



National  
Kidney  
Foundation®

30 E. 33rd Street  
New York, NY 10016

Tel 212.889.2210  
Fax 212.689.9261  
[www.kidney.org](http://www.kidney.org)

September 4, 2018

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

RE: CMS-1691-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS

Dear Administrator Verma:

The National Kidney Foundation appreciates the opportunity to comment on the proposed changes to the end-stage renal disease (ESRD) prospective payment system (PPS), including policies that will govern coverage and payment for renal dialysis services delivered to individuals with acute kidney injury (AKI), and the quality incentive program (QIP) for payment years 2021-2024. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. 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). This year we are dividing our comments into three separate letters in hopes to make it easier to review our recommendation on each section of the rule. This letter responds to the solicitation for information on transplantation and home dialysis. Two additional letters have been submitted with our comments regarding proposed changes to the PPS and the QIP.

When it comes to accountability for dialysis facilities in patient selection of renal replacement therapy options the core responsibility of the dialysis facility has been in informing and educating patients about the options. As CMS highlights, this topic is addressed within the

Conditions for Coverage (CfC) and, in greater detail, the corresponding interpretive guidance. The National Kidney Foundation is not recommending any changes to the CfC. In addition, as we mention in our comments on the QIP, we cannot support the proposed transplant waitlist measures because the final decision on whether a patient is waitlisted is made by the transplant center. However, we do believe there are significant gaps in the quality of modality education delivered and the necessary care coordination for transplant waitlist evaluation. We offer several recommendations for ways CMS can advance patient-centered, quality improvement in these areas.

The National Kidney Foundation recommends that CMS develop a measure of shared-decision making for renal replacement therapy options for inclusion in the QIP.

Selection of renal replacement therapy (RRT) should be in alignment with opportunities to help patients achieve their lifestyle preferences, values and goals. However, in healthcare significant gaps in providers discussing these topics with patients remain. CMS has made great strides in framing quality measure priorities around what matters most to patients and in working to create greater transparency in quality and cost in order to help patients make more informed decisions about their healthcare. Conversations and proposals on improving patient centeredness and patient engagement are now widely prevalent across agencies within HHS, industry, non-profit organizations and quality improvement organizations like the National Quality Forum (NQF), but the ability to evaluate patient engagement, particularly engagement in shared decision making is missing from value-based care programs. The use of validated patient decision aids that compare RRT options can be helpful in improving the quality of patient education delivered and empowering patients to make, and stick with, decisions about their treatment options. The NQF has developed the National Quality Partners Playbook™: Shared Decision Making in Healthcare, a guidance document to improve shared decision making in healthcare delivery.<sup>1</sup> Shared decision making is also referenced in many of the Center for Medicare and Medicaid Innovation (CMMI) models. Numerous resources and publications also highlight opportunities to evaluate the effectiveness of shared decision making and patient decision aids. Sepucha et al, highlight an opportunity for developing quality measures for the use of patient decision aids or a patient reported outcome measure on the quality of shared decision making.<sup>2</sup> Questionnaires like the Decision Conflict Scale<sup>3</sup> could provide the basis for patient reported outcome measure on shared decision making in RRT selection. While the in-center Hemodialysis CAHPS Survey (ICH CAHPS) includes questions related to home modality

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<sup>1</sup> National Quality Partners Playbook™: Shared Decision Making in Healthcare available at [http://www.qualityforum.org/National\\_Quality\\_Partners\\_Shared\\_Decision\\_Making\\_Action\\_Team\\_.aspx](http://www.qualityforum.org/National_Quality_Partners_Shared_Decision_Making_Action_Team_.aspx)

<sup>2</sup> Sepucha, Karen R and Scholl, Isabelle Measuring Shared Decision Making A Review of Constructs, Measures, and Opportunities for Cardiovascular Care, *Circ Cardiovasc Qual Outcomes*. 2014;7:620-626.

<sup>3</sup> The Ottawa Hospital, Patient Decision Aids, accessed from [https://decisionaid.ohri.ca/eval\\_dcs.html](https://decisionaid.ohri.ca/eval_dcs.html).

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. By creating and implementing a shared-decision making metric in the QIP for selection of RRT, CMS could drive forward significant improvements in patient understanding of their RRT options and selection of the option that allows patients to meet their lifestyle preferences, values, and goals. A measure would also allow for patients to re-evaluate these options regularly as their circumstances change over time.

The National Kidney Foundation recommends the Centers for Medicare & Medicaid Innovation foster future kidney care models that identify CKD patients earlier and foster greater collaboration and dual accountability between dialysis facilities and transplant centers.

In our consideration of the proposed QIP measures for Percentage of Prevalent Patients Waitlisted (PPPW) and the Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients we determined that holding dialysis facilities accountable for this measure, when the ultimate decision to place someone on the waitlist is up to the transplant center and the patient, is unlikely to drive significant improvement in patients selecting transplant. It would also disadvantage dialysis patients by penalizing facilities and potentially removing money from the payment system for their care. As we discuss in detail in our QIP letter there is great variability in criteria among transplant centers. Some transplant centers also include financial requirements that can cause facilities that serve lower-income patients to be at a greater disadvantage. Therefore, we believe that the most patient-centered approach to including a measure in the QIP is to develop a PRO of shared-decision making in RRT options.

However, we also believe there are additional strategies necessary to create greater opportunities for patients to receive a kidney transplant. Ideally, a patient would receive a transplant instead of starting dialysis as outcomes for preemptive transplant are much better.<sup>4,5</sup> Improving earlier wait listing and opportunities for patients to seek a living donor are necessary to increase preemptive transplant rates given the short supply of deceased donor kidneys. In addition, for current dialysis patients, there is a need for dialysis facilities and transplant centers to collaborate and have dual accountability for improving patients' opportunities for transplant. Therefore, we recommend that CMMI is best positioned to develop models that encourage opportunities for transplant.

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<sup>4</sup> Meier-Kriesche HU, Port FK, Ojo AO, et al. Effect of waiting time on renal transplant outcome. *Kidney Int.* 2000; 58:1311–1317.

<sup>5</sup> Kasiske BL, Snyder JJ, Matas AJ, Ellison MD, Gill JS, Kausz AT. Preemptive kidney transplantation: the advantage and the advantaged. *J Am Soc Nephrol.* 2002; 13:1358–1364.

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First, improvements in identifying patients with CKD earlier are critical to helping them make informed decisions about their treatment options including preemptive transplantation. The kidney allocation policy allows patients to be placed on the waitlist with an eGFR of <20. In addition, earlier identification and treatment of CKD patients can prevent or delay the need for RRT in the first place. The National Kidney Foundation has developed the CKDintercept Comprehensive Kidney Care model as an opportunity to improve earlier identification and care of patients and to ease transitions of care for those who progress. We shared these recommendations with CMMI in response to the Fall 2017 request for information.

Additionally, we encourage CMMI to explore opportunities to include transplant centers in the next generation of the Comprehensive ESRD Care Initiative. Allowing this model to be less dialysis centric and more focused on the entirety of ESRD care could produce greater collaboration and accountability for increasing kidney transplants. Including transplant centers in an ESRD model should also allow for opportunities to improve the utilization of deceased donor kidneys by ensuring donated organs are appropriately recovered and fewer organs are discarded.

The National Kidney Foundation is also aware that all ESRD networks are working on a project to engage dialysis facilities in increasing the number of patients who are on the transplant waitlist. Our understanding is that this project includes a root cause analysis on barriers to patients achieving waitlist status, and a "plan, do, study, act" approach to allow dialysis facilities to adopt new solutions to improving the number of patients who are waitlisted. We inquire as to the status of this project and its outcomes.

Early CKD care and shared decision making can also increase home dialysis use.

Many of our recommendations on improving opportunities for patients to receive a transplant also apply to increasing opportunities for patients to conduct dialysis at home, including a shared decision making measure for RRT in the QIP and CMMI implementing models for earlier CKD care. Some innovative programs in early CKD care are showing that patients who participate in early CKD education are more likely to select home dialysis and persist on the therapy.<sup>6,7</sup> In addition, there are other opportunities for CMS to remove barriers to home dialysis.

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<sup>6</sup> Fishbane, Steven, et.al, Augmented Nurse Care Management in CKD Stages 4 to 5: A Randomized Trial, Am J Kidney Dis. 2017;70(4):498-505.

<sup>7</sup> Johnson, Douglas, et.al, Going Upstream: Coordination to Improve CKD Care, Seminars in Dialysis, published online January 14, 2016 <https://onlinelibrary.wiley.com/doi/full/10.1111/sdi.12461>.

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CMMI could also test additional opportunities to promote home dialysis among incoming and current dialysis patients. For example, CMMI could test funding family caregiver support and medical professional assisted home dialysis in future ESRD models. Other countries with higher home dialysis support this type of assistance (i.e., Canada, New Zealand, France and England). In late 2017, the National Kidney Foundation held the first part of a KDOQI home dialysis consensus conference, bringing together patients and health care professionals with expertise in home dialysis to discuss barriers and proposed solutions to increasing home dialysis use in the U.S. Several barriers were identified, including caregiver support.

An additional barrier noted was the lack of availability of PD in hospitals to conduct PD in patients who are hospitalized or to start new patients on PD who start dialysis urgently. CMMI could work with hospitals and nephrologists to incentivize PD starts over hemodialysis starts when appropriate and expand use of PD in hospitals.

CMS should modify the QIP to remove disincentives for home only programs.

The QIP potentially disadvantages home programs due to the lack of quality measures applicable to home patients. There is no CAHPS for home patients; the Kt/V pooled measure masks performance for home patients, and the vascular access measures do not apply to PD patients. The National Kidney Foundation recommends that CMS adapt the ICH CAHPS for home patients, and return to separate reporting of Kt/V.

CMS should call for modifications or the rescinding of the Medicare Administrative Contractor proposed Local Coverage Determinations in order to remove uncertainty in reimbursement for more frequent dialysis for home dialysis patients.

The current Medicare Administrative Contractor (MAC) Noridian's policy of restricting reimbursement of more frequent dialysis particularly disadvantages use of home hemodialysis (HHD) and also limits opportunities for patients to participate in shared-decision making when it comes to frequency of their treatments. While we appreciate that the other MAC jurisdiction policies, which would also restrict more frequent dialysis, have not been finalized their pending status creates uncertainty in reimbursement for more frequent dialysis. This uncertainty creates a significant barrier to growth in HHD.

Other barriers to home dialysis were also noted during the conference. A paper from the conference chairs has been submitted for publication and we look forward to sharing that with CMS once it is available. In addition, the second part of the KDOQI home dialysis conference will be held November 2018 and workgroups formed during the first conference will share their proposed recommendations. CMS and CMMI staff have been invited to attend and participate

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and we hope this conference will help CMS identify additional opportunities to expand home dialysis.

The National Kidney Foundation appreciates the opportunity to share our thoughts on increasing access to kidney transplants home dialysis. We would be happy to meet with CMS to further discuss our recommendations. For questions, please contact Tonya Saffer, Vice President for Health Policy at [tonya.saffer@kidney.org](mailto:tonya.saffer@kidney.org) or 202.244.7900 x 717.

Sincerely,

*Kevin Longino*

Kevin Longino  
CEO and Kidney Patient

*Michael Choi*

Michael Choi, MD  
President