

Kidney Transplant Policy: What We Can Expect in 2024

By Rachel Nell Meyer

As 2024 dawns, it holds promise to be another transformative year in the kidney transplant policy space. In 2023, some of the most significant policy changes since the enactment of the original National Organ Transplant Act of 1984, which provided the framework for the US organ transplant system, were implemented. Many of these changes included top ASN advocacy goals, such as reforms intended to maximize patients' access to transplantation, an increase in transparency in the transplant process for patients and general nephrologists, and ensuring that all patients have access to transplantation regardless of geography, socioeconomic status, race and ethnicity, and sex or gender. The reforms initiated in 2023 are largely still ongoing as we enter 2024, and some will—by design—continue to evolve for years to come.

In response to continued challenges accessing transplant care experienced by too many people with kidney diseases, ASN's renewed focus on transplantation policy under the leadership of transplant nephrologists ASN Past President Michelle A. Josephson, MD, FASN; ASN Policy and Advocacy Committee Chair Roz B. Mannon, MD, FASN; and the late Barbara T. Murphy, MB BAO BCh, FRCPI (who would have served as ASN president in 2021), has increased advocacy for transformational changes to the US transplant system. The need for these improvements was championed by several bipartisan leaders in the US Congress, ultimately wrapped up in an initial reform bill, the Securing the US Organ Procurement and Transplantation Network (OPTN) Act.

Spearheading many of the changes to the transplant system is the Health Resources & Services Administration (HRSA), which oversees the OPTN. In March 2023, HRSA unveiled the OPTN Modernization Initiative, a sweeping set of goals aimed at increasing performance, accountability, and transparency in the US transplant system in the long term (1, 2).

Two key ways in which HRSA is working toward the OPTN Modernization Initiative goals are 1) increasing competition and allowing multiple contractors to help fill the functions of the OPTN (which had previously been held by a single contractor) and 2) establishing an independent OPTN board of directors (separate from any contractor's board of directors). Those aims received a significant boost when Congress passed the Securing the US OPTN Act last summer, a bill that revised existing law to allow for a more competitive bidding process and called for an independent board of directors, among other things (3). As ASN advocated to Congress in support of the legislation, by allowing multiple contractors, HRSA can ensure that each of the many important functions of the OPTN—including policymaking, organ matching, information technology, and data management—will be carried out by the best-in-class vendors, and a board of directors that is separate from those of any contractors will increase accountability in the system.

President Biden signed the bill into law in September 2023 (4), and in 2024, HRSA is anticipated to be fielding bids from multiple contractors for various functions of the OPTN for the first “transitional” phase of the OPTN Modernization Initiative, which will “support and enhance OPTN operations while the modernization process is underway” (2). In the future, overlapping the transitional phase (and potentially during 2024), HRSA anticipates issuing contracts for a “next generation” phase that will focus on designing, testing, and eventually implementing components like a modernized OPTN information technology system, which will allow it to serve patients better and more efficiently and transparently.

ASN is committed to continuing to advocate for the success of the OPTN Modernization Initiative, and championing needed increased funding to support it will be a hallmark of the society's appropriations advocacy in 2024. Last year, the Biden administration requested an additional \$37 million for HRSA's organ and transplant-related budget, and although funding for the last fiscal year has not been finalized, it is evident that the large-scale modernization effort will require a substantial increase in funding to fully achieve its goals.

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Meanwhile, however, HRSA is already making moves to address another ASN policy priority: data collection regarding the progression between a patient's referral for transplant and duration to the waitlist (or sadly for many, not being waitlisted). Today, many patients and their nephrologists (as well as researchers) experience this post-referral period as a frustrating “black box.”

But HRSA is not the only agency making big moves in the kidney transplant space. The Centers for Medicare & Medicaid Services (CMS) released a revised 2728 form in late 2023 that, among other items, will require the provision of information about when and where dialysis facilities refer patients to transplant centers for evaluation. Systematic data collection about referral, evaluation, and waitlisting decisions from both transplant centers (led by HRSA) and dialysis facilities (led by CMS) will help paint a complete picture of the patient journey, increase transparency, and hopefully uncover new opportunities for policymakers to help more patients overcome barriers along that journey and successfully gain access to the possibility of a kidney transplant. The timeliness of these changes was underscored by a recent study that found that fewer than one-half of patients with no other major comorbidities were waitlisted (5).

In 2024, we can expect to see more concerted policymaking efforts between CMS and HRSA. In late 2023, the agencies unveiled the Organ Transplantation Affinity Group, (OTAG) a collaboration between CMS and HRSA aimed at strengthening accountability, equity, and performance in the organ donation and transplantation system to improve access for patients (6). Given that CMS and HRSA are “working closely with our colleagues at other HHS [US Department of Health and Human Services] agencies” as part of OTAG, a task OTAG could potentially take on in 2024 is identifying solutions to address the large differences in reported patient outcomes across HHS datasets (6, 7).

An area sure to bring some controversy in 2024 is the evolution of CMS metrics for organ procurement organizations (OPOs). In 2021, CMS finalized new metrics to increase accountability for OPOs nationwide and is set to begin collecting data on those metrics in 2024. OPOs that perform the worst will be ineligible to compete for new contracts beginning in 2026, whereas the best performers will retain theirs. However, CMS has yet to release much detail about how those transitions will work—and a growing number of OPOs are being categorized as low performers. Meanwhile, the agency has indicated that it may also begin collecting data related to organ procurement from donor hospitals, and some researchers have pointed to ways in which CMS could revise the new metrics.

Last but not least, the Center for Medicare and Medicaid Innovation is expected to make announcements related to transplant care in its suite of kidney care models. ASN has advocated both for changes to existing models to better incentivize and reward transplant access, as well as for a transplant-focused model that focuses on long-term outcomes (as opposed to 1- or 3-year time horizons, which are the focus in the current system).

Notably, this is the third consecutive administration that has made kidney transplantation an area of emphasis. Although it will be many months before we know what the 2024 US election will bring, it is a safe bet that kidney transplantation will remain on the agenda heading into 2025 and beyond, and ASN will continue to advocate to maximize patients' access to the optimal therapy: kidney transplant. ■

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