



PRESS RELEASE

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U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES MOVES TO INCREASE PATIENT ACCESS TO KIDNEY TRANSPLANT WITH TRANSPARENCY AND ACCOUNTABILITY FOR THE NATION'S 58 ORGAN PROCUREMENT ORGANIZATIONS

**Top ASN Priority Will Improve Organ Procurement in the Face of Current
Dysfunction for 110,000 Americans on the Organ Waitlist**

Washington, DC (12/3/20) — The U.S. Department of Health and Human Services (HHS) took final action to increase donation rates and organ transplantation rates by applying new standards of accountability and transparency to the nation's organ procurement efforts on November 20, 2020. HHS finalized the *Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization* rule that was proposed earlier this year by the Centers for Medicare and Medicaid Services (CMS). The new regulation replaces existing metrics that evaluate the performance of the nation's 58 Organ Procurement Organizations (OPOs) with new, objective measures designed to increase accountability and help more patients access lifesaving organ transplants. The American Society of Nephrology (ASN) has long advocated for greater transparency in OPO performance and for this rule to be finalized.

The final rule means:

- More patients may get transplants with more transparent, reliable measures.
- As many as 28,000 more organs per year may be available for transplant according to a report by the Bridgespan Group *Reforming Organ Donation in America*¹ translating into an estimated 17,000 kidneys; almost 8,000 livers; 1,500 hearts; and 1,500 lungs.

¹ <https://www.bridgespan.org/bridgespan/Images/articles/reforming-organ-donation-in-america/reforming-organ-donation-in-america-01-2019.pdf>

- The final rule aims to significantly reduce variances in organ recovery success among the 58 OPOs; according to an analysis by Bloom Work Digital² reporting, there is currently “up to a 470% difference between the best and worst OPOs in terms of potential organs recovered.”³
- Equity will increase. Black Americans are half as likely to receive a kidney transplant as White Americans, and similar disparities exist for other patients of color. The causes of this disparity are multifactorial, but factors within the control of OPOs contribute to this gap.⁴ However, when OPOs follow protocol, donor authorizations from families of color rapidly increase.⁵
- Processes to successfully [recover and deliver kidneys](#) to waitlisted patients will improve with increased transparency and accountability, and standardizable measures will allow for systemwide comparison and dissemination of best practices.

“Bringing a more data-driven, transparent approach to our nation’s organ procurement efforts is a crucial and overdue change that ASN has long championed,” said transplant nephrologist Barbara Murphy, MB BAO BCh, FRCPI, Mount Sinai Health System department of medicine chair and an ASN councilor. “This final rule will enable us to better evaluate and ultimately improve our organ recovery processes, allowing thousands more patients a year to receive a kidney transplant.”

“Ensuring our transplant system is operating efficiently and equitably is of paramount importance to ASN at a time when receiving a transplant is more critical than ever. Americans with kidney failure are the most at risk population for hospitalization and death from COVID-19, and Black Americans are half as likely to receive a transplant as White Americans. We can do better, and this final rule is a huge step in the right direction,” said Anupam Agarwal, MD, FASN, ASN President.

² <https://bloomworks.digital/organdonationreform/Summary/>

³ <https://www.govinfo.gov/content/pkg/FR-2019-12-23/pdf/2019-27418.pdf>

⁴ Siminoff, L A, Lawrence, R H, Arnold, R M. Comparison of black and white families' experiences and perceptions regarding organ donation requests. 2003, Crit Care Med. doi: 10.1097/00003246-200301000-00023

⁵ Siminoff, L A, Shafer, T J. Public Comment Re CMS-3380-P: Proposed Rule on OPO Conditions of Coverage. February 18, 2020. Retrieved September 30, 2020

More than 37 million Americans are living with kidney diseases, including more than 785,000 with kidney failure, for which a kidney transplant is the optimal therapy for most patients. There are currently nearly 100,000 people waiting to receive a kidney alone, and tragically 10 Americans die every day while waiting for a kidney transplant.

The final rule will implement two new performance evaluation metrics using the data from the Centers for Disease Control and Prevention's Detailed Multiple Cause of Death Detailed Mortality File—replacing self-reported data and enabling the federal government and researchers to make meaningful comparisons across OPOs nationwide. Importantly, this approach will not require any new data reporting or administrative burden on the nation's hospitals and healthcare systems. The new metrics go into effect August 1, 2022. OPOs that are not meeting performance expectations will have four years to improve their performance before the first final assessments in 2026.

"As a transplant nephrologist, too often I see patients on dialysis who would thrive with a kidney transplant yet are unable to obtain one because of the organ shortage," said Michelle A. Josephson, a Professor of Medicine and the Medical Director of the Kidney Transplant Program at the University of Chicago and the Chair of the ASN Policy and Advocacy Committee. "Because the OPO final rule will increase transparency, equity, and the number of kidneys available, more of my patients and their families will have the hope of a transplant in their future."

The final rule is widely supported by bipartisan, bicameral policy makers and health policy experts across the US government and is seen by many as the start of future efforts to increase the number of transplants for patients.

"As Co-Chairs of the Congressional Kidney Caucus, we welcome HHS finalizing changes to organ transplant accountability rules. These necessary changes will force Organ Procurement Organizations to improve their performance and deliver more organs to Americans in need," said Representatives Suzan DelBene (WA-01) and Larry Bucshon (IN-08) in a statement. "Today, 91,949 patients are waiting for a kidney transplant but only 32,579 transplants have been performed this year. Actions like the one announced today give those waiting for transplants renewed hope."

"Saving lives must be the number one priority for organ procurement organizations, which are responsible for getting donated organs to patients in

need,” said Senator Todd Young (IN) in a statement. “Unfortunately, we have seen that this is not always the case. HHS’ new rule, which is modeled after my legislation, will finally ensure that these organizations are held accountable and subject to metrics that are clear and verifiable.”

“Today’s announcement marks an important shift towards increasing accountability and putting patient interests first,” said Senator Ron Wyden (OR) in a statement. “Too many families have lost loved ones because the organ procurement system has fallen short, and it’s high time to stop the same failures from repeating. I’ll be watching closely to ensure this key piece of our health care system gets on the right track.”

ASN is reviewing the final rule in detail and will continue to advocate for appropriate implementation that best serves the nearly 100,000 Americans on the kidney waitlist.

Since 1966, ASN has been leading the fight to prevent, treat, and cure kidney diseases throughout the world by educating health professionals and scientists, advancing research and innovation, communicating new knowledge, and advocating for the highest quality care for patients. ASN has more than 20,000 members representing 131 countries. For more information, please visit www.asn-online.org or contact the society at 202-640-4660.

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