NATIONAL KIDNEY FOUNDATION®

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December 22, 2023

Battelle
Partnership for Quality Measurement (PQM)
505 King Avenue
Columbus, OH 43201

RE: Public Comments to Battelle Partnership for Quality Measurement (PQM) Pre-Rulemaking Measure Review (PRMR) Clinician Committee for MUC2023-203, MUC2023-204, MUC2023-206, and MUC2023-138

Submitted electronically via the Battelle PQM PRMR Public Comment Platform

Dear Battelle PQM PRMR Clinician Committee Members,

The National Kidney Foundation (NKF) thanks Battelle and the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments on the following measures under consideration: MUC2023-203: Chronic Kidney Disease (CKD), MUC2023-204: End-Stage Renal Disease (ESRD), MUC2023-206: Kidney Transplant Management, and MUC2023-138 ESRD Dialysis Patient Life Goals Survey (PaLS). 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.

NKF commends the Agency for its efforts to establish effective and efficient cost measures, in addition to person-centered quality measures, for Medicare beneficiaries living with kidney disease. Further, we value the alignment of comprehensive quality measures across federal programs to improve access to care and achieve health equity. We echo sentiments of other stakeholders across the kidney care community in support of the conceptual use of episode-based costs measures in the Merit based Incentive Payment System (MIPS), while highlighting several challenges specific to people with kidney disease and their care team.

MUC2023-203: Chronic Kidney Disease (CKD)

Chronic Kidney Disease (CKD) progresses slowly over decades and is optimally treated with chronic disease management before it has become advanced, often resulting in End-Stage Renal Disease (ESRD).

- **Low Patient Volume:** Low patient volume will likely disproportionally impact nephrology clinicians in small or rural practices or those that care for disadvantaged patients. Nephrology practices with fewer resources will be less nimble to implement the necessary clinic redesign for participation and may be indirectly penalized. Quality measures are harder to achieve when populations have significant social needs as well as medical complexity that may be

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incompletely assessed by the risk adjustment. The interaction between the measure and health equity for disadvantaged populations should be monitored.

- **Reliability:** Given the very low reliability scores (0.293 for a threshold of 10 patients, 0.386 for a threshold of 20, and 0.448 for a threshold of 30; goal reliability is >0.6), use of this measure should be restricted to practitioners/practices with larger numbers of evaluable patients. Since nephrologists should see a reasonable volume of CKD stage 4/5 patients, a higher threshold within this measure may be more appropriate. Additionally, assessments for unanticipated consequences associated with the measure were not explicitly clear and should be considered in the future.

- **Ensuring High Value Care:** Patients with CKD stage 4 (with an eGFR of >20 ml/min/1.73m2) are candidates for the use of SGLT2 inhibitors that should be continued until the initiation of dialysis. Monitoring the measure for the impact of SGLT2 inhibitors will be important to better understand the interaction between expenditures and outcomes. As drugs in the SGLT2 inhibitor class become generic, the cost effectiveness will likely only improve. There is great interest in nephrology for a performance measure that incorporates SGLT2 inhibitor use that this data collection can inform. There are other novel, currently high-cost, medications that may also slow the progression of kidney disease, such as several new agents to treat glomerulonephritis (most notably IgA Nephropathy) as well as mineralocorticoid agonists and glucagon-like peptide-1 (GLP1) receptor agonists to treat diabetic kidney disease.

MUC2023-204: End-Stage Renal Disease (ESRD)

- **Reliability:** While reliability is better for this measure (0.571 for a threshold of 30 patients), there remains considerable room for improvement. Notably, with the absence of comorbidity codes on nephrologist MCP claims, there may be very little data on many patients who have a substantial comorbid condition burden. Also, nephrologists may have limited control over some cost issues given the multiple facilities and providers who may provide care for this population. We again advocate for a higher threshold of patients to be seen within this measure (such as 40 or 50 patients).

MUC2023-206: Kidney Transplant Management

- **Cost Savings vs. Health Outcomes:** Part D costs for insulin and other diabetes medications should be excluded, in order to not disincentivize their use. There is also concern regarding the inclusion of immunosuppressants within this measure. This might save costs in the short-term but have adverse effects on long-term graft survival if transplant nephrologists are pushed towards cheaper immunosuppressant regimens.

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- **Reliability:** Reliability is also low for this measure and we again advocate for higher patient thresholds.

- **Risk adjustment:** We echo sentiments of other stakeholders across the kidney care community in support of the inclusion of appropriate risk adjustment for the post-transplant patient population. This is essential to avoid unintended outcomes. A kidney transplant with even a "low quality" kidney generally confers longer and better quality of life, and lower long-term costs, for patients as compared to dialysis. Recognizing these many benefits, the kidney community is working hard to increase the use of these less-than-perfect kidneys, thereby increasing patient access to the best therapy for kidney failure. Some patients who receive a lower-quality kidney—still for most recipients a better therapy than dialysis—have greater medical care needs, not only in the months immediately following their transplant surgery but also in later months post-90 days. There has been a major movement throughout CMS and the kidney community to remove disincentives to transplant higher Kidney Donor Profile Index (KDPI) kidneys and to provide transplants to individuals with greater comorbid condition burden, including older candidates. It would run counter to the kidney community's goals of increasing access to kidney transplantation and increasing organ use to penalize clinicians providing appropriate care for people who have received less-than-perfect kidneys because that expected cost of care is not appropriately adjusted based on the quality of the donor kidney. For this reason, it is essential that information about donor kidney quality be available and be included in the risk adjustment. A data use agreement with Health Resources and Services Administration (HRSA) and/or HRSA contractors who manage the Organ Procurement and Transplantation Network (OPTN) would facilitate the necessary data-sharing for this aspect of the risk adjustment model. This is a critical step.

MUC2023-138 ESRD Dialysis Patient Life Goals Survey (PaLS)

- We continue to have concerns that the ESRD Dialysis PaLS tool has not been sufficiently validated for use in this fashion. Under validity testing, it is noted that "empirical validity testing was not performed at the measured entity level" and that entity level reliability testing was not available. While we definitely support a measure that emphasizes patient life goals, it is not clear that this measure has been sufficiently validated to ensure that it is meaningful.

- We appreciate and applaud CMS for the update provided during the public listening session on December 14, 2023 regarding plans in place to make the ESRD Dialysis PaLS tool in Spanish.

The National Kidney Foundation again thanks the Battelle PQM and CMS for the opportunity to provide comments on the select measures under consideration by the PRMR Clinician Committee on behalf of the more than 37,000,000 Americans with kidney diseases. Complimentary, innovative, and

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equitable cost and quality measures are essential to the improved health outcomes for people living with kidney disease who deserve superior care along each juncture of their care journey, from chronic kidney disease (CKD) to transplantation. We welcome the prospect of providing additional insight and collaborating as a thought leader on future policy initiatives regarding these matters. Please contact Ivory Harding, Director of Quality and Regulatory Affairs, at Ivory.Harding@kidney.org with any questions or concerns.

Sincerely,

Kevin Longino
CEO and Transplant Recipient

Sylvia Rosas, MD
President