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February 21, 2020

The Honorable Alex M. Azar, II  
Secretary  
Department of Health and  
Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

The Honorable Seema Verma  
Administrator  
Centers for Medicare &  
Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: CMS-3380-P: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization**

Dear Secretary Azar and Administrator Verma:

The American Kidney Fund appreciates the opportunity to provide comments on the proposed rule that would revise the Organ Procurement Organization (OPO) Conditions for Coverage in order to increase donation rates and organ transplantation rates.

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 reiterates our support for the Administration's *Advancing American Kidney Health* initiative and its three main objectives: increase efforts to prevent, detect, and slow the progression of kidney disease; provide patients with kidney disease with more options for treatment; and deliver more organs for transplant. As part of the initiative, the Centers for Medicare and Medicaid Services (CMS) is proposing to replace the current OPO outcome measures with new donation and transplantation rate measures that are more transparent, reliable and objective. CMS is also proposing to implement a new performance benchmark for OPOs and make changes to the outcome measure assessment and recertification process. AKF is supportive of these proposed changes with some minor modifications. We believe this proposed rule, if finalized, will be an important step in making more

organs available for transplant, and to increase the number of people receiving a kidney transplant.

### **Proposed Changes to Outcome Requirements**

CMS proposes a new donation rate measure that would be the number of actual deceased donors and a new transplantation rate measure that would be the number of organs procured within the donation service area (DSA) and transplanted. Both the donation and transplantation rate measures would be measured as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. CMS also proposes to use these new measures in the context of comparative donation and transplantation rates, such that success will be defined as how an OPO performs on these outcome measures compared with the top 25 percent of donation and transplantation rates for OPOs. OPOs will be allowed the opportunity to re-certify if their performance is not statistically significantly different from the 25 percent of OPOs.

AKF supports these proposed outcome measures and the proposed performance threshold of 25 percent. We believe these proposed measures will provide more consistency and reliability than the current measures because they will be based on independent data, as opposed to the current 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.

However, we encourage CMS to use the inclusionary cause, age, and location consistent (CALC) methodology for the denominator of the outcome measures, instead of the proposed methodology that uses exclusion criteria. While CMS' comparative analysis of the methodologies demonstrates similar results in terms of estimated increases in donors and organs transplanted, the CALC methodology has greater face validity because it limits the denominator to inpatient deaths from causes that are consistent with donation. The exclusion criteria approach might include inpatient deaths from causes that never lead to organ donation.

We also encourage CMS to closely monitor the impact of these proposed changes to ensure that patients are not unintentionally adversely affected, while also ensuring that OPOs are held accountable for their performance.

### **Proposed Changes to the Re-Certification Cycle**

CMS proposes to conduct an outcome measures assessment for OPOs at least every year and be based on data from the most recent 12 months of data from state death certificates. Currently, OPOs are recertified on a four-year cycle, with assessments based on 36 months of data. Under the proposed change, OPOs that demonstrate donation and transplantation rates that are statistically significantly less than the top 25 percent threshold rate are expected to take actions to improve their performance and include the specific actions that they will undertake to improve their outcome measures in their Quality Assurance and Performance Improvement (QAPI) program.

AKF supports the proposal to conduct outcome measure assessments at least every year. The current 36-month assessment cycle is too long of a period that allows for continued poor performance of under-performing OPOs. In addition to the use of state death certificates, we also encourage CMS to consider using other, more objective, sources of data in the assessments.

Thank you for your consideration of AKF's comments and recommendations.

Sincerely,



LaVarne A. Burton  
President and CEO