



December 22, 2023

Lewis Von Thaer
President and Chief Executive Officer
Kirkland Donald
Board of Directors Chair
Battelle
505 King Avenue
Columbus, OH 43201

Pre-Rulemaking Measure Review (PRMR) Measures Under Consideration (MUC) List

Dear Mr. Von Thaer and Admiral Donald:

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 21,000 nephrologists, scientists, and other kidney health care professionals who are members of the American Society of Nephrology (ASN), thank you for the opportunity to comment on the 2023 Pre-Rulemaking Measure Review (PRMR) Measures Under Consideration (MUC) List.

While appreciative of the opportunity to comment on this critical issue for millions of Americans, ASN is once again disappointed by the limited timeframe for public comment from December 1-22, 2023. Furthermore, several key documents were not made available until midway through the public comment period. The MUC is integral to maintaining high quality care for patients and measuring resource use of clinicians in the Merit-based Incentive Payment System (MIPS). Please see our letter from September 25, 2023, (attached) after the public was given a two-week comment window for the entire 2023 Measure Set Review (MSR): End Stage Renal Disease Quality Incentive Program (ESRD-QIP). ASN is also sharing its concerns on timing and this letter with the Centers for Medicare and Medicaid Services as this has been an annual process challenge pre-dating the existing contractor.

Although ASN supports the development of episode of care cost measures, ASN has concerns relating to the four measures under consideration impacting individuals with kidney failure as well as general and transplant nephrologists and the kidney health team. Specifically, we comment on the following proposed measures:

- MUC2023-203: Chronic Kidney Disease (CKD)
- MUC2023-204: End-Stage Renal Disease (ESRD)
- MUC2023-206: Kidney Transplant Management
- MUC2023-138 ESRD Dialysis Patient Life Goals Survey (PaLS)

For background, kidney diseases are the ninth leading cause of death in the United States, resulting in more deaths than breast cancer, and, given the heightened risk of cardiovascular diseases associated with chronic kidney disease (CKD), kidney diseases contribute to millions of additional deaths in the United States from other causes. Unfortunately, kidney diseases and kidney failure are more common among Black, Hispanic or Latinx, Native or Indigenous Americans, Asian Americans, Hawaiians and other Pacific Islanders, people with lower incomes, and older adults. Each of these populations have also been disproportionately affected by the COVID-19 pandemic, exacerbating existing disparities.

When compared to White Americans, Black Americans are 3.8 times more likely to develop kidney failure, while Hispanic or Latinx Americans are 2.1 times more likely to develop kidney failure. One out of every eleven Black American males will require dialysis during their lifetime. Further, Black, Indigenous, and Hispanic or Latinx Americans are less likely to receive a kidney transplant and are less likely to initiate home dialysis when requiring dialysis for kidney failure.

While end-stage renal disease affects only one percent of Medicare beneficiaries, it represents seven percent of Medicare's annual expenditures. Yearly costs for Medicare FFS patients on hemodialysis are approximately \$100,000, whereas annual costs for patients with a kidney transplant are approximately \$44,000. Costs for patients with CKD are more than double (\$28,162/yrⁱ) that for those without CKD (\$13,604/yr). These statistics highlight the importance of the Partnership for Quality Measurement's (PQM) actions on MIPS episode-based cost measures.

ASN supports the conceptual use of episode-based costs measures in MIPS, but we highlight the challenges with this approach for people with kidney diseases, a condition that typically is slowly progressive over decades, that is optimally treated with chronic disease management before it has become advanced, and that may have significant periods of transition.

MUC2023-203 Chronic Kidney Disease

ASN appreciates the thoughtful deliberations by the TEP and measure contractor to identify costs potentially related to CKD. We note that the TEP did not achieve consensus. We share the following considerations:

- 1) **Identifying advanced CKD:** Patients are identified using ICD-10 codes for CKD Stage 4 and 5. ASN is reassured that a previous analysis conducted by the Center for Outcomes Research & Evaluation, the measure developer for the Delay in Progression of CKD measure, found that ICD-10 codes had high specificity, with over 80% of CKD stage 4/5 patients having laboratory evidence of CKD. However, CMS should closely monitor for gaming behavior in coding, as clinicians may code N18.9 CKD, unspecified to avoid having high-cost patients attributed to the CKD cost measure. As a result, in the long-term the appropriate identification of stage 4/5 patients could be impacted.

- 2) **Heterogeneity within advanced CKD:** Individuals with CKD stage 4/5 differ tremendously from each other, with the estimated glomerular filtration rate (eGFR) and the quantification of albumin in the urine (often referred to as the urine albumin to creatinine ratio) providing substantial information about prognosis and therefore about projected costs. For example, using the Kidney Failure Risk Equation, a 70-year-old woman with an eGFR of 25 and a urine albumin to creatinine ratio of 20 mg/g has a 2.9% 2-year and an 8.7% 5-year risk of requiring dialysis. In contrast, a 70-year-old woman with an eGFR of 17 and a urine albumin to creatinine ratio of 900 mg/g has a 32.6% 2-year and a 70.9% 5-year risk of requiring dialysis. This is a TEN-FOLD higher risk. These same factors similarly identify cardiovascular disease risk and other costs. Unfortunately, despite being the best predictor of risk of dialysis and other adverse events and therefore the best predictor of cost, these critical variables are not included in the measure as they are not widely available in administrative data. Nephrologists look at these data to assign risk and plan therapies with people with advanced CKD, and any measure of risk that does not include these lacks face validity among the nephrology clinical community.
- 3) **Access to care and selection:** CMS should also closely monitor access to care for CKD Stage 4 and 5 patients, particularly those with significant comorbidities and those who are socioeconomically vulnerable. Given that nephrologists are now being held accountable for the costs of these patients, they are incentivized to see more stable early CKD (Stages 1-3) as opposed to advanced CKD patients (Stages 4 and 5) with more complex medical and social challenges.
- 4) **Risk adjustment:** Capture of hierarchical condition category [HCCs] coding is largely in the purview of primary care and other generalists, and therefore risk adjustment for nephrologists may be imperfect. Additionally, as noted above, critical risk identifiers (including social determinants of health) that account for much of the variability in risk are not included in the measure.
- 5) **Alignment with APMs:** We support CMS's efforts to align MIPS measures with CMMI measures found in APMs. In particular, we urge CMS to align MIPS CKD measures with those in the Kidney Care Choices (KCC) model. The transition to dialysis is not captured in the CKD Cost measure, but rather in the ESRD measure, which makes the scope of the CKD measure different from the optimal starts measure currently in the KCC model.
- 6) **Low Reliability: If moved forward,** use of the CKD Cost measure should be restricted to practitioners/practices with larger numbers of evaluable patients because the reliability numbers are far below the goal reliability (0.293 for a threshold of 10 patients, 0.386 for a threshold of 20, and 0.448 for a threshold of 30). ASN recommends adopting a high threshold of patients of at least 30-50 to ensure appropriate measure reliability.
- 7) **Avoiding disincentives for high value care:** ASN agrees with the decision to exclude sodium-glucose cotransporter-2 (SGLT2) inhibitor costs. Some patients with CKD stage 4 (with an eGFR of >20 ml/min/1.73m²) are candidates for initiating this drug class that should be continued until the initiation of dialysis. Avoiding disincentives for utilizing SGLT2 inhibitors is critical, and as drugs in the SGLT2 inhibitor class become generic, the cost effectiveness will likely only

improve. ASN encourages CMS to develop a performance measure for SGLT2 inhibitor use that can directly measure this utilization. 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. The use of these novel therapies that will lead to improved clinical outcomes and lower long-term costs should not be disincentivized.

MUC2023-204: End-Stage Renal Disease

Conceptually, ASN supports the development of an ESRD measure because nephrologists who care for these patients often have the ability to shape care delivery and control some modifiable costs, including emergency department visits and inpatient admissions. This was shown in the ESRD Seamless Care Organizations (ESCO) model.

ASN also has concerns regarding the measure. While reliability is better – at 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. Given the limited time provided, ASN is unable to provide more detailed comments at this time.

MUC2023-206: Kidney Transplant Management

Conceptually, ASN supports the development of a kidney transplant management episode of care cost measure. Based on the information provided, however, ASN has numerous questions and concerns. Our ability to relate these in greater detail is impacted by the limited time provided to evaluate these measures.

- 1) **Risk adjustment:** Appropriate risk adjustment for the post-transplant patient population 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.

- 2) **Data sources:** The proposal notes that the data sources for the measure are "Administrative Data (non-claims); Claims Data; Registries." ASN requests more specific information about these data sources as understanding the data sources would help ASN understand the granularity of the data and make more informed recommendations about the measure.

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

ASN continues to have concerns that the 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 ASN certainly would 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.

ASN is committed to promoting kidney health, advancing kidney care, and improving the lives of more than 37,000,000 Americans with kidney diseases. Meaningful, accurate cost measures and patient-centered quality measures are a key aspect of this commitment.

Again, thank you. To discuss this letter, ASN's concerns about the Partnership for Quality Measurement and the 2023 MSR: ESRD-QIP, or ASN, please contact ASN Regulatory and Quality Officer David White at dwhite@asn-online.org.

Sincerely,



Michelle A. Josephson, MD, FASN
President

cc: Chiquita Brooks-LaSure
Dora L. Hughes, MD

ⁱ Table 6.1 <https://usrds-adr.niddk.nih.gov/2023/chronic-kidney-disease/6-healthcare-expenditures-for-persons-with-ckd>