



August 31, 2021

The Honorable Chiquita Brooks-LaSure
Hubert H. Humphrey Building
Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

Re: CY 2022 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program

A Joint Position Statement on Improving the Patient-Centricity of the ESRD Quality Incentive Program

The National Kidney Foundation (NKF) and the National Forum of ESRD Networks are committed to improving the patient-centricity of dialysis care through the Quality Incentive Program (QIP). Quality measurement can appear philosophically opposed to individualized dialysis treatment because quality measures typically measure certain aspects of care that are delivered to all or most patients. Our organizations believe that application of a quality program to dialysis therapy does not preclude improvements to QIP measures to support the ability of nephrologists and dialysis facilities to provide individualized dialysis approaches that align with patients' values and preferences for care. Two measures, Standardized Fistula Rate (SFR) and Kt/V Dialysis Adequacy (Comprehensive), are examples and described below in greater detail. This joint position statement from NKF and the National Forum of ESRD Networks describes how these measures can be modified to improve their patient-centricity. Implementation of the recommendations below would represent considerable progress in moving towards greater customization of the patient experience on dialysis.

Standardized Fistula Rate

The arteriovenous fistula (AVF) is widely considered the optimal means of vascular access due to its reliability, cost, and association with fewer infections, hospitalizations, and lower mortality. Increasing the prevalence of AVFs was the subject of the well-known "Fistula First Initiative," which set a target of goal of 66% AVF-based access among U.S. hemodialysis patients. At the time the initiative was launched, the use of AV fistulas among prevalent ESKD patients was already on the rise. As of May 2017, 62.8 % of prevalent dialysis patients were using an AVF.¹ While an AVF is the appropriate vascular access choice for many patients with kidney failure, it is not appropriate for all patients. There

¹ https://www.usrds.org/media/1727/v2_c03_vascacc_18_usrds.pdf



are numerous reasons, some clinical and some based on patient preferences, that lead to patients choosing not to go through the process of evaluation for or maturation of an AVF. Vascular surgery may not align with patients' preferences for care, for example for patients who have been on dialysis for many years and have had multiple vascular access surgeries on their arms and legs or those with complications of these surgeries such as steal syndrome that can compromise blood supply to the limbs.

CMS' Measures Manual acknowledges that an AVF is not the best choice for all patients and asserts that the measure, in addition to its joint reporting with Hemodialysis Vascular Access: Long-term Catheter Rate, accounts for patients where a graft or catheter may be a better choice.² Our organizations believe that additional claims-based exclusions are necessary to achieve CMS' stated goal and to align with the updated KDOQI Vascular Access Guideline, which emphasizes that a patient's access needs stem from the creation of a patient-centered ESKD life-plan.³ Rather than a "fistula-first, catheter-last" approach, the guideline reflects that the "right" vascular access means different things to different patients. We acknowledge that CMS needs a standard to measure but do not believe the need for such a standard precludes improvements that will allow for greater personalization of vascular access. Accordingly, we recommend that CMS implement claims-based exclusions for severe steal syndrome affecting the partial or complete use of a limb, severe congestive heart failure, severe psychiatric illness, limited life expectancy, or other conditions in which the risk of surgery to place AV access, or use of AV access on dialysis, is deemed to be unacceptable by their physician. It would also be appropriate to exclude patients who have exhausted all potential sites for AVF or AVG placement, or in whom there are no viable vessels for AVF or AVG placement, as well as patients with advanced age or complex multi-morbid conditions or those whose main goal is palliative dialysis therapy.

Kt/V Dialysis Adequacy Comprehensive

Our organizations are concerned that the one-size-fit-all approach to Kt/V Dialysis Adequacy Comprehensive measure as constructed is misaligned with the drive towards individualized dialysis prescriptions that better enable patients to live in a manner that is aligned with their values and preferences. The measure has no applicability to home hemodialysis delivered four or more times per week, does not follow guidelines from KDOQI or the International Society of Peritoneal Dialysis (ISPD) and can adversely impact patients with residual kidney function including those who incrementally transition to hemodialysis therapy. We do understand CMS' rationale for the pooled measurement; to achieve an adequate sample size for reliability of the measure and the protection of patient information. We would point out that as home dialysis utilization increases across the country, more facilities may

have 11 or more patients, which would increase sample size and negate the need for the pooled measurement. Our organizations share a commitment to a dialysis paradigm centered on how patients live on dialysis. Quality of life on dialysis is more important to patients than targeting and achieving these dialysis measures. In regard to the Kt/V target for PD (adult ≥ 18 years old), there is very limited evidence that outcomes are improved by achieving a Kt/V ≥ 1.2 for hemodialysis or >1.7 for peritoneal dialysis. Importantly, many patients and nephrologists do not favor the concept of "adequacy" in the form of these metrics, noting that a specific adequacy target has little bearing on patients' ability to live safely,

² <https://www.cms.gov/files/document/esrd-measures-manual-v61.pdf>

³ [https://www.ajkd.org/article/S0272-6386\(19\)31137-0/fulltext](https://www.ajkd.org/article/S0272-6386(19)31137-0/fulltext)



well, and longer on dialysis. For PD patients, we recommend that CMS accept $Kt/V \geq 1.7$, or alternatively Kt/V as low as 1.3 when accompanied by a statement that the patient has acceptable biochemical parameters and no uremic symptoms or if patient is deemed to have significant residual kidney function.

With regard to hemodialysis, the strict single target of $spKt/V \geq 1.2$ does not account for the important contribution of patient's native kidneys in the form of the residual renal function. The target disadvantages patients who wish to preserve their residual kidney function longer and may lead to the acceleration of the loss of residual renal function. With regard to hemodialysis, the strict single target of $spKt/V \geq 1.2$ does not account for the important contribution of patient's native kidneys in the form of the residual kidney function. The target disadvantages patients who wish to preserve their residual kidney function longer and may lead to the acceleration of the loss of residual kidney function. For hemodialysis patients, a consensus on targets that account for residual kidney function and lead to optimal outcomes has not been well defined compared to PD. A judicious evaluation of the available observational data might inform specific targets to ensure optimal outcomes. Our organizations recommend that CMS establish a technical expert panel (TEP) that includes specific patient input to explore the current evidence and make specific recommendations that recognize that incident dialysis patients, patients with a recently failed kidney transplants, and prevalent patients with significant residual native renal function might benefit from different $spKt/V$ corrected for residual function thresholds or other appropriate measure of dialysis adequacy.

Overall, we believe patient-centered approaches should be the overarching determinant of the QIP measures.

Please contact Dr. Dave Henner, President of the National Forum of ESRD Networks, at dhenner@bhs1.org or Miriam Godwin, NKF Health Policy Director, at miriam.godwin@kidney.org with questions about this statement.

Sincerely,

Forum of ESRD Networks Signatures:

David Henner, DO, President, The National Forum of ESRD Networks

Kam Kalantar-Zadeh, MD, MPH, PhD, Chair, Forum's Medical Advisory Council

Dawn Edwards, Co-Chair, Forum's Kidney Patient Advisory Council, KPAC

Derek Forfang, Co-Chair, Forum's Kidney Patient Advisory Council, KPAC

National Kidney Foundation Signatures:

Kevin Longino, National Kidney Foundation Chief Executive Officer and Kidney Transplant Recipient

Paul Palevsky, MD, National Kidney Foundation President

Sylvia Rosas, MD, MSCE, National Kidney Foundation President-Elect

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