Kidney Health Executive Order Policy Review

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Introduction

The Health Group of Econometrica conducted a review of the Kidney Health Executive Order passed by President Trump on July 10, 2019. This essential decision impacts programs operated by the Centers for Medicare & Medicaid Services (CMS), health providers, kidney patients, and the availability of resources dedicated to treatment. Econometrica is committed to staying informed of decisions like these to better serve the interests of our clients.

Background

What Do the Kidneys Do? Why Are They Important?

The kidneys are vital organs that work to filter waste and excess fluid out of blood. They regulate chemicals and fluid levels in the body, control blood pressure, keep bones healthy, and produce a hormone to trigger red blood cell production. As the kidneys provide such integral support to the body, keeping them healthy is essential. However, approximately 37 million Americans suffer from chronic kidney disease (CKD) and more than 726,000 Americans have end-stage renal disease (ESRD), also known as end-stage kidney disease (ESKD).

What Is CKD and ESRD?

CKD is characterized by kidneys that become damaged over time and do not work properly. This causes a buildup of waste and excess water in the body, which affects kidney function and causes problems with the heart, lungs, blood, and bones.

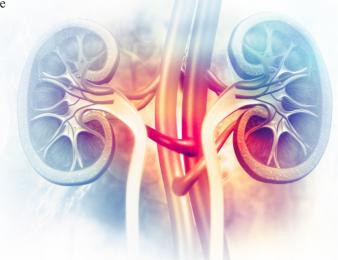
There are five stages of CKD, ranging from very mild damage in Stage 1 to complete kidney failure or ESRD in Stage 5. At Stage 5, kidney damage has progressed to the point that the kidney is at less than 15 percent of its normal function. At this point, dialysis is the only form of treatment left to assist with the lack of function. Though dialysis may slow down the progression of CKD, it is not a cure and eventually a kidney transplant will be needed.²

Risk Factors, Signs and Symptoms

The most common risk factors of CKD are diabetes, which causes kidney damage due to excess sugar, and high blood pressure, which can cause damage to the blood vessels in the kidneys over time.

CKD is a slow-progressing disease, and symptoms may not appear until the kidneys are significantly damaged. In the late stages of CKD, as a patient nears kidney failure/ESRD, the following symptoms may be noticed, caused by waste and extra fluid building up in the body:³

- · Itching.
- · Swelling in feet and ankles.
- Muscle cramps.
- Too much urine or not enough urine.
- Nausea and vomiting.
- Trouble catching a breath.
- Loss of appetite.
- · Trouble sleeping.



¹ Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 15, 2019).

² American Kidney Fund. Kidney Disease. Retrieved from https://www.kidneyfund.org/kidney-disease/.

³ American Kidney Fund. Kidney Disease. Retrieved from https://www.kidneyfund.org/kidney-disease/.

Impact of CKD and ESRD on CMS

In 2017, the total number of individuals with ESRD enrolled in Medicare Part A and B was approximately 530,000.⁴ According to CMS, Medicare spending in 2016 for beneficiaries living with ESRD was \$35.4 billion, or 7 percent of total Medicare fee-for-service spending.⁵ The prevalence of CKD has remained consistent through the decades, with a higher prevalence in individuals over the age of 65. Refocusing ESRD care and resources is vital to better assist ESRD patients and reduce ESRD-related conditions, which will help decrease Medicare spending costs.

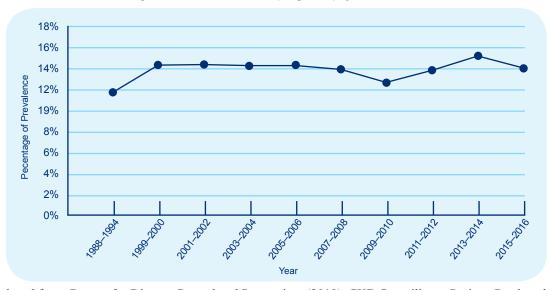


Figure 1. Prevalence of CKD (Stages 1-4) by Year, 1988-2016

Note: Reproduced from Centers for Disease Control and Prevention. (2019). CKD Surveillance Project. Retrieved from https://nccd.cdc.gov/CKD/.

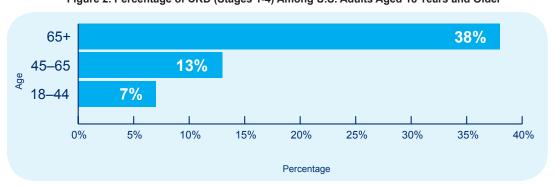


Figure 2. Percentage of CKD (Stages 1-4) Among U.S. Adults Aged 18 Years and Older

Note: Reproduced from U.S. Department of Health and Human Services. (n.d.) Advancing American Kidney Health. Retrieved from https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.

⁴ Kaiser Family Foundation. (2019). Medicare Beneficiaries With End-Stage-Renal Disease (ESRD). Retrieved from https://www.kff.org/medicare/state-indicator/enrollees-with-esrd/?currentTimeframe=0.

⁵ U.S. Department of Health and Human Services. (n.d.) Advancing American Kidney Health. Retrieved from https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.

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Executive Order on Advancing Kidney Health

On July 10, 2019, the President signed an Executive order dedicated to advancing kidney health. With kidney disease being the ninth leading cause of death in the United States in 2017, this policy will work to prevent kidney failure with better diagnoses, treatment options, and incentives; increase efforts to develop artificial kidneys and affordable ESRD treatment options and better educate patients on these options; and increase access to kidney transplants through the improvement of processes and regulations. In order to successfully meet set goals, the U.S. Department of Health & Human Services has launched six kidney health initiatives.

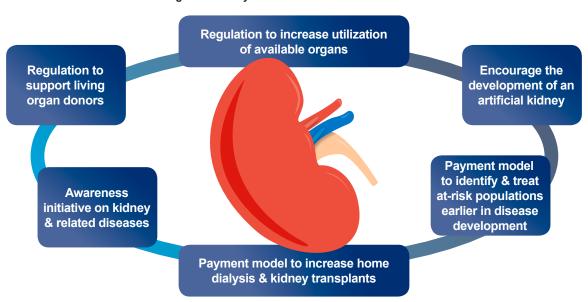


Figure 3. Kidney Health Executive Order Initiatives

New CMS Payment Models for Kidney Health

Under the Kidney Health Executive Order, CMS announced five new Center for Medicare & Medicaid Innovation payment models, which aim to transform kidney care so that patients with CKD have access to high-quality, coordinated care.

One of these models is the ESRD Treatment Choices (ETC) Model, which aims to increase the use of home dialysis and kidney transplants for Medicare beneficiaries with ESRD while enhancing the overall quality of care and reducing cost. The model will require certain ESRD treatment facilities and clinicians to participate, according to their geographic location. CMS will select model participants using the Hospital Referral Region, which accounts for approximately 50 percent of adult ESRD beneficiaries in the U.S. The model will run from January 1, 2020, through June 30, 2026.⁷

According to CMS, "the proposed model would apply payment adjustments to the adjusted ESRD Prospective Payment System per treatment base rate under the ESRD Prospective Payment System to selected ESRD facilities, as well as the monthly capitation payment to selected Managing Clinicians." Model participants will receive incentives for educating beneficiaries and caregivers of home dialysis treatment options and providing them support and resources for proper utilization.

⁶ Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 15, 2019).

⁷ CMS. (2019). Proposed End-Stage Renal Disease Treatment Choices (ETC) Mandatory Model. Retrieved from https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model.

⁸ CMS. (2019). Proposed End-Stage Renal Disease Treatment Choices (ETC) Mandatory Model. Retrieved from https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model.

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CMS' required participation for the ETC Model is related to better understanding the impact of the model within a broader set of ESRD care providers. Model evaluation will assess the quality of care provided under the ETC Model and changes in Medicare program spending. It should inform CMS of improvements of home dialysis and transplants as a treatment choice.⁹

The four other CMS models for kidney health aim to help healthcare providers reduce costs and improve the quality of care for patients with late-stage CKD and ESRD. They will also work to delay the need for dialysis and encourage kidney transplants.¹⁰

The Kidney Care First (KCF) Model will adjust fixed payments for participating nephrology practices on a per-patient basis for managing CKD and ESRD care. The Comprehensive Kidney Care Contracting (CKCC) Model includes three distinct accountability frameworks, called the Graduated, Professional, and Global Models. Payment adjustments will be similar to the KCF Model, but Kidney Contracting Entities will take responsibility for the cost and quality of their patients' care. In exchange, entities will be eligible to receive a portion of the Medicare savings they are able to achieve. These four models will run from January 1, 2020, through December 31, 2023, with the option to extend the models for 1 or 2 additional years.

References

CMS. (2019). Proposed End-Stage Renal Disease Treatment Choices (ETC) Mandatory Model. Retrieved from https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model.

Exec. Order No. 13879, 84 Fed. Reg. 33817 (July 15, 2019).

Kaiser Family Foundation. (2019). Medicare Beneficiaries With End-Stage-Renal Disease (ESRD). Retrieved from https://www.kff.org/medicare/state-indicator/enrollees-with-esrd/?currentTimeframe=0.

U.S. Department of Health and Human Services. (n.d.) Advancing American Kidney Health. Retrieved from https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf.

For more information on kidney disease, visit:

American Kidney Fund - https://www.kidneyfund.org/kidney-disease/

All About your Kidneys Fact Sheet - https://www.kidneyfund.org/assets/pdf/factsheets/kidney-disease-fact-sheet.pdf Dialysis

Tests for Kidney Health Fact Sheet - https://www.kidneyfund.org/assets/pdf/factsheets/tests-for-kidney-health-fact-sheet.pdf

Dialysis - https://www.kidney.org/atoz/content/dialysisinfo

National Kidney Foundation - https://www.kidney.org/kidneydisease

⁹ CMS. (2019). Proposed End-Stage Renal Disease Treatment Choices (ETC) Mandatory Model. Retrieved from https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model.

CMS. (2019). HHS To Transform Care Delivery for Patients with Chronic Kidney Disease. Retrieved from https://www.cms.gov/newsroom/press-releases/hhs-transform-care-delivery-patients-chronic-kidney-disease.

¹¹ Kidney Contracting Entities refer to nephrologists, transplant providers, and other healthcare providers, including dialysis facilities.

¹² CMS. (2019). HHS To Transform Care Delivery for Patients with Chronic Kidney Disease. Retrieved from https://www.cms.gov/newsroom/press-releases/hhs-transform-care-delivery-patients-chronic-kidney-disease.

¹³ CMS. (2019). Kidney Care First (KCF) and Comprehensive Kidney Care Contracting (CKCC) Models. Retrieved from https://www.cms.gov/newsroom/fact-sheets/kidney-care-first-kcf-and-comprehensive-kidney-care-contracting-ckcc-models.

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