

The Executive Order on Kidney Care: An Opportunity to Improve Outcomes for Individuals With Kidney Disease



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On July 10, 2019, President Trump and the United States Department of Health and Human Services announced the Advancing American Kidney Health initiative (Table 1). This executive order outlines 3 principal goals and 7 objectives (Table 2). These goals and objectives are comprehensive and well conceived, and if acted upon, they would do much to reduce the tremendous health burdens and costs associated with chronic kidney disease (CKD) and end-stage renal disease (ESRD) in the United States. These goals are accompanied by ambitious specific targets, including a 25% reduction in the number of Americans who develop ESRD by 2030, initiation of home dialysis or transplantation for 80% of new patients with ESRD by 2025, and doubling the number of kidneys available for transplantation by 2030.

Central components of these plans include both the mandatory

ESRD Treatment Choices model, which will randomly enroll half of US nephrologists and dialysis facilities, and the voluntary Kidney Care First and Comprehensive Kidney Care Contracting models, which will build on the existing Comprehensive ESRD Care model. These new payment models will operate under traditional Medicare (parts A and B) through the Center for Medicare and Medicaid Innovation. The intent of these payment models is to provide resources and incentives for the management of patients with CKD stages 4 and 5, use of home dialysis therapies, and facilitation of kidney transplantation. These models will be initiated starting on January 1, 2020. Depending on the model, alternative funding approaches will be implemented in 2020 or 2021 and extend through 2023 or 2026. Cost and clinical outcomes resulting from these models will be evaluated and decisions will be taken regarding modification or continuation of these new funding algorithms.

A partial list of additional components of the Advancing American Kidney Health initiative include

deployment of open-source portable electronic care plan tools for patients with multiple chronic conditions; enhanced education opportunities for patients with kidney disease; development of new diagnostics and therapies through KidneyX, a public-private partnership between the US Department of Health and Human Services and the American Society of Nephrology; new guidance for development of organ preservation technologies; learning collaborative engagement to reduce kidney discard rates, increase organ recovery, and accelerate organ placement; research on the use of donors with HIV, hepatitis C, and the apolipoprotein L1 (*APOLI*) gene; and expansion of travel, subsistence, and lost wage reimbursement for potential living kidney donors who are in need of such assistance to move forward with donation.

Patients with renal disease ultimately may benefit from successful implementation of the incentives, innovations, and practice-pattern changes that these initiatives are designed to enhance. However, it is uncertain whether the nephrology community is resourced and positioned to respond in the short term to many of these new proposed changes.

Kidney disease is a public health catastrophe. Risk factors for the development and progression of kidney disease have long been recognized. Despite readily available and effective treatments, poorly controlled diabetes and hypertension are both causes and accelerants of renal insufficiency. Furthermore, kidney disease amplifies the consequences of cardiovascular disease and increases frailty.¹ CKD is associated with increasing mortality to the extent that substantially fewer Americans have stage 5 than stage 4 CKD,

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Table 1. Links to additional information elaborating on the Advancing American Kidney Health initiative

	Link
1	Advancing American Kidney Health executive order: https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/ . Accessed August 28, 2019.
2	Report by the Health and Human Services Assistant Secretary for Planning and Evaluation: https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf . Accessed August 28, 2019.
3	Centers for Medicare and Medicaid Innovation ESRD Treatment Choices Model Web site: https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/ . Accessed August 28, 2019.
4	Centers for Medicare and Medicaid Innovation Voluntary Kidney Models Web site: https://innovation.cms.gov/initiatives/voluntary-kidney-models/ . Accessed August 28, 2019.
5	Proposed rule for the ESRD Treatment Choices Model: https://www.regulations.gov/document?D=CMS-2019-0101-0001 . Accessed August 28, 2019.

ESRD, end-stage renal disease.

and even fewer have stage 4 when compared with stage 3 CKD, reflecting in part the high and increasing likelihood of death associated with progressive renal diseases.

Whereas patients experience few, if any, symptoms until kidney disease is far advanced, criteria for diagnosing and staging chronic kidney disease are well characterized and readily available to providers and payers through direct patient contact and by examination of electronic medical records, laboratory databases, and insurance claims.² Yet little has been accomplished previously at national, health system, payer, or individual practice levels to systematically leverage these data to identify and monitor patients with

CKD or risk factors for CKD and to implement early diagnosis and interventions. Public education is largely absent.

In the United States, late recognition commonly leads to delayed referrals to nephrologists and kidney transplant programs; patients and their families are often incompletely appraised of their options and poorly prepared to choose and begin treatment; and preparations for renal replacement therapies often are hastily arranged and emergent. Consequently, most patients with progressive CKD are funneled toward perpetual in-center hemodialysis.³ Whereas outcomes in general favor persons who receive early or preemptive kidney transplantation or may be improved in some respects for persons who

initiate peritoneal dialysis or home hemodialysis, as opposed to in-center hemodialysis, barriers often exist to implementing these treatment options at the individual patient level, as well as at payer and provider levels. To the extent that ESRD is a disease that disproportionately affects chronically ill and elderly persons, not all patients are suitable for transplantation or home dialysis options. Furthermore, not all patients have social support and the functional capacity necessary to maintain themselves outside of in-center treatment environments. A sizeable minority of older patients and, particularly, frail patients with kidney disease may in fact not benefit from either dialysis or transplantation, instead achieving better quality and duration of life through supportive therapies. Identifying these patients is an emerging challenge to providers of kidney disease care.

Workforce, resource, organizational, and financial obstacles facing the Advancing American Kidney Health initiative are considerable. Although it is possible that implementation of this initiative eventually may lead to overall cost savings, it is probable that considerable investment will be needed during the transition from present to future payment models. Current and prior administrative and financial incentives have led most nephrologists to concentrate their practices and expertise on either in-center hemodialysis or on kidney transplantation. Tremendous resources have been invested in in-center hemodialysis, and interests are entrenched. Historically, payment for management of CKD has been low, and because nephrologists often are fully committed to in-center dialysis or transplantation, patients with CKD usually are managed in primary care settings. Absence of engagement by

Table 2. Goals and objectives outlined in the July 10, 2019, executive order announcing the national Advancing American Kidney Health initiative^a

Goal	Advancing American Kidney Health: goals and objectives
1	<p>Reduce the risk of kidney failure</p> <p>OBJECTIVE 1: Advance public health surveillance capabilities and research to improve identification of populations at risk and those in early stages of kidney disease</p> <p>OBJECTIVE 2: Encourage adoption of evidence-based interventions to delay or stop progression to kidney failure</p>
2	<p>Improve access to and quality of person-centered treatment options</p> <p>OBJECTIVE 1: Improve care coordination and patient education for people living with kidney disease and their caregivers, enabling more person-centric transitions to safe and effective treatments for kidney failure</p> <p>OBJECTIVE 2: Introduce new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life</p> <p>OBJECTIVE 3: Catalyze the development of innovative therapies including wearable or implantable artificial kidneys with funding from government, philanthropic, and private entities through KidneyX and coordinate regulatory and payment policies to incentivize innovative product development</p>
3	<p>Increase access to kidney transplants</p> <p>OBJECTIVE 1: Increase the utilization of available organs from deceased donors by increasing organ recovery and reducing the organ discard rate</p> <p>OBJECTIVE 2: Increase the number of living donors by removing disincentives to donation and ensuring appropriate financial support</p>

^aReport by the Health and Human Services Assistant Secretary for Planning and Evaluation: aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf. Accessed August 28, 2019.

nephrology professionals in turn leads to non-evidence-based and inconsistent care, lack of standardization of interventions to monitor and delay disease progression, failure to engage the patient in choice of treatment options, and a disorderly transition from CKD to ESRD.

Furthermore, diagnosis and treatment of patients with kidney disease is complex and frequently requires care during evening and nighttime hours. Nephrologist practice hours are long, and compensation for nephrologists is less than that of procedure-oriented medical subspecialties, such as cardiology and gastroenterology. Consequently, nephrology does not present itself as an attractive career choice to medical students and house officers. Nephrology fellowship programs no longer attract top-tier trainees, and many programs have difficulty filling positions or compromise on background and quality when accepting applicants into their fellowships.⁴ Consequently, the United States has a shortage of nephrologists, and many are not comprehensively trained in all aspects of the management of CKD and ESRD, including diagnosis of renal and urological diseases, home hemodialysis, in-center hemodialysis, peritoneal dialysis, transplant medicine, and supportive alternative and palliative care.⁵ Practice settings rarely provide patients with the full range of therapeutic alternatives. Similarly, nephrology office and dialysis administrators, mid-level providers, nurses, social workers, dieticians, and patient educators are not trained to provide and support the full range of CKD and ESRD treatment options. Practices and facilities in US Territories and in rural, isolated, and highly underserved urban areas are presented with especially severe barriers to providing comprehensive kidney

care alternatives. Developing resources and training substantial numbers of general nephrologists, staff, and nonphysician providers to offer the entire list of options that ideally would be available to guarantee quality comprehensive treatment for patients with CKD and ESRD will be costly and require investments in personnel and resources and are unlikely to be achieved within the anticipated time frames of the proposed payment models.

As shown in Goal 3 and the related objectives from Table 2, increasing kidney transplantation is a critical element of the Advancing American Kidney Health initiatives. Challenges to increasing kidney transplantation include improving access to the waiting list and living donor transplantation, optimizing organ availability, and refining allocation policies.

It is well documented that access to live donation and deceased donor kidney transplant waiting lists varies across the United States. Similarly, organ procurement organization performance and transplant center organ acceptance practices are highly variable. Models developed at previous US Department of Health and Human Services-sponsored donation and transplantation collaboratives have demonstrated opportunities for sizably increasing donation and transplantation rates. Adoption of these strategies were compromised by resource limitations, absence of incentives, distrust of adjustment models used to rank organ procurement organizations and transplant programs, and fears that utilization of nontraditional donors might result in unfavorable regulatory organ procurement organization and transplant center performance reviews.

Increasing living donor kidney transplantation will be necessary to the aim of “doubling the

number of kidneys available for transplantation by 2030.” However, concern for the well-being of the live donor must be the first and foremost consideration in any such expansion. In addition to the pain and anxiety associated with the surgery, living donation is often a financial hardship on the donor and the donor’s family. Expansion of travel, subsistence, and lost wage reimbursement for potential living kidney donors who are in need of such assistance to move forward with donation would be an important contribution to the well-being of many donors and potentially increase opportunities for transplantation for their loved ones and their intended recipients. Multiple proposals to ensure and monitor living donor well-being were developed at a 2011 conference on living donor follow-up. Key among these were calls to fund a scientifically sound, adequately powered, long-term living donor follow-up study and to provide a mechanism by which living donors could self-report late complications arising from donation to the Organ Procurement and Transplantation Network.⁶ These recommendations should be revisited and acted upon.

In addition, one of the important developments for promoting living donor transplantation has been the introduction of kidney paired donation. Adoption of a living donor standard acquisition charge has been proposed to facilitate and provide cost certainty for kidney paired donation across payers and institutions.⁷ The Centers for Medicare and Medicaid Services should formally institute this payment mechanism.

After nearly 10 years of intense study and negotiation, a new US deceased donor kidney allocation system was adopted in December 2014.⁸ This system is an important step forward in allocation policy

and has reduced barriers to transplantation for minorities and sensitized transplant candidates. To a limited extent, it also allows for survival matching between donor kidneys and waitlisted candidates with the longest potential for posttransplant survival. However, it has been shown through allocation modeling that, even without increasing the size of the deceased donor pool, tens of thousands of additional posttransplant life years could be obtained from alternative kidney allocation systems that allocate kidneys to maximize incremental posttransplant patient survival.⁹ Consideration of alternative allocation systems that improve the survival potential arising from the deceased donor pool should be reconsidered as efforts focus on increasing opportunities for transplantation.

In announcing the Advancing American Kidney Health initiative, the administration emphasized its intent to “shift from paying for sickness and procedures to paying for health and outcomes.” These proposals reflect input from government agencies, patients, patient advocates, providers, professional organizations, dialysis entities, pharmaceutical companies, and device manufacturers. Current

funding mechanisms, policies, and practices in renal medicine are far from ideal and poorly serve the patient, payer, and physician communities. As previously described, this initiative is likely to face many challenges, and true reform will require appropriate incentives and new adequately directed resources both during and after the transition from current to future payment models. However, altering the current national kidney care model has the potential to motivate shifts in values, funding, patient care strategies, outcomes, and culture. This initiative deserves the community's active engagement, participation, and support.

DISCLOSURE

All the authors declared no competing interests.

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