



HHS Kidney Care Policy Changes Incentivize CKD Care, Home Dialysis, and Transplantation; Incorporate RPA Payment Model Recommendations

- **Executive Order places high priority on improving kidney care delivery**
- **ETC Model mandatory for 50% of nation to provide bonus payments for home dialysis, other adjustments based on home, transplantation rates**
- **Two voluntary models: KCF is the nephrology practice specific model; CKCC requires participation by only nephrologists and transplant providers with other participants (e.g., dialysis facilities) optional**
- **KCF Model creates MCP for CKD care in addition to ESRD MCP, and offers substantial bonuses for patients receiving kidney transplants**
- **New models incorporate elements of RPA Clinical Episode Payment Model and CKD capitation proposals**

July 10 was a momentous day in the history of American kidney health, with the signing of the Executive Order (EO) by the President, and the preliminary release of a proposed rule that set forth a kidney specialty care model dubbed the ESRD Treatment Choices (ETC) Model, which would be mandatory for a randomly selected 50% of the country, to be determined in the fall. This rule also mentions several voluntary models that are based on RPA's ESRD Clinical Episode Payment Model that was recommended for implementation by the Physician-Focused Payment Model Technical Advisory Committee (PTAC): The Kidney Care First (KCF) and Comprehensive Kidney Care Contracting (CKCC) Models. These models will be formally released via a Request for Application (RFA) process in August. Comments on the proposed rule will be due on or around September 12, 2019.

These changes also must be considered in the context of the normal rulemaking that occurs this time of year, i.e., the physician fee schedule, the ESRD Prospective Payment System (PPS) and the HOPPS/ASC rule that determines outpatient vascular access reimbursement. A summary of the EO, the proposed rule, and the voluntary models is provided below.

Executive Order

Section 1—Purpose: This section presents the rationale for why action in kidney disease policy is necessary, the scope of the disease, and the numbers of patients on dialysis and waiting for a transplant.

Section 2—Policy: Presented as official U.S. policy are the following three objectives: (1) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care; (2) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and (3) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

Section 3—Announcing an Awareness Initiative on Kidney and Related Diseases: A kidney disease awareness campaign is to be launched by HHS within 120 days (mid-November).

Section 4—Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development: This section requires the Secretary of HHS within 30 days to develop a model which would “broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis.” This appears to be the voluntary model CMS has titled the “Kidney Care First” model (see details below).

Section 5—Payment Model to Increase Home Dialysis and Kidney Transplants: This section requires HHS to develop a model within 30 days that would evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. This appears to be the ESRD Treatment Choices (ETC) Model which is to be mandatory for 50% of the country and which is the subject of the proposed rule.

Section 6—Encouraging the Development of an Artificial Kidney: This section lays out the administration’s plan for advancing use of artificial kidneys, requiring HHS within 120 days to have the FDA consider requests for premarket approval of wearable or implantable artificial kidneys and to produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX).

Section 7—Increasing Utilization of Available Organs: HHS is directed 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. Additionally, within 180 days, the Secretary is required to streamline and expedite the process of kidney matching and delivery to reduce the discard rate.

Section 8—Supporting Living Organ Donors: This section sets forth plans to provide financial assistance for living organ donors, specifically stating “the regulation 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.”

Section 9—General Provisions: This is an administrative section that states that this order should not interfere with government authorities and functions outlined elsewhere in federal code, should be legal, and doesn't create any rights or benefits that can be used against the government.

Proposed Rule on Specialty Care Models

Overview

The Specialty Care Model Notice of Proposed Rule Making (NPRM) includes models for radiation oncology and ESRD. The ESRD Treatment Choices (ETC) model is intended to test the effectiveness of increasing home dialysis and transplantation via a series of payment incentives or ‘adjustments’ (positive or negative) over a six and one-half year period beginning in either January 2020 or April 2020 (more on this later). Within the ESRD model section, CMS uses a parallel structure for how the model would pay incentives or ‘adjust’ reimbursements to ESRD facilities and “managing clinicians”; this summary focuses on the impact on managing clinicians. CMS defines a managing clinician as essentially whoever bills an MCP, whether it is a nephrologist, an internist, or even a non-physician practitioner.

Scope and Effective Date

The ETC would be mandatory for a randomly selected 50% of the country based on hospital referral regions (HRRs). The rule states that “an HRR is a unit of analysis created by the Dartmouth Atlas Project to distinguish the referral patterns to tertiary care for Medicare beneficiaries, and is composed of groups of zip codes.” It further discusses the reasons why

other geographical classifications weren't chosen, such as Standardized Metropolitan Statistical Areas (SMSAs—too urban), states (too big), or counties (too small). A randomized selection will ensure (hopefully) inclusion of an appropriate diverse representation of urban, rural, large, small, etc. provider types. CMMI staff have advised RPA that CMS will release the list of randomly selected HHR's and thus the facilities and managing clinicians for whom the model will be mandatory in the fall after a final rule is issued, probably October or November. The model start date is set for January 1, 2020, but CMS does solicit comment on whether the effective date should be delayed until April 1, 2020, given that the preparation window for participation would be short with a January start date.

Home Dialysis Payment Adjustment (HDPA)

CMS proposes in the rule to make upward only adjustments in both the PPS payment to facilities and to MCP providers on home dialysis claims using CPT codes 90965 (for patients age 12-19), and 90966 (for patients 20 years and older) provided with dates of service over a three-year period from January 1, 2020 to December 31, 2022 (or three months later if an April start date is used). The upward adjustments would be 3% for calendar year (CY) 2020, 2% for CY 2021, and 1% for CY 2022.

Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment (PPA)

In this section CMS states its plans to assess ETC participants' rates of home dialysis and kidney and kidney pancreas transplants during a 12-month measurement year, which would be set up in six-month increments such that they would overlap to create a rolling average type of structure where using a six month period of performance payment adjustment (PPA) could be determined. CMS would use Medicare claims data, administrative data, and Scientific Registry of Transplant Recipients (SRTR) data to measure these rates. In general, 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, and these PPAs would begin July 1, 2021, and conclude June 30, 2026.

Risk Adjustment

To achieve appropriate risk adjustment in the ETC model, for the home dialysis rate CMS proposes to use the most recent final risk score for the beneficiary, calculated using the CMS-

HCC (Hierarchical Condition Category) ESRD Dialysis Model used for risk adjusting payment in the Medicare Advantage program.

CMS notes in the proposed rule that it considered using the same risk adjustment methodology for both home dialysis patients and transplant patients but determined that the risk factors for home dialysis patients and transplant patients are sufficiently different to merit use of different methodologies. As such, the Agency proposes that the transplant rates should be risk adjusted for beneficiary age, using the similar age categories, with corresponding risk coefficients, used for purposes of the Percentage of Prevalent Patients Waitlisted (PPPW) measure.

Exclusions

The following categories of patients are excluded from the ETC:

- Beneficiaries not residing in the United States
- Beneficiaries under 18 years of age
- Beneficiaries not enrolled in Medicare Part B.
- Beneficiaries enrolled in Medicare Advantage or other Medicare managed care plans
- Beneficiaries who have elected hospice
- Beneficiaries receiving dialysis for acute kidney injury (AKI) only
- Beneficiaries with a diagnosis of dementia

Overlaps with Other Innovation Center Models and CMS Programs

CMS addresses potential overlap of the ETC Model with other CMS programs and models, including those focused on dialysis care. They note that while they believe the ETC Model would be compatible with other dialysis-focused models, the Agency will work to resolve any potential overlaps between the ETC Model and other Innovation Center models or CMS programs that could result in repetitive services or duplicative payment of services. Payment adjustments made under the ETC Model would be counted as expenditures under the Medicare Shared Savings Program and other shared savings initiatives. Additionally, ESRD facilities would remain subject to the quality requirements in ESRD Quality Incentive Program (QIP) and Managing Clinicians who are MIPS eligible clinicians would remain subject to MIPS.

Waivers and Kidney Disease Education Benefit

The section of the proposed rule on waivers is primarily focused on the kidney disease education (KDE) benefit, with the exception of waiving the requirement for beneficiary cost-

sharing in the payments made for the HDPA and PPA incentives. CMS notes in the rule that if these payments weren't waived from beneficiary cost-sharing, it would create a perverse incentive for patients to seek care from lower performing participants since their cost share would be lower, running counter to the purpose of the model.

As for the KDE benefit, CMS proposes to waive 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 Medicare-enrolled participating Managing Clinician. The staff need not be Medicare-enrolled but would furnish these services incident to the services of a clinician authorized to bill Medicare for KDE services. The rule goes on to note that CMS considered waiving the restriction preventing ESRD facilities from providing the services but decided not to since it is not necessary for the testing of the model and because ESRD facilities are already required to perform the activities associated with KDE.

Importantly, CMS is waiving the restriction that KDE services only be provided to CKD stage 4 patients, and now will allow the services to be provided to stage 5 patients and those in the first six months of an ESRD diagnosis. The Agency is also waiving: (1) the requirement that within the KDE curriculum the issues of comorbidities and delaying the need for dialysis be covered, since this would seemingly be moot for a stage 5 patient, although if relevant to the specific patient, they should be covered; and (2) the requirement that an outcomes assessment be performed within a KDE session (CMS says that an outcomes assessment should still occur, but it is just not required to occur within a session). Finally, the rule notes that CMS also considered waiving the co-insurance requirement for the KDE benefit and certain telehealth requirements to allow the KDE benefit to be delivered via telehealth for beneficiaries outside of rural areas and other applicable limitations on telehealth originating sites, but did not believe those waivers were necessary for purposes of testing the model.

Monitoring and Quality Measures

The Agency notes in the rule that they will monitoring implementation and outcomes associated with the model, via the use of claims audits, documentation requests, interviews (with both ETC leadership and staff and beneficiaries and caregivers), site visits, and other means. The rule also states that:

Specific to the ETC Model, we would use the most recent claims data available to track utilization of certain types of treatments, beneficiary hospitalization and Emergency Department use, and beneficiary referral patterns to make sure the utilization and

beneficiary outcomes are in line with the Model's intent. We believe this type of monitoring is important because as ETC Participants adapt to new payment incentives, we want to ensure to the greatest extent possible that the Model is effective and Medicare beneficiaries continue to receive high-quality, low cost, and medically appropriate care.

And that:

We recognize that one of the likely outcomes of this Model would be an increase in utilization of home dialysis, however, in testing payment incentives aimed at increasing utilization of this modality there may be a risk of inappropriate steering of ESRD Beneficiaries who are unsuitable for home dialysis. Therefore, to avoid inappropriate use of home dialysis, we propose to use risk adjustment to account for factors related to good candidacy for home dialysis. We also propose to exclude from beneficiary attribution certain categories of beneficiaries not well suited to home dialysis, including beneficiaries with a diagnosis of dementia. We are proposing these eligibility criteria to exclude certain categories of beneficiaries from attribution up front so Managing Clinicians and ESRD facilities that are ETC Participants do not attempt or believe that it is wise to attempt to place these particular beneficiaries on home dialysis. In addition, CMS would monitor for inappropriate encouragement or recommendations for home dialysis through the proposed monitoring activities. Instances of inappropriate home dialysis may show up in increased patient hospitalization, infection, or incidence of peritonitis. For example, multiple incidences of peritonitis would be a good indicator that the patient should not be on PD. If claims data show unusual patterns, we propose to review a sample of medical records for indicators that a beneficiary was not suited for home dialysis. Through patient surveys and interviews, CMS would look for instances of coercion on beneficiary choice of modality against beneficiary wishes. If such instances of coercion were found, we would take one or more remedial action(s).

Regarding quality measurement, the overview proposes that CMS use two quality measures for the ETC Model for dialysis facilities: the Standardized Mortality Ratio and the Standardized Hospitalization Ratio. These measures are NQF-endorsed and are currently calculated at the ESRD facility level for Dialysis Facility Reports and the ESRD QIP, respectively, and so would require no additional reporting by ETC Participants.

However, it appears that there will be no unique quality measures for the managing clinicians in the rule; the text from this portion of the NPRM reads as follows:

We considered including quality measures for Managing Clinicians that are reported by Managing Clinicians for MIPS or other CMS programs. However, whereas all ESRD facilities are subject to the same set of quality measures under the ESRD QIP, there is no analogous source of quality measure data for Managing Clinicians. Managing Clinicians may be subject to MIPS, or they may be participating in a different CMS program – or an Advanced APM – which has different quality requirements. In addition, most Managing Clinicians participating in MIPS select the quality measures on which they report. Taken together, these factors mean that we would be unable to ensure that all Managing Clinicians in the ETC Model are already reporting on a given quality measure, and therefore would be unable to compare quality performance across all Managing Clinicians without imposing additional burden.

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

CMS will send out RFAs for the two voluntary models in August. The first (the KCF) is a nephrology-specific model and seems analogous to RPA’s ESRD Clinical Episode Payment Model, with a CKD MCP added (that is, an MCP for services provided to stage 4 and 5 CKD patients). The second (the CKCC) provides the opportunity for groups of healthcare providers to provide integrated kidney care. CMS specifically notes that in the CKCC model nephrologists/nephrology practices and transplant providers are the only required participants, with dialysis facilities and other providers being optional.

Other highlights include:

- The CMS fact sheet on the voluntary models notes that they seek to build on the lessons from the CEC/ESCO experience, while adding both CKD and transplant patients to the models (as opposed to only having ESRD patients previously).
- The 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. Health care 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 KCF model as noted will include separate MCPs for CKD and ESRD, plus a bonus for attributed transplant patients, paid over a three-year period to encourage effective post-transplant care.

- 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 risk-bearing CKCC models will qualify as Advanced APMs in 2021; participants on the one-sided CKCC model will not.

Summary

Recognizing that implementation has yet to begin and many details have yet to be determined, the proposed payment models outlined by CMS appear to portend significant advancements in kidney care via the encouragement of home dialysis and transplantation. Additionally, nephrology's primacy as the leader of kidney care delivery systems and teams has been underscored. Given that RPA's ESRD Clinical Episode Payment Model and input on CKD payment seems to have had a substantial influence on the direction of CMMI staff developing these proposals, this also represents a significant policy victory (or series of victories) for RPA.