

Policy Update

Kidney Care Policy: An Update on AAKH, Payment Models, and Predictions for Action Ahead

By David White

On Sunday, November 10, at Kidney Week, the final policy session of the week, “Hot off the Press,” drew an unprecedented packed crowd to hear the latest details on kidney care policy, with a strong focus on the Advancing American Kidney Health (AAKH) Executive Order. A wide range of policy efforts are underway to support the following objectives of the AAKH:

- Reducing the risk of kidney failure.
- Improving access to and quality of person-centered treatment options.
- Increasing access to kidney transplants.

Kevin F. Erickson, MD, MS, and Crystal A. Gadegbeku, MD, FASN, moderated the session with presenters Tom Duvall, Acting Division Director at the Centers for Medicare and Medicaid Innovation (CMMI); Nick Uehlecke, advisor in the office of the Secretary of Health and Human Services (HHS); Suzanne Watnick, MD, FASN, CMO of Northwest Kidney Centers; and Rachel Meyer, ASN Director of Policy and Government Affairs.

The session provided a glimpse into the thinking inside the office of HHS Secretary Alex M. Azar II on the development of kidney policy, particularly in the area of innovation, contained within the Executive Order. Speaking personally and not on behalf of Secretary Azar, Uehlecke described how kidney healthcare policy took on an urgent status with the arrival of the new HHS Secretary. Azar was personally invested in improving kidney healthcare after watching his father develop kidney failure, endure dialysis, and, ultimately, receive a kidney transplant. Uehlecke provided the backdrop for how the most sweeping changes in kidney healthcare in 50 years came into existence.

The session also provided a deeper dive into aspects of the voluntary and mandatory kidney care models, while mixing in some old-fashioned predictions for the road ahead on the regulatory and legislative fronts.

In his talk, “Deep Dive on New Kidney Care Delivery Models,” Duvall provided a firsthand look at the provisions in the Kidney Care Choices (KCC) Model—the voluntary model with its four payment pathways. Duvall and his team at CMMI created the KCC Model, which is based on the Comprehensive ESRD Care (CEC) Model that began in 2015 and expires at the end of 2020. The four payment pathways are the Kidney Care First (KCF) Option for nephrologists/nephrology practices only and the three Comprehensive Kidney Care Contracting (CKCC) Options that must include nephrologists/nephrology practices and transplant providers; however, they may also include dialysis facilities, and other kidney care providers on an optional basis (Table 1).

The KCC Model is expected to run from 2020 through December 31, 2023, with the option for one or two additional performance years at CMS’s discretion. Those healthcare providers that apply and are selected to participate will begin their participation in 2020, although financial accountability will not begin until 2021. During 2020, referred to as the Implementation Period, participants will focus on building necessary care relationships and infrastructure. Applications are due through January 22, 2020.

The following are the five payment mechanisms in the KCC model:

1. **Adjusted Monthly Capitated Payment (AMCP):** capitated payment paid to model participants to manage ESRD, based on the monthly capitated payment.
2. **CKD Quarterly Capitated Payment (CKD QCP):** capitated payment paid to model participants to manage CKD 4/5 patients.
3. **Kidney Transplant Bonus (KTB):** incremental reimbursement for successful kidney transplant up to \$15,000 over three years of allograft survival.
4. **Shared Savings/Losses:** based on total cost of care compared to benchmark (available to CKCC option

participants only).

5. **Performance Based Adjustment (PBA):** upward or downward adjustment to the CKD QCP and AMCP based on participant’s year-over-year continuous improvement and performance relative to peers (available to KCF practices only).

The AAKH Executive Order also included some very ambitious goals:

- Reducing the number of Americans developing kidney failure by 25% by 2030.
- Aiming for 80% of new kidney failure patients in 2025 to be receiving home dialysis or transplant.
- Doubling the number of kidneys available for transplant by 2030.

The inclusion of the 80% incident ESRD number in the proposed rule for the mandatory ESRD Treatment Choices (ETC) Model created consternation for many in the kidney community. ASN’s comment letter, like the overwhelming majority of comment letters provided to CMMI, urged the Innovation Center to drastically reduce that number. Watnick embraced the goal in principle in a sometimes tongue-in-cheek presentation that played on the 1980s titled “Incident Home Dialysis & Transplant: Aim for 80!” She described past policies that led to the impetus to aim for such an ambitious combined rate of home dialysis and kidney transplantation, such as passage of the Medicare Improvement for Patients and Providers Act (MIPPA) of 2008, creation of the ESRD Prospective Payment System (PPS) bundle in 2011 and the ESRD Quality Incentive Program (QIP) in 2012, and the biggest contributor to value-based care: passage of the Affordable Care Act (ACA) in 2010. The ACA directly created CMMI with authority to test new models with reimbursement based on the volume of shared risk (and shared savings) and create Accountable Care Organizations (ACOs).

When asking, “Why now?” Watnick outlined the kid-

Table 1. Overview of the Kidney Care Choices (KCC) Models

Payment Options	Overview	Participants
Kidney Care First (KCF) Option	Based on the Primary Care First (PCF) Model – nephrology practices will be eligible to receive bonus payments for effective management of aligned beneficiaries	Nephrologists/nephrology practices only
CKCC Graduated Option	Based on existing CEC Model One-Sided Risk Track – allowing certain participants to begin under a lower-reward one-sided model and incrementally phase in risk and additional potential reward	Must include nephrologists and nephrology practices as well as transplant providers; may also include dialysis facilities and other kidney care providers on an optional basis
CKCC Professional Option	Based on the Professional Population-Based Payment Option of the Direct Contracting Model – with 50% of shared savings or shared losses in the total cost of care for Part A and B services for aligned beneficiaries	
CKCC Global Option	Based on the Global Population-Based Payment Option of the Direct Contracting Model – with risk for 100% of the total cost of care for all Part A and B services for aligned beneficiaries	

ney disease statistics known to all nephrologists including prevalence, mortality rates, expense of care, but, ultimately concluded that this time the nation has an HHS Secretary for whom kidney failure and kidney health are personal. That personal approach has led to an HHS-wide set of policies to increase kidney transplantation and access to alternatives to in-center hemodialysis, especially peritoneal dialysis (PD).

Infrastructure and the need for patient and provider education are among the barriers to increased use of PD. Watnick reviewed how the models and the overall Executive Order could address these challenges. For example, the models waive numerous restrictions on providing kidney disease education, from who must provide it to who may use it, adding stage 5 and the first six months of dialysis all in service of increased home dialysis.

The government is also undertaking multiple steps to increase organ supply by issuing new regulations to create transparent metrics for Organ Procurement Organizations (OPOs), streamlining organ allocation procedures, and expanding living donor support to remove barriers to living donation. Watnick consistently encouraged Kidney Week participants to embrace the direction HHS has identified for improvement but to not get obsessed with the 80% goal—it is very likely to be reduced.

ASN's Meyer closed the session with a snapshot of current kidney care policy:

1. Kidney health policy is enjoying unprecedented attention in Washington, DC.
2. The administration is outstripping Congress on kidney health policy.
3. The presidential Executive Order is only the starting point for change.

She followed with “Five Must-Hear Debuts in Kidney Health Policy”:

1. The appropriations stalemate continues.
2. Legacy transplant legislation lingers.
3. Bold HHS action on transplant care is underway.
4. The Kidney Awareness Campaign mandated by AAKH kicks off.
5. (Some) reimbursement changes are coming into focus.

In more detail, at press time, the appropriations process has stalled and another short-term continuing resolution is being crafted. For 2020, ASN is currently advocating for a \$2 billion increase for the National Institutes of Health (NIH), \$10 million for KidneyX, and \$10 million for the National Living Donor Assistance Center—a \$6.5 million increase over current funding.

ASN and other kidney advocacy groups are still pushing for a change in the three-year limit on Medicare immunosuppressive drug coverage. However, this year, HHS has directed the agency to review the costs of such a move

and has reported that it estimates a savings of at least \$300 million over 10 years. With the Living Donor Protection Act building more cosponsor support in Congress, Meyer was cautiously optimistic on the transplant legislation front.

As for bold HHS action on transplant care, the Trump administration is planning to address the procurement of organs by OPOs, the allocation of those organs, and ways to reduce barriers to living donation. At press time, ASN's policy team awaited two proposed rules: 1) OPO Metrics Overhaul and 2) Living Donor Reimbursement Expanded Access.

The nationwide kidney awareness campaign mandated by AAKH got off the ground on November 4, 2019, when HHS, ASN, and the National Kidney Foundation signed a memorandum of understanding to jointly conduct the awareness campaign. More details will follow.

Last, some reimbursement changes are coming into focus. Meyer outlined some of the success ASN and others have had in bringing new devices into the bundle but also pointed out how much more needs to be done, such as adding new money to the bundle to cover these items.

Meyer concluded with a set of macro and micro predictions that thematically stressed that most advancements in kidney policy are coming from the executive branch. Her last prediction was that “Nephrology will become cool again.” ■

Pipeline of Wearable Kidney Devices Grows

By Bridget M. Kuehn

Results from the first-in-humans trial of the automated wearable kidney (AWAK) found the device to be safe, according to work presented at Kidney Week 2019. And results from an animal study of a similar device, the Wearable Artificial KIDney (WEAKID) presented at the meeting set the stage for that device to progress to human trials as well.

The developments are the latest steps in progress toward the development of a wearable artificial kidney.

Developing an artificial kidney is now a priority of the US government under Advancing American Kidney Health, established by Executive Order in July 2019. The Kidney Health Initiative has provided the technical roadmap to achieve this goal, and KidneyX, a public-private partnership between the US Department of Health and Human Services (HHS) and ASN is holding a series of prize competitions to advance development of innovative solutions to improve the lives of those living with kidney diseases. To actualize this goal, a formal Request for Information (RFI) was released by KidneyX for an artificial kidney prize.

Nanotechnology and the use of sorbent technology that can regenerate dialysate have made it possible to create a wearable or implantable artificial kidney, according to a recent review in the *American Journal of Kidney Diseases*. Now, those early devices are being tested in animals and small human trials to pave the way for the larger human studies that would be needed to gain US Food and Drug Administration clearance for the devices. If these efforts are successful, they could reduce the burden of care on patients receiving in-center or home dialysis.

“With all of the current modalities, patients are hooked up for hours a day,” said Megha Salani, MD, assistant professor in the Department of Nephrology at Vanderbilt

University Medical College and lead author of the review. “It really affects their ability to work and do things they enjoy. With wearables they would be able to keep on a more normal schedule.”

In the AWAK trial, 15 peritoneal dialysis patients in Singapore underwent 9 AWAK therapies over the course of 3 to 4 days. None of the patients experienced serious adverse events during therapy or at 1-week or 1-month follow-up visits after the trial, although 71% reported abdominal discomfort, 36% reported bloating, and 36% had fibrin in the drain. All the patients who completed at least one AWAK therapy achieved weekly peritoneal Kt/Vurea ≥ 1.7 with median weekly peritoneal Kt/Vurea = 3.04.

“The 15-patient first-in-human trial has shown that the device is safe to use for up to 9 therapies each running up to 7 hours each,” said lead author Marjorie Wai Yin Foo, MD, head and senior consultant in the Department of Nephrology at Singapore General Hospital in China, who presented the results from the AWAK trial.

Vanderbilt's Salani called the results “very promising,” although she cautioned that it is difficult to draw conclusions from the short duration of the follow-up.

“At the very least we can feel satisfied the labs are better and certainly not inferior,” she said.

Results of a small study in uremic pigs of 8 hours of daytime, 3 animals, or nighttime, 8 animals, use of WEAKID, another wearable kidney that uses sorbent technology to regenerate dialysate, were also presented at the meeting.

Senior author Giulia Ligabue, PhD, of the Laboratorio di Nefrologia Policlinico at the University of Modena, Italy, said the results compare well to conventional peritoneal dialysis. “WEAKID treatment was well tolerated and no serious adverse events occurred,” Ligabue said. “Treatment

improves the mass transfer area coefficient (MTAC) and plasma clearance. In the pig model, the system enhances clearance of creatinine [2-fold] and of phosphate [1.6-fold], significantly increases the MTAC [1.9-fold], and it doesn't show acute systemic toxicity.” The group hopes to next test the device in clinical trials.

“This innovative treatment may offer improved blood purification, prolonged technique survival and optimal patient tolerability compared to conventional peritoneal dialysis,” Ligabue said. “WEAKID will represent a huge leap forward for dialysis patients and it is expected to significantly improve health and quality of life.”

Salani said having multiple devices in development may drive competition and lead to improved quality in artificial kidney devices. It may also help increase funders' interest in this area.

“It's a great thing for the field of nephrology,” she said. She cautioned that there may still be hurdles ahead, such as unanticipated complications associated with the use of the devices.

Foo said the next step for her team will be conducting a multi-center, international trial to demonstrate the safety and efficacy of the AWAK over a longer time frame.

“If future studies prove to be successful, this technology will revolutionize the way peritoneal dialysis has been done for the past decades,” Foo said. “Patients on peritoneal dialysis will have greater freedom in terms of traveling, flexibility of therapy, and ease of doing the procedure.” ■

“Effect of Automated Wearable Artificial Kidney (AWAK) Device on Toxin Clearance and Safety in Peritoneal Dialysis Patients” Oral Abstract 101

“Evaluation of a Wearable Artificial Kidney for Peritoneal Dialysis in a Uremic Pig Model” Poster 522