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February 5, 2021

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Acting Secretary  
Department of Health and  
Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Elizabeth Richter  
Acting Administrator  
Centers for Medicare &  
Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: CMS-3380-F2: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations; Public Comment Period; Delay of Effective Date**

Dear Acting Secretary Cochran and Acting Administrator Richter:

The American Kidney Fund appreciates the opportunity to provide comments on the temporary 60-day delay of the effective date of the final rule referenced above, from February 1, 2021 to March 30, 2021 (except for amendment 3).

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

AKF urges the Centers for Medicare and Medicaid Services (CMS) and the Biden Administration to act quickly to implement the final rule on Organ Procurement Organizations (OPO) Conditions for Coverage. Echoing our comments on the proposed rule, we believe the final rule is an important step in making more organs available for transplant, and to increase the number of people receiving a kidney transplant.

We believe the new donation rate and transplantation rate measures will provide more consistency and reliability than the previous measures because they will be based on independent data, as opposed to self-defined and self-reported data that can lead to inadvertently rewarding poor performance. We also believe the 25 percent performance benchmark will help encourage OPOs to successfully transplant organs they procure and reduce the number of discarded viable organs.

AKF also supports the change in frequency of CMS OPO performance reviews to every 12 months throughout the four-year recertification cycle. This will ensure fewer viable organs are wasted and more timely transplants occur. The previous 36-month assessment cycle was too long of a period that allowed for continued poor performance of under-performing OPOs.

Kidney transplantation is considered the best treatment option for many people facing kidney failure because it can increase their chances of living a longer, healthier life. However, the number of people on the organ transplant waiting list is great—about 108,000 Americans are on the list, with nearly 85 percent of those in need of a kidney. Many will die before they receive one because of the dire shortage of kidneys for transplant. The OPO Conditions for Coverage final rule makes critical changes to increase accountability for organ procurement organizations that will help more people receive transplants. We ask that CMS and the Biden Administration implement this final rule as soon as possible.

Thank you for your consideration of AKF's comments.

Sincerely,



LaVarne A. Burton  
President and CEO