CBE ID

5320

Title

Percentage of Chronic Hyperphosphatemia in Dialysis Patients

Project

Advanced Illness and Post-Acute Care

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2030

Previous Endorsement Cycle

Fall 2025

Initial Endorsement

Wed, 02/25/2026 - 14:10

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

New

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Percentage of adult dialysis patients with a rolling average phosphorus value greater than or equal to 6.5 mg/dL and pediatric dialysis patients with a rolling average phosphorus value greater than or equal to 7.0 mg/dL.

1.7 Measure Type

Intermediate Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

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 hyperphosphatemia and adverse patient outcomes including cardiovascular complications, bone fracture, and increase mortality. In addition, prospective studies have reported lower mortality in patients treated with improved phosphorus control or who used phosphate-binding medications. Currently dialysis facilities report whether a phosphorus level was obtained on a monthly basis, but are not evaluated on how well phosphorus levels are controlled. This measure will help facilities identify patients with chronic elevation in phosphorus that may need additional intervention such as nutritional counseling, phosphorus binding medications or adjustment of dialysis prescription. Improvements in the proportion of patients with a chronically elevated phosphorus should help to decrease cardiovascular complications, hospitalizations, and overall mortality.

This measure was originally developed for use in the adult dialysis population (CBE4650) and received endorsement from PQM during the fall 2024 cycle. At that time, the original TEP recommendation was to exclude pediatric patients since we were unable to obtain sufficient input from pediatric providers. After obtaining additional expert input from pediatric dialysis providers over the past year, pediatric (ages 1-17 years old) dialysis patients have been added into the measure. We considered developing a stand-alone pediatric measure, or using age-stratification, but noted several limitations to these approaches related to the small pediatric population. Specifically, there are <1,500 pediatric patients who receive maintenance dialysis and there are only 240 (out of >7,500 dialysis facilities) dialysis facilities that treat pediatric patients. Since the measure is only reported for facilities that have 10 or more patients, this means that only 49 of the 240 facilities that treat pediatric patients would be eligible for a measure score if we had either a stand-alone measure or relied on stratified reporting. As an alternative, including pediatric patients into the existing measure, although with different criteria for the numerator, allows the entire pediatric population to be included.

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

1.13a-Data-dictionary_All-Patient-Hyperphosphatemia.xlsx

1.14 Numerator

Number of adult patient reporting months in the denominator with a 6-month rolling average phosphorus greater than or equal to 6.5 mg/dL and pediatric patient reporting months with a 3-month (12-17 years old) or 6-month (1-11 years old) rolling average phosphorus greater than or equal to 7.0 mg/dL.

1.14a Numerator Details

A patient reporting month is defined as the last month of the observation period; There are two different length observation periods based on the patient's age. For patients age 13 and up, this is a 6-month time period and for patients ages 1-12, this is a 3-month time period. For example, for an adult patient the June 2023 reporting month is the average phosphorus value of the reporting month + the past five months (January – May 2023). August through December of the prior calendar year will be used to calculate the 6-month rolling average for January – May of the current reporting year. The 6-month rolling average phosphorus is calculated by taking the first phosphorus value from the current month and up to 5 prior consecutive calendar months for a given patient. The 3-month rolling average phosphorus value is calculated by taking the first phosphorus value from the current month and up to 2 prior consecutive calendar months for a given patient (if age is 1-12 years old). These values are averaged to create a rolling average for the current reporting month. A facility's patient reporting months are included in the numerator when their rolling average phosphorus is greater than or equal to 6.5 mg/dL for adult patients (ages 18 and up) or greater than or equal to 7.0 mg/dL for pediatric patients (ages 1-17 years of age). If there are multiple phosphorus measurements during the month, only the first value in the calendar month will be used for the calculation.

For the 6-month rolling average, missing is defined as no phosphorus value in >2 of the six months used in the reporting period. Up to 2 missing phosphorus values are allowed in a 6-month period. If more than 2 missing values are present in the 6-month period, then the patient-month is included in the numerator as having hyperphosphatemia. For the 3-month rolling average, missing is defined as no phosphorus value is >1 of the three months used in the reporting period. If more than 1 missing value is present in the 3-month period, then the patient-month is included in the numerator as having hyperphosphatemia.

Please refer to the data dictionary attachment under 1.13a for the list of EQRS data elements.

1.15 Denominator

Number of patient reporting months among all 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.

1.15a Denominator Details

A patient reporting month is included if the patient is >1 year of age, has had ESRD for 90 or more days, and has been receiving treatment at the same facility for the entire calendar month.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the most recent month of the reporting period. The patient's time on dialysis will be determined by subtracting the patient's date regular chronic dialysis began from the first day of the most recent month of the reporting period. New ESRD patients who are 13 and up must be at the same dialysis facility for seven consecutive months before being included in the measure (first three months excluded due to the 90-day ESRD rule above, plus an additional four months to meet minimum number of reporting months to be included in the denominator since two missing months are allowed). New ESRD patients who are 1-12 years of age must be at the same dialysis facility for five consecutive months before being included in the measure (first three months excluded due to the 90-day ESRD rule above, plus an additional two months to meet the minimum number of reporting months to be included in the denominator since one missing month is allowed). Established ESRD patients who are over the age of 13 years old who transfer to a new facility must have four consecutive months at the new facility to be included in the denominator (since two missing months are allowed) while patients ages 1-12 years old who transfer must have two consecutive months at the new facility to be included.

Patients on dialysis are included if the primary Type of Dialysis is In-center Hemodialysis, Home Hemodialysis, CAPD or CCPD in the most recent month of the reporting period. Patients are assigned to a facility if they have had care there for at least 30 days. The patients time under care at the facility is calculated from the admission date to the last day of the most recent month of the reporting period. If the patient is discharged from the facility prior to last day of the most recent month of the reporting period, then the patient is excluded from the denominator.

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. EQRS is the primary basis for placing patients at dialysis facilities and dialysis Medicare claims (if available) are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from EQRS (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

Please refer to the data dictionary attachment under 1.13a for the list of EQRS data elements.

1.15b Denominator Exclusions

In addition to exclusions that are implicit in the measure definition (age <1 years old, <90 days of ESRD, or not receiving treatment at the facility for the full calendar month) there are two

additional exclusions:

- 6-month rolling average albumin of less than 3.5 mg/dL for patients who greater than or equal to 13 years old.
- BMI under 18.5 for patients greater than or equal to 18 years old.

Please refer to the data dictionary attachment under 1.13a for the list of EQRS data elements.

1.15c Denominator Exclusions Details

For a given patient reporting month, the exclusion criteria must not be met within the entire 6-month window used to calculate rolling averages for phosphorus and albumin. Therefore, age and duration of ESRD at start of each rolling average "window" is needed to calculate denominator exclusions, as well as valid albumin and phosphorus values. A patient needs at least 4 out of a possible 6 valid values in the rolling average window to have a valid 6-month rolling average phosphorus or albumin value.

BMI is calculated from the height and weight that are present on the CMS Form 2728.

1.15d Age Group

Children (0-17 years), Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

Patient reporting months with a rolling average phosphorus of 6.5 mg/dL or greater (for patients 18 and older) or 7.0 mg/dL or greater (for patients 1-17 years old) are included in the numerator. The number of patient reporting months with an elevated phosphorus is divided by the total number of patient reporting months, by facility. This value is multiplied by 100 to get the percentage of patient reporting months with hyperphosphatemia for each facility.

1.18a Attach measure score calculation diagram

Flowchart_All-Patient-Hyperphosphatemia_508.pdf

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Registries, Other

1.20a Other Data Source

ESRD Quality Reporting System (EQRS): national registry of dialysis patients with mandatory participation from all Medicare-certified dialysis facilities.

1.20d Format: Other Data Source

Digital

1.21a Data Collection Tool URL(s)

http://example.com

1.25 Data Source Details

When dialysis facilities obtain monthly serum phosphorus levels as part of routine clinical care, most clinics have a process to automatically upload these results into EQRS (a mandatory reporting mechanism for all CMS-certified dialysis facilities) in a process referred to as “batch-submission”. Phosphorus values to calculate the measure are sourced from EQRS. We did not encounter any issues related to the data collection that would impact the feasibility, reliability, or validity of the measure.

Data for patient placement at a specific dialysis facility are also primarily based on EQRS facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data). If needed, supplemental information is obtained from the Renal Management Information System (REMIS), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data when available. In addition, we obtain transplant data from the Scientific Registry of Transplant Recipients (SRTR), and other data from the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Care Compare.

1.26 Minimum Sample Size

Public reporting of this measure on Care Compare or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

2.1 Attach Logic Model

2.1-Phosphorus_Logic-Model_508.pdf

2.2 Evidence of Measure Importance

Kidney disease is almost always associated with complex alterations of mineral metabolism. The magnitude and severity of these alterations typically become more severe with worsening kidney

failure and progression to End Stage Kidney Disease (ESKD). Primary mineral alterations include loss of active vitamin D (calcitriol) synthesis by the kidneys and reduced renal clearance of serum phosphorus, leading to hypercalcemia, hyperphosphatemia and secondary hyperparathyroidism. Disruptions have been identified for other interrelated markers such as FGF-23 and circulating Klotho receptor. These primary alterations create a pathologic milieu that, over a period of years, predisposes patients to metabolic bone disease and other complications. (Hamato Kidney Int 106:191-195, 2024; Murray AJKD 83(2):241-256, 2024) End stage Kidney Disease (ESKD) mineral and bone disease (MBD) has been associated with several adverse clinical outcomes including increased mortality, cardiovascular complications, several bone disorders including osteitis fibrosa cystica (consequent to chronic high-turnover bone disease), osteomalacia (consequent to low turnover bone disease), osteopenia/porosis, among others contributing to the excessive outcome and symptom burden in this population. (Noordzij NDT 21(9):2676-7, 2006; Kestenbaum AJKD 60(1):3-4, 2012; Waheed NDT 28(12):2961-8, 2013; Doshe Kidney Int Reports 2022; Scialla AJKD 77(1):132-141, 2021; KDIGO 2017 Update Kidney Int Supplements 7(1), 2017)

Dialysis facilities and clinical providers have been at the center of efforts to treat ESKD MBD for over fifty years in order to mitigate the deleterious effects of MBD on the individuals they treat. Blood biochemical markers associated with ESKD MBD and its treatments are regularly obtained from almost all US dialysis patients (i.e. monthly blood calcium and phosphorus, alkaline phosphatase and other enzymes reflecting bone metabolic activity; quarterly to annual parathyroid hormone concentrations; etc.). (see Dialysis Facility Care Compare for details) Medicare ESKD Dialysis Facility regulations (Interpretive-Guidance-Version1.1-508.pdf, downloaded from https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-... 8/7/2024) specify diagnosis and treatment of ESKD MBD as the responsibility of the dialysis facility's Interdisciplinary Treatment team (CfC 494, V505, V508, V545, V546). The majority of ESKD dialysis patients are treated with phosphorus binders alone or in combination with other agents to treat MBD. (Hall CJASN 15:1603-13, 2020-) Federal statute require quality metrics that inform policy makers on the effectiveness of ESKD MBD treatment in the US chronic dialysis population. Finally, many national and international evidence-based consensus quality guidelines defining goals for high-quality treatment and prevention of ESKD MBD and its complications have been published and/or updated over the last two decades. (The most recent guideline is: KDIGO 2017 Update Kidney Int Supplements 7(1), 2017)

Historically, extensive observational literature established a strong association between hyperphosphatemia and adverse outcomes (all-cause and/or CV mortality; hospitalization, esp. CV-related) in chronic dialysis patients. A large number of observational studies, mostly at the patient-level, over two decades convincingly demonstrate the consistent association between hyperphosphatemia and clinically important increases in patient adverse outcomes. (Block AJKD 31(4):607-17, 1998; Block JASN 15(8):2208-18, 2004; Ganesh JASN 12(10):2131-2139, 2001; Kalantar-Zadeh Kidney Int 70:771-780, 2006; Young Kidney Int 67(3):1179-87, 2005; Zitt CJASN 6(11):2650-56, 2011; Block CJASN 8:2132-40, 2013; Fukagawa AJKD 63(6):979-87, 2014; Rivara JASN 26(7):1671-81, 2015; Zhang JAMA Network Open 6(5):e2310909, 2023; Kim NDT 2024 online ahead of print.)

The purported mechanisms linking hyperphosphatemia and these outcomes include acceleration of calcific uremic vasculopathy and related cardiovascular, cerebrovascular, and peripheral vascular events either directly, or potentially in part, through stimulation of hyperparathyroidism. (Cannata-Andia Nephrol Dial Transplant. 2002;17 Suppl 11:16-9; Gross Circulation J 78:2339-2346, 2014) More recently, identification of additional circulating hormones associated with MBD in general and hyperphosphatemia specifically (e.g. FGF-23, circulating Klotho receptor, etc.) have increased interest in the potential link between hyperphosphatemia and cardiac hypertrophy and clinical consequences of cardiac hypertrophy on clinical outcomes in this patient population (Moe Circulation 132(1):27-39, 2015). Experimental laboratory animal models support all of the potential causal mechanisms described above. (Gross Circulation J 78:2339-2346, 2014).

Most ESKD MBD treatment algorithms suggest mitigation of hyperphosphatemia as a foundational component of efforts to reduce the debilitating and potentially lethal complications of this condition. Strategies recommended to control hyperphosphatemia include patient education, counselling, and dietary planning by registered dietitians at each dialysis facility to facilitate dietary phosphorus reduction, reduction of GI tract absorption of phosphorus with dietary phosphorus binders and/or more recently developed GI phosphorus absorption inhibitors, and increasing dialytic clearance of phosphorus with intensified dialysis regimens. (Navaneetham Cochrane Database Systemic Review 16(2), 2011- meta-analysis; Noori CJASN 5(4):683-92, 2010; Floege J Nephrol 33:497-508, 2020; FHN Trial Investigators NEJM 363(24):2287-2300, 2010; Rocco Kidney Int 80(10):1080-91, 2011; Schorr J Renal Nutrition 21(3):271-6, 2011; Ok NDT 26(4):1287-96, 2011; Walsh Hemodialysis Int 14(2):174-81, 2010; Culleton JAMA 298(11):1291-99, 2007;)There are a relatively large number of phosphorus lowering drug trials that demonstrate the ability to reduce phosphorus concentrations. Some of those trials include endpoints that inform on the outcomes of interest. However, there are no placebo-controlled trials that allow determination of the magnitude of effect of these phosphorus-reducing interventions on ESKD patients. (Palmer AJKD 68(5):691-702, 2016- meta-analysis) These phosphorus-control interventions are clearly and unequivocally under the control of the ESKD dialysis interdisciplinary team.

The initial KDIGO Consensus Guidelines for treatment of MBD were published in 2009. In 2017, KDIGO consensus guidelines for treatment of CKD-related MBD updates were published. (KDIGO 2017 Update Kidney Int Supplements 7(1), 2017) The following table, including the 2017 guidelines for control of hyperphosphatemia, summarize the updated guidelines (Section 4.1) relevant to the measure topic presented here.

Prior to convening a clinical technical expert panel in 2024 charged with recommendation of new quality measures for dialysis facility MBD treatment, the UM-KECC team supplemented the prior KDIGO systematic literature searches by replicating the KDIGO search strategy from the 2017 update, using January. 2015 through early 2024 as the publication search date range. We also searched known sources for both U.S. and international CKD MBD consensus guidelines, published since the KDIGO 2017 update. We identified the 2017 KDIGO Bone and Mineral Guideline Update as the most recent comprehensive guideline set for this topic. Several national and regional international consensus organizations have subsequently commented on the 2017 KDIGO updated guidelines.

One KECC investigator scanned the initial search result set of approximately 16,800 citations to identify extraneous or off-topic results. We excluded any citations not directly related to primary MBD management, focusing primarily on the ESKD chronic dialysis patient population.

After exclusions, our search returned approximately 2600 unique citations of varying quality, including reviews, meta-analyses and original scientific publications. The UM-KECC team identified three primary topics (phosphorus control, clinical lab target values, and treatment of secondary hyperparathyroidism) of interest for our primary review. Three KECC investigators with clinical experience in management of chronic dialysis treatment reviewed the citation set for potentially informative studies related to the clinical topics of interest. Potentially informative citations, including abstract and comments from the primary KECC reviewer, organized by primary topic were provided to our clinical TEP members for review prior to the TEP meetings. In addition, the TEP co-chairs contributed additional related citations to facilitate TEP discussion.

As a result of our supplemental searches, we identified several recent observational studies confirming the association between hyperphosphatemia and patient outcomes previously reported (generally mortality and/or hospitalization). Two of these studies were of particular interest to TEP members and were central to their strong recommendation to develop a quality measure based on chronic hyperphosphatemia with a definition threshold of 6.5 mg/dL for hyperphosphatemia. (Lopes NDT 35:1794-1801, 2020- TAC phos in HD; Lopes NDT 38: 193-202, 2023- TAC phos in PD.) Lopes, in separate publications for in-center hemodialysis and peritoneal dialysis DOPPS populations, described the associations between time-averaged concentration (TAC) of phosphorus over 6 months with patient outcomes. In addition, we identified two prospective observational cohort studies (ArMORR and COSMOS) studies demonstrating associations between use of phosphorous binders and survival, using rigorous risk-adjustment. In the ArMORR study, intent-to-treat analysis with extensive risk adjustment and stratification based on facility-level Standardized Mortality Ratio (SMR) revealed 29% lower mortality in incident patients treated with phosphorus binders. Similar magnitude of mortality reduction was seen in a propensity score matched model. (Isakova JASN 20(2):388-96, 2009) In the COSMOS study using patient-level Propensity Score modeling, phosphorus binder use was associated with approximately 50% and 36% reduction in all-cause and cardiovascular mortality, respectively. (Cannata-Andia Kidney Int 84:998-1008, 2013) The COSMOS study also utilized facility percentage of patients treated with a phosphorus binding agent in an instrumental variable analysis and demonstrated 8% and 7% risk reduction for all-cause and cardiovascular mortality, respectively, for each 10% increase in percent of patients treated with phosphorus binders at the dialysis facility. A 2012 DOPPS study used indicator variable analysis to associate facility level phosphorus control to predict patient outcomes. Subsequently, Block, et al also demonstrated risk reduction in patient mortality for patients treated in dialysis facilities with better MBD treatment outcomes. (Lopes AJKD 60(1):90-101, 2012- includes indicator variable facility-level analyses; Block BMC Nephrol 2016).

Finally, we identified a publication describing secondary analyses of the prospective, case-controlled, Japanese MBD-5D Study. (Fukugawa AJKD 63(6):979-987, 2014) Kato, et al. describe

their secondary analyses of the MBD-5D study investigating the association between changing patterns of achieved phosphorus over time with mortality in Japanese chronic dialysis patients. (Kato BMC Nephrol 21: 432, 2020) In this study, individual patient results for phosphorus (and other MBD-related labs) were averaged over 3-month periods and categorized as Low (<4mg/dl), Middle (4-7 mg/dl) and High >7 mg/dl). Risk adjusted mortality in the current 3-month observation period was associated with patient-level achieved phosphorus category in the prior two 3-month periods (e.g. L-L, L-M, L-H, H-H, H-M, H-L) in order to evaluate the short-term effect of phosphorus category change on mortality risk. Compared to patients whose phosphorus category did not change, change from Low to Moderate or from High to Moderate was associated with significantly lower mortality compared to those remaining in the Low and High categories, respectively. Patients moving from Moderate to either Low or High categories were found to have increased mortality relative to the Moderate control group. Although observational in nature, these results from a carefully executed prospective, case-controlled study strongly suggest that treatment of hyperphosphatemia in this population may affect a reduction in mortality, and that avoidance of hypophosphatemia is prudent.

There is a small group of publications describing the pathophysiology and consequences of CKD-MBD in children along with the similarities and some important differences in presentation and treatment issues between children and adults. The pediatric literature, similar to adults, points to increased risk of bone fractures with elevated phosphorus and a decline in fracture risk with the use of phosphate binders. Vascular calcification has also been well described in pediatric population as well as the ensuing vascular stiffness.

Two major differences between the adult and pediatric CKD-MBK literature are evident. First, because of the very small number of pediatric dialysis patients in the United States (and elsewhere), as expected, the pediatric literature is lacking in both number and quality of observational and interventional studies compared to the adult literature. Second, there are numerous summary reviews that describe the specific differences related to growth physiology between children and older adults. Specifically, pediatric CKD patients have impaired growth/maturation of multiple organ systems, including musculoskeletal and neurological systems, resulting in specific concerns about provision of adequate nutrition and careful monitoring of these parameters in children. During the Pediatric Focus group discussions that UM-KECC convened in support of this measure, participants expressed concern that the 6-month average phosphorus was too long given the concern about the potential impact of CKD-MBD and its treatments on optimizing growth in the pediatric dialysis population targeted here.

Summary

There is a large and consistent body of representative observational literature that strongly and consistently supports the clinical association between phosphorus control and reduction of ESKD MBD-related complications. This observational literature clearly demonstrates the association of phosphorus control with better survival in both cross-sectional and prospective cohort studies. In addition, while choice of phosphorus binder class remains under debate, there is evidence that

use of any phosphorus binders in this population is associated with significant reduction in all-cause and cardiovascular mortality in studies of patients treated in both the U.S and Europe. Finally, the primary responsibility for treatment of MBD in this population is clearly focused on dialysis facilities and clinicians. It is also important to restate that proven, effective, phosphorus reduction techniques are available and in widespread use worldwide by dialysis providers in the treatment of ESKD chronic dialysis patients. Although there is a paucity of high-quality randomized trials indicating that phosphorus reduction results in better patient outcomes, the existing literature supports this conclusion and has had consistent findings for several decades.

The literature from the pediatric population is consistent with the adult population for selected outcomes (fracture risk, accelerated cardiovascular disease) and we believe it is appropriate to extrapolate findings from the adult population since similar mechanisms in disease pathology are present, as are treatment options and interventions by the dialysis facility team.

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2.3 Anticipated Impact

Reducing the number of patient months with chronic hyperphosphatemia is expected to have the following impact: (1) reduction in hospitalization and (2) reduction in all-cause and cardiovascular mortality at the dialysis facility level. The cost-savings from reduced hospitalization rates are offset by increased costs associated with phosphate binder and phosphate absorption inhibiting medications. There are two main unanticipated consequences for the measure. First, the 2024 TEP raised the concern that patients could become malnourished in the process of trying to control chronic hyperphosphatemia. To mitigate against this risk, we exclude adult patients who are at increased risk for malnutrition as indicated by a low serum albumin or underweight body status as defined by BMI. The other potential unintended consequence relates to the pill burden associated with phosphate binders, their palatability, and the subsequent impact on quality of life.

2.4 Performance Gap

Data are from EQRS Clinical files for years 2021-2022. All reporting months are for calendar year 2022. Data from August 2021 – December 2021 were only used to calculate 6-month rolling averages for the first five months of 2022 which needed data from months prior to January 2022. The total number of dialysis facilities included in the performance scores was 7,540. The total number of patients included in the performance scores was 448,775. There is a significant performance gap: facilities in decile 1 (highest performing group) have only 7.8% of patient months with an elevated phosphorus above threshold compared to decile 10 facilities (lowest performing group) at 46.0% of patient months.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	23.1%	0%	7.8%	13.1%	16.0%	18.4%	20.6%	22.9%	25.4%	28.4%	32.2%	46.0%	100%
N of Entities	7,540	15	754	754	754	754	754	754	754	754	754	754	27
N of Persons / Encounters / Episodes	3,767,112	2,265	301,389	382,065	402,511	413,028	412,596	408,306	402,699	402,791	363,238	278,489	7,465

2.5 Health Care Quality Landscape

There is currently no measure of chronic hyperphosphatemia for dialysis patients. There is only a reporting requirement currently that a phosphorus level is being checked on a monthly basis. This is insufficient to assess chronic control of elevated phosphorus. At best, dialysis facilities review on a monthly basis the number of patients who have an elevated phosphorus, but this does not differentiate those patients who have chronically elevated phosphorus levels and are at highest risk for adverse cardiovascular morbidity and mortality. In addition, as of January 2025, oral phosphate binder medications have been included in the bundle payment system, so that they are no longer separately billable under Part D for Medicare beneficiaries. As a result, dialysis facilities are now under increased financial pressure to provide effective phosphate binding medications in a cost-effective manner. The ability to measure chronic hyperphosphatemia will be critical to safeguard against the unintended consequences of having phosphate binders added into the bundled payment system.

2.6 Meaningfulness to Target Population

Although some patients have symptoms related to chronic hyperphosphatemia such as itching or other dermatologic manifestations, many patients are asymptomatic. However, less time spent in the hospital and living longer, particularly if it allows a dialysis patient to reach kidney transplantation, are meaningful outcomes.

3.1 Contributions Towards Closing Care Gaps

This field is optional for Fall 2025.

4.1a Data Structure and Availability

Phosphorus levels are routinely checked during routine care delivery in a dialysis facility, and the data is a required submission element for the End Stage Renal Disease Quality Reporting System (EQRS) for Medicare certified dialysis facilities (the measured entity of this measure).

4.1b Implementation Costs and Burden

All required data elements for the measure are routinely generated during care delivery for dialysis patients. Therefore, there is no additional cost or burden for data collection and no impact on clinical workflow. Given the existing processes in place for data collection, we have no concerns about feasibility if the measure is implemented.

4.1c Confidentiality

N/A

4.3 Feasibility Informed Final Measure

Due to the high feasibility of the measure, no adjustments were needed during measure development to address feasibility.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

Data used for testing is from EQRS clinical files for years 2021 and 2022. All reporting months with a 6-month phosphorus average are from 2022, and only phosphorus values in months from 2021 needed to calculate these averages are used from that year.

5.1.1a Dates of Testing Data

EQRS - January 2021 to December 2022

5.1.2 Differences in Data

None.

5.1.3 Characteristics of Measured Entities

7,540 facilities with 10 or more eligible patients during January 2022 – December 2022 were included in the analysis.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 10 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small sample size. We have applied this restriction to all the reliability and validity testing reported here.

5.1.4 Characteristics of Units of the Eligible Population

A total of 448,775 patients who belonged to the facilities with 10 or more patients were included in this analysis. Among these patients, the average age was 63, 41.4% were female, 56.5% were white, 35.1% were black, 20.5% were Hispanic, and 45.9% had diabetes as primary cause of ESRD.

5.2.1 Level(s) of Reliability Testing Conducted

Person or encounter level (i.e., data element) (e.g., inter–abstractor reliability), Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Data element reliability: Data for this measure comes from the End Stage Renal Disease Quality Reporting System (EQRS), a CMS-owned data system that collects data directly from all Medicare-certified dialysis facilities. EQRS has processes in place [1] to ensure the reliability and validity of the patient level data used for a broad array of measure calculations, including this measure. Briefly, CMS performs a random selection of 300 eligible dialysis facilities each year. Ten patient records are randomly selected from a single quarter each year from each of the facilities selected to participate. Experienced nurse reviewers assessed the data obtained from the medical records on each of 24 data elements in EQRS, including the phosphorus value for the reported month and the date the phosphorus was collected in the reporting month.

1. Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. 88 FR 76344. 42 CFR 413 (2023), 42 CFR 512 (2023) https://www.federalregister.gov/d/2023-23915 (accessed 10/22/2025)

Accountable entity level reliability: We used January 2022 – December 2022 data to calculate the inter-unit reliability (IUR) for the overall 12 months to assess the reliability of this measure. One of the PQM-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based IUR was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. We note that the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. Since this measure is not normally distributed, the IUR value should be interpreted with some caution.

5.2.3 Reliability Testing Results

Data element reliability: Per the executive summary [1], the rate of correct matches was 96.5% for all data elements. 1.6% of entries in either EQRS (.2%) or Medical Records (1.4%) contained missing information. The rate of discrepant comparisons was 1.9%.

1. Executive Summary End Stage Renal Disease Quality Incentive Program Data Validation & Reliability (ESRD QIP DV&R) Clinical Performance Measures (CPMs) Project. Centers for Medicare and Medicaid Services, September 2023. https://qualitynet.cms.gov/files/654aaa312a222d001c16aa45?filename=2023... (accessed 10/22/2025)

Accountable entity reliability: the overall IUR is 0.77. See Table 2 for results by decile. Please note the IUR deciles were calculated based on the sample size within each facility and some facilities had the same values, so were grouped into the same decile. Due to this reason, deciles may not have a consistent distribution of facility counts.

5.2.4 Interpretation of Reliability Results

Data element reliability: The estimated error rate of 1.9% obtained in this project is below the threshold of about 2.5% for achieving strong statistical power with the current sample size.

1. Executive Summary End Stage Renal Disease Quality Incentive Program Data Validation & Reliability (ESRD QIP DV&R) Clinical Performance Measures (CPMs) Project. Centers for Medicare and Medicaid Services, September 2023. https://qualitynet.cms.gov/files/654aaa312a222d001c16aa45?filename=2023...; (accessed 10/22/2025)

Accountable entity reliability: The overall IUR for the sample dataset was 0.77. The IUR's per deciles of patients ranged from 0.47 to 0.88. The overall IUR of 0.77 indicates 77% of variation in the overall measure can be attributed to between facility variations. This is considered to be a high degree of reliability.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.766	0.355	0.474	0.586	0.649	0.693	0.728	0.757	0.782	0.810	0.838	0.883	0.951
Mean Performance Score	23.1%	0%	7.8%	13.1%	16.0%	18.4%	20.6%	22.9%	25.4%	28.4%	32.2%	46.0%	100%
N of Entities	7,540	15	777	695	826	695	794	725	765	751	757	755	27
N of Persons / Encounters / Episodes	3,767,112	2,265	94,710	140,058	224,227	233,154	317,739	339,384	419,394	493,875	611,341	893,230	7,465

5.3.1 Level(s) of Validity Testing Conducted

Person or encounter level (i.e., data element) (e.g., sensitivity and specificity), Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.3.3 Method(s) of Validity Testing

Data element validity: Data for this measure comes from the End Stage Renal Disease Quality Reporting System (EQRS), a CMS-owned data system that collects data directly from all Medicare-certified dialysis facilities. EQRS has processes in place [1] to ensure the reliability and validity of the patient level data used for a broad array of measure calculations, including this measure. Briefly, CMS performs a random selection of 300 eligible dialysis facilities each year. Ten patient records are randomly selected from a single quarter each year from each of the facilities selected to participate. Experienced nurse reviewers assessed the data obtained from the medical records on each of 24 data elements in EQRS, including the phosphorus value for the reported month and the date the phosphorus was collected in the reporting month.

1. Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model. 88 FR 76344. 42 CFR 413 (2023), 42 CFR 512 (2023)

https://www.federalregister.gov/d/2023-23915 (accessed 10/22/2025)

Accountable entity level validity: We used January 2022 – December 2022 EQRS clinical data to assess facility level performance scores. 7,540 facilities with 10 or more patients were used for validity testing, which includes 448,755 patients.

We assessed validity using Poisson regression models to identify the predictive strength of facility level performance scores for the measure, on mortality and days hospitalized, using the 2022 SMR and SHR related data. We anticipate a positive correlation with the SMR and SHR, and a dose-response with increasing rate ratios from lowest quintile of hyperphosphatemia to highest quintile of hyperphosphatemia.

5.3.4 Validity Testing Results

Data element validity: Per the executive summary [1], the rate of correct matches was 96.5% for all data elements. 1.6% of entries in either EQRS (.2%) or Medical Records (1.4%) contained missing information. The rate of discrepant comparisons was 1.9%.

1. Executive Summary End Stage Renal Disease Quality Incentive Program Data Validation & Reliability (ESRD QIP DV&R) Clinical Performance Measures (CPMs) Project. Centers for Medicare and Medicaid Services, September 2023. https://qualitynet.cms.gov/files/654aaa312a222d001c16aa45?filename=2023... (accessed 10/22/2025)

Accountable entity validity: *see attached table.*

5.3.4a Attach Additional Validity Testing Results

5.3.4a-Validity-Testing-Results-Hyperphosphatemia_508.pdf

5.3.5 Interpretation of Validity Results

Data element validity: The estimated error rate of 1.9% obtained in this project is below the threshold of about 2.5% for achieving strong statistical power with the current sample size.

1. Executive Summary End Stage Renal Disease Quality Incentive Program Data Validation & Reliability (ESRD QIP DV&R) Clinical Performance Measures (CPMs) Project. Centers for Medicare and Medicaid Services, September 2023. https://qualitynet.cms.gov/files/654aaa312a222d001c16aa45?filename=2023...; (accessed 10/22/2025)

Accountable entity validity: The results of the Poisson regression suggests that facilities with a higher percentage of patient-months with chronic hyperphosphatemia experience a higher mortality rate and higher hospitalization rate relative to facilities with a lower percentage of patients with chronic hyperphosphatemia. Using quintiles defined by mean facility performance score, we find that facilities in the 5th quintile have mortality that is 18% higher when compared to facilities in the 1st quintile group. Similarly, facilities in the 5th quintile have hospitalization that is 13% higher when compared to facilities in the 1st quintile group. The direction of the relationship is as expected.

5.4.1 Methods Used to Address Risk Factors

No risk adjustment or stratification

5.4.1b Rationale For No Adjustment or Stratification

Analyses that we conducted indicated that the disparities in hyperphosphatemia were not in the expected direction, with traditionally underserved populations performing better on the measure in patient level analyses and minimal impact in facility level analyses. This was discussed with our technical expert panel who unanimously agreed that the measure should not be risk adjusted.

6.1.1 Current Status

Not in use

6.1.2 Current or Planned Use(s)

Public Reporting, Payment Program

6.2.1 Actions of Measured Entities to Improve Performance

There are two main actions that facilities can take to improve performance on this measure. First, regular dietary counseling on a nutrition plan that is low in phosphorus containing foods is considered the cornerstone for management of hyperphosphatemia. Since phosphorus content of most foods can be difficult to determine, a detailed assessment of patients eating habits and food choices by the dietician (required to be present at all Medicare-certified dialysis facilities) with feedback on low-phosphorus alternatives is critical. The second main action is the prescription of phosphorus binding medications. Regular assessment of the dose and adherence are key since the pill burden is often quite high and some of these medications have gastrointestinal side effects. Therefore it is not unusual to need to change phosphate binders or use combinations of different phosphate binders to achieve the desired outcome. Other actions that facilities can take would be more frequent measurement of serum phosphorus to provide rapid feedback to interventions. Optimizing the dose of dialysis may also help achieve improvement in phosphorus control. These interventions can be challenging, but coordinated effort by the interdisciplinary team can overcome obstacles such as prescription coverage for medications, improved adherence with a nutrition plan, and optimal dialysis.

6.2.5a Potential Unintended Consequences

None are anticipated.

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