The Honorable Alex Azar  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Azar,

The President’s Executive Order on Advancing American Kidney Health will establish much needed objective and outcome measures for Organ Procurement Organizations (OPOs). The Executive Order has already had a great impact on the kidney community with positive changes included in various policy updates and regulations. One of those changes is proposed revisions to OPO conditions for coverage and outcome measure requirements. While I firmly support the intent of the proposed rule to increase procurement opportunities for transplantation, I am concerned with several of the provisions and the impact they may have on my local OPO and the people they serve.

I have three areas of concern with the proposal:

First, the performance threshold for OPOs is set at the top 25th percentile which will ensure a high number of OPOs will not meet the metrics and therefore be eligible for decertification. If the purpose of the program is to help OPOs improve their performance in order to increase organ donation and transplantation, decertifying 75% of OPOs in a given year could destabilize the US organ donation and transplantation system and potentially lead to the loss of lives.

**Recommendation:** Establish a performance threshold for the donation and transplantation rate metrics based on a specified standard deviation from the mean.  
**Rationale:** Using a standard deviation performance threshold would more accurately and fairly assess OPO performance. It balances the need to incentivize continual performance improvement while establishing a rational basis for the threshold as supported by the data and valid statistical methodology.

Second, the use of death certificates as the data source for calculating the potential donor pool. Studies show that 30-60% of death certificates inaccurately report the cause of death. In addition, death certificates show primary cause of death and inconsistently document secondary conditions such as if the deceased donor was COVID-19 positive and therefore ineligible for donation. For example, a patient can die of a head trauma from an accident but be infected with the coronavirus or have metastatic cancer and this would not be noted in the death certificate. As a result, the death would be mistakenly included in the calculation of potential donors. Such a patient would not actually be medically acceptable for donation and transplant.
Recommendation: Use inpatient ventilated deaths as the data set for donation rates.
Rationale: A potential donor must be on a ventilator in a hospital at the time of death for organ donation to occur. The calculation of a donation rate should include only these inpatients for the most accurate performance metric.

And finally, the two proposed metrics share the same data source as a denominator, i.e. death certificates. Because of this, they are based on a faulty data set AND statistically highly correlated. Stated another way, both metrics measure the same thing and in effect there is only one measure not two. Measuring the performance of an organization based on only one measure will not provide an accurate view of their actual performance.

Recommendation: Retain the current Observed to Expected (O:E) Yield measure as the measure of organ transplantation rates.
Rationale: The observed versus expected ratio calculates the number of organs expected to be transplanted from a given donor (based upon data from actual donors) and compares it to the number of organs the OPO actually provides for transplant. If the ratio is 1.0, the OPO is performing as expected, if the ratio is > 1.0 the OPO is exceeding expectation, and if the ratio is < 1.0 the OPO is performing below expectation. Retaining this metric would also satisfy the statutory requirement for OPOs to be evaluated based on multiple metrics. The data is independently reported, verifiable, calculated, and widely supported by all stakeholders in the donation and transplantation community.

Thank you for your consideration of my concerns and I look forward to working with you on our mutual objective of increasing organ donation and transplantation.

Sincerely,