

Policy Update

The Advancing American Kidney Health Initiative Payment Models, Public Awareness Initiative, and Incentives for Innovation

By David White

On July 10, 2019, President Donald J. Trump and Health and Human Services (HHS) Secretary Alex M. Azar II unveiled a much-anticipated new HHS-wide kidney care initiative called *Advancing American Kidney Health* (AAKH). The initiative will bring sweeping changes to care for people with kidney diseases, including more focus on upstream treatment to slow the progression of kidney diseases, choices for dialysis modalities, greater access to transplantation, and concerted support for development of innovative therapies, including artificial kidneys.

Executive Order

The initiative was rolled out in a public signing of an Executive Order accompanied by a white paper published by HHS and the release of a proposed rule from the Centers for Medicare and Medicaid Services (CMS) to create the End-Stage Renal Disease (ESRD) Treatment Choices Model (ETC Model)—four additional nephrology payment models will be released this month. The Executive Order established the following three objectives as official U.S. policy:

- Reduce the risk of kidney failure.
- Improve access to and quality of person-centered treatment options.
- Increase access to kidney transplants.

In the Executive Order, the White House and HHS laid out the case for a national focus on kidney diseases and the urgent need to realign policies to achieve greater

kidney health. “Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant” (1).

“Today was a gamechanger for people with kidney disease and for the care of these people. For the entire government and president to show this much interest in kidney disease and kidney failure is unprecedented,” said ASN President Mark E. Rosenberg, MD, FASN, following the unveiling. “Having the president sign an Executive Order that increases the recognition of the value, diagnosis, development, and use of alternative dialysis therapies, and increasing the number of transplants signals to the kidney community that they are serious about changing the care of kidney patients.”

In addition to establishing the three objectives above as official policy, the Executive Order announced several kidney health action items and directs HHS and its various agencies to execute these items. These items closely mirror recommendations ASN has made to HHS over many years and, in development of this initiative, specifically over the last year. To begin, the Order announced an Awareness Initiative on Kidney and Related Diseases and directs HHS to launch a kidney disease awareness campaign within 120 days (by mid-November). Placing kidney diseases in the category of an urgent healthcare

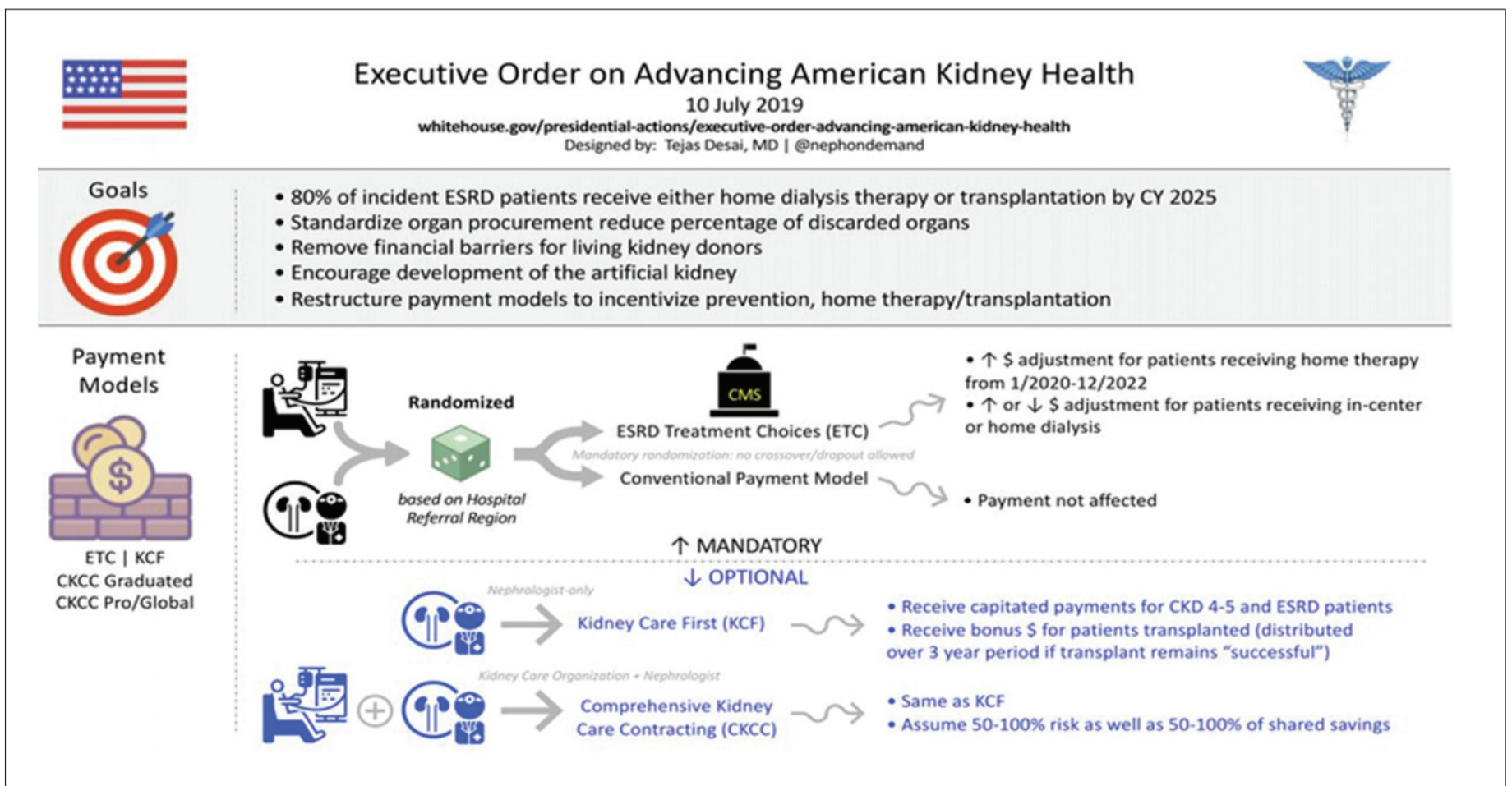
priority is a step ASN leadership views as long overdue.

The White House also directed HHS to develop several new payment models for testing by the Innovation Center in CMS (Figure 1). These models include the proposed ETC Model and the four additional models that are discussed in more detail later in this article.

In service of encouraging the development of an artificial kidney, the Order directs HHS to “(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration (FDA); and (b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology” (1). These directives will help streamline the process for reviewing and approving innovation in the development of artificial kidneys at FDA and boost the role of KidneyX in developing strategies to foster innovation in kidney health.

In order to increase the utilization of available organs, the Order directs HHS to revise, within 120 days, Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO’s performance. HHS is also required to streamline and expedite the process of kidney matching and delivery to reduce the discard rate within 180 days. The initiative plans to boost transplantation using several levers, in ad-

Figure 1.



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dition to OPO metrics, such as more support for living organ donors.

The White House had already announced in its spring agenda for rulemaking that HHS would be issuing a proposed rule to provide financial assistance for living organ donors. ASN, the American Association of Kidney Patients (AAKP), and others in the kidney community have been advocating for more support for living donors, including coverage of lost wages, with HHS and Congress for many years. The Executive Order specifically directs HHS that new regulation in this area “should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, 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 child-care and elder-care expenses.”

Payment Models: ETC

The proposed ETC Model, which is a mandatory model, and the four voluntary models that will be unveiled this month are designed to test the effectiveness of increasing home dialysis and transplantation through realigned payment incentives within the five models as well as support more nephrology care upstream before a person reaches kidney failure. The four voluntary models soon to be unveiled are the Kidney Care First (KCF) Model, Graduated Comprehensive Kidney Care Contracting (CKCC) Model, Professional CKCC Model, and Global CKCC Model.

Participants in the proposed ETC model will be “managing clinicians” and ESRD facilities. CMS defines a managing clinician as a healthcare professional who bills the Monthly Capitated Payment (MCP), whether it is a nephrologist, an internist, or even a non-physician practitioner. Across the five models, managing clinicians may participate in the KCF Model or one of the CKCC Models. If assigned to the ETC Model, managing clinicians may still participate in the KCF Model or one of the CKCC Models.

Managing clinicians and ESRD facilities will be assigned to the ETC model if located in randomly “selected geographic area(s).” The “selected geographic area(s)” to be used will be Hospital Referral Regions (HRRs). The use of HRRs in the model is a new approach for the CMS Innovation Center.

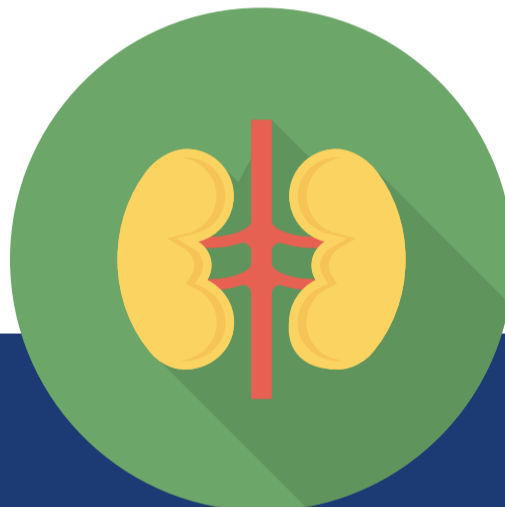
CMS explains the use of HRR for the selection of participants in the model in the proposed rule. Primarily, CMS wanted to capture approximately 50% of U.S. adult ESRD beneficiaries, include rural as well as metropolitan areas, and ensure the model has a cross-cutting sample of kidney transplantation. There are 306 HRRs in the U.S., and CMS will randomly select HRRs from all 50 states and the District of Columbia, stratified by region: South, Midwest, West, and Northeast (Maryland will be included under a slightly different approach due to its participation in the Maryland Total Cost of Care [TCOC] Model).

The ETC model payment adjustments will be based on rates of home dialysis utilization and rates of kidney and kidney-pancreas transplantation for both managing clinicians and ESRD facilities. The model would begin January 1, 2020, or April 1, 2020 (CMS is asking for comments on the start date). There are two model payment adjustments: Home Dialysis Payment Adjustment (HDDPA) and

the Performance Payment Adjustment (PPA).

The HDDPA would be a + payment adjustment on home dialysis/home dialysis-related claims during the initial 3 years of the ETC Model. Year one (2020) is a +3% adjustment, year two (2021) is a +2% adjustment, and year three (2022) is a +1% adjustment.

The PPA would be a + or - payment adjustment, increasing over time, on dialysis/dialysis-related claims, both home and in-center, based on the ETC model participant’s home dialysis rates and transplant rates during a 12-month measurement year in comparison to achievement and improvement benchmarks. The 12-month measurement year would be in six-month increments with an overlap to create a rolling average approach for calculating PPA. CMS proposes using Medicare claims data, administrative data, and Scientific Registry of Transplant Recipients (SRTR) data to measure these rates. The numerators would be attributed patients on either home dialysis or who received a transplant (including preemptive transplants), and the denominators would be all attributed patients. The magnitude of the positive and negative PPAs would increase over the course of the model while the HDDPA’s magnitude decreases and ends after year three. The PPAs would begin July 1, 2021, and conclude June 30, 2026.



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The proposed ETC model will also include a low-volume threshold exclusion specifically for the PPA. For managing clinicians, CMS proposes excluding those who fall below the low-volume threshold of the bottom 5% of managing clinicians in terms of the number of beneficiary-years for which the managing clinician billed the MCP during the measurement year. For ESRD Facilities, CMS proposes excluding ESRD facilities that have fewer than 11 attributed beneficiary-years during a given measurement year from the application of the PPA. This means that a facility must have at least 132 total attributed beneficiary months for a measurement year.

As with most CMS payment programs, the ETC model will include risk adjustment. CMS considered using the same risk adjustment for home dialysis patients and transplant patients but decided that the risk factors

for both groups is sufficiently different to justify different risk adjustment methodologies. For risk adjusting home dialysis rates, CMS proposes using the CMS-5 HCC (Hierarchical Condition Category) dialysis model approach. For transplant patients, CMS proposes using the methodology of the percentage of Prevalent Patients Waitlisted (PPPW) from the ESRD Quality Incentive Program (QIP) with similar exceptions of not including anyone over 75 years of age, in a skilled nursing facility, or in hospice.

The ETC model also addresses another high priority policy issue of ASN: the kidney disease education (KDE) benefit. CMS proposes waiving the requirement that KDE be performed by a physician, physician assistant, nurse practitioner, or clinical nurse specialist, to allow additional clinical staff such as dietitians and social workers to furnish the service under the direction of a managing clinician. The staff are not required to be Medicare-enrolled as long as the managing clinician is authorized to bill Medicare for KDE services. CMS is also waiving the restriction that KDE services only be provided to CKD stage 4 patients and will allow the services to be provided to stage 5 patients and those in the first six months of an ESRD diagnosis. CMS is also waiving: (1) the requirement that the KDE curriculum cover issues of comorbidities and delaying the need for dialysis be covered, since it will now cover stage 5 patients in the model; and (2) the requirement that an outcomes assessment be performed within a KDE session (CMS maintains that an outcomes assessment should still occur, but it is not required to occur within a session).

Payment Models: Kidney Care First (KCF) and Comprehensive Kidney Care Contracting (CKCC) Models

In August 2019, CMS will send out a Request for Applications for the four voluntary models. The four voluntary models soon to be unveiled are the Kidney Care First (KCF) Model, Graduated Comprehensive Kidney Care Contracting (CKCC) Model, Professional CKCC Model, and Global CKCC Model. The first (the KCF) is a nephrology-specific model with a chronic kidney disease (CKD) MCP added for services provided to stage 4 and 5 CKD patients. The CKCC models provide the opportunity for groups of healthcare providers to jointly provide integrated kidney care. CMS specifically notes that in the CKCC models nephrologists/nephrology practices and transplant providers are required participants, with dialysis facilities and other providers being optional.

The KCF and CKCC models will run from January 1, 2020, through December 31, 2023, with the option for one or two additional performance years at CMS’s discretion. Healthcare providers interested in participating will apply to participate in the fall of 2019, and if selected, begin model participation in 2020. However, financial accountability will not begin until 2021. During 2020, or Year 0, model participants will focus on building necessary care relationships and infrastructure.

Payment in the CKCC model will have three options, a one-sided risk model, a model where participants can earn 50% of shared savings or be liable for 50% of shared losses based on the total cost of care for Part A and B services, and a 100% risk/reward model. Participants in the KCF and the Professional and Global risk-bearing CKCC models will qualify as Advanced APMs in 2021; participants on the one-sided CKCC model will not. ■

Kidney News will continue reporting on the *Advancing American Kidney Health* initiative.

1 .<https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>Ibid