



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

Via electronic submission

October 1, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3346-P; Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction (CoPs) (Proposed Rule); RIN 0938-AT23

Dear Administrator Verma:

As President of the American Society of Transplant Surgeons (ASTS), I am writing to thank you for supporting the above-referenced Proposed Rule to eliminate outcomes, clinical experience, and data reporting requirements as Transplant Center Conditions of Participation (CoPs) for transplant center re-approval.

We applaud CMS for taking this important first step in eliminating specific regulatory requirements because it will result in increasing access to transplantation as a treatment option for Medicare beneficiaries and other patients throughout the United States.

This change will diminish a constraining effect of CoPs on the inclination of Transplant Centers to offer transplantation to medically challenging patients. The removal of the outcomes-related requirements for re-approval will have a positive effect on increasing patient access to transplantation because Transplant Centers will be more likely to expand their transplant acceptance criteria, allowing more individuals to be candidates. Adoption of this proposal in its current form will eliminate a significant regulatory obstacle to the conduct of more transplants for Medicare beneficiaries and other potential recipients alike.

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We also appreciate CMS' solicitation of public comments on regulatory requirements that might be modified or eliminated. As you are aware, transplantation is among the most heavily regulated of all clinical disciplines. At the federal level alone, Transplant Centers are required to meet numerous detailed clinical, financial, and operational requirements to meet Medicare CoPs and to meet HRSA/OPTN membership requirements. In fact, there are at least 123 distinct process requirements imposed on Transplant Centers, and, with the exception of Quality Assurance and Performance Improvement requirements (which are applied in substantially more comprehensive form by CMS) and requirements related to organ distribution (which are imposed exclusively by HRSA/OPTN), many of these process requirements are duplicative.

ASTS is strongly in favor of quality outcomes for transplant recipients. It is also dedicated to participating in offering solutions to improve streamlining and unifying the regulations of Transplant Centers by CMS and HRSA/OPTN policies to achieve this objective. Our review of the CMS CoPs and the HRSA/OPTN Bylaws and Policies suggests that there are opportunities to address four broad areas in which regulatory elements imposed by CMS and those imposed by the OPTN are largely duplicative:

- Organ Recovery and Receipt
- Patient and Living Donor Management
- Transplant Patient and Living Donor Rights
- Human Resources

We look forward to working with CMS and HRSA officials and OPTN representatives in the near future to offer suggestions that will advance efforts to unify and simplify regulatory oversight in these areas.

Once again, we very much appreciate and strongly support CMS' proposal to eliminate outcomes, clinical experience, and data submission requirements as a condition of Transplant Center re-approval. We believe that this proposal is an important first step in making transplantation more accessible to Medicare patients and in reducing the regulatory burden on Transplant Centers that interferes in the delivery of optimal patient care.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Dixon Kaufman". The signature is fluid and cursive, with the first name "Dixon" and last name "Kaufman" clearly distinguishable.

Dixon B. Kaufman, MD, PhD
President
American Society of Transplant Surgeons