and effort.

Sincerely yours,

A handwritten signature in black ink that reads "Dixon Kaufman". The signature is fluid and cursive, with the first name "Dixon" and last name "Kaufman" clearly legible.

Dixon Kaufman, MD, PhD
ASTS President

Cc:

Peggye Wilkerson, Director, Division of Continuing Care Providers
Tennille Rogers, Acting Deputy Director QSOG
Daniel Schwartz, MD, Medical Officer QSOG
Danielle Miller, Transplant Team
Michele Walton, Transplant Team
Valerie Caldwell-Johnson, Transplant Team
George Sigounas, MS, PhD, Administrator, HRSA
Diana Espinosa, MPP, Deputy Administrator, HRSA

¹ Both agencies impose outcomes requirements, but ostensibly for different purposes. Both impose clinical experience requirements, but the OPTN imposes them on the surgeons/physicians and CMS imposes them at the facility level.