CMS Finalizes New Payment Model for End-Stage Renal Disease

On September 18, 2020, the Centers for Medicare & Medicaid Services (CMS) announced the publication of its final rule on specialty care models, which included a new End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model. The ETC Model was created in response to a July 10, 2019, executive order that launched the "Advancing American Kidney Health" initiative. This model amends regulations originally set forth in the National Organ Transplant Act of 1984.2 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." Specifically, it aims to: (1) move the majority of dialysis services away from dialysis centers and into patients' homes; and, (2) double the number of kidneys available for transplant.⁴ CMS will be randomly selecting ESRD facilities and "Managing Clinicians" in all 50 states and Washington, D.C. to participate in the model.⁶ CMS is aiming to recruit enough participants so as to represent approximately 30% of all eligible facilities and clinicians nationwide, a decline from their original goal of 50%. The ETC Model will run between January 1, 2021, and June 30, 2027.8

The ETC Model is one of five proposed payment models to come out of the Trump Administration's initiative, which seeks to reduce the incidence of ESRD by 25% by the year 2030.9 The ETC Model is the only one of the five models that is mandatory - the other four 10 will be voluntary for providers. 11 The model includes several payment changes for randomly-selected participants in the initial launch of the program. Many of these payment adjustments will occur in the first three years of the program, with CMS phasing in greater positive and negative adjustments for model participants over the sixyear model period. 12 Payments under the ETC Model will be adjusted to ensure that beneficiaries with ESRD have access to vital education about their treatment options in order to achieve the model's goal of giving beneficiaries the ability to choose a treatment that works best for their lifestyle. 13 CMS will positively adjust payments for home dialysis and related services through two specific adjustments to encourage a shift from in-center to home dialysis.¹⁴ First, a uniform, positive adjustment, termed the Home Dialysis Patient Adjustment (HDPA), will be applied to Medicare claims for home dialysis during the first three years of the model.15 In 2016, only 12% of ESRD patients were treated through home dialysis, far less than the proportion of home dialysis ESRD patients in other developed countries; consequently, CMS has highlighted supporting home dialysis as a top priority for this ETC Model. The ETC Model aims, with these payments, to shift from a *fee-for-service* (FFS) reimbursement to a *value-based reimbursement* (VBR) model that incentivizes providers to invest in their home dialysis program so that patients are able to choose a more flexible plan and stay in their homes if desired. 17

Second, CMS will provide adjustments, called Performance Payment Adjustments (PPAs), to home and in-center dialysis. 18 These adjustments, which could be positive or negative, will be made depending on the sum of the transplant waitlist rate and the living donor transplant rate. 19 Transplantation is considered to be the optimal treatment for most ESRD patients as it increases survival rate and quality of life, and reduces healthcare expenditures, for these patients.²⁰ According to CMS, less than 30% of ESRD patients had a functioning transplant kidney in 2017, with less than 3% receiving that transplant before they commenced dialysis.²¹ Because approximately 20% of Medicare funds (or about \$114 billion) are spent each year on beneficiaries with kidney disease, and because 20% of patients who begin dialysis for ESRD die within one year, these survival and cost reduction measures are of vital importance to CMS and the overall healthcare system.²² In fact, the ETC Model is estimated to save Medicare approximately \$23 million over its five and a half year execution period.²³ This payment system represents another facet of CMS's effort to shift reimbursement under this new model to a value-based system that rewards higher transplant rates to improve patient choice and outcomes.²⁴ The Department of Health and Human Services (HHS) Secretary, Alex Azar, said in a statement that he hopes this payment model will afford patients with "more convenient dialysis options or the possibility of a transplant."25

Subsequent rules released by the *Health Resources and Services Administration* (HRSA) and HHS lays out efforts and reimbursement expansion to increase the living donor transplant rate. As reported by HRSA, only 19% of all transplants in 2019 were from living donors, and the organization sees resources and support as a key way to increase the number of living donors and, thereby, lessen the number of patients on the organ transplant

waiting list.²⁶ This new rule adds child and elder care, as well as lost wages, to the list of reimbursable expenses, which previously included items such as travel to appointments, lodging, meals, and other incidental expenses incurred by living organ donors and others accompanying them.²⁷ Individuals qualify for this reimbursement based on the incomes of both the donor and recipient.²⁸ Need is currently defined as household income below 350% of HHS Poverty Guidelines.²⁹ This percentage is an increase from the originally-proposed threshold of 300%, but still falls short of the 500% (or the outright elimination of an income criterion) called for in many of the comments submitted in response to the proposed rule.30

Several stakeholders, including the National Kidney Foundation (NKF), Kidney Care Partners, and the American Society of Nephrology (ASN), released statements regarding the recently-released final rule. NKF noted that approximately 90% of the 37 million adults suffering from chronic kidney disease (CKD) do not know that they have the disease, and currently, almost 90% of patients with failing kidneys begin their dialysis in a treatment facility.31 Most of these patients, NKF reported, did not even know that transplants or at-home dialysis were options available to them.³² Because of these facts, NKF applauded CMS's focus on education, support of the transplant process, and encouragement of dialysis in the patient's home. 33 Kidney Care Partners, which represents over 30 organizations that care for

individuals with CKD, similarly applauded the increased incentives for living donors and short supply of organs for those on the transplant waiting list.34 ASN reiterated the need for more in-home dialysis care. 35 One important limitation in the ETC Model final rule is that skilled nursing facilities (SNFs) and nursing homes are not included in the model coverage.³⁶ While many commenters offered their feedback both for and against including these facilities in the final rule, CMS ultimately decided that this frail population may "not be appropriate candidates for home dialysis" and excluded these facilities.37

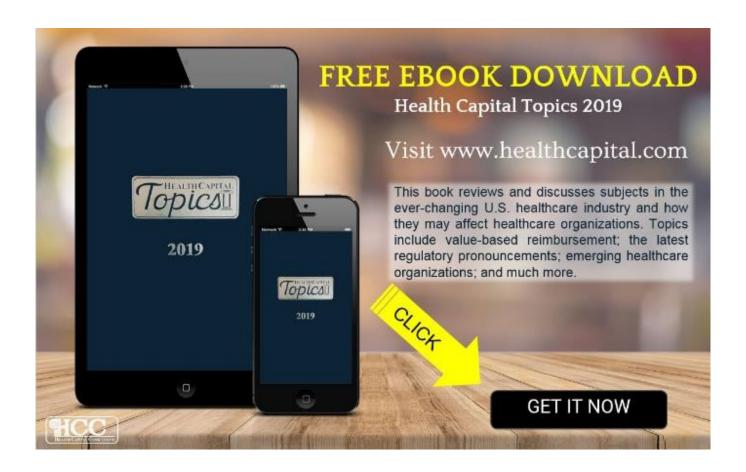
Statements from CMS and industry stakeholders identify patient choice, access, and outcomes as primary motivations for the creation of this new model. The fragility of ESRD patients has been highlighted in 2020, as many suffer from complications and comorbidities; likely as a result, these patients have seen higher rates of hospitalizations during the COVID-19 pandemic.³⁸ A lack of education means that many ESRD beneficiaries are currently traveling to receive their dialysis treatments, allowing for a greater possibility of COVID-19 exposure.³⁹ Both during the pandemic and long after, CMS hopes that the new ETC Model will be successful in educating patients and increasing their access to inhome dialysis, as well as to transplants, to improve patient comfort and outcomes while producing cost savings for Medicare.

- "CMS Announces Transformative New Model of Care for Medicare Beneficiaries with Chronic Kidney Disease" Centers for Medicare and Medicaid Services, September 18, 2020, https://www.cms.gov/newsroom/press-releases/cms-announcestransformative-new-model-care-medicare-beneficiaries-chronickidney-disease (Accessed 9/21/20).
- Ibid; "HHS Launches President Trump's 'Advancing American Kidney Health' Initiative" U.S. Department of Health and Human Services, July 10, 2019, https://www.hhs.gov/about/news/2019/07/10/hhs-launchespresident-trump-advancing-american-kidney-healthinitiative.html (Accessed 9/21/20); "New Rule Expands the Scope of Reimbursable Expenses for Living Organ Donation" Health Resources & Services Administration, September 18, 2020, https://www.hrsa.gov/about/news/press-releases/new-ruleexpands-scope-living-organ-donation (Accessed 10/5/20).
- U.S. Department of Health and Human Services, July 10, 2019; for more information about this initiative, please refer to following the Health Capital Topics article: "Newly-Announced Program Shifts Dialysis Services to the Home" Health Capital Topics, July 2019, Vol. 12, No. 7, $https://www.healthcapital.com/hcc/newsletter/07_19/HTML/DI$ ALYSIS/convert_hc_topics_dialysis_7.17.19.php.
- U.S. Department of Health and Human Services, July 10, 2019.
- CMS defines Managing Clinicians as simply "clinicians caring for beneficiaries with ESRD"; "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce' Department of Health and Human Services, September 18, 2020, https://innovation.cms.gov/media/document/specialty-caremodels-rule (Accessed 9/21/20), p. 2.
- U.S. Department of Health and Human Services, July 10, 2019. "ESRD Treatment Choices (ETC) Model" Centers for Medicare and Medicaid Services, July 11, 2019, https://innovation.cms.gov/initiatives/esrd-treatment-choicesmodel/ (Accessed 7/17/19); "ESRD Treatment Choices (ETC) Model" Centers for Medicare and Medicaid Services, September 18, 2020, https://innovation.cms.gov/innovation-models/esrdtreatment-choices-model (Accessed 9/21/20).

- Department of Health and Human Services, September 18, 2020,
- U.S. Department of Health and Human Services, July 10, 2019.
- The four voluntary models are the Kidney Care First (KCF) Model and the Comprehensive Kidney Care Contracting (CKCC) Graduated, Professional, and Global Models; "HHS To Transform Care Delivery for Patients with Chronic Kidney Disease" Centers for Medicare and Medicaid Services, July 10, 2019, https://www.cms.gov/newsroom/press-releases/hhstransform-care-delivery-patients-chronic-kidney-disease (Accessed 9/23/20).
- 11 U.S. Department of Health and Human Services, July 10, 2019.
- Centers for Medicare and Medicaid Services, September 18, 2020.
- 13
- 14 Ibid.
- 15 Department of Health and Human Services, September 18, 2020, p. 12-13.
- Centers for Medicare and Medicaid Services, September 18, 2020.
- Centers for Medicare and Medicaid Services, September 18, 2020, https://www.cms.gov/newsroom/press-releases/cmsannounces-transformative-new-model-care-medicarebeneficiaries-chronic-kidney-disease.
- Department of Health and Human Services, September 18, 2020, p. 13.
- Centers for Medicare and Medicaid Services, September 18, 2020.
- Centers for Medicare and Medicaid Services, September 18, 2020, https://www.cms.gov/newsroom/press-releases/cmsannounces-transformative-new-model-care-medicarebeneficiaries-chronic-kidney-disease.
- Centers for Medicare and Medicaid Services, September 18, 2020.
- Centers for Medicare and Medicaid Services, September 18, 2020, https://www.cms.gov/newsroom/press-releases/cmsannounces-transformative-new-model-care-medicarebeneficiaries-chronic-kidney-disease.
- 23 Ibid.

- 24 Ibid.
- 25 Ibio
- 26 "New Rule Expands the Scope of Reimbursable Expenses for Living Organ Donation" Health Resources & Services Administration, September 18, 2020, https://www.hrsa.gov/about/news/press-releases/new-rule-expands-scope-living-organ-donation (Accessed 10/5/20).
- 27 "Removing Financial Disincentives to Living Organ Donation" Federal Register Vol. 85, No. 184 (September 22, 2020) p. 59438-59439.
- 28 Ibid, p. 59439.
- 29 *Ibid*, p. 59530.
- 30 *Ibid*, p. 59530-59532.
- 31 "National Kidney Foundation Statement on the ESRD Treatment Choices Model (ETC) and Policies to Improve Kidney Patient Choice" Cision PR Newswire, September 18, 2020, https://www.prnewswire.com/news-releases/national-kidney-foundation-statement-on-the-esrd-treatment-choices-model-etc-and-policies-to-improve-kidney-patient-choice-301134069.html (Accessed 9/21/20).
- 32 Ibid.
- 33 Ibid.

- "Statement by Kidney Care Partners on The ESRD Treatment Choices (ETC) Model" Kidney Care Partners, September 18, 2020, https://kidneycarepartners.com/press/statement-by-kidney-care-partners-on-the-esrd-treatment-choices-etc-model/ (Accessed 9/21/20); "Who We Are" Kidney Care Partners, https://kidneycarepartners.com/who-we-are/ (Accessed 9/21/20).
- Kidney News Online, September 18, 2020.
- 36 "Skilled Nursing Residents Shut Out of New End-Stage Renal Disease Payment Model" By Maggie Flynn, Skilled Nursing News, September 18, 2020, https://skillednursingnews.com/2020/09/skilled-nursingresidents-shut-out-of-new-end-stage-renal-disease-paymentmodel/ (Accessed 9/21/20).
- Department of Health and Human Services, September 18, 2020, p. 660.
- Centers for Medicare and Medicaid Services, September 18, 2020, https://www.cms.gov/newsroom/press-releases/cmsannounces-transformative-new-model-care-medicarebeneficiaries-chronic-kidney-disease.
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