2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-011	Dialysis Facility Discussion of Patient Life Goals (D-PaLS PRO-PM)
Measure Steward & Developer	**Proposed CMS Programs**
Centers for Medicare & Medicaid Services (CMS)	End-Stage Renal Disease (ESRD) Quality Incentive Program Link: End-Stage Renal Disease Quality Incentive Program

Measure Overview

Rationale (excerpt from submission): For people on chronic dialysis, discussion of patient life goals with their dialysis facility care team can lead to better understanding of these goals at the facility-, provider- and patient-levels, facilitating decision making that explicitly takes these goals into consideration and enhances patient shared decision making about modality selection, vascular access, and other treatment options for their dialysis and ESRD care. Discussing personal life goals that are important to the patient also results in patient-centered care which is an outcome in its own right.[1] This measure is intended to provide information to users about one particular aspect of patient-centered care, identification and discussion of patient life goals with those delivering care.

We spoke with both ESRD patients and nephrology physicians to directly elicit stakeholder feedback on the importance and usability of the D-PaLS PRO-PM. We held 3 focus groups with patients in December 2023. Each focus group included 7-9 participants with a final overall attendance of 25 patient participants. The groups included broad representation across the ESRD treatment modalities including in-center hemodialysis, home hemodialysis, peritoneal dialysis, and kidney transplantation. Key takeaways from the three focus groups about the usability and importance of the Patient Life Goals Survey (PaLS) include:

- The Patient Life Goals Survey (PaLS) is important
- It is important for facilities to ask about life goals during care planning
- Focus group participants would recommend the PaLS to other dialysis patients
- PaLS is easy to complete
- PaLS should be taken at least annually (or more frequently)
- PaLS should be administered anonymously
- Focus group participants also supported public reporting of facility-level PaLS scores

The feedback we received from the focus groups and the TEP indicate the PaLS is important and will provide a way for providers, payers, and others to assess how well a facility is doing in identifying and discussing life goals with ESRD chronic dialysis patients as part of the treatment planning process. A discussion of life goals between a patient and his/her/their provider(s) can inform modality option selection, such as a home dialysis therapy (home hemodialysis, peritoneal dialysis) or kidney

[1] Blake, PG., and Brown, EA. Person-centered peritoneal dialysis prescription and the role of shared decision-making. 2020. Peritoneal Dialysis Int, published ahead of print, 1-8.

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transplant, and help ensure that modality selection is aligned with the patient's life goals. Results from the PaLS can also provide payers and other stakeholders national level information about patients' experience with discussions of life goals (or absence of) with their care team, and whether patients feel their treatments are aligned with their life goals.
CMS-provided program rationale: CMS is considering adding the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) measure to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) as a new clinical quality measure. This patient-reported outcome measure reports patients' satisfaction with how well their care team discussed life goals as part of treatment planning using the Patient Life Goals Survey instrument and allows facility-level comparison of patient satisfaction around discussion of life goals by generation of a t-score. This measure will fill a gap in the Patient and Family Engagement domain.
Description: Dialysis Facility Discussion of Patient Life Goals is a patient-reported outcome performance measure (the D-PaLS PRO-PM). The D-PaLS PRO-PM is a patient-specific measure that can be used to generate a t-score that is indicative of patient satisfaction with their care team about life goals discussions during the treatment planning and ongoing treatment process. The D-PaLS PRO-PM uses the patient specific scores to generate a performance-based facility level score. The performance-based measure is the percentage of adult chronic dialysis patients at a given ESRD facility that have a t-score of greater than 40.
Measure background: Measure previously submitted to Measure Applications Partnership (MAP) Workgroup or Pre-Rulemaking Measure Review (PRMR), refined, and resubmitted per MAP or PRMR recommendation.
Numerator: The numerator is the number of eligible patients from the denominator that had a t-score of >40. Details: We begin with the number of patients at a given facility that took the PaLS survey and completed at least five of the six Likert-type scorable PaLS items that comprise the "quality of facility care team discussions" score. The response options for these six items are scored from 1 to 5. Higher scores indicate greater overall patient reported agreement that the care team is asking about and discussing life goals with the patient. IRT scores are initially estimated on the theta metric (M=0; SD=1). In order to enhance the clinical utility of our PaLS measure, we converted theta scores to standardized scores on the t-score metric (M=50; SD=10). The conversion from a theta score to a t-score can be made using the following linear transformation: t-score=(theta x 10)+50. This patient-level t-score represents a patient's perceptions about how well the facility is doing in discussing life goals as part of the treatment planning process. Next, we sum the number of eligible patients at the facility with a t-score of >40. This facility-level score represents how overall patients' perceptions about how well the facility is doing in discussing life goals as part of the treatment planning process. Scoring notes: For response pattern scoring, patients need to answer at least one of the Likert-scale items to receive a t-score. For look-up table-based scoring, patients must answer at least five of the six Likert-type scorable PaLS items to receive a t-score. **Exclusions:** None
Denominator: All adult chronic dialysis patients (>18 y/o) treated by the facility (both In-Center and Home Dialysis) for greater than 90 days during the reporting period. Details: To be in the denominator, chronic dialysis patients must be (a) at least 18 years of age; (b) receiving long-term dialysis in the United States or any U.S. Territory for greater than 90 days during the reporting period, and (c) not missing a survey. Receiving long-term dialysis in the 90-day period was selected in order to allow time for the patient to stabilize after beginning chronic dialysis, and for the dialysis care team to initiate discussions about patient life goals as part of the treatment planning process. This 90-day period also reduces facility-related burden.

 The analyses upon which this publication (or document) is based were performed under Contract Number 75FCMC23C0010, entitled, "National Consensus Development and Strategic Planning for Health Care Quality Measurement," sponsored by the Department of Health and Human Services, Centers for Medicare & Medicaid Services. Restricted: Use, duplication, or disclosure is subject to the restrictions as stated in Contract Number 75FCMC23C0010 between the Government and Battelle.

Measure Overview	
To construct our denominator for testing, we used the following data from survey participants: first name, last name, and birthdate. Participants were given a pre-filled out form that included their facility name and CCN so that we could match them to EQRS clinical and administrative data. We also used CMS administrative data to confirm dialysis modality for participants (in-center hemodialysis, home hemodialysis, peritoneal dialysis, or kidney transplant). In some cases, we could not match participants to their EQRS data. In these cases, participants were not included in the analysis using dialysis modality. At present, the D-PaLS is available in both English and Spanish. **Exclusions:** Patients are excluded from the denominator if at the time of the survey any of the following are true: they are not on chronic dialysis; are less than 18 years of age; not receiving long-term dialysis in the United States or any U.S. Territory for greater than 90 days during the reporting period; patient has a kidney transplant with a functioning allograft; and patient recovered renal function, or is lost to follow up. In our testing we also excluded duplicate patient surveys. Items to calculate these exclusions for this testing are derived from CMS administrative and EQRS data. Patients with a missing survey are also excluded. **Exceptions:** None	
Substantive changes from prior version (if applicable): Not Applicable	
Measure type: PRO-PM or Patient Experience of Care	**Measure is a composite:** No **Measure is digital and/or an eCQM:** No **Measure is a paired or group measure:** No
Level of analysis: Facility	**Data source(s):** Digital-Administrative systems: Administrative Data (non-claims) Digital-Administrative systems: Claims Data
Care setting(s): Dialysis facility	**Risk adjustment or stratification:** None
CBE endorsement status: Not Endorsed	**CBE endorsement history:** Not Endorsed by the Primary Care and Chronic Illness committee in the Spring 2023 cycle based on concerns that the evidence provided did not show a clear patient desire for this type of measurement and there was a lack of alignment with patient-preferred outcomes.
Is measure currently used in CMS programs? No	**Measure addresses statutorily required area?** No

Evaluation

Meaningfulness

Importance	
Type of evidence:	Peer-Reviewed Original Research [Source: MUC Entry/Review Information Tool (MERIT) Submission Form]
Importance: The D-PaLS PRO-PM reports on the level of patient satisfaction with the facility about care team discussions regarding life goals during the treatment planning process using the Patient Life Goals Survey instrument. Satisfaction is measured by the patient-level t-score, with a t-score >40 indicating patients are satisfied with those discussions. The performance-based measure is the percentage of adult chronic dialysis patients at a given ESRD facility who have a t-score of greater than 40, which indicates how many patients at the facility are satisfied with dialysis facility care team discussions about life goals. As outlined in the literature cited for the measure rationale, the integration of patient life goals into care planning for individuals on chronic dialysis is a critical component of high-quality, patient-centered care. Evidence from peer-reviewed studies, systematic reviews, and clinical practice guidelines demonstrate that gathering and incorporating patient life goals into treatment decisions enhances shared decision-making, aligns care with patient values, and improves both satisfaction and outcomes for people with end-stage renal disease (ESRD). Such shared decision-making also has the potential to increase uptake of home dialysis modalities and transplant, two CMS priorities for improving care and outcomes for people with ESRD. The developer cites research that consistently finds that patients value discussions about their life goals and that such conversations are often lacking in current practice. Focus groups with ESRD patients and input from a multidisciplinary technical expert panel confirms the importance and usability of the PaLS. Patients across diverse dialysis modalities endorsed the value of discussing life goals during care planning, found the PaLS easy to complete, and recommended its routine use.	
Rating: Met	

Conformance
Measure alignment with conceptual intent: This measure is designed to assess the extent to which dialysis facilities engage adult chronic dialysis patients in meaningful discussions about their personal life goals as part of the treatment planning process. The measure's numerator, denominator, and exclusions are clearly defined and directly support the conceptual intent of promoting patient-centered care and shared decision-making in ESRD management. Specifically, the numerator includes the number of eligible patients at a facility who report a t-score greater than 40 on the survey, indicating positive patient perceptions of the quality and frequency of life goals discussions with their care team. The denominator consists of all adult chronic dialysis patients (age 18 and older) who have been treated at the facility for more than 90 days during the reporting period, encompassing both in-center and home dialysis modalities. The denominator exclusions are appropriate to the population and measure intent. However, excluding individuals lost to follow-up from the measure denominator may artificially inflate a facility's score especially if those individuals left due to negative experiences. This measure aligns with the objectives of the ESRD QIP to promote high-quality, patient-centered services in renal dialysis facilities. By quantifying and reporting the frequency and quality-of-life goals discussions, the measure supports individualized care; facilitates shared decision-making about modality selection, vascular access, and other treatment

Conformance
options; and provides actionable data to drive improvements in patient experience and outcomes.
Rating: Met

Feasibility	
eCQM feasibility testing/analysis conducted:	No, not an eCQM [Source: MERIT Submission]
Feasibility: For this measure, some data elements are in structured fields in electronic sources. For general implementation, the survey can be administered in paper or electronic mode. Feasibility testing showed minimal burden on reporting entities, and the measure can be implemented without significant workflow changes because data elements are generated or collected and used by health care personnel during the provision of care. While the developer generally characterized the measure as feasible, they did note multiple barriers to facility-level data collection for the D-PaLS Survey that should be considered potential threats to feasibility, including limited facility and patient motivation, inaccurate patient address data, and poor engagement from dialysis organizations. Only one national dialysis corporation agreed to share recruitment materials, and, even then, only 30% of its facilities participated. The limited engagement of dialysis facilities is a common barrier to development of measures and is not unique to this development effort. A revised direct-to-patient strategy also failed to improve response rates. The use of this measure has the potential to increase the burden on patients who may be asked to complete multiple patient-reported instruments for their clinical visit. CMS ESRD QIP leadership indicated that they plan to address these known implementation challenges during rulemaking finalization. **Considerations for the committee:** Are there potential mitigations strategies or implementation resources that should be considered to address threats to feasibility of this measure within the selected program?	
Rating: Not Met but Addressable	

Validity	
Validity testing method(s):	Empiric Validity, Face Validity [Source: MERIT Submission Form, Facility Discussion of Patient Life Goals Documentation Form]
Testing level(s)	U.S. Chronic Dialysis Population (patient level). The measure testing was performed on a sample that reflected the U.S. chronic dialysis population at the patient level. [Source: MERIT Submission Form Supplemental Testing Attachment]
Was this measure tested in the same target population as the CMS program?	Yes
Validity: Focus group survey results from 2023 and TEP deliberations in 2024 support the face validity of the measure. To establish empirical validity, the developer tested validity of the PaLS instrument using methods described below. However, committee	

Validity
members should note that the empirical testing focused on the PaLS tool scores themselves, rather than the overall measure score that incorporates PaLS scores in its calculation. The developer should conduct further testing to evaluate the empirical validity of the PRO-PM score specifically, rather than limiting analysis to validation of the PaLS tool itself. • Known-groups validity testing showed that patients on home dialysis reported greater life goals satisfaction than those on in-center dialysis in the calibration sample (effect size = 0.50, moderate). Additionally, participants with poor health-related quality of life (HRQOL) consistently reported greater dissatisfaction with life goals discussions than those with good HRQOL across all Patient-Reported Outcome Measurement Information System (PROMIS) domains examined. • The developer found no evidence of floor or ceiling effects in both calibration and validation samples. In the calibration and validation testing samples, floor and ceiling effects were both below 20% (floor effects 0.39% and ceiling effects 6.1% in the calibration sample; floor effects 0.48% and ceiling effects 5.8% in the validation testing sample), indicating that the PaLS captured a broad range of patient responses without clustering at the extremes. • Convergent and discriminant validity showed that the patient-level PaLS t-score was moderately correlated (r=0.46) with PROMIS Meaning and Purpose scores, supporting convergent validity as hypothesized. All other correlations between PaLS scores and PROMIS measures were below 0.36, providing evidence of discriminant validity. • Responsiveness in the validation testing sample showed that the PaLS t-score was responsive to changes in participants' life circumstances over a 3-month period. Participants who experienced a higher number of life events, or more impactful life events, showed significantly greater changes in their PaLS t-scores, indicating increased dissatisfaction with care team discussions about life goals. The developer posits that major life events prompt patients to re-evaluate their life goals and treatment plans, which highlights the importance of revisiting discussions about life goals during these periods. The developer also explored responsiveness at 6 months; however, this was not found to be statistically significant.
Threats to validity: Calibration and validation testing showed PaLS t-scores changed meaningfully for a substantial proportion of participants over time, indicating that patients' life goals can shift and should be discussed regularly with the care team. The PaLS survey can differentiate patient responses across time points. However, statistical analysis revealed negligible or small standardized response means (SRMs) for related health domains, and changes in PROMIS measure scores did not predict changes in PaLS t-scores. This suggests that changes in physical or mental health, or sense of meaning and purpose, do not necessarily correspond to changes in life goals. Additionally, the developer noted that there was a low level of missing data which did not bias performance results since a t-score can still be calculated even if one item is missing from the six Likert-type scorable PaLS items.
Rating: Not Met but Addressable

Reliability	
Reliability testing method(s):	Random Split-Half Correlation [Source: MERIT Submission Form]
Testing level:	U.S. Chronic Dialysis Population (patient level). The measure testing was performed on

Reliability	
	a sample that reflected the U.S. chronic dialysis population at the patient level.
Reliability discussion: In the calibration and validation testing samples, response pattern reliability, Cronbach's alpha reliability, and marginal reliability all supported the internal consistency reliability of the set of six Likert-type scorable items included in the PaLS instrument (i.e., all values were ≥0.84, indicating "very good" internal consistency). Additionally, all measures of reliability were consistent across both testing samples. However, further reliability testing of the PRO-PM measure across facilities should be conducted to establish this measure as capable of consistently differentiating quality of care across measured entities.	
Additional Reliability Analyses: No additional reliability analyses were performed.	
Rating: Not Met but Addressable	

Usability	
Usability considered in application:	Measure usability in the selected program and settings is not documented as the developer noted the measure is not yet implemented in a public reporting program. [Source: MERIT Submission Form]
Usability discussion: While the measure submission materials do not address the measure's usability in the selected program and settings, the developer noted that most ESRD patient focus group participants supported public reporting of PaLS scores to increase transparency and motivate facility improvement, although some worried about negative reactions to poor scores. Additionally, most focus group participants supported the periodic assessment of the PaLS, ranging from more often in the year (e.g., every 3 months) to annually. The TEP agreed that the PaLS instrument is important and noted that life goals conversations are not happening consistently among dialysis patients. The developer did not identify any potential unintended consequences if implemented within the ESRD QIP program. The developer noted that they faced multiple barriers to facility-level data collection for the D-PaLS Survey, including limited facility and patient motivation, inaccurate patient address data, and poor engagement from dialysis organizations. Only one national dialysis corporation agreed to share recruitment materials, and, even then, only 30% of its facilities participated. A revised direct-to-patient strategy also failed to improve response rates. The developer may wish to consider additional use of an implementation guide to mitigate these challenges.	
Rating: Not Met but Addressable	

Appropriateness of Scale

Appropriateness of Scale	
Similar or related measures in program(s):	None specified
Measure balance, burden, and value across target populations/measured entities: This measure reports on patients' satisfaction with their care team and whether the care team asked about life goals and discussed these life goals as part of treatment planning to the satisfaction of	

Appropriateness of Scale
the patient. Rural facilities, under-resourced facilities, and facilities that serve complex or disadvantaged populations are still expected to have treatment planning discussions with patients; therefore, the measure does not adjust for these facility or patient characteristics. This approach is also consistent with CMS regulations for dialysis facilities that require discussions about kidney replacement modality and other aspects of treatment, including consideration of how treatment can be planned to best support the patient's personal values and life goals. **Considerations for the committee:** The committee should consider whether public reporting of PaLS scores creates accountability without penalizing facilities that care for complex or disadvantaged populations.

Time-to-Value Realization

Time-to-Value Realization	
Plan for near- and long-term impacts after implementation:	None specified
Measure implementation impacts over time: While the measure developer highlights potential benefits of the measure to patient populations, there may be need for further examination of near- and long-term impacts of this measure after implementation. **Considerations for the committee:** • What are the potential near- and long-term impacts of this measure on measured entities, proposed CMS programs, and patient populations? • Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame? • How will this measure mature through revisions in the future if added to ESRD QIP's measure sets?	