

Advocating for Policy Changes to Improve Kidney Care in 2023

Protecting kidney care and funding kidney research are crucial for the 37 million Americans living with kidney diseases and the more than 800,000 living with kidney failure. With the 118th Congress confirmed and the Biden administration entering its third year, ASN is advocating for must-pass legislative and regulatory priorities, building off past efforts to educate and build support among policymakers.

ASN is leading efforts to improve care for people with kidney diseases by raising the profile of kidney health in the federal government by engaging policymakers in Congress and within the US Department of Health and Human Services. In 2021, ASN launched the We're United 4 Kidney Health campaign (www.4kidneyhealth.org) to galvanize and educate the kidney community about the “dramatic changes and new opportunities taking place in kidney care, research, and education...” The campaign, structured from four key priorities—Intervene Earlier, Transform Transplant, Accelerate Innovation, and Achieve Equity—has driven awareness about kidney diseases and alignment on strategies to improve kidney health. These priorities will continue to inform ASN’s advocacy efforts with Congress and the Biden administration. In 2023, ASN will support these priorities by expanding patient choice in care, continuing efforts to build stability in physician payment, and accelerating innovation among numerous other activities.

Key legislative priorities

ASN is continuing to engage Congress on the health coverage gap created by a change in the Medicare Secondary Payer policy. In a June 2022 decision, the US Supreme Court in *Marietta Memorial Hospital Employee Health Benefit Plan v. DaVita Inc.* created a pathway for insurers to provide drastically reduced benefits to people with kidney failure, such as below-cost reimbursement of services and network exclusion, thereby encouraging premature enrollment in Medicare and limiting access to private insurance for people with kidney failure. Prior to the Supreme Court decision, Medicare protected people with kidney failure to access private insurance for 30 months after qualifying for Medicare coverage. This transition period allowed a more seamless transfer to public insurance, maintained patient choice in care coverage, and protected dependents’ access to medical care. Although Congress did not include a fix for this coverage gap in its end-of-year package, ASN will continue to prioritize a fix for this gap by advocating for patient choice in their care. ASN encourages kidney health professionals and kidney patients through ASN’s Legislative Action Center (<https://www.asn-online.org/policy/lac.aspx>) to amplify these concerns with their local delegates.

At the end of 2022, ASN collaborated with the broader health professional community to secure a compromise deal avoiding drastic physician payment cuts within Medicare. It was projected that on January 1, 2023, kidney health professionals would face a 4.5% conversion factor cut in Medicare Part B reimbursement, resulting from updates from the Centers for Medicare & Medicaid Services (CMS). However, with advocacy from ASN members, Congress reduced the size of the looming cut, implementing only a 2% physician payment cut, which will transition to 3% in 2024. These cuts are less harmful than what was originally proposed but still present an obstacle for ASN members for obtaining reimbursement reflective of the care they provide to people living with kidney diseases. ASN will continue to advocate for these payment cuts to be addressed and future scheduled cuts to be averted.

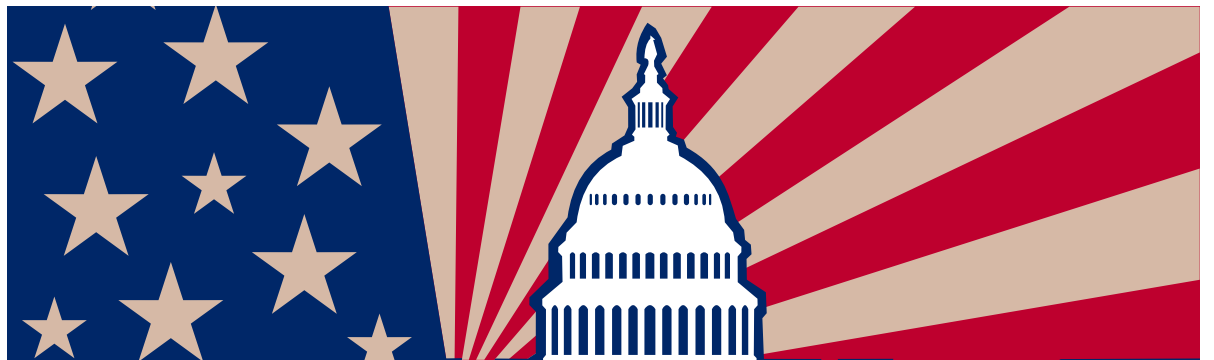
In 2018, ASN launched Kidney Innovation Accelerator (KidneyX; <https://www.kidneyx.org/>), a public-private partnership to accelerate innovation in the prevention, diagnosis,

and treatment of kidney diseases. Since then, KidneyX has supported nearly 70 innovators with solutions ranging from dialysis-accessible clothing to prototype artificial kidneys. Furthermore, KidneyX is also catalyzing private markets to support innovation in kidney health. For instance, winners of the first KidneyX competition—Redesign Dialysis—with a total prize purse of \$4.125 million, have gone on to raise more than \$300 million from private funders. In 2019, Congress demonstrated its commitment to accelerating innovation for people living with kidney diseases by providing KidneyX its first \$5 million. Congress has continued its support of KidneyX by providing an additional \$5 million each year through annual appropriations, now totaling \$20 million and nearly matching ASN’s initial \$25 million contribution to KidneyX. However, increased support from Congress for KidneyX and other efforts to accelerate innovation is needed to foster the development of the artificial kidney and other advancements in kidney health. ASN is advocating for Congress to provide KidneyX \$25 million in fiscal year 2024, the current fiscal year, to accelerate advancements such as the artificial kidney.

patient access to home dialysis, ASN was disappointed by the organization’s silence on the topic of home dialysis for patients with AKI. ASN reiterates that it remains dedicated to ensuring the success of all patients with AKI and in doing so, will continue to push for CMS to allow for a treatment pathway and reimbursement program for treatment of AKI with home dialysis in the coming year.

In 2022, ASN stressed that the current payment-adjustment system for the ESRD PPS is not elastic enough to deal with the strong inflationary forces and real-time staffing crisis facing dialysis providers today. ASN will continue to advocate for policies that positively address this issue. CMS also finalized a proposal to apply a permanent 5% cap on decreases on the ESRD PPS wage index beginning in CY2023.

In November 2022, ASN and the National Kidney Foundation (NKF) sent a letter to the US Food & Drug Administration (FDA) Commissioner Robert M. Califf,



Key regulatory priorities

ASN will continue to engage CMS to address greater equity in the Medicare End-Stage Renal Disease (ESRD) program, increase quality efforts in home dialysis, support payment for innovation in kidney care, and bring balance to payments in the ongoing COVID-19 public health emergency.

In August 2022, CMS released the proposed rule for the 2023 ESRD Prospective Payment System (PPS), Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI), ESRD Quality Incentive Program (QIP), and ESRD Treatment Choices (ETC) model. This proposed rule builds on policies that were finalized in the previous year’s rule that sought to improve health equity and enhance access to treatment. This year’s final rule continues to have a strong focus on home dialysis.

In this year’s proposed rule, CMS:

- ▶ sought public comment on numerous requests for information on a potential add-on payment adjustment for certain new renal drugs and biological products and on health equity issues with a focus on pediatric patients.
- ▶ proposed an update to the ESRD base rate, wage index, and outlier policy for calendar year (CY)2023. CMS also proposed the addition of the word “functional” to the definition of “oral-only drug.” Furthermore, functional category definitions were clarified.
- ▶ included numerous updates to the ESRD QIP, which included the suppression of certain payment measures from CY2023 and updates for subsequent payment years. CMS also sought comment on potentially adding quality measures. Despite CMS’s effort to support

MD, offering to help cultivate the growing interest in therapeutic developments to benefit individuals with kidney diseases (1). In the letter, ASN and NKF discussed the need for therapeutic development and innovation to target kidney diseases and offered several approaches to ensure these patients receive valuable access to care. One of these approaches offered bringing the expertise of the kidney community to the FDA in the development of safe and effective therapies across the spectrum of kidney care through the Kidney Health Initiative (<https://khi.asn-online.org/>). The letter also urged the FDA to take measures to ensure that participants in clinical trials designed for people living with kidney diseases accurately reflect the patient population in terms of race and socioeconomic status. ASN will continue advocating for this issue this year.

To keep track of ASN’s efforts to intervene earlier, transform transplant, accelerate innovation and expand patient choice, and achieve equity, and to learn more about ASN’s 2023 policy agenda, follow coverage in *Kidney News* and the ASN podcast feed (<https://www.asn-online.org/media/podcast.aspx?p=ASN>), and visit the ASN Advocacy and Public Policy webpage (<https://www.asn-online.org/policy/>). For real-time updates, follow ASN policy on Twitter (@ASNAdvocacy). ■

Reference

1. Quaggin SE, Rosas SE. American Society of Nephrology and National Kidney Foundation letter to Robert M. Califf, MD, Commissioner, Food and Drug Administration. November 8, 2022. https://www.asn-online.org/policy/webdocs/ASN_NKF_FDA_Letter_.pdf