Policy Update

ASN Submits Comments about ETC Model to CMS

By David White

Creation of payment models is a critical component of the Executive Order on the Advancing American Kidney Health (AAKH) initiative issued by President Donald J. Trump on July 10, 2019. At the time this article was written, the Innovation Center of the Centers for Medicare and Medicaid Services (CMS) had only released the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model, a mandatory model that tests using payment policy to drive higher rates of home dialysis and kidney transplantation. The proposed payment policies will affect the managing clinicians and dialysis facilities assigned to the model. The four voluntary models to accompany the ETC model were still to be released.

With a clear perspective of the breadth of what CMS proposed in the ETC model—and the overall AAKH initiative—American Society of Nephrology (ASN) President Mark E. Rosenberg, MD, FASN, submitted comments and recommendations developed by the ASN Quality Committee to CMS on September 16, 2019. The recommendations were developed with guidance from the ASN Council and input from numerous ASN members and in collaboration with other kidney community members. While ASN provided its own specific recommendations, ASN, the National Kidney Foundation, and the Renal Physicians Association also submitted a high-level overview outlining five areas for improvement in the model (See Table 1).

Essentials for ensuring success

ASN maintained its support for the objectives of the proposed ETC model to expand patient access to a variety of dialysis modalities and to kidney transplantation. ASN has emphatically maintained—in meetings with the agency and in this comment letter—that the agency needs to focus the model on "access" to modality choices, not on requiring every program to offer home dialysis, and that the evaluation methods and payment adjustments in the model need to be aligned with more investment in building capacity and significantly reducing the penalties.

ASN maintains there needs to be more safety guardrails for patients in the model to incent patient-centered choice. As such, the society identified several key essential elements that "must be addressed to maximize the likelihood of optimal outcomes for patients and ensure the success of the model":

- Establishing appropriate targets and benchmarks with a top combined home dialysis and transplant rate of 50% as opposed to 80%
- Using shared decision-making tools and incorporating additional risk adjustment to mitigate the risk of non-patient–centered decision-making
- Aggregating home dialysis rates at a geographic level such as a hospital referral region—not the facility level
- Incentivizing and investing wisely by reducing the performance payment adjustment (PPA) to a level comparable with the ESRD Quality Incentive Program (QIP), investing in the home dialysis payment adjustment (HDPA) at 3-5% annually for the life of the model, and making the model an advanced alternative payment model (AAPM)
- Increasing access to transplantation by incorporating adjusted transplantation rates as an outcome
- Delaying both the start date of the model until April 2020 and implementation of downside adjustments until measurement year three
- Using the rulemaking process for the model annually

Establishing appropriate targets and benchmarks

Dr. Rosenberg shared the concern of ASN members and other kidney community organizations that critical guardrails for patients need to be strengthened in the model by emphasizing throughout the letter that the optimal kidney replacement therapy differs from patient to patient.

"Establishing appropriate thresholds and benchmarks provides those important guardrails for patients with contraindications—absolute or relative—or insurmountable barriers for home dialysis or transplant," he wrote. "We recommend lowering the target goal of 80% combined home dialysis and transplant rate in the final years of the ETC model to 50%—a still audacious, but achievable, target."

CMS was also encouraged to review the risk adjustment of the patient population that is to be placed in the denominator for evaluating ETC participants—clinicians and dialysis facilities—to support their ability to make truly shared, patient-centered choices. The recommendations specifically asked the agency to add to its risk adjustment neighborhood census socioeconomic data linked at the zip code level as has been done for the Agency for Healthcare Research and Quality.

In detail, ASN demonstrated the math needed to reach an 80% rate and declared it to not be achievable in the timeframe allotted. Also, the society cautioned CMS to avoid unfairly penalizing programs that have already been successful at increasing rates of home dialysis and transplant and are therefore "topped out." Similarly, ASN urged the agency "to not implement a forced bell curve approach that could apply penalties to as much as 30% of participants regardless of their improvement and achievement scores." The letter pointed out that a forced bell curve was not essential to achieving the program's goals of increased patient choice among in-center, home, and transplant—goals ASN has previously endorsed and did so again in these comments.

Empowering patients and care teams to evaluate the range of treatment options

ASN's comment letter recognized that current reimbursement and delivery systems for kidney care often do not emphasize patient choice, tending to default to in-center hemodialysis (HD). To achieve balance in the new payment model, the society encouraged the use of shared decision-making tools. ASN also urged CMS to reconsider its position on self-care. In the proposed rule, the agency wrote, "We considered including beneficiaries whose dialysis modality is self-dialysis or temporary peritoneal dialysis (PD) furnished in the ESRD facility at a transitional care unit in the numerator, given that these modalities align with one of the overarching goals of the proposed ETC model, to increase beneficiary choice regarding ESRD treatment modality. However, these modalities lack clear definitions in the literature and delivery of care for these modalities is billed through the same codes as in-center HD, making it impossible for CMS to identify the relevant claims."

ASN responded by recommending the agency include in-center, self-care patients in the numerator of home patients for a given clinic/program/geographic area for a defined period of time, maintaining "these activities can serve as a bridge to home dialysis, a period of adjustment and confidence building, and a mechanism for support for patients who need an alternative to their normal home dialysis." To accomplish this, ASN proposed a definition of self-care for CMS consideration and proposed using the existing condition code for "self-care in unit" (code 72) as defined in

Table 1. Five principles in ASN, NKF, and RPA joint letter to CMS

Establishing patient-centered targets, benchmarks, and risk adjustments that ensure there are guardrails in the model for patients with contraindications or insurmountable barriers for home dialysis or transplant. In addition, correctly risk adjusting the patient population that is to be placed in the denominator for evaluating ETC participants—clinicians and dialysis facilities—would empower them to make truly shared, patient-centered choices.
Empowering patients and care teams when evaluating treatment choices. The model should encourage the use of shared decision-making tools by patients and their care team when educating and evaluating kidney replacement therapies.
Guaranteeing access to home dialysis programs. Enhancing patient access to kidney failure treatment choices and the education needed to properly evaluate those choices) is a key goal of the ETC model that we support. However, ensuring reasonable patient access to a home dialysis program does not require that every dialysis facility offer a home dialysis program.
Incentivizing and investing wisely in the proposed model. We believe the model must balance appropriate adjustments that are not overly punitive while providing more up-front investment to make possible the desired achievements in increased home dialysis and transplantation rates. The truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis—results that will require investment in order to achieve.
Providing ETC participants the time to properly prepare for the model and the opportunity to comment as the model progresses. We believe the success of all participants in the model would be enhanced by providing more time before commencing the ETC Model date for stakeholders to prepare starting April 1, 2020. We also believe the success of the model would be enhanced by using the rulemaking process throughout the life of the model."

Abbreviations: NKF, National Kidney Foundation; RPA, Renal Physicians Association; CMS, Centers for Medicare and Medicaid Services

section 50.3 of Chapter 8 of the Medicare Claims Processing Manual to track self-care patients.

Guaranteeing access to home dialysis programs

The proposed model allowed managing clinicians to aggregate their home dialysis rate to the taxpayer identification number (TIN) of their practice, or to the national provider identifier (NPI) for solo practitioners, but required facilities to be graded at the facility level. ASN expressed concern that incenting every facility to offer a home option will not actually result in better outcomes for patients. ASN recommended aggregating all facilities regardless of corporate ownership or affiliation to a geographic level such as the hospital referral region when assessing access to home dialysis.

ASN also asked the agency to examine the option of excluding companies or institutions that do not provide in-center care in their clinics in the geographic region from participating in the model unless they are contractually aligned with providers that offer in-center dialysis to prevent unintended consequences. To support this recommendation, the letter provides several examples of how home dialysis programs work in reality and how a facility-based evaluation could actually prevent the model from achieving its goals.

Incentivizing and investing wisely in the ETC model

In response to the model being weighted negatively, ASN clearly stated it did not believe the patient benefits and cost savings to Medicare could be realized by cutting costs alone. The society maintains that truly significant savings to Medicare under the proposed model derive directly from improved outcomes, less hospitalization, more transplantation, and fewer years of dialysis—results that will require investment in order to achieve.

ASN requested the agency do the following:

- Reduce the PPA and align it with penalties in the ESRD QIP
- Invest in the HDPA at 3-5% annually for the life of the model
- Make the model an AAPM

ASN urged the agency to reduce the magnitude of the PPA to lower penalty levels below the proposed up to 11% for managing clinicians and replicate the penalties in the ESRD QIP with a maximum 2% penalty and sufficiently fund the HDPA throughout the model's life to cover the investments that will need to be made. ASN also raised its concern about the availability of home dialysis nurses and other healthcare professionals who will be essential for the model's success.

ASN encouraged CMS to more transparently detail how it believes relative contraindications and other barriers to home dialysis will be factored into the model. Targets for PD utilization may be difficult to achieve because many older patients have relative contraindications to PD or barriers to self-care leading to the need for home-assist efforts or the removal of such patients from the denominator.

Increasing access to transplantation

The AAKH initiative has a stated goal of doubling the number of kidneys available by 2030. ASN offered its assistance to HHS in reaching this goal and indicated its strong support for the use of an actual transplant rate as a metric in the ETC model. Dr. Rosenberg wrote, "This approach also constitutes a fundamental shift and will necessitate greater cooperation with patients, their families and loved ones, transplant centers, Organ Procurement Organizations, and other stakeholders."

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