Renal Physicians Association

June 23, 2023

Partnership for Quality Measurement
Battelle
505 King Avenue
Columbus, Ohio 43201

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease.

RPA appreciates the opportunity to provide comments on the measures submitted to the Spring 2023 measure cycle. RPA strongly believes that nephrologists must be involved in the review and assessment of the following measures:

- Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)
- Delay in Progression of Chronic Kidney Disease (CKD) Measure
- ESRD Dialysis Patient Life Goals Survey (PaLS)

Furthermore, RPA was dismayed that no measure specifications were posted until June 5. We strongly urge PQM to make sure all measure materials are available for review when the call for comments open.

RPA's specific feedback on measures is outlined below.

Delay in Progression of Chronic Kidney Disease (CKD) Measure

While RPA applauds the goal of delaying progression to ESRD, we believe this measure as structured is not appropriate. As structured, it is less of a measure of nephrologists' performance than of their patient panel. RPA agrees with the TEP members cited in the measure specifications "concerned about the absence of eGFR data (the clinical gold standard to define stages of CKD and progression to ESRD) in the measure, as claims are potentially less granular and less consistently coded. Two other individuals cited patient-level factors outside of providers' control and potential unintended consequences that may result." The measure testing does not identify the validity of the measure based on practice size or population, only on number of eligible patients. It is unclear whether small practices or those with a sizable percentage of Medicaid patients would be unduly

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penalized by this measure. Further, the evidence cited in the ability of nephrology practices to slow progression appears to focus on ACE/ARB, rather than SGLT2 inhibitors. Given the high out of pocket cost of these SGLT2 medications and limited access based on insurer, RPA is concerned that this may create an unintended consequence of two-tiers of care – the haves and have nots.

Specifications

RPA is concerned that the use of a single ICD-10 code (N18.4) for inclusion in the denominator does not reflect the reality that patients may move between Stage 3 and 4 (or Stage 4 and 5). RPA believes the measure should require more than one Stage 4 code during the performance year to be included in the denominator.

RPA has strong concerns about potential cohort misidentification in the absence of eGFR and albuminuria clinical data. We believe that laboratory results are necessary to identify progression of disease and to provide precision in identifying the appropriate patient risk profile for the measure outcome. The international Kidney Disease Improving Global Outcomes (KDIGO) CKD Evaluation and Management Guideline as well as the US-specific Kidney Disease Outcomes Quality Initiative commentary on the CKD guideline both emphasize using eGFR and albuminuria in concert to assess risk and group individuals into risk categories for prognostication and treatment. Current risk equations for kidney failure, such as the Kidney Failure Risk Equation (KFRE) and the CKD Prognosis Consortium equation rely heavily on these two kidney disease markers for risk stratifying among individuals with CKD, achieving c-statistics of ~0.90 in multiple populations worldwide with an equation including only age, sex, eGFR and albuminuria.

Risk Factors

While the measure's specifications state "The frailty estimate (that is, the ratio of predicted to expected progression hazard) is distributed according to a lognormal distribution, $\log(wj) \sim N(0,\theta)$, where $\text{median}(wj) = 1$. The 95% confidence interval for RSRj (the frailty) will be a direct output from estimation software," there is no further detail as to what the estimation software is, who owns it and whether is accessible. Furthermore, while data dictionary includes a Risk Factors tab, which are presumably used to calculate risk of progress, information is not provide about how these factors were determined or how they will be weighted.

Exclusions

Finally, RPA has the same concerns as listed for Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD) regarding measure exclusion for patients with metastatic and advanced cancers. The requirement of specific cancer-related ICD-10 codes from an inpatient encounter do not reflect the realities of care, which may be managed exclusively as outpatient care so these codes would not be submitted. RPA recommends this be expanded to include both inpatient and outpatient ICD-10 codes for metastatic and advanced cancers.

Risk Standardized Mortality Ratio for Late-Stage Chronic Kidney Disease (CKD) and End Stage Renal Disease (ESRD)

Specifications

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RPA is concerned that the use of a single ICD-10 code (N18.4 or N18.5) for inclusion in the denominator does not reflect the reality that patients may move between Stage 3 and 4. RPA believes the measure should require more than one ICD-10 code during the performance year to be included in the denominator.

Further, RPA has concerns about potential cohort misidentification in the absence of eGFR and albuminuria clinical laboratory data. Laboratory results are necessary to identify progression of disease and to provide precision in identifying the appropriate patient risk profile for the measure outcome. This issue is of particular concern in smaller provider groups, wherein there are not a sufficient number of patients to smooth the impact of discrepant claims and clinical data.

Exclusions

RPA objects to the all-cause construct of the RSMR, believing it is too expansive in scope and will unfairly penalize clinicians and groups for outcomes beyond their control or sphere of influence. We note that the corollary facility-level mortality measure specifically excludes deaths due to street drugs or accidents unrelated to treatment; we urge CMS to revise Measure 3754 to incorporate these same numerator case exclusions.

Additionally, RPA believes that the measure exclusions should be expanded to exclude all patients for whom dialysis is ultimately not the goal of care based on shared decision-making between the clinician and patient. As written, this measure penalizes clinicians for having open conversations with their patients and supporting their patients who make the difficult decision to not pursue dialysis. Many patients want palliative care but refuse hospice because it requires them to stop dialysis or ESAs or office visits with the nephrologist. Therefore, the measure should be expanded to include those patients who choose palliative care.

Finally, while RPA supports the measure exclusion for patients with metastatic and advanced cancers, the requirement of specific cancer-related ICD-10 codes from an inpatient encounter do not reflect the realities of care, which may be managed exclusively as outpatient care so these codes would not be submitted. RPA recommends this be expanded to include both inpatient and outpatient ICD-10 codes for metastatic and advanced cancers.

ESRD Dialysis Patient Life Goals Survey (PaLS)

While the RPA appreciates the value of patient-reported measures, we are concerned that this measure would add to the survey fatigue already faced by patients with ESRD. Patients are already expected to complete the following surveys: Patient Activation Measure (PAM) twice a year; PHQ9; KDQOL; iCAHPS (also twice a year); dialysis facility specific surveys such as wellness surveys, as well as patient satisfaction every time they are discharged from a facility or have a procedure. Consequently, response rates to surveys are frequently lower than desired and can result in questionable statistical significance. RPA recommends that the measure developer explore having the survey

questions added to one of the other surveys, rather than adding addition surveys for patients and providers to track and administer.

Testing and Validity

This measure is proposed as a facility-level process measure assessing the percent of eligible patients in a given dialysis facility that completed at least one scorable item of the survey. However, only patient-level testing data on the survey instrument itself was provided; there was no information provided on the facility-level process measure being proposed for use. All information provided with the submission materials is on the survey t-score, based on the data collected during testing of the instrument—but the t-score is "currently not part of the calculation for process measure being proposed." The submission notes in the measure specifications that prior to implementation at the dialysis facility level, the response rate will need to be calculated at the dialysis facility level; it is it is unclear why this was not done prior to submission. Detailed information (performance scores, reliability, validity) for the performance metric being proposed, as specified, is an immutable component of the consensus development and endorsement processes. Therefore, an assessment of the PaLS is not feasible in the absence of this information.

As always, RPA welcomes the opportunity to work collaboratively to improve the quality of care provided to the nation's kidney patients. Any questions or comments regarding this correspondence should be directed to Amy Beckrich, RPA's Director of Projects and Operations, at 301-468-3515 or abeckrich@renalmd.org.

Sincerely,

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