

November 19, 2012

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201

Re: Support for Implementation of ACOT Recommendation on Regulatory Review

Dear Secretary Sebelius:

The undersigned organizations representing the Transplant Roundtable, a coalition of organ transplant patients, professionals, and related organizations, are pleased to strongly support the recommendation recently made by the Advisory Committee on Transplantation (ACOT). This recommendation states:

The ACOT recognizes that the current CMS and HRSA/OPTN structure creates unnecessary burdens and inconsistent requirements on transplant centers (TCs) and organ procurement organizations (OPOs) and that the current system lacks responsiveness to advances in TC and OPO performance metrics. The ACOT recommends that the Secretary direct CMS and HRSA to confer with the OPTN, SRTR, the OPO community, and transplant center representatives, to conduct a comprehensive review of regulatory and other requirements, and to promulgate regulatory and policy changes to requirements for OPOs and TCs that unify mutual goals of increasing organ donation, improving recipient outcomes, and reducing organ wastage and administrative burden on transplant centers and OPOs. These revisions should include, but not be limited to, improved risk adjustment methodologies for transplant centers and a statistically sound method for yield measures for OPOs. The ACOT recommends that this review be completed within one year and that action be taken within two years.

On behalf of the transplant community, we applaud ACOT for explicitly calling attention to the current dissonance between the outcomes metrics used to evaluate OPOs and those used to evaluate transplant centers. In our view, the inconsistent incentives provided to OPOs to maximize retrieval on one hand and to transplant centers to maximize patient and graft survival on the other, exacerbates the potential for organ wastage, unnecessarily increases the costs of transplantation, and adversely impacts outcomes.

We note that ACOT recommends a regulatory review of OPO and transplant center outcomes and related requirements be completed within two years. Moreover, ACOT specifically indicates that the revisions should include improved risk adjustment methodologies for transplant centers and a statistically sound method for yield measures for OPOs.

In order to facilitate these technically challenging tasks, we recommend that as soon as practicable CMS and HRSA, with input and recommendations from organ donation and

transplantation stakeholders including Transplant Roundtable members, establish a work plan and timetable for accomplishing the comprehensive review and revision envisioned by ACOT.

We applaud ACOT's recommendation and would welcome the opportunity to work closely with representatives from CMS, HRSA and others on this critical project. Thank you for your consideration of this request.

Sincerely,

American Society of Nephrology
American Society of Transplant Surgeons
American Society of Transplantation
American Transplant Foundation
Association of Organ Procurement Organizations
Eye Bank Association of America
NATCO, the Organization for Transplant Professionals
National Kidney Foundation
Transplant Recipients International Organization