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New York, NY 10016

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Fax 212.689.9261
www.kidney.org

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Room 314G
Hubert H. Humphrey Building,
200 Independence Avenue, SW
Washington, DC 20201

September 16, 2019

Re: File Code CMS-5527-P; Medicare Program; Specialty Care Models To Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma,

The National Kidney Foundation (NKF) appreciates the publication of the proposed rule on the ESRD Treatment Choices (ETC) Model. NKF shares the goals of the ETC Model to enhance patient access to home dialysis and kidney transplantation, ensuring that patients have free choice to select the treatment that best aligns with their goals for treatment. However, we have serious concerns that, as proposed, the Model may adversely affect choice and access for some patients, as well as patient safety. NKF supports implementation of the Model with the proposed modifications to improve its patient-centricity.

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

NKF appreciates that the aggressive goals of the ETC Model are intended to shift incentives toward home dialysis and transplantation and away from in-center dialysis as the default treatment option for U.S. ESRD patients, thereby enhancing patient choice while generating savings for Medicare. While these goals are commendable, we believe that the proposed approach may unintentionally harm patients. The Model must balance on a fine line of appropriately encouraging uptake of home dialysis and transplants in patients interested in these modalities without significantly constraining patient access to in-center dialysis or coercing patients not suitable for them into home dialysis and transplantation.

Our subsequent comments provide numerous recommendations for how to protect patients' quality of care by easing the transition into the Model, providing more support for Managing Clinicians (MCs) and facilities as they transition more patients to home dialysis and transplants, strengthening patient

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protections in the Model, including a shared decision-making quality measure, improving the methodology, and considering whether an achievement benchmark based on an 80 percent combined rate of home dialysis and transplant in MY 9 and 10 may negatively impact patient choice. In conjunction, we recommend waiving the 20 percent coinsurance on home dialysis treatments. This combination of modifications to the Model and additional empowering incentive balances our shared desire to shift the treatment paradigm for ESRD patients with the need to ensure that patient choice, access, and safety are preserved in the Model.

Though we do support this Model, in general we believe that CMS' efforts must reach beyond mandated penalties that force cuts in Medicare spending on dialysis care to supporting a broader and desperately needed transformation in kidney care. While NKF believes that adjusting payments to providers and facilities to improve home dialysis and transplant rates are elements of this vision, doing so should be coupled with education and support earlier in CKD to prevent mortality and progression to ESRD. Providing adequate payment incentives to support this upfront transformation, rather than focusing on payments for dialysis care alone, will better enable patients to make treatment decisions that align with their goals and preferences, whether the selected modality is home dialysis, transplantation, in-center dialysis or another alternative. A patient-centered model that empowers patients earlier on in their disease to select the treatment that is right for them results in better outcomes and thus is the best overall approach to achieving CMMI's stated goal of "enhancing beneficiary choice, independence, and quality of life."[1]

In 2015, NKF began work on the CKD Intercept (CKDI) Model, which addresses the need for better management of patients earlier in CKD progression by bringing primary care and nephrology practitioners together to co-manage patients.[2] While we recognize that CMMI intends to release voluntary models that will extend new kidney care payment models to patients with CKD Stages 4 and 5 who are not yet on dialysis, the details have not yet fully been released. We remain concerned that unless CMMI addresses earlier identification and diagnosis of CKD in primary care settings, patients will continue to experience high rates of mortality and crashes into dialysis having little to no prior knowledge of their kidney disease nor their treatment options. This minimizes the opportunity for patients to get waitlisted for a transplant and seek out a kidney donor early or to choose home dialysis. We encourage CMMI to continue to evaluate opportunities across its primary care models to incorporate early CKD care and to ensure that nephrology models extending to patients with CKD Stages 4 and 5 have adequate resources to support the intensive management and education that patients will need in order to be empowered to make shared decisions with their clinicians about their treatments.

NKF agrees with CMMI that payment incentives have a role in achieving higher value care for kidney patients. Aligning the reimbursement for in-center dialysis with home-based modalities appears to have influenced the uptake of peritoneal dialysis (PD), demonstrating that financial incentives drive behavior change. NKF's comments on the forthcoming voluntary models will highlight the need to appropriately

[1] https://www.regulations.gov/document?D=CMS-2019-0101-0001
[2] https://www.kidney.org/sites/default/files/20180924_ckdi-o_final.pdf

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fund the payment adjustments needed to achieve the goal of more comprehensive and intensive care of patients with CKD Stages 4 and 5, specifically limiting inappropriately early dialysis starts and subsequent dialysis-related complications. We look forward to reviewing the details of CMMI's voluntary kidney models, which would employ a similar strategy to our CKDI model of improving the care of patients with advanced CKD by applying strong financial incentives to improve the infrastructure supporting the care of patients with CKD 4 and 5 and providing the opportunity for patients to participate in shared decision-making.

We also note that the payment adjustments may not be sufficient to overcome barriers inhibiting the uptake of home dialysis and improvements in the transplant rate, for example, the shortage in trained home dialysis nurses and numerous challenges associated with increasing the supply of organs for transplant, many of which are not directly within the control of participants selected for the Model as currently proposed. In 2017 the National Kidney Foundation's KDOQI began a two-part home dialysis controversies conference series that outlined the many barriers, including financial ones, that limit uptake of home dialysis. The report from the first conference, published in March of 2019, detailed these many barriers while the second conference, held in November of 2018, discussed solutions.[3] Publication of the report from the second conference is pending, but the recommendations outline the infrastructure, patient support, clinician support, and education that is necessary to enable a patient-centered approach to increasing home dialysis.

NKF reiterates our support for the goals of the ETC Model and our appreciation for CMMI's attention to ESRD patients. The following comments follow the outline of recommendations provided below and outline NKF's position on how the ETC Model can and should be strengthened.

Summary Recommendations

- Include a provision in the Model that would allow clinicians and ESRD facilities who would like to participate to opt into the intervention group.
- Increase the Clinician HDPA, so physicians billing the home dialysis MCP are paid at least the sum of the HDPA and the MCP for four or more in-center hemodialysis visits. After the HDPA concludes, physicians billing the home dialysis MCP should be paid at least the MCP for four or more in-center hemodialysis visits. Additionally, consider increasing the Facility HDPA.
- Delay implementation of the Performance Payment Adjustment (PPA) downside risk until Measurement Year (MY) 4 beginning 7/1/2021.
- Develop and include a measure of shared decision-making and additional shared decision-making tools in the Model in order to protect patient choice and improve patient understanding of their treatment options.

[3] Chan, C. T., Wallace, E., Golper, T. A., Rosner, M. H., Seshasai, R. K., Glickman, J. D., . . . Rocco, M. V. (2019). Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report. *American Journal of Kidney Diseases, 73*(3), 363-371. doi:https://doi.org/10.1053/j.ajkd.2018.09.015

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- Address homelessness and housing insecurity in the Model by capturing in-center self-dialysis in the numerator of the transplant rate with a modifier code applied to claims for treatment. The Medicare Claims Processing Manual, Chapter 8, lists in-center self-care with a condition code of 72 and self-care in training with a condition code of 73.
- Couple transplant rate weighted at 30 percent of Modality Performance Score (MPS) with delay in PPA downside risk, system-wide improvements in the availability of organs for transplant, enhanced patient protections, and accountability in the Model for regional variation in transplant rates.
- Develop a unique risk adjustment model for the home dialysis rate.
- Aggregate facility performance to the company level.
- Create a mechanism for small and low-volume facilities to aggregate their performance to a virtual group.
- Raise the achievement benchmark each year at a rate that is reasonable based on historic performance. Consider revising the 80 percent benchmark if, based on trends in the Model, it appears to be adversely impacting patient access to their preferred treatment modality.
- Consider alternatives to an achievement benchmark based on performance in comparison HRRs.
- Implement the Model with performance based on relative rather than absolute percentages.
- Enhance monitoring activities in the following areas: resource shifting between the comparator and intervention HRRs, lemon-dropping and cherry-picking patients who are more likely to receive a transplant, market exits and reduction of in-center chairs in small and low-volume facilities serving a critical need, rates of peritonitis, BSIs in home HD patients, and attrition from home dialysis.
- Waive 20 percent coinsurance for home dialysis treatments.

ETC Participants

NKF supports CMMI's proposal for a comparator group design with a mandatory participation element for dialysis facilities and MCs in selected geographic areas. We agree that hospital referral regions (HRRs) can serve as the geographical unit by which providers are randomized. We are, however, open to other approaches to defining the geographical area such as Core-based Statistical Areas (CBSAs) with inclusion of rural areas as used in the Comprehensive ESRD Care Model.

We agree that the proposed study design will increase statistical power in evaluating whether adjustments to Medicare fee-for-service (FFS) payments result in higher rates of home dialysis and transplant, allowing for a robust evaluation of the Model's success. Given the structure of the dialysis market, we note the importance of evaluating impacts directly centered on patients in both the intervention and comparator groups throughout the Model and at its conclusion, in particular to assess the comparator group to ensure the Model is not adversely affecting the quality of care of patients in those regions. We elaborate on our concerns in the section "Monitoring" below.

NKF recommends an opt-in provision for the intervention group. Though we support the need for a level of randomization in the Model, we would point out that the assignment of HRRs for which 20 percent of

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the component zip codes are in Maryland indicates that the Model would not operate based on a faithfully randomized design. Given that there are already justifiable limitations to true randomization in the Model, we suggest CMMI consider whether MCs and dialysis facilities that would like to participate could opt into the intervention group. We do note that an opt-in provision would affect the stability of the control group benchmark throughout the Model.

Home Dialysis Payment Adjustment (HDPA)

While NKF supports both the Clinician and Facility Home Dialysis Payment Adjustment (HDPA), recognizing the value of an up-front positive incentive to support Model participants in choosing home dialysis, we are concerned that the proposed Clinician HDPA is not significant enough to overcome current payment incentives that favor home dialysis. As currently proposed, even at the 3% level, the HDPA does not equalize the MCP for a month of ESRD services provided to home dialysis patients with the MCP for ESRD services provided during four or more visits during the month. This continues the existing perverse incentive that favors in-center over home dialysis, as providers can see more patients in-center in the same or less time it takes to see a single patient in a different setting. We recommend that CMMI remove this incentive and equalize reimbursement for services provided to home and in-center patients by increasing the value of the HDPA such that, at the 3%, 2% and 1% levels, it is at least that respective percent higher than the MCP for ESRD services provided during four or more visits during the month, which in 2019 is $289.03.[4] In other words, at the conclusion of the 3-year HDPA period, the MCP for ESRD serviced provided to home patients and to patients at four or more visits during the month should be equal.

NKF is also concerned that the proposed Clinician HDPA is not adequate to support MCs in transitioning their patients to home-based modalities. Education and empowerment provided well before a patient crashes into dialysis are instrumental in improving the uptake of home dialysis. Nephrologists have the primary role in ensuring patients are educated about their choices of treatment modalities and helping patients understand and overcome perceived barriers to home dialysis. In general, NKF believes that nephrologists should have primary accountability for patients from advanced CKD, when they work to prevent and delay progression, through ESRD care, during which time they ensure the patient receives their preferred treatment modality throughout their kidney failure, recognizing that preferences in treatment may change over time. NKF continues to support the need for resources and, in general, a broader transformation of kidney care that enables these workflows.

A recent report from Shukla et al. demonstrated that structured, protocol based Comprehensive pre-ESRD Patient Education (CPE) integrated into routine nephrology care substantially improves informed choice and utilization of home dialysis.[5] The study further noted that the success of CPE is contingent upon establishing CPE resources within each nephrology practice. The HDPA 3% maximum adjustment in

[4] https://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx

[5] Shukla , A. M., Hinkamp , C., Segal , E., Baslanti , T. O., Martinez , T., Thomas , M., … Bozorgmehri, S. (2019). What do the US advanced kidney disease patients want? Comprehensive pre-ESRD Patient Education (CPE) and choice of dialysis modality. *PLoS ONE* , *14*(4). doi: https://doi.org/10.1371/journal.pone.0215091

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CY2022 amounts to a $7.26 increase per patient per month, which we do not believe is adequate to support providers in investing in the infrastructure needed to provide pre-dialysis education that gives patients the opportunity to select or transition successfully to home dialysis. We reiterate the above recommendation that the HDPA be increased at least equal to the MCP for ESRD services provided during four or more visits during the month plus the percentage increase of the HDPA as applied during the first three years of the Model. An additional recommendation is to increase the $500 physician's fee for self-dialysis training services and allow for that payment to be paid out in situations where retraining for patients is necessary.

NKF is additionally concerned that the maximum 3% adjustment under the Facility HDPA, which amounts to a $91.75 increase to dialysis facilities per patient per month, may be inadequate to support a sustainable transition to home dialysis.[6] Under the ESRD Facility Conditions of Coverage, dialysis nurses require additional training, including 12 months of experience as an RN and 3 months of experience in the specific home modality their patient will pursue, prior to being able to serve home dialysis patients. This challenge exists alongside the national shortage of dialysis nurses, which is already causing backlogs of patients waiting to begin home dialysis. Ensuring that facilities have the interdisciplinary staff needed to support patients in dialyzing at home is necessary to improve uptake by providing the education needed to support patients and caregivers in selecting home dialysis and overcoming common challenges that can lead to abandoning home therapies.

A more significant HDPA is required for both MCs and facilities, both of which have a role in increasing rates of home dialysis, however increasing the HDPA for MCs should be given priority.

Performance Payment Adjustment (PPA)

NKF generally supports the Clinician and Facility Performance Payment Adjustment (PPA). However, we strongly recommend delaying the implementation of the downside risk until Measurement Year (MY) 4 beginning 7/1/2021. We believe the delay is important to allow time for Managing Clinicians (MCs) and ESRD facilities to build infrastructure and gather the resources necessary to achieve the aggressive goals of the Model without risking closure of dialysis facilities and theoretically limiting patients' access to care, particularly in inner-city urban and rural areas where facility margins are low and housing instability issues prevalent.

1. Beneficiary Exclusions

   NKF believes that developing and including a shared decision-making quality measure and additional shared decision-making tools in the Model is the best approach to addressing both the barriers that CMMI proposes would lead to exclusion from attribution in the Model and the concern that beneficiaries may be inappropriately steered to home dialysis or transplants. We believe that there are very few clinical or other challenges that warrant up-front exclusion from

[6] Calculated based on the final CY2019 ESRD PPS base rate of $235.27 and 13 dialysis treatments per month

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New York, NY 10016

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the Model. Many perceived barriers to home dialysis and transplant are the result of bias and can be overcome with education, empowerment, caregiver support, and/or novel technology and tools. We agree that it may be appropriate to exclude patients with absolute medical contraindications to peritoneal dialysis (PD) or home hemodialysis (HHD). NKF reviewed clinical guidelines, decision support tools, and the peer-reviewed literature in order to identify contraindications to home dialysis but was unable to establish any consensus position on clinical conditions that would warrant up-front exclusion from the Model. Please see Appendix I for a summary of our review of the literature. To the extent that absolute contraindications and barriers to home dialysis are identified, they should be used to develop a unique risk adjustment methodology for the home dialysis rate. We elaborate on this recommendation in a subsequent section "Risk Adjustment Methodology."

Of significant concern to NKF is the potential for patients to feel pressured into a treatment modality that is not aligned with their preferences and goals for their care. Selection of renal replacement therapy (RRT) should be in alignment with opportunities to help patients achieve their lifestyle preferences, values and goals and we honor that in-center dialysis may be the modality that best achieves these objectives for some patients. We take the concerns raised by patients, caregivers, and providers that patients may be coerced or, due to lack of access to in-center dialysis, forced, into pursuing home dialysis seriously. Though we believe that with the right education and support, many patients can be empowered to select home dialysis and transplants, we do honor that starting on or falling back to in-center dialysis or not pursuing a transplant may be the right choice for others. While we have concerns about excluding these patients from the Model via an opt-out, we do believe the Model must include a shared decision-making measure and shared decision-making tools that will help safeguard patient choice by ensuring that patients are well-informed about their treatment options, meaningfully involved in decisions, and ultimately receive the treatment that is right for them. A shared decision-measure would allow CMMI to verify that patients are being empowered to freely select the treatment they prefer and allow for patients to re-evaluate these options regularly as their circumstances change over time. The shared decision-making quality measure should be implemented along with the revision to the 80% benchmark, which we reiterate is not reasonable and will increase the likelihood that patients feel pressured to select a treatment that is not in accordance with their preferences.

CMMI has existing authority to develop, test and deploy new quality measures in order to enhance its models. The inclusion of a shared decision-making measure would be aligned with numerous references to the value of shared decision-making in other CMMI models and with a shared decision-making model that CMMI had at one point developed. There are many available resources that CMMI can leverage as it develops the measure. The National Quality Forum (NQF) has developed the National Quality Partners Playbook™: Shared Decision Making in Healthcare, a guidance document to improve shared decision-making in healthcare delivery. Questionnaires like the Decision Conflict Scale could provide the basis for a patient reported outcome measure

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on shared decision-making in RRT selection.[7] Numerous resources and publications also highlight opportunities to evaluate the effectiveness of shared decision-making tools and patient decision aids. Sepucha et al. highlight an opportunity for developing quality measures based on the use of patient decision aids or a patient reported outcome measures. While the In-Center Hemodialysis CAHPS Survey (ICH CAHPS) includes questions related to home modality options and transplantation, the questions are not framed in a manner that allows for assessment of shared decision-making and the survey is limited to only patients on in-center dialysis. NKF would welcome the opportunity to collaborate with CMMI on the development of a shared decision-making measure for inclusion in the ETC Model. CMMI's development and use of a shared decision-making measure could also contribute the data to support its eventual inclusion in the Quality Incentive Program (QIP).

A shared decision-making measure and shared decision-making tools can drive forward significant improvements in patient understanding of their RRT options, improving the quality of patient education delivered and empowering patients to make, and stick with, decisions about their treatment options. This is especially valuable given the need in the Model to address the potential for attrition from home dialysis. Current shared decision-making tools for use in selecting RRT options already exist. Empowering Patients on Choices for Renal Replacement Therapy (EPOCH) was funded by the Patient Centered Outcomes Research Institute (PCORI) and tested whether the decision aid helped patents make more informed choices.[8] The Medical Education Institute also has an online assessment tool to help patients make lifestyle and value-based decisions about their dialysis options and discuss those choices and why with their nephrologists.[9]

Incorporating shared decision-making measures and tools into the ETC Model protects patient choice and access to care while improving patient understanding of their treatment options and thus is a key component to improving the patient-centricity of the Model. An easier, but less desirable, alternative to a shared decision-making measure is for CMMI to allow for patients to opt-out of the home dialysis rate and transplant rates if they choose to decline those options. As noted above, we do have concerns that this approach would not effectively empower patients to make informed decisions, however an opt-out is still preferable to proceeding with the current proposal, which will constrain patient access and patient choice.

2. <u>Home Dialysis Rate</u>

NKF supports the general construction of the home dialysis rate as proposed. We are gratified by CMMI's intent to include home patients receiving respite (backup) care in the facility in the numerator of total dialysis treatment beneficiary years during which attributed beneficiaries

[7] https://decisionaid.ohri.ca/eval_dcs.html
[8] https://choosingdialysis.org/DecisionTool.aspx
[9] https://mydialysischoice.org/

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receive dialysis at home. The ability for MCs and facilities to continue to be able to provision this backup care without penalty in the Model is critical for reducing patient and care partner burnout that often leads to home patients returning full time to in-center dialysis.

We note again our position that the Model must both support patients' access to their preferred treatment while accounting for patients who may face insurmountable barriers to home dialysis and/or transplants and should be excluded from the home dialysis rate. While we acknowledge the challenges of incorporating patients experiencing homelessness or housing insecurity in the home dialysis rate, we would point out that homelessness and housing insecurity are not absolute barriers to home dialysis.

In-center self-dialysis is a treatment option that is permitted under the ESRD Facilities Conditions for Coverage and could be considered an alternative to home dialysis. In this context, self-dialysis is defined by the Conditions for Coverage as "dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training."[10] In-center self-dialysis is currently a preferred treatment option to home dialysis for a small number of patients. We would, however, note that as currently practiced, in-center self-dialysis should not be considered an equal replacement to home dialysis for most patients since there is no clear path that allows in-center self-dialysis patients to perform dialysis on their own terms and thus benefit from the greater autonomy that home dialysis affords.

We appreciate CMMI's efforts to give patients experiencing homelessness and housing insecurity the opportunity to benefit from the Model. Should CMMI proceed with in-center self-dialysis as the mechanism to do so, we note that in-center self-dialysis could be captured in claims data with a modifier code applied to the treatment. The Medicare Claims Processing Manual, Chapter 8, lists in-center self-care with a condition code of 72 and self-care in training with a condition code of 73. We recommend that CMMI develop an instrument, in CROWNWeb or otherwise, to collect data on in-center self-dialysis, homelessness, and housing insecurity that can inform future modifications to the Model.

3. Transplant Rate

NKF supports including the transplant rate at a weight of 30 percent of the Modality Performance Score (MPS) for MCs and dialysis facilities in the Model. Our support for the proposed transplant rate is contingent upon delayed implementation of the PPA downside penalties, system-wide improvements in the availability of organs for transplant, enhancements to patient protections in the Model, and accountability in the Model for the wide regional variation in transplantation rates across the U.S by inclusion of a performance benchmark based on within HRR performance or a geographic adjuster for the Model.

[10] https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/ESRDfinalrule0415.pdf

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Most critically, we reiterate our request to delay implementation of the downside risk until Measurement Year (MY) 4 beginning 7/1/2021 to allow Model participants time to build the infrastructure and support necessary to be successful in increasing their rates of transplantation. Though dialysis facilities have key roles in improving the chances that a patient will receive a kidney transplant, for example improving education, referrals, helping patients understand the opportunity for a living donor, and helping to maintain adequate health status, the transplant center is the sole decision-maker regarding whether a patient is transplanted. We have serious concerns that without systemic improvements to the transplant landscape, facilities and MCs may have little ability to significantly impact transplant rates, leading to the application of financial penalties that could limit patient access.

NKF strongly supports the Administration's efforts, announced as part of the Advancing American Kidney Health initiative, to double the number of kidneys available for transplant by 2030 by increasing organ recovery from deceased donors and reducing the discard rate. However the full details of these efforts are not yet available and we are concerned about the possibility that, even when fully implemented, these efforts may not be sufficient to overcome other barriers to transplantation beyond the shortage of organs for transplant, many of which will continue to exist outside what can be directly influenced by facilities and MCs. We note that the CMS Office of the Actuary was unable to account for an increase in transplantation in its cost savings estimates, which further underscores our concern.

We are also concerned that the challenges facilities and MCs will face in increasing their transplant rates, compounded by the Model's short timeline and significant penalties, will create an incentive for dialysis facilities to compete on enrolling patients who are more likely to receive a transplant, thus exacerbating disparities in delivery and access to care. It will be imperative that CMMI both delay the PPA penalties and execute on its proposal to monitor lemon dropping and cherry picking of more and less clinically complex patients in order to mitigate these potential adverse consequences of the Model.

Despite our concerns, NKF does support implementing the Model with the transplant rate weighted at 30 percent of MPS. We recommend that CMMI revisit the weight of the rate within the MPS and adjust accordingly if little progress is seen over time. Doing so will ensure that MCs are dialysis facilities are not being unfairly penalized in the Model and that these penalties are not limiting patients' access to care.

Finally, we agree that preemptive transplants should receive credit in the Model and appreciate CMMI's recognition of the important role that MCs have in helping patients receive a preemptive transplant. However, we would request clarity as to why CMMI separates preemptive transplant recipients from ESRD beneficiaries. Under the ESRD program, kidney transplant recipients, regardless of age, are eligible for Medicare immediately at the date of transplantation with no three-month waiting period. While there can be a period during which enrollment and claims data back date to the date of transplant, these patients are considered ESRD beneficiaries if they enroll

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in Medicare. Medicare may be, during this time, secondary to commercial coverage for up to 30 months.

4. Risk Adjustment

NKF recommends that as appropriate exclusions from attribution in the Model are identified, they are used to develop a unique risk adjustment model for the home dialysis rate. The CMS–HCC ESRD Dialysis Model does not account for the many factors beyond the relative illness of a patient that may constitute barriers to home dialysis and therefore is not adequate for use in the Model. We note that CMMI developed a unique risk adjustment model for the Radiation Oncology (RO) Model announced in the notice of proposed rulemaking. We believe a unique risk adjustment model is additionally both feasible and necessary for the ETC Model. In doing so, we recommend that CMMI consult the list of possible contraindications to home dialysis as outlined in Appendix I.

5. Reliability Adjustment and Aggregation

NKF recommends that facility performance be aggregated to the company level. We are concerned that the proposed reliability adjustment methodology will compel dialysis companies to have home programs in nearly every dialysis facility in order to perform well in the Model when patients have adequate access to home dialysis through home-only clinics in the same company.

There are patient-centric and practical reasons for having an in-center only facility and offering home dialysis in another clinic. Patient-centric reasons for operating in-center only clinics include locating a facility in an area known for housing instability or living conditions that make it difficult for patients to do home dialysis, or locating them in assisted living communities to serve patients who may not be able or wish to do dialysis at home. On a pragmatic level, dialysis facilities have to be separately certified to provide home dialysis, which would place an added burden on facilities and CMS to ensure all facilities in the Model, including facilities that historically had patient-centric reasons for providing only in-center dialysis, are newly able to deliver home dialysis.

We recommend that CMMI create a mechanism for small and low-volume facilities to aggregate their performance to a virtual group, similarly to how Merit-based Incentive Payment System (MIPS)-eligible clinicians are able to pool their patient data with those of other practices, thereby leveling the playing field for smaller practices. We believe this may address concerns that aggregation at the company level may provide a consolidation advantage to larger dialysis organizations.

6. Benchmarking and Scoring

NKF recognizes the intent of the Model is to rapidly shift the incentives supporting the current paradigm of in-center dialysis as the default treatment option. Benchmarks in the Model should

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drive toward a result where facilities and MCs empower and support patients interested in home dialysis and transplants in selecting these modalities without creating incentives that inappropriately steer patients from their preferred treatment option. Though we want to encourage Model participants to improve uptake of home dialysis and transplants, we are concerned that tying the maximum achievement score in MY 9 and 10 to a combined home dialysis and transplant rate equivalent to 80 percent of attributed beneficiaries dialyzing at home and/or having received a transplant may constitute a threat to patient's free choice of the modality that aligns with their preferences and goals for treatment. We suggest that the benchmark be raised each year at a rate that is reasonable based on historic performance and that CMMI consider revising the 80 percent benchmark if, based on trends in the Model, it appears to be adversely impacting patient access and choice. In addition, CMMI should provide a transparent glide path from current performance to expected performance in MY 9 and 10, though the benchmarks should not be communicated to Model participants at the beginning of the MY as this will incentivize facilities and MCs to aim for a performance floor rather than competing to achieve higher performance.

We also note the CMS Office of the Actuary based its cost estimates on a maximum 25 percent increase in home dialysis, which is concerning as the cost savings appear to be a result of expecting that dialysis facilities and MCs will fail to meet the benchmark. NKF does not believe the Model should drive for failure to achieve payment savings to Medicare. A 25 percent increase in home dialysis is, however, consistent with a maximum achievement score based on a combined dialysis and transplant rate of 60 percent.

We are further concerned that basing the achievement benchmark on performance in comparison HRRs is problematic. We propose two alternative solutions: (1) to create a geographic risk adjuster for the Model or (2) to develop unique benchmarks for the HRRs assigned to the Model. We agree that a national benchmark for the Model would not drive performance improvement due to the limited competition among dialysis providers. However, we note that, because a benchmark based on comparison HRRs does not account for regional variation in organ availability and transplants that are beyond the control of MCs and facilities, it is vulnerable to cherry picking of patients who are most likely to choose and success on home dialysis and/or receive a transplant. This may leave patients in a position where they may struggle to access care at the facility of their choice. Either of our two recommended alternative solutions could address regional variation and mitigate this possible unintended consequence of the achievement benchmark as proposed.

Finally, we note that the proposed rule is not clear about whether the percentages on which performance is based are absolute or relative. NKF recommends that the Model be implemented with relative percentages, which will result in more modest goals that may allay some of the unintended consequences of the Model as described in these comments.

7. Low-Volume Threshold Exclusions for the PPA

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NKF opposes a low-threshold exclusion for ESRD facilities. We do believe that it is appropriate to exclude MCs billing the MCP for sufficiently small attributed beneficiary populations from the Clinician PPA. We recognize that the PPA may create challenges for smaller facilities that are less able to absorb potential risk and the impact this may have on patient access. We also agree with CMMI's assessment that excluding low-volume facilities increases statistical reliability. However, neither of these rationales nor both or in combination outweigh the need to promote home dialysis to patients in low-volume facilities who want it.

The issue of potentially inhibiting patient access, particularly in regions where there may be few or even a single dialysis provider, is non-trivial. We make our recommendation to remove the low-threshold exclusion for ESRD facilities in the context of great concern that small facilities serving a critical need, for example in rural areas, may be unable or unwilling to bear the PPA downside risk. Despite this concern, we understand that not all small facilities are equivalently risk averse and some are commonly owned, which may provide them with some financial cushion. In addition, smaller facilities would need to improve their home dialysis and transplant rates relatively less than a larger facility in order to benefit, so not all small facilities necessarily stand to lose in the Model. Our recommendation to create a mechanism for small and low-volume facilities to aggregate their performance to a virtual group will also strengthen the ability of these facilities to perform well in the Model. Finally, the delay we are proposing in the implementation of the downside risk for Clinician and Facility PPAs to MY 4 beginning 7/1/2021 will provide more time for Model participants, including smaller facilities, to ramp up their home dialysis programs in particular while spreading out the potential for financial losses.

A second issue pertains to how low-volume payment adjusters are applied in general. In our comments on the proposed 2019 ESRD PPS, we noted our concern that the ESRD PPS low-volume payment adjustment (LVPA) is being directed to facilities that are not serving a critical access need and recommended that CMS consider a tiered LVPA targeted to facilities that are both meeting such a critical access need while likely operating at a loss. We have similar concerns that excluding facilities based on volume alone may not be a sufficiently nuanced mechanism to account for facilities that are serving an important access need but that are unable to bear the downside financial risk. NKF would be pleased to work with CMS on alternatives to the low-volume exclusion that better capture these nuances while maintaining statistical soundness.

Although we remain concerned about potential impacts to patient access, our recommendation to aggregate to common ownership will eliminate the need for a low-volume adjuster for statistical accuracy in nearly all cases. In the few cases where small facilities are not commonly owned, we believe the value of ensuring that small facilities offer PD and HHD to patients interested in these modalities outweigh any theoretical consequences.

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However, NKF does encourage CMS to include evaluating market exits and reductions in available in-center chairs in its monitoring activities if impacts to small facilities do begin to impinge upon patient access.

Given the significant penalties and lack of resources provided in the Model as proposed, we agree that the bottom 5% of clinicians should be exempt. However, they should be able to opt into the Model if they so choose.

Medicare Program Waivers

NKF echoes our support for waiving the 20 percent coinsurance on home dialysis treatments. Patients in countries with higher home dialysis rates often pay to do in-center dialysis, which is how rates like those CMMI aims to achieve are possible. As constructed, patients do not have different coinsurance obligations in the Model. NKF recommends waiving the coinsurance on home dialysis treatments in order to provide a judicious incentive that is likely to improve uptake of home dialysis while preserving patient choice. We agree that the application of the payment adjustments themselves should not affect beneficiary cost sharing.

NKF appreciates and supports CMMI in waiving the requirement that Kidney Disease Education (KDE) be covered only for Stage 4 CKD patients, expanding the benefit to Stage 5 CKD patients and to patients in their first six months of dialysis, as well as expanding the types of providers who are able to furnish KDE. We agree that KDE is a valuable tool for educating and empowering patients about their treatment options, however, note that this education is most effectively provided prior to a patient initiating dialysis. NKF would be pleased to work with CMS to discuss how to improve uptake of KDE.

Monitoring

As we have elaborated on in this letter, the potential for unintended, but adverse, consequences in the Model is high. Even if the Model is implemented with the modifications we propose, CMMI must be vigilant about carrying out robust monitoring activities. NKF agrees with the proposed monitoring activities and strategy outlined in the proposed rule, however, recommend the addition of a peritonitis monitoring measures to the Standardized Mortality Ratio and Standardized Hospitalization Ratio. We strongly encourages CMMI to pay special attention to the areas where we believe the potential for unfavorable impacts is very likely, namely resource shifting between the comparator and intervention HRRs, lemon-dropping and cherry-picking patients who are more likely to receive a transplant, market exits and reduction of in-center chairs in small and low-volume facilities serving a critical need, rates of peritonitis, BSIs in home HD patients, and attrition from home dialysis.

Learning System

NKF strongly supports the proposed transplant learning system, which we have long advocated for and believe is vital to increasing the supply of organs for transplant. A key finding of the National Kidney

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Foundation Consensus Conference to Reduce Kidney Discards was the urgent need for collaborative efforts to maximize the utilization of available kidneys. We believe that bringing Model participants, transplant centers, OPOs, and large donor hospitals together to identify and spread best practices from high performers is the right approach to realizing system-wide improvements in the transplant system. Should the proposed learning system be finalized, NKF will be pleased to continue working with CMS on its patient engagement strategy to help reduce discards and ultimately increase the number of transplants.

The National Kidney Foundation is gratified by CMMI's efforts to improve the care of patients with kidney disease. We look forward to working with CMMI on the issues raised in this letter as we work to advance our shared goals on behalf of ESRD beneficiaries. We would welcome the opportunity to discuss our position on the ETC Model. Please contact Kerry Willis, Chief Scientific Officer, at kerryw@kidney.org and Miriam Godwin, Health Policy Analyst, at miriam.godwin@kidney.org.

Sincerely,

Kevin Longino
Kevin Longino
CEO and transplant patient

Holly Mattix Kramer
Holly Mattix Kramer, MD, MPH
President

National Kidney Foundation®

30 E. 33rd Street
New York, NY 10016

Tel 212.889.2210
Fax 212.689.9261
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Appendix I.

Potential Barriers to PD				
		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: UpTo Date[11]				
	Lack of functional peritoneal membrane	Yes, absolute contraindication		**Contraindication to PD**
	Significant risk factors for adhesions	Yes, possible barrier	Yes, refer to laparoscopy with simultaneous adhesiolysis. Note that very few surgeons are trained or willing to do this procedure for PD, particularly when adhesions are extensive.	**Possible contraindication to PD**
	Advanced peritoneal scarring that cannot be corrected with surgical adhesiolysis	Yes, possible barrier		**Possible contraindication to PD**

[11] https://www.uptodate.com/contents/evaluating-patients-for-chronic-peritoneal-dialysis-and-selection-of-modality?search=peritoneal%20dialysis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

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	Physical impairment (amputation, physical debility) with no available caregiver	Yes, possible barrier	Yes, assisted peritoneal dialysis available in some areas	
	Lack of cognitive ability of patient and available caregiver	Yes, possible barrier	Yes, assisted peritoneal dialysis available in some areas	
	Severe developmental delay	Yes, possible barrier	Yes, caregiver assist and CAPD (avoid cycler)	
	Lack of appropriate environment	Yes, possible barrier	Unknown	**Possible contraindication to PD**
	Patient in skilled nursing facility (many do not allow)	Yes, possible barrier	Some may allow	
	Large patient size	Yes, possible barrier	Yes, change PD prescription	
	Active inflammatory process or cancer	Yes, possible barrier	No but benefits may outweigh risks for individual patient	**Possible contraindication to PD in some patients**
	Surgical ostomies	Yes, possible barrier	Yes, use presternal catheter	
	Large abdominal wall hernia	Yes, possible barrier	Yes, can be corrected with surgery during or prior to catheter placement	
	Ventriculoperitoneal shunt	Yes, possible barrier	No but benefits may outweigh risks for individual patient	**Possible contraindication to PD in some patients**
		Possible Barrier to Self PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source MATCH-D[12]				

[12] https://homedialysis.org/documents/pros/MATCH-D-v4.pdf

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	Homeless and no supply storage available	Yes, possible barrier	Yes – refer to social services; reassess PD when housed	
	Unable to maintain personal hygiene even after education	Yes, possible barrier		**Possible contraindication to self PD**
	Home unclean/health hazard; patient/family won't correct	Yes, possible barrier		**Possible contraindication to self PD**
	Multiple or complex abdominal surgeries; negative physical evaluation	Yes, possible barrier	Yes – consider extended or daily HHD	
	No or unreliable electricity for CCPD; unable to do CAPD	Yes, possible barrier		**Possible contraindication to self PD**
	Brain damage, dementia, poor short-term memory	Yes, possible barrier	Yes – may be able to do with helper	
	Reduced awareness/ability to report body symptoms	Yes, possible barrier		**Possible contraindication to self PD**
	Malnutrition after PD trial leads to peritonitis	Yes, possible barrier	Yes – consider extended or daily HHD	
	Uncontrolled anxiety/psychosis	Yes, possible barrier	Yes – may be able to do with helper	
		Possible Barrier to PD in AKI	**Possibility to mitigate/overcome potential barrier?**	**Does this barrier apply to PD as a maintenance modality?**
Source: KDIGO Guideline on AKI[13]				
	Extremely high catabolism	Yes, contraindication	Not specified	Unknown
	Severe respiratory failure	Yes, contraindication	Not specified	Unknown

[13] https://kdigo.org/wp-content/uploads/2016/10/KDIGO-2012-AKI-Guideline-English.pdf

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	Severe ilius	Yes, contraindication	Not specified	Unknown
	Intra-abdominal hypertension	Yes, contraindication	Not specified	Unknown
	Recent abdominal surgery	Yes, contraindication	Not specified	Unknown
	Diaphragmatic peritoneum-pleura connections	Yes, contraindication	Not specified	Unknown
	Overall lower effectiveness in patients with splanchnic hypoperfusion	Unknown	Not specified	Unknown
	Overall lower effectiveness in patients on vasopressors	Unknown	Not specified	Unknown
	Risk of protein loss	Unknown	Not specified	Unknown
	Unpredictability of solute and fluid removal	Unknown	Not specified	Unknown
	Insults to intact peritoneal cavity/lack of functional peritoneal membrane	Unknown	Not specified	Unknown
	Risk of peritonitis	Unknown	Not specified	Unknown
	Diaphragmatic splinting leading to ventilatory compromise	Unknown	Not specified	Unknown
	Fluctuating blood glucose levels	Unknown	Not specified	Unknown
	Risks associated with long-term use of hypertonic solutions	Unknown	Not specified	Unknown
		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible**

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				contraindication to home-based modality?
Source: KDOQI PD Adequacy Guideline[14]				
	Risk of technique failure	Unknown	Not specified	Unknown
	Uremic cognitive dysfunction	Unknown	Not specified	Unknown
	Lack of cooperation/compliance	Unknown	Not specified	Unknown
	Nonadherence/presence of risk factors predicting nonadherence	Unknown	Not specified	Unknown
	Unavoidable insults to RKF (radiocontrast dye administered intravenously or inra-arterially, aminoglycoside antibiotics, NSAIDS including cox-2 inhibitors, ECF volume depletion, urinary tract obstruction, hypercalcemia, withdrawal of immunosuppressive therapy)	Unknown	Not specified	Unknown
	Lack of access to icodextrin	Unknown	Not specified	Unknown
		Possible Barrier to PD in children	**Possibility to mitigate/overcome potential barrier?**	**Does this barrier/contraindication apply to adult patients?**

[14] http://www.kidney.org/sites/default/files/docs/12-50-0210_jag_dcp_guidelines-pd_oct06_sectionb_ofc.pdf

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Source: KDOQI Guideline on PD Adequacy[15]				
	Omphalocele	Yes, absolute contraindication in children	Not specified	Unknown
	Gastroschisis	Yes, absolute contraindication in children	Not specified	Unknown
	Bladder extrophy	Yes, absolute contraindication in children	Not specified	Unknown
	Diaphragmatic hernia	Yes, absolute contraindication in children	Not specified	Unknown
	Obliterated peritoneal cavity	Yes, absolute contraindication in children	Not specified (see other sources)	**Possible contraindication?**
	Peritoneal membrane failure	Yes, absolute contraindication in children	Not specified (see other sources)	**Possible contraindication?**
	Inadequate living situation for home dialysis	Yes, relative contraindication in children	Not specified (see other sources)	**Possible contraindication?**
	Lack of appropriate caregiver	Yes, relative contraindication in children	Not specified (see other sources)	**Possible contraindication?**
	Impending/recent major abdominal surgery	Yes, relative contraindication in children	Not specified (see other sources)	**Possible contraindication?**
	Imminent living-related donor transplantation (within 6 months of dialysis initiation)	Yes, relative contraindication in children	Not specified	Unknown

[15] Ibid.

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		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: ISPD Cardiovascular & Metabolic Guidelines[16]				
	Inability to provide weekly evaluation of blood pressure by home blood pressure measurement[17]	Unknown	Not specified	Unknown
	Inability to manage foot care in PD patients with PAD and diabetes[18]	Unknown	Not specified	Unknown
		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: ISPD Guideline on Encapsulating Peritoneal Sclerosis[19]				

[16] https://ispd.org/ispd-guidelines/
[17] http://www.pdiconnect.com/content/35/4/379.full.pdf+html
[18] http://www.pdiconnect.com/content/35/4/388.full.pdf+html
[19] http://www.pdiconnect.com/content/37/4/362.full.pdf+html

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	Risk of EPS	Unknown	Not specified	Unknown
	High risk of technique failure (high and rising peritoneal permeability, low UF capacity, difficulty in fluid balance control, requirement for high glucose dialysate)	Unknown	Not specified	Unknown
	Peritonitis	Yes, given as reason for switching to HD	Yes (per other sources)	Unknown
	Inadequate small molecule clearance	Yes, given as reason for switching to HD	Not specified	Unknown
	Ultrafiltration	Yes, given as reason for switching to HD	Not specified	
		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: ISPD Guidelines on Peritonitis and Catheter-Related Infections[20]				
	Risk of relapsing peritonitis in patients with morbid obesity and alternatively placed PD catheters	Unknown	Not Specified	Unknown

[20] http://www.pdiconnect.com/content/37/2/141.full

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	Risk of relapsing peritonitis in patients with intestinal stomas and alternatively placed PD catheters	Unknown	Not Specified	Unknown
	Risk of relapsing peritonitis in patients with urinary or fecal incontinence and alternatively placed PD catheters	Unknown	Not Specified	Unknown
	Inability or unwillingness to manage exit-site care	Unknown	Not Specified	Unknown
	Inability or unwillingness to participate in PD training	Unknown	Not Specified	Unknown
	Inability to modify risk factors for peritonitis	Unknown	Not Specified	Unknown
		Possible Barrier to PD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: ISPD Guideline on PD Access[21]				
	Risk of infectious complications leading to catheter loss and technique failure	Yes, common cause of PD failure	Yes	Unknown

[21] http://www.pdiconnect.com/content/early/2019/04/26/pdi.2018.00232.full.pdf+html

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	Risk of mechanical failure leading to catheter loss and technique failure?	Yes, common cause of PD failure	Yes	Unknown
	Polycystic Kidney Disease (PKD)	Unknown, lack of consensus	Yes	Unknown
	Diverticulosis	Unknown, lack of consensus	Unknown	Unknown
		Possible Barrier to PD	**Possibility to Mitigate/Overcome?**	**Possible Contraindication to PD**
Source: KDOQI Membership				
	diaphragmatic defect (congenital or acquired)	Yes	Surgical correction is possible, but procedure is difficult	**Possible contraindication in some patients**
	Cachexia/severe malnutrition	Yes	Unknown	Unknown
	Has ileostomy and gastrostomy feeding tubes	Yes	Consider presternal catheter	
Potential Barriers to HHD				
		Possible Barrier to HHD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: UpToDate[22]				
	Lack of care partner to support conventional HHD using available equipment	Yes	Yes, CAPD or CCPD that can be performed without assistance or patient friendly HHD machines	Unknown

[22] https://www.uptodate.com/contents/organization-and-elements-of-a-home-hemodialysis-program?search=home%20hemodialysis&source=search_result&selectedTitle=3~33&usage_type=default&display_rank=3

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	Frequent instability during dialysis due to severe cardiovascular disease	Yes	Not specified	**Possible contraindication to HHD**
	Lack of easy to use vascular access	Yes	Not specified	Unknown
	Inability to understand elements of HHD	Yes	Not specified	Unknown
	Use of antihypertensive drugs	Yes	Not specified	Unknown
	Access to only unreliable equipment	Yes	Not specified	Unknown
	Unable to alter accommodations for water and electricity requirements	Yes	Yes, new technologies that may not require electricity and water accommodations	Unknown
	Lack of comprehensive assessment and plan of care	Yes	Not specified	Unknown
	Unable to monitor and manage drug and supplement regimens	Yes	Not specified	Unknown
	Non-compliance	Yes	Not specified	Unknown
		Possible Barrier to HHD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: MATCH-D[23]				
	Homeless	Yes	Yes, PD if storage is available	

[23] https://homedialysis.org/documents/pros/MATCH-D-v4.pdf

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	Unable to maintain personal hygiene even after education	Yes	Not specified	**Possible contraindication to HHD**
	Home is health hazard; will not correct	Yes	Not specified	**Possible contraindication to HHD**
	Unreliable or no electricity	Yes	Yes, CAPD	
	Brain damage, dementia, poor short-term memory	Yes	Yes, may be able to do with helper	
	No use of either hand	Yes	Yes, may be able to do with helper	
	Uncontrolled anxiety/psychosis	Yes	Yes, may be able to do with helper	
	Blind or severely visually impaired	Yes	May be able to do with helper; consider PD	
	Uncontrolled seizure disorder	Yes	May be able to do with helper	
	No remaining HD access sites	Yes	Consider PD	
	Reduced awareness/ability to report body symptoms	Yes		**Possible contraindication to HHD**
	Transplant is imminent		Consider PD	
		Possible Barrier to HHD	**Possibility to mitigate/overcome potential barrier?**	**If barrier cannot be overcome, possible contraindication to home-based modality?**
Source: KDOQI Guideline on HD Adequacy[24]				

[24] https://www.ajkd.org/article/S0272-6386(15)01019-7/fulltext

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	Risk of increased vascular access complications	Unknown	Not specified	Unknown
	Risk of increased caregiver burden	Unknown	Not specified	Unknown
	Possible accelerated decline in residual kidney function	Unknown	Not specified	Unknown