



September 16, 2019
Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma:

The Alliance for Home Dialysis (Alliance) appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments on the Proposed ESRD Treatment Choices (ETC) Model.

The Alliance is a coalition of kidney dialysis stakeholders representing patients, clinicians, providers, and industry. We have come together to promote activities and policies to facilitate treatment choice in dialysis care, while addressing systemic barriers that limit access for patients and their families to the many benefits of home dialysis.

We applaud the Administration's comprehensive commitment to the 37 million patients with chronic kidney disease and the more than 726,000 with ESRD. We believe that the success of any demonstration model depends on striking the right balance of appropriate incentives for health care providers and dialysis facilities to provide home dialysis treatment, support to patients who may be interested in home treatments, and minimization of unintended consequences for existing dialysis patients. The Alliance for Home Dialysis stands ready to work with the Administration towards final design and implementation of its plan. To that end, we offer the following comments, which are designed to be constructive as the Administration continues to invest in kidney patients.

I. Model Scope and Implementation Date

The Alliance urges CMS to consider modifications to the overall scope of the model, as well as the start date. We are concerned that requiring 50% of the country to participate in the model will impose changes to the system at an unsustainable pace. While we are not in a position to suggest a more appropriate percentage, we believe that a smaller, nimbler model will ultimately be more valuable and can be expanded over time. Further, we understand from our facility and clinician members that they will need time to adequately prepare for the implementation of any model. We urge you to begin the model no earlier than April 2020.

II. Facility Level Scoring

1. The Alliance urges CMS to consider market level scoring, moving away from scoring at a facility level.

Successful home dialysis – both for an individual patient, and a program of patients- requires important elements. These include adequate numbers of specialized staff to offer home training to patients and caregivers, and experienced administrators able to identify potential issues and handle them adeptly. Therefore, when patients choose a home modality, they are referred to facilities that are specifically certified to offer home training and support. Studies have shown that home patients typically have better outcomes when they are treated at facilities that have higher volumes of home patients overall. We believe that a successful model to increase home dialysis would center around these specialized facilities while offering long term support and incentives to facilities interested in home programs.

However, the ETC model proposes a less efficient and effective design. It proposes facility level scoring to better incent “ESRD facilities within the same company in the same HHR to provide the same level of care to all attributed beneficiaries.” Under the model as written, facilities certified to offer only in-center treatment will not have any attributed home dialysis beneficiaries - even if staff at those facilities are highly effective at encouraging patients to choose a home modality - because they are referred outside the clinic.

While we agree that all patients deserve high quality care, we are concerned that incenting every facility to offer a home option will not actually result in better outcomes for patients. Instead, we are concerned that such a change will lead to less efficient structure within dialysis organizations and a move away from the current “center of excellence” approach that provides patients specialized home dialysis training and support in facilities designed to accommodate such services. In order to alleviate these concerns, the Alliance would urge CMS to consider evaluation at the market level, instead of at the level of individual facilities.

2. The Alliance is concerned that the proposed scoring may have unintended consequences related to companies that provide only home dialysis.

The Alliance is concerned that as the model is currently structured, companies that provide only home dialysis with no in-center option, often called “home-onlys,” will have only upside opportunity with no downside risk that could result in a monetary penalty for poor performance when participating in the model. While home-onlys certainly have an important role to play in dialysis care, we want to make sure that the Model treats each kind of facility fairly and that everyone begins on equal footing.

Specifically, we are concerned that the model will inadvertently incentivize practices known as lemon-dropping and cherry-picking. In practice, these euphemisms refer to what occurs when facilities have a financial incentive *not* to provide care for some patients, meaning those patients are dropped and healthier ones are chosen or retained. If facilities are inadvertently encouraged to do cherry-pick or lemon-drop through this model, patient care will suffer, while the facilities engaging in the practice are still able to be rewarded through the financial incentives within the system. Further, we are concerned that if lemon-dropping occurs at the home-only level, those patients will be funneled into providers who offer both in-center and home modalities, which could negatively impact these facilities’ scores, even though they are the only ones willing to care for these patients.

3. The Alliance urges CMS to take into account the contractual arrangements that allow many academic medical centers to provide home dialysis.

Currently, many academic medical centers contract with so-called centers of excellence to place patients into home dialysis therapy. Many of these academic medical centers previously had small, but ineffective, home dialysis units, but began sending patients to centers of excellence so that they could receive more advanced care in a more cost-effective manner. Under these arrangements, patients typically receive physician care from an academic medical center nephrologist, but receive their dialysis care from a contracted facility. This method works well.

The Alliance is concerned that the model as drafted will not consider these academic medical centers to have home programs, although in practice, as explained above, they do. We worry that if space is not created for these contractual arrangements to “count” for purposes of the model, that academic medical centers will be incentivized to bring patients back into their own facilities, thereby decreasing efficiency and reducing patient care.

III. Reliability Adjustment

1. The Alliance requests additional transparency for the reliability adjustment methodology.

While the Alliance appreciates that any reliability adjustment calculation is inherently complex, we are concerned that lack of transparency into the modeling underlying the methodology will make it difficult for facilities and clinicians to adequately plan, or act in response to their scores. Specifically, we believe there would be value in CMS performing an analysis to identify how Aggregation Group performance might impair the reliability adjustment. The results of such an analysis are likely to show that some Aggregation Groups are small enough that a reliability adjuster will distort the results and not accurately reflect the performances of small dialysis programs. Ideally, the results of such an analysis could inform a strategy to match smaller HRRs together or consolidate HRRs as necessary.

Specifically, we would appreciate clarification related to the following portion of the ETC proposed rule:

*We acknowledge that for some segments of the dialysis market, companies operating ESRD facilities may operate specific ESRD facilities that focus on home dialysis, which furnish home dialysis services to all patients receiving home dialysis through that company in a given area. Therefore, assessing home dialysis rates at the individual ESRD facility level may not accurately reflect access to home dialysis for beneficiaries receiving care from a specific company in the area. We believe that the reliability adjustment approach would help to address this concern, because the construction of the reliability adjustment for subsidiary ESRD facilities would aggregate to the company level within a given HRR and thus incorporate this dynamic. **We considered using a single aggregated home dialysis rate for all ESRD facilities owned in whole or in part by the same company within a given HRR to account for this market dynamic. However, we concluded that producing individual ESRD facility rates and reliability adjusting individual ESRD facility scores would be necessary to incentivize ESRD facilities within the same company in the same HRR to provide the same level of care to all of their attributed beneficiaries.***

The Alliance is concerned that the bolded section above will have the effect of requiring every dialysis unit to have a home training program for home dialysis (both home hemodialysis and peritoneal

dialysis). Similar to the comment I(1) above, while we are in favor of expanded access to home dialysis, we are concerned that this would change the care paradigm from centering around “centers of excellence” to any facility regardless of their capability to provide adequate home dialysis care. This change would exacerbate several issues that already contribute to the low uptake of home dialysis, such as nursing workforce shortages and onerous state-level requirements necessary to open a new home dialysis program or expand an existing one.

IV. ETC Model Patient Selection Criteria

While the Alliance believes that home dialysis should be offered to each and every ESRD patient as a modality option, we also understand that home therapy is not appropriate for every patient. We are concerned that the ETC Model as written will unintentionally force facilities to attempt to make home dialysis work for patients for whom it is not the optimal therapy, such as the homeless or others who do not have an adequate living situation, patients who are frail, or patients who do not have the mental capacity to perform treatment themselves. We are also concerned that the model may penalize facilities who allow these patients to pursue in-center dialysis without trying home therapy first. We do not propose excluding these patients from the model entirely, as some of them will be able to perform home therapy, but would instead offer the following solutions:

1. In-center self-care dialysis is a stepping-stone to home dialysis and accordingly, should be compensated as such in the ETC Model.

The Alliance urges CMS to consider adding incentives for in-center self-care dialysis to the ETC Model. While some patients are unable to perform home dialysis, many of these patients still desire the increased independence, flexibility, and control that home therapy can bring. For these patients, self-care dialysis can be a good compromise, because it allows them to manage many aspects of their therapy on their own, but still have immediate access to medical professionals in-center if needed. In addition, self-care dialysis can often serve as a stepping-stone to home dialysis for patients who need additional time to learn the procedures related to home therapy or gain confidence that home dialysis is the right path for them.

In our view, the current definition in the CMS Conditions for Coverage should be modified to provide greater specificity around self-care dialysis. We suggest the following definition: Dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a) of this part. At a minimum, a self-care patient, with the dialysis machine turned toward them should:

- Set up and take down the equipment used in the treatment;
- Touch the machine during treatment and respond to alarms;
- Manage access site pre- and post-treatment, with or without self-cannulation; and
- Take and record their own weight and vital signs.

Specifically related to the ETC Model, we believe that CMS could incentivize additional self-care dialysis in any of the following three ways:

- CMS could add in-center self-care dialysis to the “numerator,” which would mean that these patients are counted as home patients for the purpose of the HDPA and the PPA;

- CMS could remove in-center self-care patients from the “denominator” in the Model, which would mean that these patients cannot count against facilities in calculation of the home dialysis payment adjustment (HDP) and the performance payment adjustment (PPA); or
 - CMS could create a separate benchmark for self-care dialysis separate from the home dialysis benchmarks in the model and award facilities for progress toward this benchmark.
2. The Alliance is concerned that the exclusion of all patients with a dementia diagnosis from the model removes some patients who could be appropriate candidates for home dialysis.

While the Alliance understands that not all patients with dementia, especially those with advanced dementia, will be appropriate candidates for home dialysis, our clinicians believe that a blanket exclusion of all patients with a dementia diagnosis is too broad. Many of our nephrologist members treat patients with dementia who dialyze at home, especially those who are determined to have only “mild cognitive impairment,” but may still have a dementia diagnosis for coding purposes. We believe that instead of removing all of these patients from the model, CMS should allow physicians the discretion of determining whether such patients are appropriate candidates for home therapy or not.

V. Financial Incentives

1. The Alliance suggests that financial incentives be modified in order to minimize unintended impact on smaller facilities.

While payment is certainly not the only motivating factor related to referring patients for home dialysis, the Alliance is concerned that the HDP upward adjustment is too small to be impactful, especially when combined with the large downward adjustment in the PPA.

Specifically, we believe that the PPA margins should be refined from +11% to -13% to narrower margins of +2.75% to -3.25%. The average here would still be -.9%, but the full downside would be less severe and therefore less likely to result in facility closure, which is possible under the current percentages. The percentages we propose are close to the percentages utilized in the ESRD Quality Incentive Program (QIP), which have proven to drive behavior and create change- even without a reward for improvement. We believe that the QIP can serve as a good model for the ETC Model since it has been so successful in creating and sustaining behavior change. Further, the Alliance is concerned that many of our smaller members will need to expend substantial capital in order to prepare for participation in the model. For example, facilities and clinician groups will likely need to hire nephrology nurses, build or expand training space, and increase administrative capabilities. All of this preparation will require large outlays at the front end of the Model.

The Alliance offers the following additional policy options, which would help alleviate these problems:

- CMS could maintain the 3% HDP increase for the duration of the model;
- An up-front payment for facilities that prove they must expend significant capital to comply with the model;
- Home training claims, under condition code 73, could be removed from the numerator as while they are technically in-center claims, they are for the purpose of home dialysis initiation;
- When the PPA cut is applied to a facility’s payments, any payments for home dialysis treatments could be excluded; and/or

- The PPA could be delayed by one year.

VI. ETC Model Waivers

1. The Alliance believes that CMS' expansion of the Kidney Disease Education (KDE) benefit will contribute to the overall success of the model, but further changes could accomplish even more.

The Alliance was encouraged to see that CMS expanded the KDE benefit to include patients with Stage 5 CKD as well as the clinicians eligible to provide the benefit. We have advocated for these changes for many years and appreciate that the voices of our patients, clinicians, and facilities were heard. In addition, we were pleased to see that CMS will allow KDE to be provided to incidence dialysis patients within 6 months of dialysis initiation. We believe that these first few months of therapy are critical to whether a patient is successful at a home modality, and the increased opportunity for education will be instrumental in helping these patients succeed.

However, there is still more that CMS can do in order to incentivize upstream education for patients with CKD.

- a. CMS should consider waiving the coinsurance requirements associated with KDE.

Currently, Medicare beneficiaries are responsible for the 20 percent coinsurance requirement associated with KDE as a Part B benefit. In general, Medicare pays 80 percent of the approved amount for a Part B covered service in excess of the annual deductible, and the beneficiary is liable for the remaining 20 percent. For some beneficiaries, the 20 percent coinsurance is prohibitive to accessing the services. The Alliance recommends that CMS waive the coinsurance requirement that would otherwise be applicable under section 1833(a)(1) of the Social Security Act with respect to KDE services for beneficiaries. Doing so would allow more beneficiaries to access KDE services.

- b. CMS should allow dialysis facilities to bill for KDE.

In order to further expand the uptake of KDE, which as CMS knows, is utilized by less than 2% of eligible Medicare beneficiaries according to the United States Renal Data System (USRDS), CMS should allow dialysis facilities to bill for and be reimbursed for providing KDE.

2. CMS should waive certain Stark/anti-kickback rules, which would allow for better coordination of care between nephrologists, facilities, and others.

- a. CMS should clarify current Stark law issues related to clinician continuing medical education (CME).

Dialysis facilities often wish to provide home dialysis intensive training to affiliated clinicians- but are unable to do so due to either real or perceived legal hurdles. The Alliance believes that properly educating clinicians on home modalities- such that they feel comfortable and confident prescribing them- will play an important role in CMMI's stated desire to see increases in home dialysis uptake and retention.

While CMS has stated that free CME could qualify as remuneration to the physician under the Stark Law, CMS did clarify in a letter to the American Medical Association (AMA) that providing CME could fall

within Stark Law exceptions if appropriate safeguards are applicable. Specifically, facility physicians who wish to provide CME could potentially meet existing Stark exceptions that allow hospitals and other entities to provide non-monetary compensation, medical staff incidental benefits, or compliance training.

The letter noted:

The traditional, on-site hospital grand rounds and other similar in-house education programs provided by hospitals are important and convenient ways for physicians to earn CME credit and for hospitals to ensure high quality patient care. We do not believe that such programs, which historically have been provided on-site at no charge, necessarily constitute remuneration to the physicians who attend them. To clarify further, for purposes of our physician self-referral rules, we do not consider on-site CME to be remuneration if it is primarily for the benefit of the hospital's patients, for example, training on the prevention of nosocomial infection. However, CME that is not primarily for the benefit of the hospital's patients is considered remuneration. Where a hospital or physician is uncertain as to whether CME would be primarily for the benefit of the hospital's patients, the hospital or physician may request an advisory opinion in accordance with the procedures set forth at 42 CFR section 411.370.11.

While this clarification appears to allow free or discounted CME to be provided, this information was provided via sub-regulatory guidance rather than in the more explicit regulatory text, which may confuse some entities seeking to provide CME. In addition, the guidance fails to address what would not be a benefit for patients, only addresses hospitals (rather than all facilities), and also fails to discuss the intersection between the Stark law and AKS requirements. These complexities are likely to further discourage entities seeking to provide free CME, even if potentially allowable.

The Alliance urges CMMI to clarify these important Stark Law related CME issues in the ETC Model.

- b. The Alliance would encourage CMS to consider waiving other Stark Law provisions in order to better prepare patients for dialysis and retain them on home therapy once they start.

Certain items that would help better prepare patients for dialysis initiation, whether at home or in-center are currently prohibited under Stark and anti-kickback laws. Specifically, the Alliance would urge CMS to consider waiving the prohibition of dialysis facilities from providing CKD care management and coordination services. In addition, the Alliance would urge CMS to waive the prohibition against allowing caregiver support and transportation assistance to be provided to patients on dialysis- since these types of support can often help keep patients at home longer.

VII. Risk Adjustment

1. The Alliance is concerned about importing the CMS-HCC risk adjustment model into a fee for service model given the unique characteristics of the kidney patient population.

Specifically, we have concerns that the CMS-HCC ESRD risk adjustment methodology is unvalidated for use in the context of this model. The proposed rule indicates that CMS used an internal analysis to show that home dialysis patients have lower HCC risk scores than in-center patients. This is plausible, of course, because home dialysis patients tend to be younger and have less comorbidity, so their total cost of care under Parts A and B is lower.

While the CMS-HCC risk-adjustment measure controls for patient severity, it does not address non-clinical dynamics of a patient's circumstances that may impede home dialysis, such as socioeconomic status (SES) or more directly, housing insecurity. In fact, CMS requested comments from the stakeholder community on ways to address housing insecurity when measuring the home dialysis rate. The Alliance believes that more effective measures can be found in existing programs.

In the Hospital Readmission Reduction Program (HRRP), CMS has implemented an adjustment to control for hospitals providing a high level of indigent care and therefore at an initial disadvantage in the HRRP. To carry out the SES risk-adjustment, CMS stratified hospitals into five peer groups, or quintiles, based on the proportion of dual-eligible stays (a proxy measure for patient population SES). Individual hospital performance in readmission metrics was compared to the median value for each peer group, as opposed to the national value.

A similar method could be implemented for the home dialysis rate. The proportion of dual-eligible attributed beneficiary-years may serve well as a proxy measure of housing insecurity at the provider level. The proportion of dual-eligible beneficiary-years could be used to determine a factor by which to adjust the home dialysis rate up or down. Alternatively, the dual eligible amount could be used to determine stratification cut points and compare a provider to a more relevant benchmark value.

VIII. Geographic Selection

The Alliance is concerned that utilizing hospital referral regions to divide the country for participation in the model ignores important distinctions between urban and rural areas, which face different challenges related to the uptake of home dialysis. We are concerned that requiring urban and rural areas to meet the same achievement metrics does not account for their unique characteristics. Further, we urge CMS to consider circumstances in which patients live in a different zip code from where they receive their dialysis, which may impact the geographic spread within the model.

IX. Home Rate Limiting Factors other than Payment

While the Alliance appreciates that financial considerations have a big role in incentivizing home dialysis uptake, we also remain convinced that many non-payment factors impact uptake as well. We urge CMS to consider the impact of the following issues as you continue to work on the model:

- Many of our members report a nephrology nursing shortage across their facilities, including home dialysis nurses. As home dialysis rates increase due to the model, we urge CMS to consider ways to simultaneously increase staffing and education of the nephrology staff to adequately provide for the expected new home dialysis patients. Creating a campaign that promotes the unique roles in nephrology practice is a starting point to consider.
- The Alliance is concerned that if new dialysis units need to open, or current facilities need to implement home programs, they could run into timing issues due to long federal survey and certification procedures as well as state certificate of need processes. The Alliance urges CMS to consider expedited processes and additional resources for certification.
- We believe that in order to increase rates of peritoneal dialysis (PD), we must incentivize the placement of PD catheters. Currently, our clinicians report that both the lack of available and qualified surgeons plus the lack of appropriate operating room time stands in the way of timely

PD catheter placement. We urge CMS to consider ways to break down these barriers to PD uptake.

X. Targeted Review and Due Process Considerations

The Alliance appreciates the due process considerations built into the proposed rule, but would offer the following suggestions:

The proposed rule acknowledges that if CMS were to compress the duration of the overall targeted review process in order to conclude before the PPA period in which the MPS in question sets the PPA, the time allotted would be insufficient for ETC Participants to review their MPS, consider the possibility of a calculation or data error, request a targeted review (within 60 days), and provide additional information upon request. Therefore, CMS proposes to simply resolve any payment discrepancy during the next PPA period following notification of an MPS error.

While we understand the fact that a payment discrepancy may require resolution in a subsequent year, we believe that CMS has correctly identified a serious timing concern that our stakeholders share, and that is the 60-day period for ETC Participants to review their MPS for possible calculation or data errors. 60 days is still an inadequate amount of time for an ETC Participant in this mandatory model to receive, review, and identify possible calculation or data errors. 90 days is more realistic.

Our stakeholders will need to operationalize this important process both at a staff and leadership level. Completing an accurate and meaningful review of the MPS will take some time to complete, and 60 days is inadequate to perform such a review, analyze the results, consult externally if necessary, and submit a formal request to CMS for a targeted review. This is particularly true because the ETC Model is a new, mandatory model, and because the MPS is a critical statistic to set the PPA going forward. We believe that our stakeholders must invest an adequate amount of time and energy in the early years of this model in order to achieve success and to assist CMS's interests in collecting accurate data from participants.

Additionally, a 90-day time period only enlarges the 60-day period of time for ETC Participants to receive, review, and identify possible calculation or data errors by 30 days. We think this is a modest enlargement of time under the circumstances and if payment errors must be resolved in a subsequent PPA period, we can see no practical reason to refuse an additional 30-days for ETC Participants.

The Alliance appreciates the opportunity to provide comments to the ETC Model proposed rule. We are eager to continue to serve as a resource for CMS as you work to increase access to all dialysis modalities. Please do not hesitate to reach out to Alliance members or staff to discuss how we can work together. Please contact Michelle Seger at michelle@homedialysisalliance.org or 202-466-8700 if you have any questions.

Sincerely,

A handwritten signature in cursive script that reads "Elizabeth Lee".

Elizabeth Lee
Executive Director
Alliance for Home Dialysis



Alliance for Home Dialysis 2019 Members

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American Kidney Fund
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