

October 26, 2020

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

Dear Secretary Azar,

We are writing as the collective organ transplant community in Colorado and Wyoming: the hospital transplant centers that provide renewed hope with lifesaving transplants to those on the waiting list, and the federally designated organ procurement organization (OPO) that facilitates donation and transplantation.

Our region is consistently among the top performing for organ donation in the country: last year 596 lives were saved through organ donation and we facilitated more organ transplants than ever by 22%, marking the fifth consecutive year of growth. *We are appealing to you today to help us keep saving lives.*

The President's Executive Order on Advancing American Kidney Health will establish much needed measures for OPOs. We support valid and continually improving performance metrics, that are based on sound data. *Unfortunately, the proposed metrics fail to meet these standards and could unintentionally lead to lives lost in Colorado and Wyoming.*

As you continue developing OPO conditions for coverage and outcome measure requirements, we request that you take into consideration the following suggestions:

Performance Threshold: Because the performance threshold for OPOs is set at the top 25 percent, 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 those on ventilated support or 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: death certificates. Because of this, the data sets are not accurately reported and are statistically highly correlated. Both metrics measure the same data, resulting in only one measure, not two.

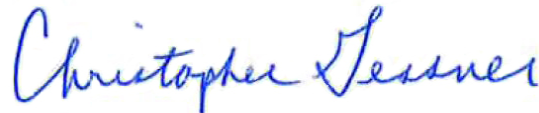
Measuring the performance of an organization based on only one measure will not provide an accurate view of their actual performance. Instead, retaining the current Observed to Expected (O:E) Yield measure, currently managed by the national federal contractor, would properly measure organ transplantation rates. This form of data is independently reported, verifiable, calculated, and widely supported by all stakeholders in the donation and transplantation community.

We respectfully request these recommendations 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,



Jena Hausmann
President & Chief Executive Officer
Children's Hospital Colorado



Christopher Gessner
President & Chief Executive Officer
University of Colorado Hospital



Todd Folkenberg
Chief Executive Officer
Porter Adventist Hospital



Jennifer Prinz
President & Chief Executive Officer
Donor Alliance



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