

A Call to Action for the Kidney Community

Nephrologists' Perspective on Advancing American Kidney Health

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Introduction

CKD affects 37 million Americans (1), is the ninth leading cause of death (2), and is estimated to cost \$114 billion annually (3). To address this public health issue, on July 10th, 2019, President Donald J. Trump announced and signed the Advancing American Kidney Health (AAKH) Executive Order (4). The objectives and ambitious goals of AAKH broadly resonate with the kidney community from patients and families to providers who have witnessed the high morbidity and mortality associated with kidney disease and stagnation in therapies. Currently, government agencies are collectively shaping the AAKH agenda, and hence, it is important that the kidney community immediately engages in this process to optimize its success. In this article, we outline AAKH initiatives and highlight potential ways the community can assist in making AAKH policy truly effective for patients.

Increasing Awareness of Kidney Disease

The AAKH calls on the Secretary of Health and Human Services (HHS) to launch an “awareness initiative” to educate patients and support programs that promote kidney disease awareness. For other health issues (*e.g.*, opioid epidemic and breast cancer), governmental agencies and professional societies have had remarkable success in generating public awareness. Although multiple kidney organizations are well positioned to ramp up existing patient education programs with the proposed federal support, it is critical that our community significantly involves patients and their families, who are well positioned to engage the general public and primary care providers through their stories and personal experiences, as well as professional organizations, which can focus subspecialists and research communities on better health promotion. To have sustainable effect and momentum for kidney care advancement, these patient-centered efforts must be met with complementary well funded initiatives to (1) effectively implement best practices; (2) appropriately compensate high-quality management; and (3) efficiently improve screening, prevention, dissemination, and therapies.

Payment Models

Central to the AAKH is the directive to revolutionize payment for kidney care beyond the Comprehensive ESRD Care models, shifting reimbursement from

in-center dialysis to home therapies, transplantation, and upstream CKD care. The HHS through the Center for Medicare & Medicaid Innovation (CMMI) has released a proposed rule outlining one mandatory model and an initial overview of four optional payment models.

The proposed ESRD Treatment Choices (ETC) model seeks to reward clinicians and dialysis facilities that provide patients with a full spectrum of choices when they transition to kidney failure, with a primary goal of increasing home dialysis and transplant rates (5). ETC, a mandatory model, automatically enrolls approximately 50% of nephrologists and dialysis facilities in the United States into the model on the basis of hospital referral region, which would then be compared with equivalent providers in a similar hospital referral region receiving standard care. The CMMI proposes giving a modest incentive of up to 3% of Medicare charges for sending patients home for dialysis during the first 3 years of the model (Home Dialysis Payment Adjustment). Over time, payment is adjusted by performance (Performance Payment Adjustment) on the basis of rates of home dialysis and transplant. This is a two-sided risk adjustment, and it is slightly asymmetric with larger downside risk, proposed to range anywhere from -11% to +10% for physicians (with slightly larger payment adjustments for dialysis facilities). The ETC is proposed to start in early 2020, with payment adjustments on the basis of performance proposed to begin in 2021. Overall, the ETC model is expected to reduce Medicare spending to dialysis facilities and managing clinicians by \$185 million over 6.5 years (5).

The CMMI also announced four optional or voluntary models for kidney care that span CKD stages 4 and 5 as well as kidney failure and transplantation, creating incentives for nephrology care teams to focus on preparation and longitudinal care of patients with kidney disease (6). The Kidney Care First model is specific to nephrologists, whereas the other three models, collectively called Comprehensive Kidney Care Contracting (CKCC) models, will include nephrologists, health care systems, and dialysis providers. After the imminent release of model details, there will be an application process for providers or organizations that would like to join the voluntary models. It is expected that the voluntary models will complement the ETC and that most ETC participants will also implement one of the voluntary models. This intentional shift away from a

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fee-for-service payment system that has primarily focused on in-center hemodialysis is an historic and important change, and the kidney community should embrace this opportunity to transform kidney care and subsequently, the practice of nephrology by refining these models for optimal success. As these voluntary models are fully elucidated, nephrologists should adopt models that best align with their practices. The CMMI and the kidney community may learn from other countries that have successfully adopted similar payment models and enhanced home therapies and transplantation using shared decision-making approaches (7). Professional kidney organizations must facilitate this process by developing a robust suite of educational tools to empower nephrologists in executing these care models, such as informational sessions on operations and best practices. Clearly, widespread adoption will help the CMMI evaluate the applicability and effectiveness of the models to ultimately implement a system that would have the best chance of national success.

Development of the Artificial Kidney

We applaud AAKH's recognition that catalyzing the development of novel therapies is key to revolutionizing kidney health management. AAKH calls on the HHS to focus on establishing premarket approval of wearable and implantable artificial kidneys and welcomes other strategies to facilitate innovation, identifying the newly established Kidney X program, a public-private partnership designed to accelerate kidney-specific innovation, as the vehicle to drive this innovation (8). Congress is still in the process of deciding appropriations for Kidney X. To ensure its success, the kidney community must push for a \$25 million Congressional appropriation for Kidney X in FY2020 and annually by calling/writing/tweeting their Congressional delegation, informing patients and families for their advocacy, and staying current on accomplishments.

Transplant Proposals

AAKH intends to address the relative shortage of kidney transplants through two main mechanisms: more efficient use of deceased donor kidneys and policies that encourage increased rates of living donation. As a community, we should embrace this opportunity to drive transformative change in our transplant system, recognizing that we can and must improve many aspects of our current processes to expand access to this well appreciated optimal therapy. Much attention has recently been focused on Organ Procurement Organizations performance, and forthcoming HHS regulation is likely to result in having first-ever objective transparent data about organ procurement, which will be fundamental to optimization. Also being considered are processes to decrease cold and warm ischemia times by optimizing organ matching and delivery approaches. However, there are a host of other inefficiencies and misaligned incentives throughout the transplant system (*e.g.*, factors leading to lengthy transplant evaluation times, transplant center performance metrics that cause centers to be overly risk averse, and suboptimal risk stratification) that the kidney community can help the HHS address to meet AAKH transplantation objectives.

With an average cost of \$5000 to donors, potential lost wages, and job insecurity, there are clear socioeconomic barriers to living donation (9). AAKH calls for expansion of the definition of allowable costs that can be paid under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program. Efforts will likely raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost wage expenses, and provide for reimbursement of childcare and eldercare expenses. Although budgetary constraints will likely create pushback, through research and advocacy, the kidney community and most notably, patients and families will need to persistently inform legislators of the personal, economic, and overall societal benefits of supporting kidney transplantation.

Potential Unintended Consequences

With any national policy change, there is potential for unintended consequences. Missing from the information that the Center for Medicare and Medicaid Services collects and analyzes is the patient perspective. For some patients with kidney failure, maintenance in-center dialysis is their preferred treatment, and despite education and prodding from providers, they will not be interested in pursuing home dialysis or a kidney transplant. Homelessness, housing insecurity, lack of resources, and functional and cognitive disability are real barriers to success in home dialysis and transplantation. The current proposals provide incentives to the health care provider, but they do not provide direct support to the patient or family to overcome these barriers; for example, home-assisted dialysis is an area, not detailed in AAKH, that may warrant further investment. Without additional patient assistance at home or support navigating the complicated transplant system, 80% home dialysis and transplant will not be achievable in the kidney failure population. It will be critically important for the CMMI to set appropriate goals and benchmarks in the ETC and the CKCC to preserve latitude to individualize care and preserve patient choice. The patient voice is important, and the community will need to support the message as models are tested.

Additionally, infrastructure is not currently optimized to support proliferation of home dialysis programs. For example, not all nephrology training programs offer adequate training in home dialysis modalities—a reality we must acknowledge and change moving forward to offer all patients this option. Additionally, the shortage of nurses with expertise in home dialysis is an impediment; bolstering their ranks will be key to ensuring success. We need to ensure that industry, dialysis providers, health systems, nephrology training programs, and local resources are prepared to support AAKH goals.

Importantly, the success of AAKH depends on the Legislative Branch. Congress will need to provide funding for kidney disease awareness and education, living donor support, and Kidney X.

In conclusion, AAKH has aspirational goals to focus well needed attention on kidney health to enhance prevention, optimize care delivery, and spur innovation. AAKH has huge positive potential to transform the national landscape of kidney care for the better. Although it has initial widespread support from patients, providers, and professional societies,

the details of the regulation are still pending, and its future effect remains uncertain. As we break new ground with AAKH, the kidney community must stay engaged *via* professional and patient organizations, *via* academic and research institutions, and most importantly, as individuals to ensure that the developing policies stay true to their intentions and continue to evolve to meet the needs of Americans who suffer with kidney disease now and in the future.

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Disclosures

Dr. Bieber serves as the Chair of ASN's Quality Committee, is a Medical Director for Northwest Kidney Centers, and is a member of the Home Dialysis University faculty. Dr. Gadegbeku reports receiving as site investigator a grant from Akebia for an industry-sponsored trial in anemia; receiving as site investigator and an advisor board member a grant from the Duke Clinical Research Institute and Bristol-Myers Squibb for a clinical trial; and receiving as a coinvestigator a grant from the National Institute of Diabetes and Digestive and Kidney Diseases for research in nephrotic syndrome outside of the submitted work. Dr. Gadegbeku also serves as the Chair of ASN's Policy and Advocacy Committee and as Fresenius Medical Care Episcopal Hospital Dialysis Medical Director in Philadelphia, Pennsylvania.

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