# Congress of the United States
## Washington, DC 20515

September 28, 2020

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Azar:

Thank you for work to ensure individuals in need have uninterrupted access to comprehensive transplantation services during the COVID-19 public health crisis. President Trump's recent Executive Order (EO) on Advancing American Kidney Health will establish an objective approach to producing outcome measures for Organ Procurement Organizations (OPOs). Although this EO demonstrates positive changes, we are concerned about changes offered by CMS to OPO conditions for coverage and outcome measure requirements [CMS-3380-P].

While we firmly support the intent of the proposed rule to increase procurement opportunities for transplantation, our concerns lie with certain provisions and the impact they may have on local OPOs, the national OPO system, and the more than 113,000 patients they serve. Florida would especially feel the impact of the rule's uncertain data as it could potentially lead to significant destabilization of the donation process in Florida, resulting in lives lost.

As you continue developing a performance structure that achieve CMS's goals, we request that you take into consideration the following suggestions:

**Performance Threshold**: Because the performance threshold for OPOs is set at the top 25th percentile, a high number of OPOs will not meet metrics and therefore potentially face decertification. To accomplish the goal of improving OPO performance, establishing a performance-based threshold for the donation and transplantation rate metrics based on a specified standard deviation from the mean may prove more effective. In doing so, a standard deviation performance threshold would more accurately and fairly assess OPO performance.

**Data Sourcing**: Studies show that 30-60% of death certificates inaccurately report the cause of death. The use of death certificates is overbroad when only 1-2% of all deaths meet the criteria for organ donation. Additionally, death certificates show the primary cause of death and inconsistently document secondary conditions (i.e. if a deceased donor was COVID-19 positive and therefore ineligible for donation). Instead, we recommend the use of hospital-supplied (or provided), inpatient ventilated deaths as the data set for calculating and comparing donation rates to improve accuracy.

**Double Denominator**: The two proposed metrics share the same data source as a denominator, i.e. death certificates. Because of this, the data sets are not accurately reported and statistically highly correlated. Both metrics measure the same data, resulting in 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. Instead, retaining the current Observed to Expected

(O:E) Yield measure, currently managed by the national federal contractor, would properly measure organ transplantation rates. This form of data is independently reported, verifiable, calculated, and widely supported by all stakeholders in the donation and transplantation community.

Florida has enjoyed wide success with its OPOs, demonstrating over two years an increase of 22 percent in the state's number of donors. As a result, more than 11 million people have registered their donation decision in Florida. However, even with this increase, Florida OPOs, and those throughout the country, may still face decertification under the proposed metrics, which could severely inhibit organ donation and transplantation throughout Florida and various states in the U.S.

For these reasons, we respectfully request these recommendations to be carefully considered to ensure patients have access to transplant services. We look forward to working with you on our mutual objective of increasing organ donation and transplantation rates for those in need.


Sincerely,


John H. Rutherford
Member of Congress

Donna E. Shalala
Member of Congress


Mario Diaz-Balart
Member of Congress

Ted S. Yoho, D.V.M.
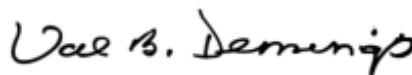Member of Congress

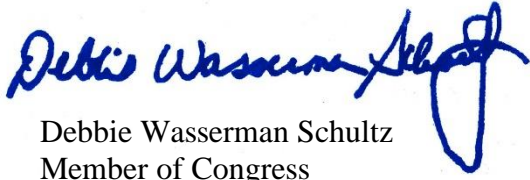
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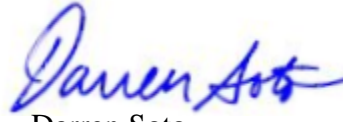
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