



PRESS RELEASE

ASN Contact: Christine Feheley
(202) 640-4638 | cfeheley@asn-online.org

AMERICAN SOCIETY OF NEPHROLOGY TRANSPLANT POLICY PRIORITIES AT CENTER OF BOLD NEW PROPOSED RULES

Department of Health and Human Services proposes to overhaul organ procurement and strengthen living donor support

Washington, DC (December 17, 2019) — The US Department of Health and Human Services (HHS) today took bold steps in two proposed rules to increase the availability of organs for the 113,000 Americans waiting for a lifesaving organ transplant – 20 of whom die each day – and to strengthen support for Americans who choose to be living donors. Both proposed rules advance policy changes the American Society of Nephrology has long been advocating for and is strongly supportive of.

President Donald J. Trump called for changes to overhaul living and deceased donor organ policy in his July 10, 2019 [Executive Order on Advancing American Kidney Health](#) (AAKH), and today's proposed rules execute on that mandate. The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule to change the way organ procurement organizations (OPOs) are held accountable for their performance, and the Health Resources and Services Administration (HRSA) issued a proposed rule to remove financial barriers to living organ donation.

ASN has long advocated for the removal of barriers to living donation through legislative and regulatory efforts, and the society has repeatedly called for the use of objective, verifiable metrics to optimize OPO performance and improve access to life-saving kidney transplants for the 720,000 Americans living with kidney failure.

“ASN and other stakeholders have been pushing for the positive changes proposed today over many years, and I applaud the Trump Administration for its leadership role in this effort,” said Mark E. Rosenberg, MD, FASN, ASN President.

“These changes are great for nephrology and, more importantly, are a tremendous boost for patients, their families, and potential American donors. Living donors literally give the gift of life when they donate a kidney and they deserve our complete support. Today's proposal to reimburse their lost wages and help with child and elder care costs during donation are long overdue,” Dr. Rosenberg continued.

“Our broken system of procuring organs and supporting kidney donors’ costs thousands of American lives each year,” said HHS Secretary Alex Azar today. “Many organ procurement organizations do wonderful work, but some aren’t performing nearly as well as they could. We’re going to stop looking the other way while lives are lost and hold OPOs accountable. On living donations, we’re going to dramatically expand support for living kidney donors, so that Americans who wish to be generous living donors don’t face unnecessary financial barriers to doing so.”

“Today’s tremendous news truly transforms the landscape for kidney patients, providing hope and a path to positive change for the future,” said Michelle A. Josephson, MD, FASN, transplant nephrologist and incoming ASN Policy and Advocacy Committee chair. “Bringing transparency to organ procurement organizations’ performance opens the door to improving transplant availability and access for patients. At the same time, we know that living donation has created financial hardships for donors and prevented others from donating altogether. Today’s proposed rule is a crucial step to eliminating those barriers and hardships for Americans who wish to give the gift of life.”

“Every day, twenty Americans die waiting for an organ and thousands of Americans are languishing on waitlists. That is unacceptable and represents a missed opportunity to save lives and improve patients’ quality of life,” said CMS Administrator Seema Verma.

“Living organ donation is an important option for thousands of people on the national transplant waiting list,” said HRSA Administrator Tom Engels. “To date, approximately 96,000 individuals are on the national waiting list awaiting an available kidney. This proposed rule will increase living organ donation by removing financial disincentives for living organ donors.”

Removing Financial Disincentives to Living Organ Donation

[Executive Order on Advancing American Kidney Health](#) emphasized that supporting living organ donors can help address the current demand for kidney transplants. HRSA’s proposed rule expands the scope of reimbursable expenses for living donors to include lost wages, and childcare and eldercare expenses for those donors who lack other forms of financial support. HRSA also is reviewing a notice that would increase the income threshold for living donors eligible for reimbursements.

Organ Procurement Organization (OPO) Conditions for Coverage Proposed Rule

“CMS is proposing much-needed changes to hold OPOs accountable and incentivize them to actively collect donated organs and improve transplantation rates in their donation service area (DSA). CMS estimates that if all OPOs were to meet both the donation and transplantation rate measures, the number of annual transplants would increase from about 32,000 to 37,000 by 2026, for a total of almost 15,000 additional transplants in that time,” said HHS in its press release.

The proposed rule would improve the current measures by using “objective and reliable data, incentivize OPOs to ensure all viable organs are transplanted, and hold OPOs to greater oversight while driving higher OPO performance,” wrote CMS. To better serve organ transplant recipients and the many people waiting for a transplant, CMS is proposing:

- **Donation rate measure:** The donation rate would be the number of actual deceased donors as a percentage of the donor potential, which would be defined as total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not preclude a potential donor from donating an organ.
- **Transplantation rate measure:** The organ transplantation rate would be the number of organs transplanted as a percentage of the donor potential, which would be defined as total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not preclude a potential donor from donating an organ.
- **Top 25 percent benchmark:** CMS is proposing that all OPOs meet the donation and transplantation rates of the current top 25 percent of OPOs, which would be made public.
- **12-month reviews:** At the end of each re-certification cycle (every four years), an OPO would have to meet the CMS requirements for both the donation rate and transplantation rate measures. CMS is proposing to review OPO performance every 12 months throughout the four-year re-certification cycle to more quickly identify OPOs that need improvement and ensure fewer viable organs are wasted and more timely transplants occur.

Most of the proposed changes would not take effect until 2022.

For a fact sheet on the CMS proposed rule (CMS--P), please visit:

<https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-proposed-rule-revisions-outcome-measures-opos>

For a fact sheet on the HRSA proposed rule, please visit:

<https://www.hrsa.gov/sites/default/files/hrsa/public-comments/NPRM-amendment-factsheet.pdf> - PDF

To view the CMS proposed rule (CMS--P), please visit:

<https://www.hhs.gov/sites/default/files/cms-3380-p-ofr.pdf> - PDF

To view the HRSA proposed rule, please visit:

<https://www.hhs.gov/sites/default/files/living-donor-nprm.pdf> - PDF

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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