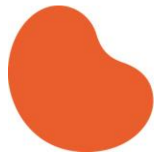



**Launch of the Advancing American Kidney Health Initiative**

*July 18, 2019*

On July 10, 2019, the Trump administration took a series of actions to advance kidney care in the United States, including releasing a report, *Advancing American Kidney Health,* and signing an Executive Order of the same name. The Executive Order (EO) states that it is the policy of the United States to prevent kidney failure through better diagnosis, treatment, and incentives for preventative care, increase patient choice of ESRD treatment modalities, encourage the development of the artificial kidney, and increase access to kidney transplants.

In *Advancing American Kidney Health,* the Department of Health and Human Services (HHS) sets three broad goals for delivering on this policy:

1. Reducing the number of Americans developing ESRD by 25% by 2030 through improved efforts to prevent, detect, and slow the progression of kidney disease.
2. Aim for 80% of new American ESRD patients receiving dialysis in the home or receiving a transplant by 2025.
3. Aim to double the number of kidneys available for transplant by 2030.

*Advancing American Kidney Health* sets out the roadmap by which HHS will target these goals. The report outlines the public health surveillance projects and evidence-based interventions that HHS will support in its efforts to reduce the risk of kidney failure and the steps HHS will take to align treatment options with patient preferences for home dialysis and transplant, increase organ recovery, reduce the discard rate, and increase the number of living donors by removing financial disincentives for organ donation.

The Executive Order, which is closely aligned with *Advancing American Kidney Health,* lays out timelines for actions that the federal government will take to achieve the goal of transforming how kidney disease is prevented and treated, including launching a kidney disease awareness initiative within 120 days, taking steps to promote the development of a wearable or implantable artificial kidney within 120 days, proposing new regulations for the oversight of Organ Procurement Organizations (OPOs) within 90 days, streamlining the process of kidney matching to reduce discards within 180 days, and proposing new regulations to remove barriers to living organ donation within 90 days. The Order also directs CMS to launch payment models intended to incentivize providers to better identify and treat at-risk populations earlier in disease progression and increase home dialysis and transplantation. Concurrent with the release of *Advancing American Kidney Health* and the signing of the Executive Order, the Center for Medicare & Medicaid Innovation (CMMI) released four voluntary payment models and one mandatory payment model, published in the Federal Register as a proposed rule on July 11,

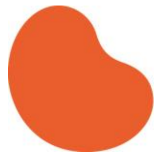
2019, that will provide financial incentives for better management of ESRD patients and improved rates of home dialysis and kidney and kidney-pancreas transplant.

In the proposed rule, CMS also announced its intent to establish a learning collaborative that focuses on disseminating best practices to increase the supply of deceased donor kidneys available for transplant.

NKF had significant influence over the policies announced on July 10 in *Advancing American Kidney Health* and in the Executive Order as demonstrated by the alignment of the initiative with NKF's public policy priorities in areas of improving kidney disease awareness, promoting early detection to slow progression, reducing the demand of dialysis, ensuring that patients can choose the treatment modality that best suits their preferences, and maximizing the use of donated kidneys including less than perfect kidneys. In the section of *Advancing American Kidney Health* on increasing access to kidney transplants, HHS notes that HRSA, through OPTN, is following recommendations from the National Kidney Foundation Consensus Conference to Decrease Kidney Discards as it develops and tests a proof of concept for expediting allocation of kidneys at high risk for discard with safety monitoring.

**CMMI Payment Models**

The payment models launched on July 10, 2019, support the administration's announced goals of driving for 80% of new ESRD patients starting renal replacement therapy with a transplant or on home dialysis in the next five years and reducing progression to ESRD by 25% over ten years. Four of the models are voluntary and build on the existing Comprehensive ESRD Care (CEC) Model, in which facilities and providers form accountable care organizations to better manage care for ESRD beneficiaries. The four voluntary models define a set of kidney care providers who are responsible for patients' care from late stage CKD through dialysis and post-transplant. In the Kidney Care First (KCF) model the group of providers is a nephrology practice. In the Comprehensive Kidney Care Contracting (CKCC) model, which has Graduated, Professional, and Global model payment options, the dialysis providers can form a group known as a Kidney Contracting Entity (KCE). Across the voluntary models, providers are financially incentivized to delay the progression to ESRD, manage the transition to dialysis, support the transplant process, and keep beneficiaries healthy post-transplant. The models expand the use of the Kidney Disease Education (KDE) benefit to stage 5 and certain ESRD beneficiaries and would allow for a wider range of providers to furnish the service. Overall, the four models incentivize a greater focus on kidney transplants. The administration simultaneously launched a mandatory payment model known as the ESRD Treatment Choice (ETC) Model.




**ESRD Treatment Choice (ETC) Model**

The ETC Model would test whether adjusting Medicare payments under the ESRD Prospective Payment System (PPS) and the Medicare Physician Fee Schedule (PFS) can incentivize ESRD facilities and clinicians (known as "Managing Clinicians") to work with adult patients to increase rates of home dialysis (both home HD and PD) and kidney and kidney-pancreas transplantation.

The payment adjustments would apply to a randomized, geographically based selection of ESRD facilities as defined by the ESRD PPS and Managing Clinicians, defined as Medicare-enrolled physicians or non-physician practitioners who furnish and bill the monthly capitated payment (MCP) for managing ESRD patients. The comparator group would be ESRD facilities and Managing Clinicians in comparator geographic areas. CMS aims to include approximately 50% of adult ESRD beneficiaries in the Model. The geographic unit of selection would be the 306 U.S. hospital referral regions (HRRs) in the 50 states and District of Columbia. Beneficiaries are not able to opt-out of the model, but ESRD facilities and Managing Clinicians must post information about the model to be transparent that they are receiving incentives for patients that get a transplant or a do dialysis at home.

The two payment adjustments are: The Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). The duration of the payment adjustments would be 6 years and 6 months, beginning January 1, 2020 and ending June 30, 2026.

Model participants would have a waiver for the billing of Kidney Disease Education (KDE) benefit requirements allowing KDE to be billed for stage 4 and 5 patients and for those within their first 6 months of dialysis. Additional healthcare professionals, beyond physicians and advanced practitioners, would be able to deliver and bill for the benefit, but dialysis facilities would still not be able to bill for KDE. Patients would still have a co-insurance for KDE.

The HDPA is a positive payment adjustment for home dialysis and home dialysis-related services billed for claims with claims dates during the first three years of the model (CY 2020 through CY 2022). The payment adjustment would begin at +3% in CY2020 and decline to +2% in CY2020 and +1% in CY2022 (See Figure 1).

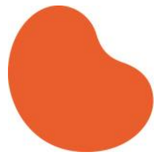
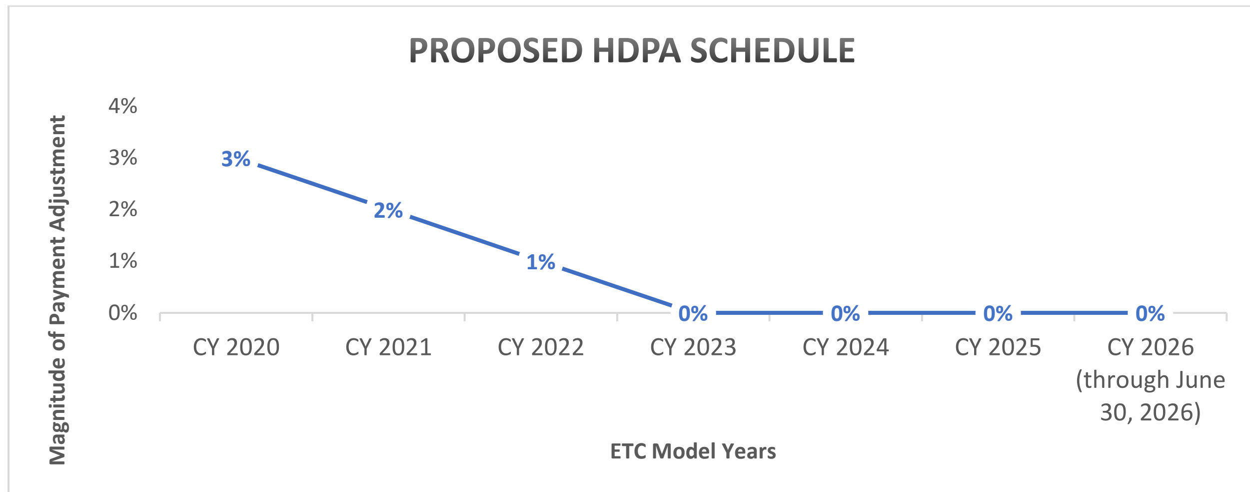

National Kidney Foundation®

**Figure 1. Proposed HDPA Schedule**




There would be both Clinician HDPAs and Facility HDPAs. Clinician HDPAs would adjust the monthly capitated payment (MCP) for a Managing Clinician's home dialysis claims. Facility HDPAs would adjust the ESRD PPS per treatment base rate for an ESRD facility's home dialysis claims. The HDPA would apply to all Managing Clinicians and ESRD facilities in selected geographic areas. Neither Clinician nor Facility HDAPs would affect beneficiary cost sharing.

The Performance Payment Adjustment (PPA) is a positive or negative payment adjustment, which would increase over time, for dialysis and dialysis-related services provided by Clinicians (Clinician PPA) and Facilities (Facility PPA). The PPA begins in the second year of the model, beginning July 1, 2021 and goes through June 30, 2026. Similarly to the HDPA, the PPA will not impact beneficiary cost-sharing. CMS clarifies that the downside risk is critical to incentivizing behavioral change in Model participants. The negative payment adjustment would be greater for ESRD facilities than for Managing Clinicians in acknowledgment of ESRD facilities' better ability to bear financial risk. While the HDPA would apply to all Model participants, the PPA would <u>not</u> apply to certain ESRD facilities and Managing Clinicians managing low volumes of adult ESRD beneficiaries.

The PPA is determined by the Model Participants' Modality Performance Score (MPS), a numeric performance score based on home dialysis rate and transplant rate. Home dialysis and transplant rates will be assessed during 12-month measurement year (MY). Actual payment adjustments would be applied for a 6-month Performance Payment Adjustment Period (PPA

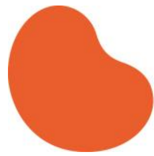
Period) between the end of one MY and the beginning of the next. See Table 1 for Model schedule of MYs and PPA Periods.

**Table 1. ETC Model Schedule of Measurement Years and PPA Periods**

| | | | | |
|---|---|---|---|---|
| Beginning CY 2020 | MY 1 | 1/1/20 through 12/31/2020 | PPA Period 1 | 7/1/2021 through 12/31/2021 |
| | MY 2 | 7/1/2020 through 6/30/2021 | PPA Period 2 | 1/1/2022 through 6/30/2022 |
| Beginning CY 2021 | MY 3 | 1/1/2021 through 12/31/2021 | PPA Period 3 | 7/1/2022 through 12/31/2022 |
| | MY 4 | 7/1/2021 through 6/30/2022 | PPA Period 4 | 1/1/2023 through 6/30/2023 |
| Beginning CY 2022 | MY 5 | 1/1/2022 through 12/31/2022 | PPA Period 5 | 7/1/2023 through 12/31/2023 |
| | MY 6 | 7/1/2022 through 6/30/2023 | PPA Period 6 | 1/1/2024 through 6/30/2024 |
| Beginning CY 2023 | MY 7 | 1/1/2023 through 12/31/2023 | PPA Period 7 | 7/1/2024 through 12/31/2024 |
| | MY 8 | 7/1/2024 through 12/31/2024 | PPA Period 8 | 1/1/2025 through 6/30/2025 |
| Beginning CY 2024 | MY 9 | 1/1/2024 through 12/31/2024 | PPA Period 9 | 7/1/2025 through 12/31/2025 |
| | MY 10 | 7/1/2024 through 6/30/2025 | PPA Period 10 | 1/1/2016 through 6/30/2026 |

ESRD beneficiaries will be attributed to ESRD Facilities and Managing Clinicians after the end of each MY, at which point CMS will provide Model Participants with a list of beneficiaries attributed to them. Beneficiaries will be attributed to the ESRD facility where they receive the plurality of their dialysis treatments. Beneficiaries that receive an equal number of treatments from two or more ESRD facilities will be attributed to the facility where they received the earliest treatment. ESRD beneficiaries would be attributed to Managing Clinicians who submit an MCP claim for their care in a given month.

The proposed rule also defines a beneficiary category for “pre-emptive transplant beneficiaries” that is separate from “ESRD beneficiary.” Pre-emptive transplant beneficiaries would be attributed to Managing Clinicians for purposes of calculating transplant rate.  Pre-emptive transplant beneficiaries may only be attributed to one Managing Clinician in a MY and cannot be attributed to ESRD facilities.




Performance based on home dialysis and transplant rates will be calculated from Medicare claims data, Medicare administrative data, and data from the SRTR in order to reduce the reporting burden on Model participants. For both ESRD facilities and Managing Clinicians, home dialysis rates will be measured as the rate of home dialysis treatment beneficiary years over a denominator of total dialysis treatment beneficiary years for attributed ESRD beneficiaries during the MY. Transplant rate will be measured as the total number of beneficiaries that received a transplant in the MY over a denominator of total dialysis treatment beneficiary years. For Managing Clinicians, pre-emptive transplant beneficiaries would be included in both the numerator and the denominator for the MY and up to and including the month of transplant.

Both home dialysis and transplant rates will be risk adjusted in order to account for underlying variation in the beneficiary population, specifically the difficulty of transitioning a sicker population to home dialysis. Home dialysis will be adjusted using the Medicare Advantage Hierarchical Condition Category ESRD Dialysis Model. Transplant rate will be risk adjusted for beneficiary age and corresponding risk coefficients according to the Percentage of Prevalent Patients Waitlisted (PPPW) QIP measure methodology. The dialysis and transplant rate risk adjustments will be conducted independently.

The Model will also make reliability adjustments to dialysis and transplant rate in order to produce reliable estimates for all Model participants to account for the low volume of transplants and home dialysis. For Managing Clinicians, performance would be aggregated to the practice level as identified by the Taxpayer Identification Number (TIN) and, at the individual level, by the National Provider Identifier (NPI). For ESRD facilities, the individual unit is the ESRD facility. In recognition of the structure of the dialysis market, CMS proposes that the aggregation group for subsidiary ESRD facilities would be all ESRD facilities located within the ESRD facility's HRR owned whole or in part by the same company.

The PPA will have two benchmarks for rates of home dialysis and transplant against which to assess Model participant performance via the Modality Performance Score (MPS). The first of these benchmarks will be constructed using 12 months of historical rates of home dialysis and transplants in comparator geographic areas known as a "benchmark year." CMS proposes to raise the achievement of the benchmarks over the duration of the model with a goal that by MY 9 and MY 10 (1/1/2024 through the conclusion of the Model on 6/30/2026), a Model participant seeking a maximum achievement score would need a combined home dialysis and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant. The second benchmark is an improvement score for Model participants on both home dialysis and transplant rates assessed in comparison to past Model participant performance. CMS notes, however, that a participant in the model cannot attain the highest

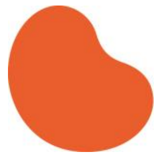
scoring level though the improvement benchmark alone. See Table 1 for the proposed scoring methodology for assessment of MY 1 (1/1/2020 through 12/31/2020) and MY 2 (7/1/2020 through 6/30/2021) achievement scores and improvement scores on home dialysis and transplant rates.

**Table 1.**

| **Achievement Score Scale for MYs 1 and 2** (1/1/2020 through 6/30/2021) | **Points** | **Improvement Score Scale for MYs 1 and 2** (1/1/2020 through 6/30/2021) |
|---|---|---|
| 90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year | 2 | Not a scoring option |
| 75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year | 1.5 | Greater than 10% improvement relative to benchmark year rate |
| 50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year | 1 | Greater than 5% improvement relative to benchmark year rate |
| 30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year | .5 | Greater than 0% improvement relative to benchmark year rate |
| <30th Percentile of benchmark rates for | 0 | Less than or equal to benchmark year rate |

The Model participant would receive the higher of the achievement score or performance score for both home dialysis and transplant rate, which will be combined to produce the MPS, with the home dialysis rate score accounting for two thirds of the MPS and the transplant rate score accounting for one third.

$$Modality\ Performance\ Score = 2 \times (Higher\ of\ home\ dialysis\ rate\ achievement\ or\ improvement\ score) + (Higher\ of\ transplant\ rate\ achievement\ or\ improvement\ score)$$




See Tables 2 and 3 for CMS' proposed facility and clinician PPA adjustment amounts and schedules.

**Table 2. Proposed Facility Performance Payment Adjustment Amounts and Schedule**

| | | **Performance Payment Adjustment Period** | | | | |
|---|---|---|---|---|---|---|
| | **MPS** | **1 and 2** (7/1/2021 through 6/30/2022) | **3 and 4** (7/1/2022 through 6/30/2023) | **5 and 6** (7/1/2023 through 6/30/2024) | **7 and 8** (7/1/2024 through 6/30/2025) | **9 and 10** (7/1/2025 through 6/30/2026) |
| Facility Performance Payment Adjustment | ≤ 6 | +5.0% | +6.0% | +7.0% | +8.0% | +10.0% |
| | ≤ 5 | +2.5% | +3.0% | +3.5% | +4.0% | +5.0% |
| | ≤ 3.5 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| | ≤ 2 | -4.0% | -4.5% | -5.0% | -6.0% | -6.5% |
| | ≤ .5 | -8.0% | -9.0% | -10.0% | -12.0% | -13% |

**Table 3. Proposed Clinician Performance Payment Adjustment and Schedule**

| | | **Performance Payment Adjustment Period** | | | | |
|---|---|---|---|---|---|---|
| | **MPS** | **1 and 2** (7/1/2021 through 6/30/2022) | **3 and 4** (7/1/2022 through 6/30/2023) | **5 and 6** (7/1/2023 through 6/30/2024) | **7 and 8** (7/1/2024 through 6/30/2025) | **9 and 10** (7/1/2025 through 6/30/2026) |
| Clinician Performance Payment Adjustment | ≤ 6 | +5.0% | +6.0% | +7.0% | +8.0% | +10.0% |
| | ≤ 5 | +2.5% | +3.0% | +3.5% | +4.0% | +5.0% |
| | ≤ 3.5 | 0.0% | 0.0% | 0.0% | 0.0% | 0.0% |
| | ≤ 2 | -3.0% | -3.5% | -4.0% | -4.5% | -5.5% |
| | ≤ .5 | -6.0% | -7.0% | -8.0% | -9.0% | -11% |

For questions about this summary and the policies related to the Administration's Advancing American Kidney Health initiative please contact Tonya Saffer, Vice President, Health Policy National Kidney Foundation at tonya.saffer@kidney.org 202.244.7900 x 717.