

# Kidney Care National Plan

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## Kidney Care National Plan

### Overview

As part of the Make America Healthy Again initiative, the Trump Administration has made combating chronic disease a central priority, and few conditions demand more urgent action than kidney disease. Kidney disease is among the most consequential and costly chronic conditions in the United States. An estimated 37 million American adults, more than one in ten, have chronic kidney disease (CKD).<sup>1</sup> This makes it one of the most prevalent yet underdiagnosed drivers of America's broader chronic disease burden. In 2024, kidney disease was the nation's eighth leading cause of death.<sup>2</sup> An estimated 87 percent of adults affected by CKD do not yet know they have it.<sup>3</sup> Many will progress over time to kidney failure, at which point the only treatment options are lifelong renal dialysis or a kidney transplant. In 2023, roughly 831,000 Americans were living with kidney failure, also known as end-stage renal disease (ESRD).<sup>4</sup>

But kidney disease exacts a heavy toll well before it reaches the level of ESRD. Patients with CKD face greatly elevated risks of high blood pressure, heart disease, stroke, and early death.<sup>5</sup> The condition also impacts daily life in other ways including difficulty with walking, hearing and seeing.<sup>6</sup> While older adults and Medicare beneficiaries account for the largest share of diagnosed cases, CKD also impacts many younger adults and children. Despite improvements in CKD outcomes, more than 55,000 Americans still died of kidney disease in 2024,<sup>7</sup> and adults with CKD died at more than twice the rate of the general population in 2023.<sup>8,9</sup> Once patients reach kidney failure, transplantations offer markedly better survival, quality of life, and long-term costs compared to renal dialysis.<sup>10,11</sup> However, roughly 90,000 Americans remain on the kidney transplant waiting list, with many waiting three to five years for a donor kidney.<sup>12</sup>

### Role of U.S. Government in Kidney Care

The U.S. government has been central to the treatment of kidney failure in America for more than fifty years. The Social Security Amendments of 1972 extended Medicare coverage to Americans with ESRD regardless of age, a decision that reflected a national commitment to treating a condition that would otherwise be a death sentence for those who could not afford care. That commitment has endured, making the U.S. government the dominant payer for kidney care, unlike any other disease.

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<sup>1</sup> <https://www.cdc.gov/kidney-disease/php/data-research/index.html>

<sup>2</sup> <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

<sup>3</sup> <https://www.cdc.gov/kidney-disease/media/pdfs/CKD-Factsheet-H.pdf>

<sup>4</sup> <https://usrds-adr.niddk.nih.gov/2025/end-stage-renal-disease/1-incidence-and-prevalence>

<sup>5</sup> <https://www.cdc.gov/kidney-disease/php/data-research/index.html>

<sup>6</sup> <https://www.cdc.gov/KDSS/detail.aspx?Qnum=Q703&topic=5#refreshPosition>

<sup>7</sup> <https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

<sup>8</sup> <https://usrds-adr.niddk.nih.gov/2025/chronic-kidney-disease/3-morbidity-and-mortality-in-patients-with-ckd>

<sup>9</sup> <https://pubmed.ncbi.nlm.nih.gov/41881385/>

<sup>10</sup> <https://www.nejm.org/doi/full/10.1056/NEJM199912023412303>

<sup>11</sup> <https://www.sciencedirect.com/science/article/pii/S0085253815596014>

<sup>12</sup> <https://www.hrsa.gov/optn/data-calculators/data-reports>

Despite renal dialysis being lifesaving for most patients with ESRD, life expectancy has remained unchanged since 2009, with a five-year survival probability of less than 50%.<sup>13</sup> Moreover, ESRD spending has begun rising again after several years of decline. Both trends underscore the urgency of a renewed focus on kidney care. Despite representing less than 1 percent of the U.S. population, patients with ESRD accounted for approximately \$24.4 billion in Original Medicare (OM) spending in 2023 (about 4.7 percent of total fee-for-service spending), and \$27.7 billion in Medicare Advantage (MA) spending. In 2023, total ESRD spending reached an all-time high.<sup>14,15</sup> The fiscal impact extends well beyond ESRD. In 2023, OM spent more than \$141.1 billion on care for beneficiaries with CKD who had not yet progressed to ESRD.<sup>16</sup> Treatment of CKD in patients younger than 65 with Medicaid costs an average of about \$19,000 per patient per year.<sup>17</sup> Improving kidney care therefore advances two objectives simultaneously: to maximize health for beneficiaries and to reduce the financial burden on taxpayers.

That federal role is also what makes kidney care distinct as a matter of policy. Given that the U.S. government finances the overwhelming majority of kidney care in America, the rules it writes profoundly shape how that care is delivered. This role carries a corresponding responsibility. Medicare occupies a dominant position in financing renal dialysis, and HHS administers the nation's transplant system. HHS thus bears a distinct obligation to ensure that these systems work effectively for the patients who depend on this care and for the taxpayers who fund it. HHS has an opportunity to strengthen competition, reward innovation, and expand access to high-quality kidney care to ensure the best outcomes for patients and taxpayers.

### **The 2019 Executive Order and Progress to Date**

In 2019, Executive Order 13879, *Advancing American Kidney Health*,<sup>18</sup> marked a turning point for the federal role in kidney care. For the first time, the federal government set out a unified vision that looked beyond in-center renal dialysis by committing to prevent kidney failure, expand patient choice, and increase access to transplantation. In the years since, that effort produced real progress, resulting in the approval of new therapies that have reached patients, including those with rare kidney diseases; an increase in home dialysis to its highest level in more than a decade; and a new period of reform and transparency for the nation's organ procurement and transplantation system to bring greater accountability. Work since 2019 laid the necessary foundation, establishing that kidney care *could* be redirected.

### *New Treatment Options*

The treatment landscape for kidney disease has evolved considerably in recent years due to research and investment by pharmaceutical and biotechnology companies. There are a growing number of available therapies that go beyond symptom management. The FDA has approved

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<sup>13</sup> <https://usrds-adr.niddk.nih.gov/2025/end-stage-renal-disease/6-mortality>

<sup>14</sup> <https://usrds-adr.niddk.nih.gov/2025/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>

<sup>15</sup> Patients with ESRD were able to enroll directly in MA beginning in 2021 as a result of the 21st Century Cures Act. See <https://www.congress.gov/crs-product/R45290>

<sup>16</sup> <https://usrds-adr.niddk.nih.gov/2025/chronic-kidney-disease/2-identification-and-care-of-patients-with-ckd>

<sup>17</sup> <https://usrds-adr.niddk.nih.gov/2025/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd>

<sup>18</sup> <https://www.federalregister.gov/documents/2019/07/15/2019-15159/advancing-american-kidney-health>

medications that help reduce kidney and cardiovascular complications in patients with type 2 diabetes, including GLP-1 receptor agonists and SGLT-2 inhibitors that support kidney function. Additionally, agents that address complications such as anemia and bloodstream infections were approved.

Equally noteworthy is the emergence of targeted treatments for rare kidney diseases that have long lacked effective options. Conditions such as IgA nephropathy, focal segmental glomerulosclerosis (FSGS), C3 glomerulopathy, and lupus nephritis frequently affect younger patients and can progress rapidly. These diseases now have dedicated therapies, representing meaningful progress for patient populations that were historically underserved by medical research.

### *Rising Use of Home Dialysis*

Home dialysis, which allows beneficiaries to manage their treatment on their own schedule has shown comparable to improved survival outcomes and improved quality of life when compared to in-center renal dialysis.<sup>19,20</sup> Home dialysis has now reached its highest utilization rate in more than a decade. Approximately 16 percent of dialysis patients received home treatment in 2023, up from 10.5 percent in 2017.<sup>21</sup>

The Centers for Medicare & Medicaid Services (CMS) has conducted policy experiments that have allowed CMS to learn and identify policy mechanisms that could result in improving kidney care.<sup>22</sup> The Kidney Care Choices Model, launched in 2022 and scheduled to run through 2027, has shown some positive clinical results, suggesting the model resulted in increased home dialysis adoption and more effectively managed treatment starts.<sup>23</sup> The ESRD Treatment Choices Model was terminated after it did not achieve its intended outcome or produce anticipated savings.<sup>24</sup> Additionally, CMS has proposed the first update since 2017 to its add-on payment adjustment for home and self-dialysis training for Medicare beneficiaries in order to better reflect the costs of those services.<sup>25</sup> Together, these initiatives have given CMS actionable information to refine future approaches aimed at sustaining that growth.

### *Transplant System Reform*

The organ procurement and transplantation system, which has historically faced concerns regarding accountability and transparency, has entered a meaningful period of reform in recent years. Updated performance standards for Organ Procurement Organizations (OPOs) have corresponded to notable improvements in outcomes, including a 21 percent increase in donors and a 24 percent increase in transplants between 2019 and 2023.<sup>26</sup> CMS has also proposed further

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<sup>19</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/226440>

<sup>20</sup> <https://journals.lww.com/jasn/abstract/10.1681/asn.2011080761>

<sup>21</sup> <https://usrds-adr.niddk.nih.gov/2025/end-stage-renal-disease/3-home-dialysis>

<sup>22</sup> <https://www.govinfo.gov/content/pkg/FR-2025-11-24/pdf/2025-20681.pdf>

<sup>23</sup> <https://www.cms.gov/priorities/innovation/innovation-models/kidney-care-choices-kcc-model>

<sup>24</sup> <https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model>

<sup>25</sup> <https://www.federalregister.gov/documents/2026/06/26/2026-12925/medicare-program-cy-2027-changes-to-the-end-stage-renal-disease-esrd-prospective-payment-system>

<sup>26</sup> <https://www.hrsa.gov/net/optn?base=hrsa&path=/data/view-data-reports/national-data>

rulemaking building on the 2020 rule to further accountability for OPOs. Building on that progress, the Organ Procurement and Transplantation Network (OPTN) Modernization effort, launched in 2023, began addressing longstanding structural challenges within the transplant network.<sup>27</sup> Key initiatives include reforms to governance and oversight, a shift away from reliance on a single contractor, the establishment of a reimbursement program to help cover living donors' non-medical costs, and investments in modernizing data infrastructure.<sup>28</sup> With the decertification of an OPO for persistent failure to meet federal standards and steps taken toward decertifying another,<sup>29,30</sup> federal oversight continues to promote safer, fairer, and more reliable organ procurement while strengthening accountability and preventing repeat failures. The Increasing Organ Transplant Access (IOTA) model is also encouraging transplant hospitals to increase transplant volume and improve transparency for patients on waiting lists.<sup>31</sup>

## **The Next Step**

This national plan represents the next critical step in a broader reform agenda. The task now is to address the structural deficiencies in kidney care. Across renal dialysis, transplantation, and the broader landscape of prevention and innovation, there is a shared opportunity to modernize longstanding structures. The aim of this plan and its policy recommendations is to reward innovation, give patients meaningful choice, and hold down costs while improving quality.

This plan follows the principle that government should consider actions that better promote competition in the marketplace and remove the barriers and anti-competitive practices that entrench incumbency, rather than layer additional cumbersome regulation on top of the structure that produced the problem. In many cases, government should do less, focusing its efforts on promoting accountability, competition, and innovation. An affirmative federal role is warranted in the narrow circumstances where a specific, identifiable market failure prevents private actors from serving the public interest. This is a deliberate departure from the reflex to answer every shortcoming with a new mandate. In kidney care, more than almost anywhere else in health care, policymakers historically have broadly overregulated in attempts to remedy market failures, resulting in a weakened market.

The plan below applies this principle in three areas. The first addresses the renal dialysis market, where concentration, inefficiency, and stagnation result from a non-competitive market. The second addresses transplantation, where limited competition, insufficient accountability, and a lack of transparency have kept the system from realizing its maximum life-saving potential. The third addresses prevention and innovation across the entire continuum of kidney care, to encourage greater development and utilization of new therapies and to incentivize prevention efforts that have been underutilized.

## **The Renal Dialysis Market**

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<sup>27</sup> <https://www.hrsa.gov/optn-modernization>

<sup>28</sup> <https://www.hrsa.gov/optn-modernization/updates/july-2026>

<sup>29</sup> <https://www.hhs.gov/press-room/hhs-decertifies-miami-organ-agency-reforms-transplant-system.html>

<sup>30</sup> <https://www.hhs.gov/press-room/hhs-decertifies-kentucky-organ-procurement-organization.html>

<sup>31</sup> <https://www.cms.gov/priorities/innovation/innovation-models/iota>

The renal dialysis market is highly concentrated and notoriously resistant to innovation,<sup>32</sup> with two large companies controlling over three-quarters of the renal dialysis market. Concentration and stagnation stem from a regulatory structure that rewards incumbency and anti-competitive behavior. Two distinct policy challenges lead to this issue: (1) policies around dialysis facility enrollment that could hinder the development of a competitive dialysis market and implicitly benefit consolidated providers; and (2) entrenched incumbents that can use their market power to thwart potential competitors. By identifying what hinders competition, the government could streamline or eliminate regulatory barriers to improve efficiency in the market.

Over the last two decades, renal dialysis facility ownership has further consolidated steadily. The two largest chains' share of the renal dialysis market was roughly 59 percent in 2006,<sup>33</sup> but has risen to roughly 74 percent in 2026.<sup>34</sup> As of 2019, roughly one-third of the U.S. population lived in an area where the only available renal dialysis supplier was one of the two dominant firms, resulting in a lack of choice in renal dialysis supplier.<sup>35</sup>

The largest renal dialysis chains leverage their market power into higher prices. In geographic areas served by only one firm, commercial prices for outpatient hemodialysis are higher than in areas where large firms face competitors.<sup>36</sup> Private insurance and MA plans pay up to 500 percent and 25 percent more for renal dialysis than OM, respectively, and the largest suppliers benefit from this difference.<sup>37,38</sup> Given that MA now pays for more ESRD patients than OM since the increased enrollment by beneficiaries with ESRD with implementation of the 21<sup>st</sup> Century Cures Act in 2021,<sup>39</sup> these elevated prices for care have a direct impact on overall costs to the taxpayer and the Medicare Trust Fund. Additionally, because individual market plan premiums are heavily subsidized, higher pricing in the commercial market negatively impacts taxpayers.<sup>40</sup> In many insurance plan designs, higher renal dialysis prices can result in higher out-of-pocket costs.

### *Barriers to Competition and Innovation in Existing Treatment*

Medicare pays for renal dialysis services furnished to ESRD beneficiaries through a single bundled payment per treatment to ESRD facilities, with rates set annually. From a conventional renal dialysis perspective, fixed bundled payments should provide a neutral basis for ESRD facilities to compete for delivery of standard renal dialysis treatments, based on other non-cost factors such as convenience or quality. Unfortunately, to receive these payments, new renal dialysis suppliers must comply with regulatory requirements that require large up-front capital investments for new suppliers. An example is CMS's conditions for coverage for renal dialysis facilities that include physical infrastructure and staffing requirements for new suppliers. However, this infrastructure may not be necessary to successfully deploy home dialysis (e.g., training can be supported in a

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<sup>32</sup> <https://www.healthaffairs.org/content/forefront/innovation-stagnation-plight-dialysis-patients-us>

<sup>33</sup> <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2835489>

<sup>34</sup> Data from the CMS End Stage Renal Disease Quality Reporting System

<sup>35</sup> <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2835489>

<sup>36</sup> Ibid

<sup>37</sup> <https://schaeffer.usc.edu/research/how-regulatory-failures-have-crippled-dialysis-care/>

<sup>38</sup> <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2021.02009>

<sup>39</sup> [https://www.medpac.gov/wp-content/uploads/2026/03/Mar26\\_Ch12\\_MedPAC\\_Report\\_To\\_Congress\\_SEC.pdf](https://www.medpac.gov/wp-content/uploads/2026/03/Mar26_Ch12_MedPAC_Report_To_Congress_SEC.pdf)

<sup>40</sup> <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2777844>

patient's home rather than at a dialysis facility). CMS could examine streamlining its requirements for participation, which could reduce the cost of entry and potentially encourage new entries into the market.

### *Alternative Technologies*

Lack of competition may also limit the uptake of new technologies that could improve patient experiences and outcomes. Limited uptake in turn slows the development of such technologies in the first place because developers do not expect a return on their investment. Without other facilities competing for patients, renal dialysis companies may have little or no incentive to make capital investments toward modernizing their care practices if those updates will not drive significant new profits.<sup>41</sup> The result is a fragile market reluctant to adopt new technologies and consequently, lackluster investment in research and development by private actors. Government should reform policies that impede the adoption of new renal dialysis technologies that meaningfully improve patient outcomes and quality of life. Allowing innovative treatments to be brought to market in a cost-sustainable way could reduce the reliance on old, incumbent technologies and promote competition rather than consolidation.

### *Exploiting Market Power to Concentrate Patients and Profits*

Large incumbent renal dialysis chains take advantage of current regulatory frameworks to increase their competitive advantage in the kidney care marketplace, often at patients' and taxpayers' expense.<sup>42</sup> Rather than generate high-value healthcare, these tactics serve to financially reward the largest firms. For example, renal dialysis chains build strong financial relationships with nephrologists through medical directorships, joint ventures, and value-based care partnerships that lock in nephrologists and discourage them from referring patients elsewhere.<sup>43</sup> These financial relationships may give physicians a financial incentive to refer patients to a given supplier rather than to a competitor, and the contracts can have terms restricting the physicians from working with other suppliers for a period after their contract ends. In another notable example, one study suggests that the largest renal dialysis chains may use all-or-nothing bargaining tactics to force higher prices in MA, which can be passed on to beneficiaries through higher premiums.<sup>44</sup> By threatening to exit all of an MA organization's networks, large renal dialysis chains could force MA plans to agree to higher prices in all of their markets, including competitive markets that should otherwise have lower prices.<sup>45</sup> Additional evidence is needed to understand the impact of these actions and how large incumbent renal dialysis chains may be preventing new competitors from entering the market in order to drive up prices.

Additionally, large chains could benefit from a strategy that keeps patients in higher-paying commercial coverage rather than transitioning to Medicare (while ESRD renal dialysis patients generally qualify for Medicare, they can choose to pay for commercial insurance instead of using Medicare coverage). Renal dialysis facilities are prohibited from directly providing patients with monetary assistance for insurance premiums, but they can use certain existing pathways that permit

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<sup>41</sup> <https://www.sciencedirect.com/science/article/abs/pii/S1548559522000052>

<sup>42</sup> <https://www.sciencedirect.com/science/article/pii/S0149291822004064#bib0002>

<sup>43</sup> <https://academic.oup.com/qje/article-abstract/135/1/221/5607794?redirectedFrom=fulltext>

<sup>44</sup> <https://pubmed.ncbi.nlm.nih.gov/35914212/>

<sup>45</sup> Ibid

third-party charities to act as a “pass-through” for these payments.<sup>46</sup> Renal dialysis chains make large charitable donations to nonprofit third-party charities that in turn provide monetary assistance to patients paying for individual market plans offered through the Health Insurance Exchanges.<sup>47</sup> These donations perform multiple functions, and may impact patients’ decisions around whether to pay for ACA commercial insurance instead of enrolling in Medicare coverage. This may result in profits to renal dialysis chains as ACA commercial plans often pay more than Medicare for renal dialysis. Given that total spending per new renal dialysis patient was approximately 2.5 times higher under ACA commercial coverage than under Medicare<sup>48</sup>, this effort may increase the cost of Exchange plans under the ACA,<sup>49</sup> which may impact ACA premium subsidies paid by taxpayers.

### *Opportunities for Reform*

Well-intentioned regulations that promise to protect patients may protect incumbents instead, resulting in the ballooning cost of stagnant renal dialysis care. HHS should consider policymaking in a series of areas that could better promote competition in this market.

The government should consider policies in three different areas: (1) lift entry barriers that favor incumbency; (2) encourage innovative technologies; and (3) prevent large actors from exploiting regulatory loopholes to financially engineer profits without benefiting patients. To restore competition within existing treatment options, market entry for new suppliers should be made easier, faster, and less costly. Certification could be streamlined and oversight simplified, so that innovative suppliers can compete on an even footing with the largest firms. Additionally, CMS should work with federal partners to investigate and address the anti-competitive strategies used by the largest firms to garner larger reimbursements without providing superior patient care. Finally, these efforts should be complemented by additional research to help identify innovative therapies that reduce the high mortality and morbidity of dialysis and improve the poor quality of life.

## **Kidney Transplant**

Organ transplantation represents one of the most profound interventions in modern medicine, offering patients with end-stage organ failure restored health, extended life, and dramatically improved quality of life. For HHS, a well-functioning transplantation system is not only a clinical imperative but a fiscal one. Every additional organ successfully recovered and transplanted represents a life saved and significant downstream savings to the Medicare and Medicaid programs. Kidney transplantation can more than double the life expectancy of patients with kidney failure at less than half the annual cost of renal dialysis.<sup>50</sup>

Transplantation is uniquely high stakes because any systemic underperformance carries real human and financial costs. To reduce bureaucratic overhead, HHS is actively streamlining and

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<sup>46</sup> <https://oig.hhs.gov/documents/advisory-opinions/370/AO-97-01.pdf>

<sup>47</sup> <https://www.kidneyfund.org/get-assistance/health-insurance-premium-program>

<sup>48</sup> <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2827155>

<sup>49</sup> <https://pmc.ncbi.nlm.nih.gov/articles/PMC7985814/>

<sup>50</sup> <https://usrdk-adr.niddk.nih.gov/2025/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd>

aligning regulatory and financial policies for organ transplantation across all regulatory and administrative actors. This includes CMS, which certifies and surveys specific system participants for compliance with Medicare health and safety requirements and finances much of the organ transplant system; the Health Resources and Services Administration (HRSA), which administers and provides oversight of OPTN; and OPTN, which develops policies for organ allocation to recipients awaiting transplant, among other functions. Despite this alignment, more work is needed to ensure the entities involved in each stage of the organ procurement and transplantation system effectively support the goal of maximizing organ availability, patient safety, and transparency. Limited competition among OPOs and among governance for the OPTN, insufficient accountability, and a lack of meaningful transparency for patients and families contribute to many of the organ transplant system's failures.

OPOs are responsible for obtaining organs from deceased organ donors under the National Organ Transplant Act of 1984 (NOTA), and they operate as regional monopolies across 54 Donation Service Areas under Section 1138 of the Social Security Act.<sup>51</sup> Unfortunately, monopoly status has insulated OPOs from competitive pressure, shielding OPOs from consequences of poor performance. Moreover, Medicare reimburses OPOs on a cost basis, meaning there is no financial pressure to operate efficiently or improve performance. CMS holds the authority to decertify OPOs for failure to meet the Secretary's performance standards. In 2020, CMS finalized performance standards for OPOs and set up a new accountability structure based on the number of organs procured and transplanted for each OPO. However, since 1984, no OPO had ever been decertified for performance reasons until the first OPO decertification was announced in September 2025.<sup>52</sup> The combination of monopoly status and cost-based reimbursement uniquely shielded OPOs from the pressure to act efficiently and effectively. Though we have seen an improvement in the number of organs procured and transplanted, significant performance variation across OPOs persists. Recent safety concerns have also surfaced, including allegations of OPOs attempting to procure organs from patients who had not yet progressed to death.<sup>53</sup>

The OPTN serves as the national framework for organ matching and allocation policy. For most of its existence since its statutory creation under NOTA, the OPTN has been managed by a single contractor. While this structure initially supported growth in organ donation, procurement and transplantation, this single-vendor arrangement epitomizes a lack of market competition and contributed to a system marked by outdated technology, inefficient organ allocation methodologies, weak accountability mechanisms, poor data quality, and limited transparency for patients, donor families, and registered organ donors. HRSA's OPTN Modernization Effort, launched in March 2023, has begun to address these structural challenges through governance reform, competitive multi-vendor contracting, and enhanced oversight.<sup>54</sup> The depth of the remaining challenges identified by HHS reflects the need for continued reformative action.

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<sup>51</sup> [National Organ Transplant Act of 1984](#) (NOTA; 42 U.S.C. 273 et seq.) and [Section 1138 of the Social Security Act](#) (42 U.S.C. 1320b-8).

<sup>52</sup> <https://www.hhs.gov/press-room/hhs-decertifies-miami-organ-agency-reforms-transplant-system.html>

<sup>53</sup> <https://www.hhs.gov/press-room/hhs-decertifies-kentucky-organ-procurement-organization.html>

<sup>54</sup> <https://www.hrsa.gov/optn-modernization>

Transplant hospitals exercise broad control over the transplant process, from waitlist eligibility determinations and organ acceptance decisions to post-operative care. However, this landscape has in part led to large variation in transplant center practices, volume, and performance, particularly in managing the living donation process. For example, while the rate of deceased donor kidney transplants among people on renal dialysis increased 33 percent from 2018 to 2024, living donor transplant rates remained largely unchanged and have been largely flat since 2000.<sup>55</sup> Additionally, there is major variation in performance between transplant hospitals in the scope of their living donor programs. These outcomes highlight a potential need for additional accountability or for a push from HHS and the OPTN to encourage investment in these programs to return the focus to increasing life-saving transplants.<sup>56</sup>

### *Opportunities for Reform*

The entire transplantation ecosystem reflects a pattern of structural insulation that has shielded actors from competition, accountability, and transparency to the patients they serve. Reform efforts are currently underway and offer a meaningful foundation to ensure that the system fulfills its life-saving potential. However, sustained progress will require addressing poor incentives and oversight gaps that have contributed to the persistence of these shortcomings for decades. CMS and HRSA will ensure that OPOs are accountable for their performance, use taxpayer dollars appropriately, and, most importantly, protect patient safety. HHS will also streamline and monitor policies to ensure transplant centers are appropriately incentivized to facilitate more transplants, more effectively coordinate deceased donor organ transplants, and grow living donation programs.

### **Prevention**

Renal dialysis and transplant reform will improve care for the people who already have kidney failure. But these reforms only reach patients when kidney failure has already occurred and do not address the root cause of disease. The U.S. government's role in financing care for end stage renal disease care has significantly reduced incentives for private insurers to invest in care that prevents kidney failure in the first place. As a result, the American health care system paid little attention to kidney care before patients developed kidney failure, to the detriment of American health. CKD is one piece of the larger chronic disease crisis facing this country, and like much of that crisis, it is driven in large part by conditions that we can influence. Prevention reduces how many Americans reach late-stage kidney disease in the first place, and with it the long-term burden of ESRD. The U.S. government finances the bulk of ESRD treatment, and the magnitude of that obligation is set years before it is paid, when the disease is progressing quietly and often undetected. Reducing kidney disease progression would reduce much of the high federal cost of ESRD care. But more importantly, empowering Americans to protect their own health means fewer people will face the devastating and often preventable reality of kidney disease by staying healthier. For Americans with kidney disease, the persistence of poor preventive care has had massive negative consequences to health. Fewer than half of patients initiating renal dialysis for ESRD are alive

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<sup>55</sup> <https://www.hrsa.gov/net/optn?base=insights&path=/OPTN-metrics/>

<sup>56</sup>The IOTA Model is testing the efficacy of financial incentives on transplant center practices to see if transplant centers are able to increase transplant rates.

more than five years later, a mortality rate that rivals many newly diagnosed cancers.<sup>57</sup> The highest priorities in addressing earlier-stage CKD are to slow the progression to kidney failure and to encourage more innovation across the full continuum of kidney care. In both areas, HHS can remove barriers and address poorly designed incentives where they impede progress.

### *Early Detection*

Early prevention activities are a lost opportunity because CKD is common but usually unrecognized until it has progressed to more advanced stages. We now have many good treatment options that slow kidney disease, mitigate cardiovascular disease, and reduce mortality, in part because of sustained investment in research funded by the National Institutes of Health. The Centers for Disease Control and Prevention (CDC) monitors gaps in CKD detection and management, and its data show that tens of millions of Americans are unaware that they have CKD because early-stage disease is typically asymptomatic and goes undetected without screening.<sup>58</sup>

When kidney disease is caught late, the treatment options narrow and costs rise. But progression can be slowed once CKD is identified, and early referral to nephrologists is associated with better outcomes.<sup>59</sup> The interval between disease onset and diagnosis is therefore the greatest opportunity for clinical benefit and cost avoidance. The earlier that CKD is found, the more likely patients' kidney function can be preserved, and the less likely patients progress to kidney failure. The need for screening is especially important for rare kidney diseases because patients with rare diseases are much more likely to progress quickly to end-stage. This progression is often preventable when patients are treated with specific clinical therapies that can only be utilized with early diagnosis and treatment.<sup>60</sup>

A major reason this opportunity goes unrealized is structural rather than clinical. The benefits of prevention are real, but they are delayed, unpredictable over time, and often captured by a different party than the one that pays for the preventive care. The cost of screening and early CKD management falls immediately on healthcare providers, payers, and patients. However, most patients with CKD qualify for Medicare when they reach ESRD, meaning that healthcare payers do not financially benefit from the cost of screening and earlier preventive interventions. Conversely, because the federal government absorbs the full cost of ESRD treatment, no single provider of earlier kidney treatment carries the full consequences of a patient's progression. The result is a system that has limited incentive to screen for CKD or prevent the development of ESRD. Addressing this issue is paramount given the expensive new therapies that are available for treating chronic kidney diseases, such as sodium-glucose cotransporter 2 (SGLT-2) inhibitors, a non-steroidal mineralocorticoid receptor antagonist, and a glucagon-like peptide-1 (GLP-1) agonist. These therapies slow CKD progression but require expensive upfront costs either by the payer or the patient.

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<sup>57</sup> [https://www.ajkd.org/article/S0272-6386\(18\)31126-0/abstract](https://www.ajkd.org/article/S0272-6386(18)31126-0/abstract)

<sup>58</sup> <https://www.cdc.gov/kidney-disease/media/pdfs/CKD-Factsheet-H.pdf>

<sup>59</sup> <https://link.springer.com/article/10.1186/s12882-025-03944-4>

<sup>60</sup> <https://www.nature.com/articles/s41581-024-00844-y>

Prevention is first and foremost a question of care quality and patient wellbeing, sparing people the decline in health and quality of life from advanced kidney disease. The fiscal stakes make the case even stronger. As noted above, ESRD is among the most concentrated and predictable liabilities in the federal health budget. Unlike many drivers of health spending, that trajectory is often knowable years in advance. A patient with early-stage CKD and uncontrolled diabetes represents a foreseeable future ESRD case whose eventual cost and decline in quality of life is dictated as progression goes unchecked. That financial burden should not be borne by taxpayers alone. Given that kidney disease develops over years, its costs should also be shared across employers, private insurers, and health systems. Unfortunately, as patients move between coverage types, no individual payer captures enough of the benefits of prevention to justify an investment. Because the benefits of prevention are spread across multiple actors and because investments in prevention do not yield short-term healthcare savings, most actors are not incentivized to act, despite the large, potential collective returns to prevention efforts.

### *Innovation*

Innovation across the broader spectrum of kidney care is constrained by structural barriers similar to those that impede innovation in the dialysis market: the lack of a durable pathway to finance new technology, and entry barriers that fall most heavily on smaller developers seeking to innovate on kidney disease. These conditions are not confined to renal dialysis. Diagnostics, earlier-stage therapeutics, and care models that fall outside existing payment categories encounter the same lack of financing and the same barriers that dialysis innovators face. New technologies reach patients slowly and often not at all. Financing new technology sustainably and lowering barriers to entry could open the whole of kidney care to innovation.

Innovative kidney disease treatments and especially treatments for early-stage CKD may be further deterred because renal dialysis costs are often deferred to Medicare. As a result, non-Medicare payers that finance new innovative CKD treatments may not recoup those investments. Payers may be further discouraged to pay for expensive, innovative early-stage treatments because of the slow and unpredictable average rate of CKD progression and because the most expensive kidney care costs primarily concentrate during late-stage CKD and ESRD. The resulting anemic market for new therapies may deter research and development (R&D), which further stagnates care and reinforces renal dialysis as the primary therapy for kidney disease.

### *Opportunities for Reform*

The U.S. government could address underinvestment in prevention and innovation by realigning incentives in five ways. The first three approaches attempt to address the problem that the actor that pays for prevention is rarely the actor that benefits from it. The goal of this plan, therefore, is to outline how incentives could be restructured so that the actors best positioned to slow disease progression have a genuine reason to do so. The remaining two approaches focus on sustaining progress made by the FDA and closing the research gaps that limit how far prevention and treatment can go.

First, providers should be rewarded for keeping patients healthy and preventing them from advancing to late-stage disease. Payment policies could focus on holding providers accountable

for the total cost and quality of a patient's care across the full arc of disease and not just a single episode. This continuous perspective would convert prevention from an uncompensated good into a source of value that providers can capture, closing the gap between who pays and who benefits. Second, early detection could be expanded so that at-risk patients are identified early enough for effective interventions to make a meaningful difference on disease progression. Third, a more sustainable pathway could be built to finance new technologies and innovation that focus on preventing ESRD.

The CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center) can play an important role in these first three actions by testing models that promote upstream CKD care. Through its unique authority, the CMS Innovation Center could create and test a payment model to incentivize better diagnosis and treatment for patients with early-stage kidney disease, which could have long-term benefits for both patients and the Medicare Trust Fund.

Such models could build on the work from the current Kidney Care Choices Model, which has improved the transition to renal dialysis, to also focus on delaying or preventing CKD progression. The recently announced ACCESS Model provides an example of this approach, testing outcome-aligned payments to support proactive, technology-supported care for CKD and other conditions.<sup>61</sup> By rewarding providers for the trajectory of a patient's health rather than the volume of services delivered, this approach could promote integrated, patient-centered care and support the parts of the system best positioned to slow disease.

Fourth, the FDA should continue working with clinicians and researchers to identify and validate the endpoints that best capture meaningful progress against kidney disease. By building on the acceptance of measures such as eGFR slope, sustained collaboration can give developers earlier, reliable signals of whether a therapy is working, shortening the path from research to patients without sacrificing rigor. There is room to extend this approach further, including potential attention to albuminuria as a surrogate for CKD progression in non-glomerular diseases and consideration of its role alongside proteinuria in glomerular diseases.<sup>62</sup> Actively identifying and advancing endpoints where science supports it can carry this momentum forward while preserving the standards for safety and for substantial evidence of effectiveness.

Fifth, sustained research investment is needed to deepen our understanding of how kidney diseases develop and progress, including their effects on the cardiovascular system, which can help identify future targets, and widen the set of tools available to prevent, treat, and even reverse kidney diseases. Several research priorities stand out. (i) Research should identify how best to implement screening across both easy- and hard-to-reach populations with the goal of identifying common and rare genetic kidney diseases. Efforts should focus on how to identify patients early, when treatment windows are still open. (ii) Research should investigate how best to implement a precision medicine approach -- to match patients with the right treatment at the right time. The arrival of multiple classes of therapy is a real advance, but we do not yet know how to determine who should receive which therapy, or which combination, and when. (iii) Research should study

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<sup>61</sup> <https://www.cms.gov/priorities/innovation/innovation-models/access>

<sup>62</sup> [https://www.ajkd.org/article/S0272-6386\(19\)30883-2/pdf](https://www.ajkd.org/article/S0272-6386(19)30883-2/pdf)

how to close gaps left by current treatment. Even the best available options do not work for everyone, and some forms of kidney disease remain untreatable by treatments on the market today.

Underlying these strategies is a fundamental shift in the government's role to one that prioritizes making America healthy again by confronting chronic disease at its source rather than managing its consequences. Government can help finance the cost of preventive treatments in federal programs. But more importantly, it should use its position as the primary payer for kidney failure to give every actor in the healthcare system a reason to invest in slowing kidney disease before it becomes a cost the government must finance in full. Efforts such as HHS's Operation TrialBlazer, which aims to accelerate patient access to powerful new treatments by reimagining the clinical trials enterprise, illustrate how federal action can pull innovation toward patients more quickly. That is where forward-looking policy can move the system: not just by managing ESRD more efficiently, but by keeping more Americans off renal dialysis in the first place, and healthier in the process.

## **Conclusion**

The relative lack of innovation in kidney care is not coincidental. Rather, it is the structural outcome of anti-competitive and burdensome actions that have exacerbated the national crisis of kidney disease and kidney failure. Restoring vibrancy in kidney care, thereby improving patient outcomes and reducing costs, would require thoughtfully reviewing and modernizing the regulatory framework governing kidney care to better encourage competition, innovation, and patient-centered care. This plan identifies the highest priority challenges since Executive Order 13879 was signed in 2019. The proposed strategic actions could address these challenges by streamlining regulations and allowing the market for kidney care efforts to thrive. Through these actions, HHS could detect, prevent, and treat kidney disease before kidney failure; introduce new and impactful innovation in renal dialysis care through vigorous competition; and promote kidney transplantation as the optimal treatment for kidney failure.

## *Policy Recommendations*

### Screening and Earlier Detection

- HHS should consider a systematic evidence review on kidney disease screening in at-risk populations, including those with diabetes, hypertension, cardiovascular disease, a family history of kidney failure, or a family history of rare kidney disease, incorporating perspectives from clinicians, patients, and kidney advocacy organizations.

### Supporting Comprehensive, Holistic Disease Management

- HHS should consider offering evidence-based nutritional guidance at community health centers, including technical assistance for screening diet-related risk factors and connecting patients to food resources.
- HHS should consider developing a provider toolkit to educate providers on newly approved therapies for primary and secondary kidney disease.

### Prioritizing Prevention

- HHS could explore model designs to prioritize prevention and improve care for dialysis patients.
- HHS should consider convening a multi-payer summit to coordinate with other payers on a shared approach to chronic kidney disease.

### Expanding Access and Choice

- HHS should examine the statutory and operational considerations to allow alternative settings for renal dialysis services to be evaluated.

### Encouraging Competition

- HHS should consider how to continue Modernization of the OPTN through a competitive, multi-vendor contracting approach, with focus on the transplant information technology system.
- HHS should consider publishing a report evaluating innovation in end-stage renal disease treatment, identifying opportunities to promote new, effective kidney care technologies.

### Protecting Patients and Taxpayers

- HHS should consider having charitable activities purportedly conducted on behalf of kidney patients reviewed by appropriate agencies for fraud or violations of federal law, with additional oversight considered as warranted.

- HHS should consider evaluating the potential relationship between the individual insurance market and third-party premium payments made on behalf of Medicare-eligible enrollees.

### Strengthening Living Kidney Donation

- HHS should consider what actions could be taken to strengthen living kidney donation and expand access to transplantation, including approaches to identify and engage potential donors and ensure transparent information for patients and families.
- HHS should consider launching a public awareness initiative to promote living donation which could include outreach through beneficiary touchpoints and partnerships with transplant centers.
- HHS should consider developing expanded reimbursement eligibility for living kidney donors through the National Living Donor Assistance Center.
- To facilitate increased living kidney donation, HRSA should continue to implement the HOLD Act and modified eligibility criteria for the Living Donor Assistance Center to ease access, reduce administrative burden, simplify documentation requirements, and expand eligibility for living donors.

### Enhanced Accountability for Organ Procurement Organizations

- HHS should consider opportunities to safeguard transplant access and eliminate potential fraud by ensuring OPOs are appropriately billing organ acquisition costs and adhering to their obligations as non-profit entities.
- HHS should consider reviewing payment processes to ensure that incentives and educational resources promote patient safety.
- HHS could consider fast tracking efforts to implement a certification process for new OPOs to enable more competition.
- HHS should consider updating its enforcement authority for actions that violate OPTN rules.

### Restoring Patient Safety Oversight

- HHS should consider efforts to restore trust in the organ transplant system through approaches like direct oversight of patient safety.
- HHS should consider creating an Organ Donation Corruption and Safety Task Force, in coordination with relevant law enforcement agencies and state and federal partners, to ensure timely investigation of safety and fraud concerns.
- HHS should consider how to improve patient safety oversight within OPOs, through efforts like monitoring the implementation of requirements to have dedicated Patient Safety Officers to monitor safety events, and through better communication with patients and families.

### Prioritizing Research and New Technologies

- HHS should consider the opportunity to work with researchers and clinicians to identify additional surrogate endpoints when scientifically validated, with the goal of facilitating earlier FDA approvals when there are clear signals that new treatments can benefit patients sooner.
- HHS should consider the opportunity to establish research pathways to facilitate the development of new kidney treatments and to improve the delivery of already existing, novel therapies for kidney disease.