December 7, 2022

Measure Applications Partnership
c/o National Quality Forum
1099 14th Street NW
Suite 500
Washington DC 20005

Subject: Comment on Measures Under Consideration for Use in Federal Health Programs, 2022-2023 Pre-Rulemaking Cycle

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 Measures Under Consideration (MUCs) for use in Federal Health Programs for the Measure Applications Partnership (MAP) 2022-2023 Pre-Rulemaking Cycle. These measures shape critical components of kidney care for the approximately 800,000 Americans with kidney failure, including more than 550,000 individuals who are dependent on maintenance dialysis – many of whom may not survive long enough to receive a life-prolonging transplant.

Kidney diseases are the ninth leading cause of death in the United States, resulting in more deaths than breast cancer. These deaths are due in part to an extremely high risk of cardiovascular disease associated with chronic kidney disease (CKD) as well as a high risk of progression to kidney failure. Kidney diseases and kidney failure are more common among Black, Hispanic or Latinx, and Native or Indigenous Americans, Asians, Hawaiians and Other Pacific Islanders, people with lower incomes, and older adults; these are populations that also have been disproportionately affected by the COVID-19 pandemic, exacerbating existing disparities. For this reason, measures used in the kidney care space must be finely tuned and aligned with the care delivery approach for people with kidney diseases and must address equity.

ASN greatly appreciates the MAP undertaking this important work. ASN supports the work concepts represented here while voicing concerns that these measures do not contain the appropriate level of detail for a thorough evaluation and the compressed time frame allowed to evaluate and comment on these measures. In addition, many of the proposed measures have not been tested, particularly in the dialysis setting, and require further delineation of the numerator and denominator including more detailed risk adjustment strategies, needs greater detail. Critically, these measures also are intended for a healthcare setting stretched to its limit with work force challenges, and several of these will require increased effort for data acquisition and data entry in addition to current care. If resources do not exist for accurate data collection, the validity of the measures comes into question.

ASN offers the following comments addressing 10 measures proposed for use in the MAP. The bottom line is that ASN believes that most of the measures related to nephrology are not ready to move forward in the MAP.

MUC2022-027—Facility Commitment to Health Equity (CMS)

ASN is committed to addressing health equity for all individuals impacted by kidney diseases and supports the efforts of the National Quality Forum (NQF), MAP, and CMS. ASN has concerns with the use of attestation in the metric, as it limits the ability to understand disparities that may exist in a given facility and any related action plans that are implemented. There is also risk of this measure having limited impact on addressing disparities, with time and resources dedicated to the attestation rather than any meaningful interventions. In addition, ASN is concerned about the sensitive nature of the information being sought, particularly given the mandatory congregate hemodialysis setting. Dialysis facilities may lack the necessary expertise, training, and resources to build equity-focused organizational competencies. The extent of each facility's commitment to advancing health equity may vary widely, even among facilities that complete the attestation. Measure testing with dialysis patient and advocate input is a crucial step that does not seem to have occurred to date.

While ASN concurs that assessing social determinants of health is critical for health equity, ASN strongly urges their structured collection be tested within the intended population and care setting before it is endorsed by NQF. ASN considers both testing within the intended population as well as endorsement by NQF as critical components in this process.

MUC2022-050—Screen Positive Rate for Social Drivers of Health (CMS)
MUC2022-053—Screening for Social Drivers of Health (CMS)

In its August 22, 2022 comment letter on the ESRD QIP proposed rule, ASN wrote "ASN supports both measures conceptually, noting that, without this level of data collection, it is challenging to consistently capture and trend disparities in kidney care delivery." ASN also encouraged the agency to avoid unintended consequences brought on by increased reporting burden.

ASN notes the information provided in the MUCs list lacks the specificity required to meaningfully evaluate the measure at this time. Detailed specifications (including proposed approaches to risk adjustment and/or stratification), statistical findings of reliability and validity testing, and information on measure performance specifically within the dialysis population are needed during the MAP process to allow stakeholders to determine if a metric is feasible and will provide an accurate, actionable assessment of care within the unique dialysis facility setting.

As presented here, ASN does not believe there is sufficient detail to evaluate and support these measures nor have the measures been tested in dialysis facilities. ASN

believes that, to accurately and systematically capture these data, dialysis facility staff will require training and that processes of care to protect patient privacy will need to be tested and refined in order to obtain honest and meaningful responses to questions about social drivers of health. There will also need to be investment in time, staffing, and resources to enable data collection, which is particularly challenging during the current facility staffing crisis.

Additionally, while not specifically mentioned in the MAP materials, it appears that the metrics would eventually require use of a specific instrument, the Accountable Health Communities Model Screening Tool, an HRSN survey used in a pilot program in unrelated healthcare settings. The referenced AHC HRSN survey is lengthy, and the related fielding requirements are complex, such that the screening measure could be expected to add considerable burden to already overburdened dialysis patients and providers. We suspect that the proposed measures focus on the first 10 questions within this instrument, but this is unclear. Moreover, the survey itself has not been reviewed by NQF to confirm it is appropriate for use in the unique dialysis facility setting and to provide assurance that its psychometric properties are sufficient to support its use in the QIP and other quality programs. In the absence of such evidence, the proposal to incorporate the measures in the program cannot be fully assessed by stakeholders and is thus premature.

Following testing as described above, we would urge NQF and CMS to indicate that MUC2022-050 would be a reporting measure rather than a performance measure in order to avoid penalizing facilities that serve more socially vulnerable patients.

MUC2022-075—Standardized Modality Switch Ratio for Incident Dialysis Patients (CMS)

ASN is supportive of the concept of a Standardized Modality Switch Ratio (SMoSR) measure; however, we have concerns regarding several aspects of this proposed SMoSR measure. CMS indicates the basic premise of the measure is that patients who consent to changing their treatment modality from in-center to home do so as a result of iterative education efforts and effective decision support by nephrology clinicians and the dialysis facility, which can help patients select a modality that is best aligned with their personal goals and values.

The Technical Expert Panel (TEP) that convened in Spring 2021 to offer feedback on a draft modality switch measure had broad consensus that: 1) home dialysis rates are very low in the US; 2) a quality measure to monitor facility performance on home dialysis would be useful to patients, providers, and other stakeholders; and 3) there must be greater emphasis on effective and on-going education by both nephrologists and the facility care team to allow more patients to make a more informed modality choice. The TEP also recognized that a majority of switches to home dialysis occur within the first year of beginning chronic dialysis.

ASN agrees with all of the TEP's above conclusions. While the measure may incentivize switching in-center patients to home dialysis, there appears to be no mechanism for the measure to discern whether such conversions are the result of the "iterative education efforts and effective decision support" that CMS envisions. Additionally, there are no guardrails to ensure that the "switch" is appropriate, a need that requires an indicator of success with the home modality. This is a critical element to minimize unintended consequences and is not present within the current proposed measure.

The SMoSR measure requires use of a complicated two-part regression model connected through an estimated "mixture structure" to account for the many facilities that do not offer home dialysis ("zero-patient facilities"). We believe this issue is more effectively addressed in the approach deployed in CMS's ESRD Treatment Choices (ETC) Model, wherein the home dialysis rate is aggregated across dialysis facilities under the same legal entity/parent organization within the same Hospital Referral Region (HRR). We believe that this HRR approach better respects the existing structure many organizations have developed around home dialysis. Finally, additional information regarding risk adjustment is necessary to ensure patient complexity and other patient factors are incorporated into performance.

The NQF, in Spring 2022, voted to Not Recommend this measure for endorsement. ASN concurs with the NQF Renal Standing Committee and does not support this measure as currently proposed.

MUC2022-076 Standardized Fistula Rate for Incidents Patients

ASN has serious concerns with the AV Fistula rate for incident patients. As explained, the numerator is patient months with an AVF, and the denominator is total patient months with limited exclusions for patients in their first year of hemodialysis. The time period used is unclear (calendar year versus a continuous 12-month period).

It would seem that the attributable clinician seemingly is the monthly capitated payment (MCP) nephrologist following the patient at dialysis and/or the dialysis facility. This remains unclear. Regardless, ASN believes neither are appropriate here and that the proposed incident measure is substantially worse than the current prevalent AVF measure due to attribution issues. ASN concurs with the measure developer that "Medicare ESRD regulations (CfC494) clearly hold the dialysis facility care team (Interdisciplinary Care Team with the treating clinician as a required member) responsible for patient vascular access education and facilitation." However, ASN feels strongly that this misses the point, particularly with regard to attribution.

Specifically ASN raises the following issues:

1. Potentially insufficient risk adjustment based on life expectancy, reliant on the 2728
2. Insufficient accounting for access "life plan" as presented in the most recent KDOQI guidelines, including the incident measure not accounting for individuals

receiving peritoneal dialysis within the denominator, another desirable form of dialysis access.

3. Flawed attribution. Critically, the pre-dialysis clinician is responsible for access creation at the time of dialysis initiation. For a new hemodialysis patient starting with a catheter only, the time from a fistula surgery to a usable fistula is three to four months at best. In addition, often, the fistula may have primary failure or require additional procedures to be usable. If a patient has not previously been evaluated by a surgeon, this process could take six months. This catheter time is attributed to a clinician/facility that has no ability to modify this course. With prevalent access measures, there is a 90 day window, in part for this reason, and there is sufficient patient month time in the numerator and denominator to dilute the impact of patients initiating hemodialysis with a catheter. This is not the case with the incident measure.

ASN does not support this measure.

MUC2022-024 Hospital Harm - Acute Kidney Injury (AKI)

The title of “Hospital Harm” for this measure is misleading and prejudicial. Determining the cause of AKI is often nebulous, and more often AKI is linked to the underlying disease that resulted in the patient being admitted to the hospital as opposed to substandard or harmful care. Excluding creatinine elevations in the first 48 hours may not adequately address the delay in kidney injury seen due to progression of disease particularly in patients with complicated medical conditions that require complex interventions, patients who present with end-of-life conditions or futile medical conditions. Exclusions attempt to adjust for this, but the exclusions listed are numerous and very challenging to sort out administratively. This measure would neither reflect kidney care nor would it reflect the performance of kidney health professionals, given that most patients with the complication of AKI are not seen by nephrologists prior to the incidence of AKI. In addition, it will be challenging for institutions to accurately report on this measure given the reliance on EHR-based laboratory capture and automated calculation, which can lead to variable performance based on reporting.

Furthermore, in some occasions, a modest rise in serum creatinine may be expected and appropriate, potentially representing an indicator of high quality care rather than of harm as is alluded to by the moniker assigned to this metric. For example, there is an extensive literature that a rise in serum creatinine among individuals with congestive heart failure that is accompanied by evidence of decongestion is associated with medical benefit and not harm (please see McCallum et al, “Acute Kidney Function Declines in the Context of Decongestion in Acute Decompensated Heart Failure”). While this is more often stage 1 AKI, it can be appreciated with stage 2 AKI, especially if the baseline or nadir creatinine is falsely low (as may be the case here given the requirement for baseline eGFR above 60 mL/min per 1.73m^2). A non-harmful rise in serum creatinine may be particularly evident when decongestion is accompanied by treatments that are kidney protective but cause a rise in serum creatinine, such as SGLT2 inhibitors and agents that block the renin-angiotensin-aldosterone system, or

following initiation of agents that block creatinine excretion, such as trimethoprim-sulfamethoxazole (Bactrim).

Hospitals that see more critically ill patients are likely to have more patients with AKI. These differences are difficult to adequately risk adjust. There are multiple denominator exclusions for this measure that lack validity. For example, many diagnoses and procedures are associated with higher risk of AKI, so it is unclear which would merit denominator exclusions.

In summary, ASN finds this measure confusing and imprecise and feels the measure needs work before NQF endorsement. In particular, we would like see far greater clarity around the risk adjustment strategy for this measure and efforts to account for 'beneficial' rises in serum creatinine.

MUC2022-043 Kidney Health Evaluation for Patients with Diabetes (KED) - Health Plans

ASN fully supports this measure. Early identification of CKD by assessing estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (UACR) is crucial for facilitating use of evidence-based therapies and reducing the impact of advanced chronic kidney disease.

MUC2022-060 First Year Standardized Waitlist Ratio (FYSWR)
MUC2022-063 Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

ASN has previously expressed reservations on these measures. Specifically, there are issues with insufficient denominator exclusions and with accounting for pre-emptive transplants for nephrology clinicians. The latter actually penalizes nephrologists for practicing high quality care. Among denominator exclusions, cancer is an obvious comorbidity that needs to be incorporated into this metric. Many other criteria that are common elements that result in individuals with kidney failure not being eligible for transplant are also not incorporated into this measures. The NQF Renal Standing Committee did not recommend either of these measures for NQF endorsement. These should be revisited and should be NQF endorsed prior to use in clinical programs.

MUC2022-125 Gains in Patient Activation Measure (PAM) Scores at 12 Months

This measure is currently being tested in the Kidney Care Choices (KCC) Model. There are limited published data to support its use in the kidney disease population (without a clear association with clinical or financial outcomes established), and, critically, the PAM requires considerable financial and personnel investment to implement. ASN recommends that this measure not be added at this time while testing in the model is ongoing, particularly given the costs and burdens with implementing this measure.

Thank you for your consideration of ASN's comments. If you have any questions, please reach out to David L. White, ASN Regulatory and Quality Officer at dwhite@asn-online.org.

Scott D. Bieber, DO
Chair, Quality Committee