

Congress of the United States

Washington, DC 20510

September 15, 2020

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

Dear Secretary Azar:

We are encouraged by the effects of the President's Executive Order on Advancing American Kidney Health in improving care for patients with kidney disease. One major aspect of this Executive Order seeks to increase the number of kidneys available for transplant by promoting outcome measures for Organ Procurement Organizations (OPOs). This is certainly a laudable goal that could improve the lives of many Mississippians awaiting transplantation. However, we write to raise three specific concerns about the OPO proposal and ask that the Department address these as it works toward a final rule.

First, we are concerned that setting the OPO performance threshold at the top 25th percentile could destabilize the U.S. organ donation and transplantation system. This high threshold will mean that up to 75 percent of OPOs could face decertification in any given year. As we understand it, the goal of this rule is to increase organ donation and transplantation, and this high threshold may undermine that goal. We encourage the Department to consider alternative metrics other than the 25th percentile. For example, a metric based on a specified standard deviation from the mean could still incentivize continual performance improvement without destabilizing the system quickly.

Second, we are concerned that using death certificates to identify the potential donor pool may render the metrics inaccurate. Studies show that 30-60 percent of death certificates inaccurately report the cause of death. In addition, death certificates only show primary cause of death and inconsistently document secondary conditions that may render an individual medically ineligible for organ donation. We know you share our interest in ensuring these metrics are as accurate and fair as possible, and we encourage you to consider alternative ways to identify the potential donor pool other than the use of death certificates. It is our understanding that a potential donor must be on a ventilator in a hospital at the time of death for organ donation to occur, which would make using the number of deaths among ventilated patients in an inpatient facility a better means of identifying actual potential donors.

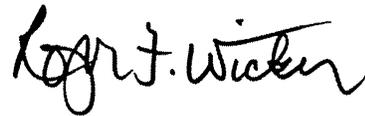
Finally, we are concerned that the two proposed metrics are statistically correlated and in fact only provide one measure by which to judge OPOs. Since the two proposed metrics share the same data source as a denominator, the metrics may be redundant since the two metrics are likely to correlate closely. Multiple metrics are better, and we encourage the Department to consider ways to incorporate the current Observed to Expected Yield ratio, which would diversify the metrics being used and help satisfy the statutory requirement for OPOs to be evaluated with multiple metrics. It is our understanding that this ratio is already independently reported, so it should be administratively simple for the Department to incorporate into the planned OPO metrics.

Thank you for your consideration of these three concerns. We applaud your work to increase organ donation and transplantation and look forward to working with you toward this important goal.

Sincerely,



CINDY HYDE-SMITH
United States Senator



ROGER F. WICKER
United States Senator



Steven M. Palazzo
United States Representative



TRENT KELLY
United States Representative



MICHAEL GUEST
United States Representative