

## 2025 Pre-Rulemaking Measure Review Preliminary Assessment

MUC ID	Title
MUC2025-064	Facility Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients
Measure Steward & Developer	Proposed CMS Programs
Centers for Medicare & Medicaid Services (CMS)	End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Link: <a href="#">End-Stage Renal Disease Quality Incentive Program (ESRD QIP)</a>

Measure Overview
<p><b>Rationale:</b> The hyperphosphatemia measure was developed based on the recommendations of a clinical technical expert panel’s (TEP) consideration of the multiple large, risk-adjusted observational studies demonstrating a consistent relationship between presence of chronic hyperphosphatemia and adverse patient outcomes including cardiovascular complications, bone fracture, and increased mortality. In addition, prospective studies have reported lower mortality in patients treated with improved phosphorus control or who used phosphate-binding medications. This measure will help facilities identify patients with chronic elevation in phosphorus that may need additional intervention such as nutritional counseling, initiating of phosphorus binding medications or adjustment of dialysis prescription. Improvements in the proportion of patients with a chronically elevated phosphorus should decrease cardiovascular complications, hospitalizations, and overall mortality.</p>
<p><b>CMS-provided program rationale:</b> CMS is considering adding the Facility Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients measure to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) as a new clinical quality measure. The purpose of this measure is to focus quality efforts on those patients with significant, chronic elevations in phosphorus who would benefit from additional intervention, as improvement in chronic hyperphosphatemia can improve cardiovascular complications, fracture, hospitalizations, and mortality. The intent would be to replace the current Hypercalcemia reporting measure with this new measure while maintaining compliance with statutory requirements to include a bone and mineral metabolism measure in the ESRD QIP measure set.</p>
<p><b>Description:</b> Percentage of adult dialysis patients with a 6-month rolling average phosphorus value greater than or equal to 6.5 mg/dL.</p>
<p><b>Measure background:</b> New measure never reviewed by the Measure Applications Partnership (MAP) Workgroup, or PRMR or used in a Medicare program.</p>
<p><b>Numerator:</b> Number of patient reporting months in the denominator with a 6-month rolling average phosphorus greater than or equal to 6.5 mg/dL.</p> <p><b>Exclusions:</b> N/A</p>
<p><b>Denominator:</b> Number of patient reporting months among adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had ESRD for greater than 90 days.</p> <p><b>Exclusions:</b> In addition to exclusions that are implicit in the measure definition (age &lt;18 years old, &lt;90 days of ESRD, or not receiving treatment at the facility for the full calendar month) there are two</p>

Measure Overview	
additional exclusions: 6-month rolling average albumin of less than 3.5 mg/dL BMI under 18.5 <b>Exceptions:</b> N/A	
<b>Substantive changes from prior version (if applicable):</b> N/A	
<b>Measure type:</b> Intermediate Outcome	<b>Measure is a composite:</b> No <b>Measure is digital and/or an eCQM:</b> No <b>Measure is a paired or group measure:</b> No
<b>Level of analysis:</b> Facility	<b>Data source(s):</b> Digital-Administrative systems: Administrative Data (non-claims) Digital-Administrative systems: Claims Data
<b>Care setting(s):</b> Dialysis Facilities	<b>Risk adjustment or stratification:</b> No
<b>CBE endorsement status:</b> Endorsed	<b>CBE endorsement history:</b> <a href="#">Endorsed</a> 2024
<b>Is measure currently used in CMS programs?</b> No	<b>Measure addresses statutorily required area?</b> Yes, mineral and bone metabolism is a statutorily required area of quality measurement in the ESRD QIP.

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## Evaluation

## Meaningfulness

Importance	
<b>Type of evidence:</b>	Clinical Guidelines or U.S. Preventive Services Task Force (USPSTF) Guidelines, Peer-Reviewed Original Research [MUC Entry/Review Information Tool (MERIT) Submission Form]
<p><b>Importance:</b> Chronic hyperphosphatemia is a common complication in patients with ESRD, associated with increased risks of cardiovascular events, bone disorders, and mortality. Management of serum phosphorus is a routine part of dialysis care, and dialysis facilities are responsible for implementing interventions such as dietary counseling, phosphorus binders, and dialysis adjustments. National guidelines recommend monitoring and lowering elevated phosphate levels. While randomized controlled trials in this topic area are lacking, the measure developer conducted a comprehensive literature review and presented extensive observational evidence linking elevated phosphorus levels to adverse outcomes. The developers noted that this measure was meaningful to patients, with less time in hospital cited as important to quality of life. During CBE endorsement review in 2024, the committee found the evidence supporting the importance of this measure to be sufficient.</p>	
<b>Rating:</b> Met; Prior CBE Endorsement	

Conformance	
<p><b>Measure alignment with conceptual intent:</b> The intent of this measure is to help facilities identify patients with chronic elevation in phosphorus that may need additional intervention such as nutritional counseling, initiating of phosphorus-binding medications, or adjustment of dialysis prescription. The measure’s numerator, denominator, and exclusions are clearly defined and directly support the intent of this measure. Specifically, the numerator captures the number of patient reporting months in the denominator with a 6-month rolling average phosphorus greater than or equal to 6.5 mg/dL. The denominator captures the number of patient reporting months among adults (greater than or equal to 18 years old) receiving in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had ESRD for greater than 90 days. This measure aligns with the End-Stage Renal Disease Quality Incentive Program goal to promote high-quality services in renal dialysis facilities.</p>	
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Feasibility	
<b>eCQM feasibility testing/analysis conducted:</b>	No, not an eCQM
<p><b>Feasibility:</b> Phosphorus levels are routinely monitored as part of standard dialysis care, and the relevant data are already required for submission to the End Stage Renal Disease Quality Reporting System (EQRS) for Medicare-certified dialysis facilities—the entities participating in ESRD QIP. Because all necessary data elements are generated during routine clinical workflows and available in electronic sources, implementation of the measure is not expected to introduce additional data collection burden or disrupt existing care processes.</p> <p>During CBE endorsement review in 2024, the committee found the feasibility of this measure to be sufficiently demonstrated.</p>	
<b>Rating:</b> Met; Prior CBE Endorsement	

Validity	
<b>Validity testing method(s):</b>	Empiric validity [MERIT submission form; Supplemental Materials]
<b>Testing level(s)</b>	Facility
<b>Was this measure tested in the same target population as the CMS program?</b>	Yes
<p><b>Validity:</b> Poisson regression analysis indicates that dialysis facilities with higher rates of chronic hyperphosphatemia have correspondingly higher mortality and hospitalization rates. Facilities in the highest quintile had 18% higher mortality and 13% higher hospitalization compared to those in the lowest quintile. These results align with expectations and support the measure’s validity in reflecting facility-level performance.</p> <p>During CBE endorsement review in 2024, the committee found the validity of this measure to be sufficiently demonstrated.</p>	
<p><b>Threats to validity:</b> The measure developer did not discuss potential threats to validity of the measure at the facility level. Risk adjustment and stratification are not indicated for this measure.</p> <p><b>Consideration for the committee:</b> Based on committee members’ professional experience, are there additional threats to validity such as patient- or facility-level confounding factors that should be considered for this measure? If so, how might these be mitigated during data collection and reporting?</p>	
<b>Rating:</b> Met; Prior CBE Endorsement	

Reliability	
<b>Reliability testing method(s):</b>	Signal-to-Noise [MERIT Submission Form]
<b>Testing level:</b>	Facility

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Reliability
<p><b>Reliability discussion:</b> Reliability testing using 2022 data showed an inter-unit reliability (IUR) of 0.77, indicating that 77% of the variation in the measure is due to differences between facilities. This suggests a high level of reliability, because the distribution is non-normal. Interpretation of the IUR should be approached with caution, as it may not fully capture variability across providers.</p> <p>During CBE endorsement review in 2024, the committee found the reliability of this measure to be sufficiently demonstrated.</p>
<p><b>Additional reliability analyses:</b> Battelle staff performed additional assessment of reliability testing data in Table 2 to provide committee members a standardized format to assess reliability by decile across measures.</p>
<p><b>Rating:</b> Met; Prior CBE Endorsement</p>

### Reliability Tables

The developer provided information by decile for performance scores and calculated reliability for the 7,494 entities described in the testing submission. Tables 1 and 2 show deciles by performance score and reliability. For this proportion measure, a lower score indicates better quality of care.

**Table 1. MUC2025-064 Performance Score Deciles**

Highest Performers ←—————→ Lowest Performers

-	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Score	23.1%	0%	7.8%	13.4%	16.0%	18.4%	20.6%	22.9%	25.4%	28.3%	32.1%	45.8%	100%
Entities	7,497	15	749	750	749	751	749	750	750	746	754	749	28

**Table 2. MUC2025-064 Mean Reliability (by Reliability Decile)**

Mean	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10
0.767	0.476	0.590	0.652	0.694	0.728	0.757	0.783	0.810	0.839	0.883

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Usability	
<b>Usability considered in application:</b>	Yes, the submission materials briefly discuss the measure’s usability within the ESRD QIP.
<p><b>Usability discussion:</b> The measure has high usability within the CMS ESRD QIP due to its reliance on routinely collected data, alignment with clinical guidelines, and potential to reflect meaningful differences in facility-level care. The developer anticipates that reducing chronic hyperphosphatemia could lead to lower hospitalization and mortality rates, potentially generating cost savings. However, these savings may be offset by increased medication costs for phosphate binders and absorption inhibitors.</p> <p>The developer identified two unintended consequences in submission materials. First, efforts to lower phosphorus levels may risk patient malnutrition. To address this, the measure excludes patients with indicators of malnutrition, such as low serum albumin or underweight BMI. Second, the pill burden and poor palatability of phosphate binders may negatively affect patients’ quality of life. These considerations highlight the importance of balancing clinical outcomes with patient-centered care in measure implementation.</p> <p>During CBE endorsement review in 2024, the committee found the use/usability of this measure to be sufficiently demonstrated.</p>	
<b>Rating: Met; Prior CBE Endorsement</b>	

## Appropriateness of Scale

Appropriateness of Scale	
<b>Similar or related measures in program(s):</b>	None specified
<p><b>Measure balance, burden, and value across target populations/measured entities:</b> The measure offers a balanced mix of burden and benefit for both patients and dialysis facilities. For facilities, the burden is low because the measure uses data already collected during routine care and it aligns with existing clinical responsibilities. The potential benefit includes improved patient outcomes and reduced hospitalization rates, though facilities may face increased medication costs.</p> <p>For patients, the measure supports better health outcomes by targeting a known risk factor—chronic hyperphosphatemia. However, it may also introduce challenges such as increased pill burden and potential impacts on quality of life. To reduce harm, the measure excludes patients at risk of malnutrition. Overall, the measure is designed to improve care while minimizing disruption and unintended consequences.</p> <p>The developer’s literature review and analysis do not indicate a potential for differential benefit or harm to specific subgroups of participating entities or their patient populations.</p> <p><b>Considerations for the committee:</b> Based on clinical and professional experience, the committee should consider the distribution of benefit and risks/burdens of the measure within the proposed program population.</p>	

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Time-to-Value Realization

Time-to-Value Realization	
<b>Plan for near- and long-term impacts after implementation:</b>	Yes, near- and long-term impacts are identified in submission materials.
<p><b>Measure implementation impacts over time:</b> The developer notes several new and long-term impacts of the measure. In the short term, reducing chronic hyperphosphatemia is expected to lower hospitalization and mortality rates at the facility level, potentially improving patient outcomes and generating cost savings. Over the long term, the measure may encourage more consistent and proactive management of mineral and bone disorders (MBD) across dialysis facilities, aligning care with clinical guidelines and improving overall treatment quality.</p> <p><b>Considerations for the committee:</b></p> <ul style="list-style-type: none"> <li>• Will benefits and burdens associated with this measure be realized within an appropriate implementation time frame?</li> <li>• How will this measure mature through revisions in the future if added to these programs' measure sets?</li> </ul>	