



September 16, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-5527-P; Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures; Proposed Rule

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. Part of RPA's mission is to promote excellence in the delivery of high-quality kidney care within an environment that supports patient access to care and safety.

RPA is writing to offer comment on the ESRD Treatment Choices (ETC) provisions in the Specialty Care Models Proposed Rule. We commend CMS for the lofty ambitions that characterize the ETC and share the Agency's belief that the goals of increasing the rates of home dialysis utilization and successful kidney transplants are of primary importance to improving kidney care in the U.S., and that the need is urgent. We recognize that this level of commitment is unprecedented and want to be clear that it is tremendously appreciated. However, RPA also believes that at a minimum, significant refinement of the proposed rule is necessary to ensure that kidney patient care is not adversely affected. We therefore strongly urge CMS to delay proceeding with the rule as proposed and to take the time necessary to revise the model in order to minimize unintended negative consequences. RPA believes a partial list of the potential unintended negative consequences includes:

- **The model may harshly penalize communities with limited resources;**
- **Similarly, dialysis clinics providing care to marginalized patient populations will be put at greater risk;**

- **The model could lead to reduced access to all dialysis care if the substantial financial penalties force clinics to close;**
- **The possibility of compromised patient choice is clearly present;**
- **There will be an incentive for sicker or otherwise unsuitable patients to start peritoneal dialysis, leading to an increase in early failure rates;**
- **Clinics currently without home programs will be doubly penalized in that not only will their relatively healthy patients who are good candidates for home dialysis likely leave the clinic, but since those patients typically are also the best candidates for transplantation, those clinics will not have the opportunity to realize those incentives;**
- **The model does not account for the wide degree of demographic and care delivery variability that can occur within a hospital referral region (HRR).**

RPA offers comment and recommendations on the following areas:

- **Onset of Proposed Model Performance Period**
- **Scope of Proposed Model**
- **80% Benchmark for Combined Home Dialysis/Transplant Patients**
- **Home Dialysis Payment Adjustment**
- **Performance Payment Adjustment**
- **Need for Aggregation at Group TIN and Dialysis Facility Level**
- **Potential Unintended Negative Impact on Patient Choice**
- **Necessity of Additional Waivers**
- **Additional Exclusions for Home Dialysis and Transplants**
- **Use of Organ Transplant Rates**
- **Need for Increased In-Center Peritoneal Dialysis Payments**
- **Need for Increased Home Dialysis Training Payments**
- **Exclusion of Non-Medicare Beneficiaries from Transplant Attribution**
- **Implementation of Payment Models in Geographies with Large Integrated Health Systems**

Onset of Proposed Model Performance Period

In the proposed rule, CMS notes that as currently proposed the duration of the payment adjustments under the ETC model would begin on January 1, 2020, and end on June 30, 2026, and also solicits comment on the possible use of an alternative start date, April 1, 2020 and the subsequent three-month adjustment to all ETC Model dates, including the implementation of the home dialysis payment adjustment (HDP) and performance payment adjustment (PPA). As noted, RPA is deeply concerned that the model as proposed could inadvertently have an adverse impact on kidney patient care. Additionally, we believe that ETC model implementation must be coordinated with the possible integration of the voluntary models (which as of the ETC

proposed rule comment due date have not been released) so that nephrology practices can make informed decisions on voluntary model participation. Therefore, RPA urges a delay in implementation, beyond April 1 if necessary, to ensure that any necessary changes can be made to ensure that patient care is not compromised.

RPA urges CMS to delay implementation of the ETC model to such time that unintended adverse consequences can be minimized, until at least April 1, 2020, or later.

Scope of Proposed Model

With regard to the scope of the ETC as proposed, CMS states in the rule that the threshold of 153 hospital referral regions (HRRs) being included in the intervention group (out of a possible 306 HRRs) was necessary to ensure that the model was sufficiently powered to detect changes in transplant rates, since under the structure of the current system transplants are relatively rare events. In the same passage of the rule, CMS notes that for the home dialysis aspect of the model, it would need few HRRs to sufficiently power the model. Thus, the sole rationale for subjecting 50% of the nation's kidney patients and providers (clinicians and dialysis facilities) is to make sure the model is sufficiently powered to detect changes in transplant rates.

RPA does not believe this justification suffices for making a change of such magnitude. It is important to note that the disparate nature of local providers and availability of associated ancillary care such as quality surgical services are issues beyond the control of nephrologists and dialysis clinics alike, and such anomalies create an inappropriate and unfair basis for assessment between the selection and comparison groups. Further, we are aware of statistical analyses developed on behalf of Kidney Care Partners (KCP) that offer an alternative methodology that bases the comparison on the number of ESRD patients attributed to the model rather than on the number of HRRs (or similar geographic designation), and that KCP recommends a 25% threshold of Medicare beneficiaries included in the model to limit the possible impact of any unintended negative consequences. We believe that use of the alternative model and the reduced threshold would be a much more prudent and safer path for moving forward.

RPA urges CMS to evaluate alternative methodologies for determining the scope of the ETC model, and to consider limiting the threshold to 25% of Medicare beneficiaries included in the model to see if the ETC model can impact the variables in question while limiting any unintended negative consequences.

80% Benchmark for Combined Home Dialysis/Transplant Patients

As part of the Advancing American Kidney Health initiative, the Administration has in numerous communications established a goal of having 80 percent of new ESRD patients in 2025 either

receiving dialysis at home or receiving a transplant. RPA unequivocally supports efforts to increase the rates of both home dialysis and transplantation, and we commend the Administration in the strongest terms possible for its leadership in this area.

Despite our firm commitment to assist CMS in increasing both home dialysis and transplantation rates, we believe that a goal of an 80% combination of new ESRD patients either being on home dialysis or having a transplant is unrealistic. CMS notes in the proposed rule that in other countries such as Hong Kong and New Zealand the rate of home dialysis far exceeds that of the U.S., according to the USRDS. RPA believes that international comparisons lack validity due to differences in demography and delivery models so that the provision of dialysis is more selective.

Given the current rate of home dialysis solely, we believe that achievement of the 80% goal in six years is impracticable. Of greater concern would be efforts to increase the rate of transplants given the current structural barriers associated with organ procurement. RPA is aware that rulemaking to revise the organ procurement organization (OPO) process is underway and planned for release in the coming months and hopes those revisions will address concerns such as variability in selection process by centers and extreme variability in opportunity and access across the country. However, with that timeline the positive impact of an updated regulatory methodology for organ procurement and allocation is probably years away, and thus unlikely to contribute enough to achieve the 80% goal. We are also concerned that having an unrealistic goal that comes with harsh penalties for underachievement will only work against what the Administration is trying to accomplish.

RPA urges CMS to reduce the percentage goal of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant, in consultation with the kidney community.

Home Dialysis Payment Adjustment

RPA appreciates the intent of CMS' proposal to provide an upside-only payment adjustment for home dialysis services in the first three years of the model, as it is indicative of an understanding that additional resources are required to successfully transition increased numbers of dialysis patients to home modalities. Unfortunately, we believe that the incentive payments are insufficient as a means for practice transformation

Further, the proposed rule does not provide the underlying rationale for creating the 3%, 2%, and 1% increase structure for the incentive payment adjustment. Rather than set the payment adjustment on what appear to be arbitrary levels, RPA recommends that CMS ascertain the practice expenses associated with establishing the clinical and administrative staff infrastructure necessary to support substantially increased numbers of patients on home therapies, and determine the incentive payment adjustment based in some way on those costs.

RPA stands at the ready to help clarify the specifics we believe are needed to come up with a better rationale.

RPA urges CMS to transparently develop incentive payments for the HDPA that account for the resources necessary for nephrology practices to manage home dialysis care.

Performance Payment Adjustment

RPA is deeply concerned with the structure and design of the performance payment adjustment. Acknowledging that Medicare is seeking to maintain budget neutrality if not recognize savings in dialysis care, imposing an asymmetrical system where the bonus payments are exceeded by the penalties will unfairly subject a majority of nephrologists (members of an already undersubscribed specialty) to payment reductions based on somewhat arbitrary indicators of performance. As such, RPA believes that the PPA as proposed will result in draconian penalties in the out years of the model, and create inappropriate incentives for providers to direct patients to home or hospice, compromising the physician-patient relationship in situations where the patient may choose in-center care.

Further, RPA believes that the range between the highest bonus payments and highest payment penalties as proposed in the PPA (+10% to -13% for facilities, and +10% to -11% for clinicians) is far too wide. CMS can create incentives for home dialysis and transplantation without utilizing a methodology that has the potential to reduce payments by double-digit figures for participating entities.

Additionally, we share the concern of the AMA that the 50% of nephrologists in the model will be required to participate in simultaneous but uncoordinated performance measurement schemes, since participation in the ETC does not exempt nephrologists from the Merit-based Incentive Payment System (MIPS) requirements. While RPA believes that CMS should rethink whether the ETC broadly and the PPA specifically are designed to achieve stated goals, if the model is to proceed, we urge CMS to exempt nephrologists participating in the model from MIPS participation so that they would not be subject to penalties twice under separate measurement schemes.

RPA urges CMS to re-evaluate the PPA to determine whether it will achieve its intended goals, account for the likely unintended adverse consequences that will result from its implementation, and if implemented, to reduce the range of bonuses and penalties and exempt nephrologists in the model from MIPS participation.

Need for Aggregation at Dialysis Facility Level

RPA supports CMS' efforts to seek accountability among model participants but urges the Agency to allow aggregation of facilities within an HRR to reflect the reality of ESRD care delivery. This could be done based on local geography and dialysis provider or medical director group, such as by holding a nephrology group accountable at the tax identification number (TIN) level and holding dialysis facilities accountable by all units owned by the same business within the HRR. An individual clinic should not be forced to provide home therapies if there is a clinic reasonably close by for patients to receive care.

The ETC should also account for innovative processes already in place that are advancing the use of home dialysis. For example, transitional dialysis facilities have been created in many markets to facilitate and support home therapies. Smaller clinics and networks have established local/regional home therapy training centers to achieve economies of scale, maintain expertise and to improve care delivery. Also, the use of self-care dialysis needs to be directly incentivized in the ETC program.

RPA urges CMS to allow aggregation of facilities within an HRR to reflect the reality of ESRD care delivery and allow for the use of innovative solutions already in place to promote the use of home dialysis such as transitional dialysis facilities and self-care dialysis.

Potential Unintended Negative Impact on Patient Choice

RPA completely supports the Administration's overall goals of increasing the rates of home dialysis and transplantation, but we also believe that the proposed rule if implemented would invariably compromise patient choice. While transplantation is the gold standard for renal replacement therapy (RRT) and home dialysis is a better option for many individuals who will need dialysis, there will be a percentage of kidney patients whose choice of modality will be in-center care, and CMS should exercise caution to not compromise that choice and to honor those persons' autonomy.

Clearly, every effort needs to be made to ensure that all patients approaching or already on dialysis are aware of their options for their care, and that all patients who are possible candidates for transplant or who have the home environment, appropriate support, and wherewithal to dialyze at home are given that opportunity. RPA is concerned that the proposed model does not account for those patients who prefer in-center dialysis, and in an era of ostensible patient empowerment CMS may be creating a system where patients will be subject to significant influence to choose home dialysis where they might not be otherwise. Given that patients will have the choice not to go to home dialysis, the penalties should be reduced to lessen the potential inappropriate incentives for both clinicians and dialysis facilities.

RPA urges CMS to give further consideration to the potential adverse impact of the proposed rule on patient choice to minimize undue influence on patients who would prefer in-center dialysis to choose other modalities.

Necessity of Additional Waivers

RPA strongly believes that CMS should make every effort possible to provide additional waivers to facilitate dialysis facility/clinician collaboration. We fully understand that Stark and anti-kickback restrictions exist for a reason, but also believe that in the current era of coordinated and value-based care, they may be anachronistic and run counter to achieving the goals of the Administration. RPA would point to the recent success of the ESRD Seamless Care Organization (ESCO) demonstration for proof that allowing dialysis facilities and nephrologists to openly share information and coordination strategies improves care and saves money.

Potential topic areas for waivers could include: (1) information sharing and increased coordination of care between dialysis facilities and nephrologists; (2) ability to assist patients with improving social determinants of health; (3) ability to provide transportation to dialysis treatments, vascular access procedures, and other medical appointments (4) payments to family members for providing care, and payment for staff assisted home therapy; (5) waivers for kidney disease education (KDE) to allow dialysis facilities to provide KDE care; and (6) waivers to eliminate the patient's co-pay and other out-of-pocket expenses for KDE services.

RPA urges CMS to provide additional waivers in the proposed model to address issues such as information sharing, assisting with social determinants of health, providing transportation for dialysis treatments, vascular access procedures, and other medical appointments, payments for family assisted and staff assisted home care, KDE services provided by dialysis facilities and to eliminate the patient's co-pay expenses.

Additional Exclusions for Home Dialysis and Transplants

In the proposed rule, CMS excludes certain categories of beneficiaries from attribution to ETC participants, including beneficiaries not residing in the U.S., those under 18 years old, those not in Medicare Part B, those who are enrolled in Medicare Advantage or other Medicare managed care plans, patients who have elected hospice, are receiving dialysis for acute kidney injury (AKI) only, or have a diagnosis of dementia. RPA concurs with including these categories on a list of exclusions.

However, RPA believes that to minimize the degree to which the ETC model is unfairly punitive for nephrologists and dialysis facilities, CMS should provide an expanded list of exclusions, accounting for patients for whom home dialysis or transplantation are not appropriate modalities. These should include an expanded list of diagnoses that accounts for those patients

not appropriate for home dialysis or transplantation; RPA would welcome the opportunity to work with CMS in developing an expanded list. Additionally, RPA recommends that CMS reduce the proposed upper age limit from 75 years old to 70 for patients to be included in the transplant metric.

RPA supports the proposed list of categories of patients for exclusion from the model but urges CMS to expand the list of exclusions to include patients with diagnoses not appropriate for home dialysis or transplantation, and to reduce the upper age limit from 75 to 70 in the transplant metric.

Use of Organ Transplant Rates

RPA believes that use of the organ transplant rate as a measure to evaluate nephrologists and dialysis facilities is inappropriate and premature. Nephrologists and dialysis facilities should be measured on activities and processes within their control, and at present the complexities surrounding the organ procurement organizations and the control of transplant centers over organ allocation as well as the selection/acceptance of candidates limit the ability of nephrologists and dialysis facilities to impact the actual transplantation rate. We recognize the limitations of using other measures such as referral rates for evaluating efforts to increase transplantation, but it is simply inappropriate to hold ETC participants accountable for events out of their control. CMS may want to consider the use of waitlists as a part of the process through which dialysis facilities and clinicians can be held more accountable.

RPA urges CMS to not use organ transplant rates for evaluating nephrologists and dialysis facilities in the ETC model, and rather identify an alternative methodology for such measurement such as referral rates or wait lists.

Need for Increased In-Center Peritoneal Dialysis Payments

The proposed rule for the ETC excludes in-center peritoneal dialysis (PD) when considering the cost for home dialysis training. RPA believes that in-center PD is an important part of the process of “urgent start” PD and will become increasingly so in any effort to increase utilization of home dialysis. The use of urgent start PD allows a person to avoid intervening in-center hemodialysis when there is not sufficient time between placement of the PD catheter and the usual course of training. By performing urgent start PD, one can have the PD catheter be the first dialysis access placed and avoid placement of central venous catheter for hemodialysis. In-center PD is more resource intense than usual peritoneal dialysis training both for the dialysis center and the nephrology practice; thus, RPA believes those increased costs should be included in the ETC model.

RPA urges CMS to increase reimbursement for in-center peritoneal dialysis to facilitate the transition to home dialysis for persons on in-center PD.

Need for Increased Payment for Home Dialysis Training

As noted throughout this comment, RPA strongly supports the Administration and CMS increasing its emphasis on home dialysis in the Medicare ESRD program, and increased efforts to assist patients in successfully transitioning to home dialysis. RPA believes that to facilitate this success, CMS should consider as part of the ETC rulemaking increasing the payment for home dialysis training. Relative to the program-wide savings that will be realized if there is a significant increase in the volume of patients choosing home dialysis, increasing home dialysis payments would be a modest and prudent investment toward making such an increase occur.

RPA urges CMS to increase home dialysis training payments as part of its overall strategy to increase utilization of home dialysis modalities.

Exclusion of Non-Medicare Beneficiaries from Transplant Attribution

In the proposed rule, CMS states that it considered non-Medicare beneficiary pre-emptive transplant patients for attribution, but notes that:

Due to data limitations about patients who are not Medicare beneficiaries, however, we concluded that we could not include patients who received pre-emptive transplants but were not Medicare beneficiaries in the construction of the transplant rate. Therefore, we are proposing to limit the definition of pre-emptive transplant beneficiary to include Medicare beneficiaries only.

RPA believes CMS should explore ways for overcoming the data limitations, given that majority of pre-emptive transplants occur in the non-Medicare eligible patient population, and this does represent a large cost-savings to Medicare.

RPA urges CMS to include non-Medicare beneficiaries in the definition of pre-emptive transplant beneficiary, in order to account for the preponderance of transplants occurring in the population.

Implementation of Payment Models in Geographies with Large Integrated Health Systems

CMS should address how participants in the ETC model will interact with large integrated health systems in geographies where many of the activities associated with determining modality choice, transitioning to home dialysis, or receiving a kidney transplant are controlled by the integrated health system. Presence of a large integrated health system will in many cases affect

the ability of nephrologists and dialysis facilities to impact decision making regarding home dialysis or transplantation, and this concern is not addressed in the proposed rule, particularly for the purposes of the PPA.

RPA urges CMS to address the interaction of ETC participants with large integrated health systems in those geographies where they exist pertaining to home dialysis and transplantation.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to CMS in its future work on innovative kidney care payment models. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

A handwritten signature in cursive script that reads "Jeffrey A. Perlmutter MD". The signature is written in black ink and includes a small arrow-like flourish at the end.

Jeffrey A. Perlmutter, MD
President