



A Vision for Advancing American Kidney Health

View from the US Department of Health and Human Services

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Introduction

The time has come for dialysis to take its place in a museum among the most revolutionary, lifesaving, and soon to be historical medical devices.

For most of humanity’s history, the failure of critical organs, such as kidneys, resulted in immediate death. That began to change when, in 1928, Philip Drinker and Louis Agassiz Shaw Jr. built the first widely used mechanical respirator known as the Drink or “iron” lung (1). Fifteen years later, Willem Kolff created the first artificial kidney for acute kidney failure (2), and then, Belding Scribner’s new shunt in 1960 paved the way for the first continual dialysis machine (3) that began a revolution in kidney care.

Concurrently, in 1954, the capability to surgically transplant functioning organs from deceased or living donors was introduced marked by the first kidney transplant (4). This has become and still is the best treatment option for most patients on the basis of survival, quality of life, and use of health care resources (5). In 2017, a record 34,768 organ transplants were performed in the United States (6).

However, currently, 13 people die each day in the United States waiting for a transplant, over 90,000 Americans are waiting for a kidney transplant, and about 120,000 Americans annually began dialysis (7). As a nation, we have permitted unnecessary scarcity in the supply of transplantable organs; a recent study estimated that 17,000 usable kidneys were discarded from 2004 to 2014 (8). Alternatively, home dialysis has been shown to improve outcomes and quality of life compared with in-center dialysis, but among Medicare beneficiaries, only 12% dialyze at home, a rate well below that in other developed nations (9).

The 545,000 United States patients on dialysis suffer from poor health outcomes, often the result of the inadequate physiologic kidney replacement of dialysis, underlying disease complications, and multiple comorbidities. These can lead to high rates of hospital admissions and readmissions, reduced quality of life, and a mortality rate that rivals most cancers.

Advancing Kidney Health into the 21st Century

On July 10, 2019, President Trump signed an Executive Order to Advance American Kidney Health (AAKH) outlining a bold, comprehensive vision to

break out of policies and practices that have done a disservice to Americans suffering from kidney disease. The Executive Order formally launched a major effort at the Department of Health and Human Services (HHS) to improve Americans’ kidney health. Kidney health has been identified by HHS Secretary Alex Azar as one of the top health challenges in which the department can make a significant effect.

For several decades, United States kidney health policy has been playing a game of whack-a-mole. In 1972, when Congress extended Medicare coverage to individuals with permanent kidney failure regardless of age, they rightly recognized the unique role that dialysis plays to sustain life, one that should be accessible to every American. One unintended consequence, however, was the creation of a market that undervalues prevention; clinically superior alternatives, such as transplant; and investments in innovative technologies to benefit future patients. When the number of Medicare beneficiaries with ESKD sharply rose in the past two decades, the 2011 ESKD Prospective Payment System was implemented to contain costs but again, further focused the United States health care system on dialysis. Perhaps most remarkable is that our system of care is nearly completely designed around dialysis. It is a perfect example of how American health care has focused on paying for procedures rather than outcomes.

In seeking to modernize the system to deliver the outcomes that patients value and deserve, we must not only incent those outcomes but simultaneously, ensure that the system is capable of delivering them.

Supply and Demand for Transplants

AAKH recognizes the unmet demand for home dialysis, transplants, and innovative alternatives to dialysis. The CMS Innovation Center introduced and proposed new payment models that, coupled with other actions, aim to shift 80% of new patients with kidney failure to these modalities. These new payment models are intended to give health care providers better incentives to reorient our system away from its current focus on dialysis, including the delivery of more lifesaving transplants.

First, there is a proposed rule to implement the mandatory ESKD Treatment Choices model, which

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includes as participants certain ESKD facilities and clinicians caring for beneficiaries with ESKD located in selected geographic areas and focuses on encouraging greater use of home dialysis and kidney transplants to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. Second, the Kidney Care First and the Comprehensive Kidney Care Contracting models are expected to enroll >200,000 Medicare patients in arrangements in which their kidney care providers have incentives to prevent the progression of kidney disease.

Giving all eligible patients on dialysis the option for a transplant would change little, because there are simply not enough transplantable kidneys available. We, therefore, need to address the barriers to the supply of organs, and AAKH aims to double the number of available kidneys through proposed long-overdue reforms to the organ procurement system aimed at reducing discards as well as measures to support living donation by expanding the support that HHS provides for living donors, broadening the eligibility criteria, and allowing more reimbursable expenses, such as child care.

Artificial Kidney

Ultimately, delivering robustly better quality of life for patients requires an ambitious research and innovation agenda. For treating kidney failure, that includes development of ambitious technologies, like an artificial kidney. Advances in nanotechnology, materials science, and biomedical engineering coupled with increased understanding of kidney physiology and function are making the possibility of developing implantable devices to replace a failing kidney ever more feasible. Advances in tissue engineering, regenerative medicine, and gene editing are making xenotransplantation and bioartificial kidneys a possibility.

These technologies can transform the entire care paradigm just as dialysis and transplantation had in decades previous. We, therefore, created the public-private partnership KidneyX in conjunction with the American Society of Nephrology to catalyze the development and commercialization of next generation therapies to prevent and treat kidney failure.

Increased Focus on Upstream Kidney Health

As a country, we have made too few substantive efforts to understand and treat underlying causes leading to kidney failure and provide the care that patients need to avoid or delay kidney failure. One in two people with very low kidney function who are not on dialysis does not know that he/she has kidney disease (10). There are two important components of AAKH that address these issues.

First, we will launch a national campaign in partnership with other organizations to raise awareness of kidney diseases, encourage patients to seek care early, highlight opportunities to become an organ donor, and ensure that clinicians are aware of the warning signs.

Second, as noted earlier, the CMS Innovation Center has proposed an optional payment model that includes four different participation options designed to enable

nephrologists and other health care providers to treat patients before kidney failure and in the case of kidney failure, ensure that there are smoother paths toward kidney transplants or more appropriate dialysis modalities, such as home hemodialysis or peritoneal dialysis.

More advances are needed to enable nephrologists and other clinicians to treat patients with kidney disease early. The development of new pharmaceutical therapies, dietary and lifestyle intervention models, and other therapeutics designed to slow progression and delay or prevent kidney failure will provide clinicians with even more powerful tools to help patients.

Putting Patients and Caregivers First

Underpinning AAKH is an increased focus on empowering patients by addressing the issues that patients care most about and ensuring that they have real choice among treatment options. Most patients effectively have little power in choosing the option for a transplant due to the scarcity of organs and lack of awareness of eligibility criteria. Additionally, before kidney failure, patients experience even less choice in care driven primarily by the lack of awareness of their own kidney health and the lack of effective treatment options. In the long term, we can further empower patients by developing better options for treatment through innovation, whether through research funded by the National Institutes of Health or partnerships, like KidneyX.

Only the Beginning

Although we have a long way yet to realize these goals, we are within the grasp of declaring kidney failure to not be a death sentence. Dialysis brought us partially there, but the road forward will ultimately require a combination of avoiding permanent kidney failure where possible and providing better long-term survival options where we have not. Let us complete the vision that began with Wilhem Kolff.

HHS is only one of many stakeholders that plays a role in the care of patients with kidney disease. The siloes of care and perverse incentives for modes of care delivery have deep roots and engrained patterns that have developed over the decades. The current state of kidney care is a result of both government policies and market forces. Therefore, we call on all communities—including patients, clinicians, researchers, both large and small service providers, product developers, and investors—to use this opportunity to drive the collective transformational change that patients with kidney disease today and tomorrow deserve. Together, we can make meaningful change in a disease area that has seen too little improvement for too long.

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Disclosures

Mr. Boehler, Dr. Patel, and Mr. Uehlecke have nothing to disclose.

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