We write as the five past Chief Technology Officers for the U.S. Department of Health and Human Services (HHS) in support of the Center for Medicare and Medicaid Services (CMS) pro-patient rule issued on November 20, 2020: Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F.

We understand that this OPO Rule was caught up in the Biden-Harris Administration’s blanket review of all midnight regulations, and therefore its implementation is now delayed until March 30 to give agency officials “the opportunity for further review of the issues of fact, law, and policy raised by this rule.” We write to assure you that this is a well-researched, well-structured, scientifically-based rule. Its immediate implementation will save more than 7,000 lives every year, $1 billion annually to Medicare in avoided dialysis costs, and will mark a major step toward addressing a key health equity issue. Given that COVID-19 is known to cause organ failure, these reforms are more urgent now than ever.

We have all worked on organ donation reform, one of the very few issues that is so bipartisan that it has been supported across administrations. This work began under the Obama-Biden Administration, including a 2016 White House Organs Summit; that these reforms persisted speaks to the uniquely bipartisan support they receive, including with ongoing support from many senior alumni of the Obama Administration.

Even in a time of hyper-partisanship, this rule has been supported by as diverse an expert group as any public health initiative in recent memory, including: the organ donation leads for both the past two White Houses; Nobel Laureate Al Roth; DJ Patil, the former Chief Data Scientist of the United States under President Obama; policy leaders varying from Andy Slavitt, the former Acting Administrator of the Centers for Medicare and Medicaid Services for President Obama to the Executive Director of the Senate Conservatives Fund; leading national philanthropies including Schmidt Futures and Arnold Ventures; and the former President of the NAACP.

Likewise, the OPO Final Rule has the support of every major patient group engaged on the issue, including the National Kidney Foundation, Global Liver Institute, American Society of Nephrology, and Organize, advocacy groups including Families USA, and the past President of the Association of OPOs.

In Congress, support for OPO reform includes Senators Wyden, Grassley, Young, Cardin, Warren, Bennet, Hyde-Smith, and Blumenthal; as well as Representatives including both co-Chairs of the House Kidney Caucus; the co-Chair of the House Diabetes Caucus; the Deputy Chair of the House Progressive Caucus, and the former Chair of the Congressional Black Caucus; and the House Committee on Oversight.
and Reform, which noted “The burden of OPO failures is disproportionately borne by patients of color, making OPO reform an urgent health care equity issue”; among other champions.

It is easy to understand why. OPOs operate as unaccountable, government monopoly contractors. Historically, OPOs have been allowed to self-interpret and self-report their own performance metrics. Not only did this allow OPOs - which are now the subject of separate Congressional investigations by the House Committee on Oversight and Reform and the Senate Finance Committee, which was forced to issue a subpoena for non-compliance with its investigation - to game their performance reporting, but it actually rendered the regulation itself legally unenforceable.

This created a dynamic wherein no OPO has ever lost its government contract despite severe performance failures, fatal patient safety lapses, documented Medicare fraud, obstructionism, and even criminality.

The November 2020 Final Rule moves HHS’s evaluation of OPOs from self-interpreted and unenforceable to an objective standard using reliable data already held by the Centers for Disease Control and Prevention. Because performance varies by an astounding 470% across OPOs, enabling basic OPO accountability is projected to save more than 7,000 lives every year as well as $1 billion annually to Medicare in avoided dialysis costs.

As both Ben Jealous, former President of the NAACP, and Rep. Karen Bass, past Chair of the Congressional Black Caucus, have noted, the OPO Final Rule will also mark a meaningful step toward addressing racial inequities in the organ donation system.

In the absence of objective and enforceable performance standards, research finds that OPOs have systematically deprioritized care for patients of color, to whom OPOs often provide deeply substandard care. As a direct result, ethnic minorities are both far more likely to need lifesaving organ transplants as well as far less likely to receive them.

The merits of OPO reform are so self-evident that Politico has noted “bipartisan support for cracking down on organ procurement organizations,” with both the Washington Post and New York Times editorial boards calling for urgent adoption of the OPO Final Rule. In fact, the New York Times wrote: “an astounding lack of accountability and oversight in the nation’s creaking, monopolistic organ transplant system is allowing hundreds of thousands of potential organ donations to fall through the cracks.”

Having all worked on this issue across our tenures at HHS, we agree wholeheartedly, which is why, in November 2020, we endorsed research from alumni of the United States Digital Service cataloguing severe deficiencies in the OPO system and advocated for the Final Rule.

While the Administration is likely to receive critical comments from the OPO contractors themselves as part of an ongoing special interest campaign, we have all heard similar, baseless claims from OPOs, and have not found them to be grounded in science or made in good faith. For further review of the Rule’s mechanics, we refer you to research from DJ Patil, former United States Chief Data Scientist under President Obama, published in the Journal of the American Medical Association; for research outlining
how HHS can implement these reforms seamlessly and while foregrounding racial equity, we refer you to research from the Bridgespan Group, supported by Schmidt Futures and Arnold Ventures.

We appreciate the need to review all regulations finalized in the last 60 days of the previous Administration. However, we write to lend our full support to the immediate and forceful implementation of this rule at the conclusion of such review. As we have written before: We are strongly motivated by data that show organ donation reform can save thousands of lives every year - as well as billions of dollars to the taxpayer - and help address racial disparities in our healthcare system.

We stand ready to support the Administration in this critical health equity issue.

Sincerely,

Todd Park
Bryan Sivak
Susannah Fox
Bruce Greenstein
Ed Simcox

cc: Dr. Marcella Nuñez-Smith, COVID Equity Task Force Chair
Sean McCluskie, HHS
Norris Cochran, HHS