THE NATIONAL FORUM OF ESRD NETWORKS

FORUM OF END STAGE RENAL DISEASE NETWORKS

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September 16, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, D.C. 20201

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

Dear Ms. Verma,

The Forum of ESRD Networks appreciates the opportunity to comment on the proposed changes in CMS-5527-P. The National Forum of ESRD Network mission is to support and advocate on behalf of the ESRD Networks and to improve the quality of care to patients with kidney disease. In line with our mission we focus on quality of care, outcomes, and the quality of life of kidney patients. The Forum commends the focus of the administration to include HHS, CMS and CMMI to raise kidney health to the level of concern warranted. The AAKH initiative provides a template to allow for long overdue change and innovation to improve outcomes for people with kidney disease. Focusing on early diagnosis and improved coordination of care will allow for the potential for earlier transplantation and the ability to educate patients on choices for dialysis modalities, transplantation, and focus provider efforts on delaying the progression to kidney failure, while simultaneously enhancing a more optimal initiation on renal replacement therapies if needed. We hope that the experience of the Forum and the ESRD Networks will be able to be fully utilized as we transition into new models of care and all work towards the goals described in the AAKH initiative. We truly appreciate the ongoing efforts and commitment of CMS to developing and testing new payment models, however, do have some concerns with the mandatory ESRD (ETC) ETC Model. In reviewing the proposed changes, we considered how the proposed model would help to answer the question, "How will the patient do?"

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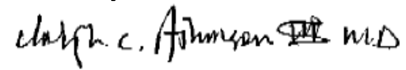
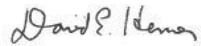
Below are our comments.

Sincerely,



Ralph Atkinson III, MD
President, Forum of ESRD Networks



David Henner, DO
Chair, Forum Medical Advisory Council

Derek Forfang
Chair, Forum Kidney Patient Advisory Council

1.Timeline 1/1/2020-6/30/2026: The Forum believes that this timeline begins too soon and is too brief to achieve optimal results in getting new patients on the active waitlist transplanted. Given this proposed timeline, dialysis facilities won't learn that they are taking part in the ETC model until just prior to the proposed start date. The proposed start date does not give dialysis facilities nearly enough time to prepare for this significant change in practice. Many dialysis facilities don't currently offer home dialysis, and for facilities to plan and build a new home dialysis program, a later start time than is currently proposed is necessary. We do have significant concerns with numerous potential unintended consequences resulting from every facility in the intervention group attempting to offer home hemodialysis and peritoneal dialysis. These include, however are not limited to the dilution of the expertise required for training and support, addition of significant inefficiency to operations of dialysis facilities and Nephrologists, who will now need to travel to additional facilities to see the home patients. In addition, state survey agencies will need more time than proposed to be able to survey and certify new home training dialysis facilities. The proposed start date allows CMS very little time to test collection of the proposed methodologies concerning the accurate measurement of changes in the rates of home dialysis and transplantation. According to the proposed timeline, as new beneficiaries are added to the active transplant waitlist, there won't be enough time to realize the desired result of more patients being transplanted, since the average waitlist time is over five years in most areas of the US. This wait time is also likely to increase, despite the other initiatives as part of the AAKH Initiative to increase organ availability, since many more dialysis patients will likely be added to the active transplant waitlist.

Recommendations:

- The Forum of ESRD Networks recommends delaying the start of the ETC model until 1/1/2021
- We recommend that the timeline should be changed to 1/1/2021-6/30/2030

2. **Exclusions**:

The Forum agrees with the following exclusions proposed for **Home Dialysis** including:

- Patients not enrolled in Medicare Part B
- Patients enrolled in Medicare Advantage or other Medicare Managed plans
- Patients that don't reside in the US
- Patients under 18 years old
- Patients receiving hospice
- Patients with diagnosis of dementia
- And patients receiving dialysis for AKI
- We also believe that patients who are homeless should be excluded from home dialysis calculations in the ETC model. However, the Forum also believes that homeless patients performing self-dialysis in-center should be counted in the ETC model as a home dialysis patient, since there is no other option for these patients to perform dialysis at home. In addition, the Forum believes that patients that reside in a group home or nursing home that doesn't allow home dialysis should be excluded.

The Forum of ESRD Networks acknowledges the proposed exclusions for **Transplant** including:

- Patients 75 years of age or older
- Patients that reside in a skilled nursing facility
- Patients on hospice
- The Forum also believes that patients with an active diagnosis of cancer should be excluded, as these patients will be excluded from transplant centers active waitlist.

- In addition, the Forum believes that patients with recent MI within 6 months, and patients with severe CHF or cardiomyopathy with EF<20% should be excluded, as these patients will also be excluded from transplant centers' waitlists.
- Also, the Forum believes that in addition to patients on hospice, patients whom are seriously ill that have a high risk of death in 6-12 months according to a validated risk calculator should also be excluded from the ETC model. For these patients, quality of life really needs to be considered, and referring these patients for transplantation or having them train for home dialysis would likely not be appropriate care at the end of life. Instead, focusing on palliative care measures would be more appropriate.
- Consider adjusting transplant rates for regional differences of transplant rates across the US to allow for differences that aren't under the control of dialysis facilities or Nephrologists.

3. Home Dialysis Facility Rate: Many dialysis facilities do not offer home dialysis within the facility, but instead refer patients to other dialysis facilities, either under the same ownership or different ownership to receive their home dialysis training and monthly visits. The referring facilities must educate the patients on home dialysis modalities and assist patients in shared decision making to choose home dialysis modalities. The facility must then refer the patient to a center that performs home dialysis training if not offered at that facility. The proposed rule does note that the aggregation group for subsidiary ESRD facilities would include all facilities located within the HRR owned whole or in part by the same company. It is not entirely clear how this will operate in a given HRR and independent, small dialysis organizations and those facilities that are owned by a medium or large dialysis organization, however located in a rural geographic area with limited or perhaps only a single facility will be uniquely challenged. We are concerned that the facility that receives the home dialysis patient receives full credit since the patient is fully attributed to their facility, and not the referring facility. The referring facility receives no credit, and if they don't offer home dialysis modalities within their facility, they will always receive 0 points on 2/3 of the MPS during the PPA period. This will unfairly penalize facilities without existing home training programs that routinely refer patients to other facilities with home training programs. Additional unintended consequences include decisions from larger dialysis organization concerning resource allocation, potential facility closure and the approach toward facilities in the comparison HRRs.

Since the penalties for the PPA can be as high as -13% by PPA period 9 and 10, many facilities may be forced to close as a result, which can adversely affect beneficiaries' access to care, especially in rural areas. In many cases, it is not necessary to have multiple facilities offering home dialysis training in a geographic area. Furthermore, if all dialysis facilities in the ETC model that don't offer home training currently attempt to apply for licensure to offer home training, then state survey agencies will likely not be able to survey facilities quickly enough to allow facilities to be successful in this model.

Similar to facilities, referring Nephrologists may not care for some of the beneficiaries that they educate, help decide to undergo home dialysis via shared decision making, and refer patients to facilities that do offer home dialysis. The referring Nephrologist, whom did most of the work to get the beneficiary to home dialysis would receive a score of 0 MPS on the PPA, similar to facilities whom refer patients.

The Forum believes that beneficiaries referred to another dialysis facility for home training should be attributed to the referring facility for a period of time before being attributed to the receiving home

dialysis training facility. Similarly, the patients should be attributed to the referring Nephrologist for a period of time.

Recommendations:

- The Forum recommends that beneficiaries referred from one dialysis to another facility for home training be attributed to the referring facility and referring Nephrologist for one PPA period in the ETC model before being attributed to the home training facility and Nephrologist. The home training dialysis facility and Nephrologist can still bill for home training during this period, and after 1 PPA period, the beneficiary can then be attributed to the home training facility and Nephrologist. This change from the proposed rule would encourage Nephrologists and facilities that don't offer home training to continue to refer patients to other facilities and Nephrologists for home dialysis.
- Alternatively, instead of providing MPS to individual facilities, CMS should consider applying the MPS by organization within each HRR participating in the ETC model. This would allow dialysis organizations to optimally locate their resources to maximize performance and meet patient needs throughout the region, instead of at each facility as currently proposed, which may lead to inefficient allocation of resources and unintended consequences such as a shortage of home training RNs or inadequately trained RNs or patients leading to poor outcomes.

4. **Transplant Rate - facility and numerator**: The forum acknowledges the numerator for facility and managing clinician. However, as described above under timeline, the timeline is too short to see results in getting new patients on deceased donor active list transplanted. If new beneficiaries are added to the active transplant waitlist during this timeline, there isn't enough time to see the desired result of more patients being transplanted, since the average waitlist time is over five years in most areas of the US. This wait time is likely to increase, despite the other initiatives to increase organ availability, given that more dialysis Providers will be working to get more patients on the active transplant list.

Recommendations:

- We recommend that the timeline should be changed to 1/1/2021-6/30/2030
- The Forum recommends including transplants in the numerator for subsequent years after the year of transplant for the MCs, as the MC whom referred the patient for transplant will also be helping to care for the patient and preserve the transplant after the transplant.

5. Payment Adjustments- HDPA: The Forum believes that the proposed HDPA is too small to incentivize facilities or Nephrologists to significantly increase home dialysis rates. We would suggest increasing the HDPA for both MC and facilities and consider extending it beyond the 3-year period proposed. in addition to the proposed HDPA we would also suggest increasing the MCP for MC to be equivalent to the MCP for four or more visits, rather than the current MCP for home visits, which is equivalent to 2-3 visits and may serve as a disincentive to MC to refer their patients to home dialysis modalities.

6. Payment Adjustments- PPA:

The Forum of ESRD Networks acknowledges the benefits of home dialysis and transplantation and agree that a positive payment adjustment may incentivize MCs and dialysis facilities to pursue home dialysis or transplantation. However, we do not agree with the proposed large negative payment adjustment for facilities with low MPS. By PPA period 9 and 10 the negative payment adjustment

may reach as much -13% for facilities, and -11% for Nephrologists or other managing clinicians. These large reductions for facilities may be on top of QIP penalties that can amount to as much as 2%. Larger dialysis organizations may be in a more advantageous position to sustain initial losses, although even at this scale, the viability of rural facilities and financially challenged facilities with a potential disproportionate impact on urban facilities, owned by these providers will face potential closure. The potential impact could be devastating to small independent or hospital-based not-for-profit dialysis facilities. Independent or hospital-based facilities are also likely to be vulnerable to suffering from poor MPS due to lack of corporate resources to quickly change practices in response to the ETC and short time frame proposed. Closure of any facilities that are located in rural, underserved areas or challenged urban areas due to these potential large negative payment adjustments, could mean that beneficiaries in these regions may be left with significant issues with access to dialysis services. Similar to dialysis facilities, many Nephrologists or other managing clinicians are employed by hospitals or groups which may operate on small margins. In addition to the potential large negative payment adjustments proposed, Clinicians are also subject to potential losses in MIPS, and similar to vulnerable facilities, some Nephrology groups may not survive a few years of potential large negative payment adjustments. Solo or small groups of Nephrologists are especially vulnerable in this model. If these Nephrologists are forced to close their practice or relocate, that can also lead to significant access of care issues for beneficiaries.

The Forum believes that eliminating the negative PPA from the proposed rule, and only keeping a smaller positive PPA will still incentive facilities and clinicians towards increased transplant and home dialysis referrals, which will likely still increase transplant and home dialysis rates without the potential large negative losses some facilities and clinicians will experience under the proposed rule. The increased rates of transplant and home dialysis that will result from a small incentive will still lead to cost savings for Medicare, without the negative effect on dialysis providers and beneficiaries.

Recommendations:

- The Forum recommends changing the PPA payment adjustments to only positive PPA for facilities and managing clinicians that perform well in ETC model, without any negative PPA

7. Treatment Options and Shared Decision Making: The Forum believes that when discussing treatment options with patients, shared decision making with the patients is of critical importance so that patients receive the treatment that is best suited for their individual preferences and goals of care. In addition to home dialysis and transplantation, there are several other treatment modalities that may be just as beneficial to certain patients, and may better suit certain patients' goals of care, health status, or choices.

One such modality is Transitional Care that allows incident patients to begin training for home modalities while in-center. We acknowledge the challenges raised in the proposed rule regarding Self-Care dialysis in-center although we wish to note that this has been demonstrated to result in superior outcomes to regular in-center hemodialysis and increases choices for patients with the potential to offer those patients challenged by homelessness with additional choices. We support the decision not to include these patients in the Home Dialysis rate at the present time.

Another important treatment modality, other than home dialysis is supportive care. With proper education and shared decision making, some patients may choose not to start dialysis and instead pursue conservative care. This may be very appropriate in some patients who are elderly or suffering

from declining health. When Nephrologists take the time and effort to educate their patients on conservative care, and work with patients in shared decision making to pursue conservative care, there is nothing in the proposed ETC model to credit the MC or facility. For appropriate patients that chose supportive care as an option, not only will these patients be spared suffering against their wishes on dialysis, but this more compassionate patient care will lead to cost savings for Medicare. In addition to some patients choosing conservative care and not starting dialysis in the first place, some patients may choose to stop dialysis and not pursue hospice. Other patients may choose to undergo palliative dialysis to alleviate suffering, but without the goal of prolonging life or achieving optimal dialysis. Expanding hospice access at later stages of illness is a parallel requirement to enabling patients to have a full array of choices, rather than having to forgo dialysis if they wish to receive hospice care.

Recommendations:

- The Forum believes that shared decision- making tools should be included as part of the model to help patients better understand their options and to protect their choices.
- Include Transitional-Care in the Home Dialysis rate in the ETC model for both PPA and HDPA.
- Include supportive care, or conservative care, and palliative care dialysis as treatment modalities that count equivalent to home dialysis and transplantation in the ETC model for both MC PPA and Facility PPA.
- Accepts waivers for expanded Hospice access for dialysis patients to receive dialysis services if referred for Hospital greater than 2 weeks before anticipated death.

8. The Kidney Patient Advisory Council of the Forum believes that patients who chose home dialysis modalities should be rewarded by waiving the 20% coinsurance for home dialysis treatments. Many patients who are currently undergoing in-center hemodialysis are comfortable with their treatments, and don't wish to risk sacrificing that comfort to try home dialysis. For these patients, offering a waiver to their coinsurance may help them pursue home dialysis.

Recommendations:

- Consider waiving the 20% coinsurance for beneficiaries choosing home dialysis therapies
- Adjustment of the HDPA and PPA for facilities and managing clinicians to mitigate any negative financial consequence

9. Monitoring: The Forum acknowledges the intention in the proposed rule to monitor SMR and SHR to assess quality and mitigate unintended consequences. Since patients on home dialysis with inadequate training, or patients that are not ideal candidates for PD or home HD may develop BSI or peritonitis, the Forum feels monitoring the rate of infection, both blood stream infection for HHD and peritonitis for PD is necessary for patient safety. It will not only be an indicator for how patients have been trained, for home therapies, but the patients of the KPAC also feel that monitoring hospitalization and mortality is not enough to protect patients. Currently blood stream infections nor peritonitis are measured and reported for home modalities. Patient safety and infection prevention will be critical to the model's success.

Recommendations:

- Consider monitoring for blood stream infection in patients receiving HHD and peritonitis for those choosing PD