



National
Kidney
Foundation®

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November 5, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Room 314G
Hubert H. Humphrey Building,
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

Dear Administrator Verma,

The National Kidney Foundation is pleased that the Centers for Medicare & Medicaid Services (CMS) is taking an important step towards reducing organ discards with this proposed rule. These proposed changes to the Conditions of Participation (CoP) are in alignment with recommendations made from experts in transplantation and kidney recipients as part of the National Kidney Foundation's May 2017 Kidney Discard Conference. We support the CMS proposal to remove § 482.82, the requirements under the Conditions for Participation (CoP) that transplant centers submit certain duplicative data and report 1-year post-transplant survival and the conforming changes to §482.102(a)(5) "Condition of participation, Patient and living donor rights" and § 488.61 "Special Procedures for Approval and Re-Approval of Organ Transplant Centers." Given that these are already requirements by the Organ Procurement and Transplant Network (OPTN) for transplant programs, we agree that this will remove unnecessary administrative burdens. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

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There are over 3,000 deceased donor kidneys discarded each year. These kidneys considered are considered higher risk, but organs transplanted with similar donor characteristics demonstrate that many could be successfully transplanted substantially improving outcomes for patients and potentially lowering costs to Medicare when compared to remaining on dialysis. The National Kidney Foundation brought together 70 key opinion leaders in organ donation and transplantation, including kidney patients and families, transplant surgeons, nephrologists, organ procurement organization leadership, the federal government, and payers to identify reasons that deceased donated kidneys are discarded, as well as practical solutions to increase utilization of these life-saving allografts. One key recommendation was to test removing regulatory requirements to report 1-year survival post-transplant for higher risk for discard kidneys as it is believed that this requirement has caused some transplant programs' to be overly conservative in what kidneys they will accept, even though there is no evidence that using higher risk kidneys alone has a negative impact on 1-year survival rates. We believe this proposed rule would fulfill this consensus recommendation of the kidney and transplant communities and help to change overly conservative behavior due to a perceived risk of program status and Medicare coverage secondary to regulatory oversight and improve outcomes and access to transplantation for kidney patients.

While not a part of this proposed rule the National Kidney Foundation believes there are many additional opportunities for CMS to facilitate quality improvement and reduce barriers to increasing kidney utilization. Another opportunity is to explore risk adjusted reimbursement or other changes in payment policy to remove barriers to transplanting high-risk for discard kidneys, as these are costlier transplants to perform. Recipients of kidneys with a high risk for discard often result in longer hospital stays, inpatient dialysis treatments due to an increased rate of Delayed Graft Function (DGF), on-going invasive procedures to assess the quality of the transplant and concomitant risk of organ rejection, and more frequent readmissions for complications all of which increase the hospital costs yet still reimbursed under a single DRG.

In addition, a formal ongoing initiative to increase kidney utilization that brings together government agencies including CMS and HRSA with the kidney transplant community to share best practices and discuss opportunities to improve high-risk kidney allocation and patient education would allow for increased opportunities to reduce kidney discards, improve access to transplantation, and allow patients to participate in shared-decision making about high-risk for discard kidney offers.

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The National Kidney Foundation appreciates the opportunity to comment on this proposed rule and encourages CMS to take additional steps to increase kidney utilization and transplantation. Please contact Tonya Saffer, Vice President for Health Policy at tonya.saffer@kidney.org with any questions.

Sincerely,

Kevin Longino

Kevin Longino
CEO and Kidney Patient

Holly Mattix-Kramer

Holly Mattix-Kramer, MD, MPH
President