

Newly-Announced Program Shifts Dialysis Services to the Home

On July 10, 2019, President Donald Trump signed an executive order launching “*Advancing American Kidney Health*,” an initiative that seeks to move the majority of dialysis services away from dialysis centers, and into patients’ homes, as well as double the availability of kidneys for transplants.¹ The initiative generally seeks to achieve three goals: “*fewer patients developing kidney failure, fewer Americans receiving dialysis in dialysis centers, and more kidneys available for transplant.*”²

Specifically, the initiative seeks to reduce the incidence of *end-stage renal disease* (ESRD) by 25% by the year 2030 through HHS’s establishment of five proposed payment models – one of which will be mandatory, and four of which will be voluntary³ – to “*adjust payment incentives to encourage preventative kidney care, home dialysis, and kidney transplants.*”⁴ The mandatory *ESRD Treatment Choices (ETC) Model* would randomly select approximately 50% of all ESRD facilities and *managing clinicians*, from randomly selected geographic areas, to participate in the pilot; those that serve low volumes of ESRD patients would not be selected.⁵ The providers would be subject to two types of adjustments to payments under the *ESRD Prospective Payment System* (ESRD PPS). First, a uniformly positive adjustment would be applied to home dialysis claims (i.e., an additional payment would be rendered to facilities/clinicians that support that beneficiary dialyzing at home).⁶ Second, per-treatment adjustments would be applied to “*both home and in-center dialysis and related claims, and could be either positive [up to 3%⁷] or negative.*”⁸ The model is slated to run from January 1, 2020 through June 30, 2026.⁹

In addition to the mandatory *ETC Model*, the four voluntary payment models, i.e., the *Kidney Care First* (KCF) and *Comprehensive Kidney Care Contracting* (CKCC) Models (which includes CKCC Graduated, CKCC Professional, and Global Models) will test new Medicare payment options that aim to improve the quality of care for patients with kidney disease, delay the need for dialysis, and encourage kidney transplants.¹⁰ Under the KCF Model, nephrology practices that choose to participate “*will receive adjusted fixed payments [based on utilization and outcomes, utilizing historical benchmarks] on a per-patient basis for managing the care of patients with late-stage chronic kidney disease and...ESRD.*”¹¹ The three CKCC models will also reimburse utilizing capitated payments, wherein the

Kidney Contract Entities (nephrologists, transplant providers and other providers, including dialysis centers) will be responsible for the total cost and quality of the patient care, but can share in any savings achieved.¹² Both the KCF and the CKCC models will run from January 1, 2020 through December 31, 2023, with the option for additional performance years.¹³

The *Advancing American Kidney Health* initiative, which established these five payment models, will work to increase the proportion of dialysis patients receiving dialysis at home (or receiving a transplant), from the current 12% (a rate far lower than other countries) to 80% by 2025.¹⁴ As noted by the *Department of Health and Human Services* (HHS), “[*s]tudies have shown that...dialyzing at home is often preferred by patients and physicians,*” as the home setting is more comfortable and allows for more independence and a better quality of life.¹⁵ The initiative also plans to double the number of kidneys available for transplants by 2030 through increasing public awareness for the need, and expanding the coverage for donors. Currently, donors’ medical costs are covered; the initiative would also include financial assistance for child care and missed time from work.¹⁶

This initiative could have a large impact on the U.S. healthcare industry, as kidney disease and ESRD affect a significant number of Americans. Approximately 37 million Americans have chronic kidney disease (which is the ninth leading cause of death in the U.S.), and over 726,000 have ESRD (which incidence is increasing by 5% annually).¹⁷ Of this patient contingent, almost 100,000 patients are on the kidney transplant waiting list (although only “*21,000 donor organs were available for transplant*” in 2012).¹⁸

ESRD treatment has been covered, for all patients, by Medicare since 1973.¹⁹ Although ESRD patients are only 1% of the overall Medicare population, they account for 7% of overall Medicare spending.²⁰ In 2016, Medicare served as the primary or secondary payor for approximately 67% of all ESRD patients,²¹ and total Medicare expenditures for ESRD totaled approximately \$35.4 billion, of which approximately \$11.4 billion were spent on outpatient dialysis services.²² More broadly, kidney disease accounts for approximately 20% of Medicare spending.²³

The Trump Administration anticipates that the initiative will result in 17,000 additional patients receiving kidney transplants each year by 2030, which they hope will meet the rising need for donor kidneys (that need is rising at a rate of 8% annually).²⁴ Additionally, the administration believes that this program would also motivate the transplant of other organs, and anticipates that 11,000 additional patients would receive hearts, lungs, and livers each year.²⁵ Because kidney transplant costs are less than dialysis, the administration anticipates the plan would save \$4.2 billion per year.²⁶

Reactions from industry stakeholders regarding this new initiative have been generally supportive. The *National Kidney Foundation's* CEO stated that “*The administration’s commitment to charting a new course for kidney health will help revolutionize transplantation and dialysis and advance new innovations, therapies and treatments, which patients everywhere have been waiting on for far too long.*”²⁷ Additionally, the *American Society of Nephrology* noted that the initiative has “*only ‘upside’*

potential for doctors,” who, currently, are only reimbursed for seeing patients in dialysis centers, and thus are not incentivized to promote a home dialysis option.²⁸ DaVita, the country’s largest home dialysis provider, simply stated that it looked forward to working with the administration.²⁹

Ironically, the new payment models were established by HHS under its *Center for Medicare and Medicaid Innovation* (CMMI), which was created by the *Patient Protection and Affordable Care Act* (ACA), the landmark legislation that is currently being disputed by the presidential administration in federal court.³⁰ Should the courts find the ACA to be unconstitutional, the CMMI, and likely any program within CMMI (including these five new models), would be canceled.³¹ Therefore, while this new program could radically change the dialysis and nephrology industries, its long-term viability may be subject to outside political and legal forces. The proposed rule was published in the Federal Register on July 18, and will be open to comments until September 16, 2019.³²

1 “Using Obamacare Authority, Trump Aims To Shift Dialysis Care To Patients’ Homes” By Phil Galewitz, Kaiser Health News, July 10, 2019, <https://khn.org/news/using-obamacare-authority-trump-aims-to-shift-dialysis-care-to-patients-homes/> (Accessed 7/17/19); “HHS Launches President Trump’s ‘Advancing American Kidney Health’ Initiative” Department of Health and Human Services, Press Release, July 10, 2019, <https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html> (Accessed 7/17/19).

2 Department of Health and Human Services, July 10, 2019.

3 “ESRD Treatment Choices (ETC) Model” Centers for Medicare and Medicaid Services, <https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/> (Accessed 7/17/19).

4 Department of Health and Human Services, July 10, 2019.

5 CMS, <https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/>.

6 *Ibid.*

7 “CMS releases ESRD Treatment Choices payment model for increasing home dialysis, transplant” Healio, July 12, 2019, <https://www.healio.com/nephrology/policy-and-politics/news/online/%7B0f66a65c-8afd-4766-bf1d-de816e531aae%7D/cms-releases-esrd-treatment-choices-payment-model-for-increasing-home-dialysis-transplant> (Accessed 7/17/19).

8 CMS, <https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/>.

9 “Proposed End-Stage Renal Disease Treatment Choices (ETC) Mandatory Model” Centers for Medicare and Medicaid Services, Fact Sheet, <https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model> (Accessed 7/17/19).

10 “HHS To Transform Care Delivery for Patients with Chronic Kidney Disease” Centers for Medicare and Medicaid Services, Press Release, <https://www.cms.gov/newsroom/press-releases/hhs-transform-care-delivery-patients-chronic-kidney-disease> (Accessed 7/17/19).

11 *Ibid.*

12 *Ibid.*

13 *Ibid.*

14 Galewitz, July 10, 2019.

15 CMS, <https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/>.

16 Galewitz, July 10, 2019.

17 ESRD is the final stage of chronic kidney disease (CKD), marked by the complete or nearly complete irreversible loss of renal function, which results in the body retaining fluid and harmful waste build up “The Kidney Diseases Dictionary” By The National Kidney and Urological Diseases Information Clearinghouse, U.S. Department of Health and Human Services, NIH Publication No. 03-4359, 2003, p. 6; “Statistics” The Kidney Project, University of California San Francisco, <https://pharm.ucsf.edu/kidney/need/statistics> (Accessed 7/17/19).

18 Department of Health and Human Services, July 10, 2019; University of California San Francisco, <https://pharm.ucsf.edu/kidney/need/statistics>.

19 Galewitz, July 10, 2019.

20 University of California San Francisco, <https://pharm.ucsf.edu/kidney/need/statistics>.

21 “Table D.21 – Counts of Point Prevalent ESRD Patients, by Payer Category: All Patients” United States Renal Data System, 2018, <https://www.usrds.org/reference.aspx> (Accessed 1/23/17). Accessible by clicking on link entitled, “Treatment Modalities,” then clicking on tab entitled “D.21.” On this page, the categories “Medicare Fee for Service,” “Medicare/Medicaid,” “Medicare Secondary Payer-Employer Group Health Plan,” and “Medicare Secondary Payer-non-Employer Group Health Plan” were summed for 2016 Columns under the “All” row, then divided by the total number of ESRD patients in 2016.

22 “Table K.1 – Total Medicare Spending (\$) of Reported ESRD Patients: by Claim Type” United States Renal Data System, 2018, <https://www.usrds.org/reference.aspx> (Accessed 7/17/19). Accessible by clicking on the link entitled, “Economic Costs of ESRD,” then clicking on tab entitled “K.1.”

23 Department of Health and Human Services, July 10, 2019.

24 University of California San Francisco, <https://pharm.ucsf.edu/kidney/need/statistics>.

25 Galewitz, July 10, 2019.

26 *Ibid.*

27 *Ibid.*

28 *Ibid.*

29 *Ibid.*

30 For more information on the ACA court case, see the other *Health Capital Topics* article in this July 2019 issue entitled, “*Parties Argue Constitutionality of ACA before 5th Circuit.*”

31 Galewitz, July 10, 2019.

32 “Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures; Proposed Rule” Centers for Medicare & Medicaid Services, Federal Register, Vol. 84, No. 138 (July 18, 2019), p. 34478.



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