ASN Policy Team Interviews Expert on Transplant and Organ Procurement Policy

In late 2019, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule for Organ Procurement Organizations (OPOs) Conditions for Coverage. The proposed rule intends to require transparent, verifiable, and uniform metrics by which CMS can evaluate OPO performance. The American Society of Nephrology (ASN) provided comments of support and recommendations for improvement in February 2020.

The proposed rule would replace the existing outcome measures for OPO recertification with two new outcome measures that would be used to assess an OPO's performance: "donation rate" and "organ transplantation rate," effective beginning in 2022. The "donation rate" would be measured as the number of actual deceased donors as a percentage of total inpatient deaths in the donation service area (DSA) among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. The "organ transplantation rate" would be measured as the number of organs procured within the DSA and transplanted as a percentage of total inpatient deaths in the DSA among patients 75 years of age or younger with any cause of death that would not be an absolute contraindication to organ donation. These important changes to evaluating OPO performance are expected to be finalized in rulemaking in the near future.

The ASN Policy team interviewed Jennifer Erickson, who served in the White House Office of Science and Technology Policy in the Obama administration, about the changes. Erickson's portfolio included organ policy and innovation efforts. She has been a strong advocate for changing OPO regulations inside and outside of government.

You have played a major role in guiding transplant policy for the foreseeable future. What drew you to this issue? Do you agree with the characterization that we are on the cusp of major change?

I've seen the horrors of organ failure firsthand. I've spent far too much time sitting next to a dialysis chair and talking to people desperate for a call about an available organ transplant. When I learned that thousands more patients each year could receive organ transplants if government contractors were more efficient, I was committed to being part of reform efforts.

Thanks to the leadership of the Department of Health and Human Services (HHS), we are on the verge of changing what's possible for patients and saving tens of thousands of lives. I am hugely heartened by Secretary Azar's promise that "We're going to stop looking the other way while lives are lost and hold OPOs accountable." That's what patients deserve.

In your view, what should the future of organ procurement look like?

It should be efficient and driven by data and accountability, and there needs to be a lot more oversight, both from HHS and from Congress. I have a huge respect for the importance of coordinating organ donation and the work it takes to do that. After all, the vast majority of Americans support it—it's something we agree on as a country. So learning that there is a 400% variation for organ recovery across the country and that no OPO has ever lost a government contract due to poor performance—not even in cases of fraud, waste and abuse or criminality—is mind-boggling. OPOs that are performing this sacred public trust at a high standard should keep their contracts. As Baylor College of Medicine stated: " [O]nly the best performing OPOs should be surviving, while those underperforming centers are subject to consolidation or closure." It's a life and death issue, and patients can't wait.

What does the future hold for individuals in need of a kidney transplant?

That depends on when the proposed regulatory changes from HHS are finalized and how they are implemented. Keep in mind: HHS said the majority of OPOs are failing. If HHS moves to hold OPOs accountable right away by decertifying underperformers and giving those territories to higher performers, then a lot more kidney patients will get transplants. That goes for patients with other types of organ failure too. So hearing that some OPOs are arguing for delay or for unworkable metrics is deeply concerning. As former NAACP President Ben Jealous recently wrote: "Astoundingly [OPOs] are also asking that the new standards not be implemented until 2026, during which time tens of thousands more patients—disproportionately people of color—would die." That is unconscionable. And I agree with Reps. Katie Porter and Karen Bass, who wrote to Secretary Azar and CMS Administrator Verma: "We cannot consign 20,000 or more patients to die waiting for organ transplants while federal contractors are not held accountable, and therefore urge you to use the new standards in the next recertification cycle."

In your view, why are new rules for OPOs needed?

Patients are dying, every day and unnecessarily, because of massive underperformance by some OPOs. It's like the Wild West, and in all of my years in government I've never seen anything else like it. No one should be able to write their own report card—and that's the current system we have. Not only is it unreliable, it makes the current standards unenforceable.

Consider this: In my home state of Virginia, research shows the OPO recovered the organs of only 34% of potential donors. OPOs including Los Angeles, New York City, northern New Jersey, South Carolina, and Kentucky had even lower recovery rates. Transplant centers can't perform surgeries with organs that were never recovered. And the story earlier this year from *Kaiser Health News* that showed "UNOS is approximately 15 times as likely to lose, damage. or mishandle an organ as the airline industry is your luggage" was shocking. So we need rules that hold government contractors accountable at every step of the process. The government has to step in on behalf of patients. That's also why it's been great to see bipartisan oversight efforts from Sens. Chuck Grassley and Ron Wyden on the Senate Finance Committee, and calls for reform from Reps. Katie Porter and Karen Bass, chair of the Congressional Black Caucus, in the House.

What are the major changes proposed by the Department of Health and Human Services? How will they benefit patients? What role do you see for nephrologists—both transplant and nontransplant?

HHS is proposing accountability based on objective data, and while it's truly alarming that we haven't done this before, it's a big deal that HHS is doing it now. Ted Kennedy asked about underperformance in the nation's organ donation system in 1997, and since then, more than 200,000 Americans have died waiting for organ transplants. Patients do not need more studies or consensus conferences, they need action. Nephrologists know that patients deserve better. Hopefully increased accountability means they will be able to help more of their patients access transplants soon.

If the proposed rule is finalized and successfully implemented, what do you anticipate the effects could be on the organ shortage?

Simple: thousands more patients will live each year. Right now, 33 patients are removed from the organ waiting list every day because they have died or become too sick to transplant, and even that number likely grossly understates what the true demand is, given that so many patients who would benefit from transplant are never even listed in the first place. HHS' own proposed rule suggests that OPOs just hitting minimum compliance standards would translate to 5000 more transplants per year. Seth Karp, MD, the transplant chief at Vanderbilt, says data suggest that reforming the system could end the waiting lists for livers, lungs, and hearts within 3 years and dramatically decrease waiting times for kidney transplants.

Besides working to optimize organ procurement, what are other steps the kidney community can take, now or in the future, to increase patient access to transplantation?

Be impatient. Kidney patients deserve better than they are getting in terms of treatments, technology, and the whole system of care. The Advancing American Kidney Health Executive Order lays the groundwork for transformation, but rules still need to be finalized and implemented to reform deceased donation and support living donors, and Congress needs to invest in research and innovation via KidneyX and other mechanisms. And, as I've written about in the past, along with co-authors from the Trump administration and ASN leadership, we need to make sure there is real accountability and oversight.

ASN Continues Advocacy for International Medical Graduates

A robust and diverse group of health professionals and researchers serves as an asset to the nation's healthcare system, provides a sound foundation of scientific and medical expertise, and ensures the highest quality of patient care.

ASN and its members have long tracked federal policies that impact international medical graduates who are citizens of other nations (non-US IMGs) given their strong representation in the nephrology workforce. In 2017, the US nephrology workforce had the second highest percentage among medical specialties of active physicians who were international medical graduates at 49% (1). Non-US IMGs are necessary to maintain a strong healthcare workforce that is able to protect the health of all Americans as the nation battles the COVID-19 pandemic and prepares for future health challenges. ASN has recently taken steps to address concerns about federal policies related to non-US IMGs on both the legislative and executive fronts.

First, ASN endorsed the Healthcare Workforce Resilience Act (S. 3599, H.R. 6788), bipartisan, bicameral legislation that aims to strengthen the healthcare workforce and increase healthcare access during the COVID-19 pandemic.

The Healthcare Workforce Resilience Act directs the U.S. Citizenship and Immigration Services (USCIS) to "recapture" up to 40,000 previously unused immigrant visas and to reserve 25,000 of these visas for nurses and 15,000 for physicians. Previously unused immigrant visas can also be used for the families of these medical professionals and will not be counted toward the 40,000 cap. Visas recaptured as a result of the Healthcare Workforce Resilience Act will not be subject to country caps. To qualify, medical professionals will need to meet licensing requirements, pay required filing fees, maintain a clean criminal background, and clear a national security check. ASN will continue to track and advocate for passage of this legislation.

Second, ASN, recognizing that a collaborative approach is necessary to make significant progress in this policy area, has worked closely with partners across the medical and scientific communities. Most recently, in response to the administration's Proclamation Suspending Entry of Aliens Who Present a Risk to the U.S. Labor Market Following