

Intent to Submit

Endorsement and Maintenance (E&M) Cycle *

Select the intended measure review cycle for endorsement consideration.

Spring 2024

ITS deadline: Monday, April 1st, 2024

Full Submission deadline: Wednesday, May 1st, 2024

☐ Spring 2024

Fall 2024

ITS deadline: Tuesday, October 1st, 2024

Full Submission deadline: Friday, November 1st, 2024

☒ Fall 2024

Spring 2025

ITS deadline: Tuesday, April 1st, 2025

Full Submission deadline: Thursday, May 1st, 2025

☐ Spring 2025

Measure Information

1.1 New or Maintenance *

☒ New

☐ Maintenance

*[If a maintenance measure] 1.1a Provide CBE ID **

1.2 Measure Title *

Facility Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients

1.3 Measure Description *

Percentage of adult dialysis patients with a 6-month rolling average phosphorus value greater than or equal to 6.5 mg/dL.

1.4 Project *

- ☐ Advanced Illness and Post-Acute Care
- ☐ Cost and Efficiency
- ☐ Initial Recognition and Management
- ☒ Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health
- ☐ Primary Prevention

1.5 Measure Type *

- ☐ Cost/resource use
- ☐ Efficiency
- ☒ Intermediate Outcome
- ☐ Outcome
- ☐ Population Health
- ☐ Process
- ☐ Patient-reported Outcome Performance Measure (PRO-PM)
- ☐ Structure
- ☐ Other (1.5a Please specify *)

1.6 Composite Measure *

- ☒ No ☐ Yes

1.7 Electronic Clinical Quality Measure (eCQM) *

Title

- ☒ No ☐ Yes

1.8 Level of Analysis *

- ☐ Accountable Care Organization
- ☐ Clinician: Group/Practice
- ☐ Clinician: Individual
- ☒ Facility
- ☐ Health Plan
- ☐ Population or Geographic Area (1.8a Specify Population or Geographic Area Level of Analysis *)

- ☐ Other (1.8b Specify Other Level of Analysis *)

1.9 Care Setting *

- ☐ Ambulatory Care: Clinic
- ☐ Ambulatory Care: Clinician Office
- ☐ Ambulatory Care: Office
- ☐ Ambulatory Surgery Center
- ☐ Behavioral Health: Inpatient (e.g., Inpatient Psychiatric Facility)
- ☐ Behavioral Health: Outpatient
- ☐ Birthing Center

- ☐ Clinician Office/Clinic
- ☐ Emergency Department
- ☐ Emergency Medical Services/Ambulance
- ☐ Home Health
- ☐ Hospice
- ☐ Hospital: Acute Care Facility
- ☐ Hospital: Critical Access
- ☐ Hospital: Inpatient
- ☐ Hospital: Outpatient
- ☐ Imaging Facility
- ☐ Inpatient Rehabilitation Facility
- ☐ Long-Term Acute Care Facility
- ☐ Nursing Home/Skilled Nursing Facility
- ☐ Outpatient Rehabilitation
- ☐ Pharmacy
- ☐ Urgent Care: Ambulatory
- ☐ No Applicable Care Setting *(1.9a Please explain*)*

- ☒ Other Care Setting *(1.9b Please specify*)*

Dialysis Facility

[Note: Responses to items 1.10 – 1.13 and other measure specification details are to be provided in the Full Measure Submission]

1.14 Numerator *

Number of patient reporting months in the denominator with a 6-month rolling average phosphorus greater than or equal to 6.5 mg/dL.

1.15 Denominator *

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.

Attestations: Preparing for Full Measure Submission for Endorsement Consideration

☒ **A.1 Detailed Measure Specifications ***

I will provide detailed measure specifications, including how to calculate the measure, data dictionaries, and code sets.

☒ **A.2 Logic Model ***

I will provide a logic model and evidence that support the link between structures / processes / intermediate outcomes and the desired outcome.

☒ **A.3 Impact and Gap ***

- For initial endorsement, I will provide a description of the measure's anticipated impact on important outcomes supported by the scientific literature and other sources (e.g., functional improvement, disease prevented, adverse events or costs avoided).
- For maintenance endorsement, I will supply evidence of a continued performance or measurement gap by providing performance scores on the measure as specified (current and over time) at the specified level of analysis.

☒ **A.4 Feasibility assessment methodology and results ***

I will provide feasibility assessment methodology and results. I will show how the assessment considered the people, tools, tasks, and technologies necessary to implement the measure, and if an eCQM, I will provide the completed feasibility scorecard.

A.5 Measure Testing (reliability and validity)

A.5a Empirical person- or encounter-level¹ *

Will empirical person- or encounter-level evidence, testing, methodology, and results be presented for this endorsement?

☒ No ☐ Yes

*[If A5a = No and this is an initial endorsement] **A.5a1 Why not presented ****

Provide a rationale for why empirical person- or encounter-level testing for reliability and validity will not be presented for this initial endorsement.

Patient level data for phosphorus values that are extracted from EQRS are considered reliable and valid by stakeholders in the dialysis community. We do not have a mechanism for validating those data.

A.5b Empirical accountable entity-level *

Will empirical accountable entity-level evidence, testing, methodology, and results be presented for this endorsement?

☐ No ☒ Yes

¹ For patient- or encounter-level testing, prior evidence of reliability and validity of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that: includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

[If A5a = No and this is a maintenance endorsement] **A.5b1 Why not presented ***

Provide a rationale for why empirical accountable entity-level testing will not be presented for this maintenance endorsement.

This is not a patient level measure, so we performed reliability and validity testing at the facility level, which is the entity being measured. In addition, 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 to ensure the reliability of the patient level data used for a broad array of measure calculations.

[If a maintenance endorsement] **A.5c Systematic assessment of face validity of performance measure score ***

Will systematic assessment of face validity of performance measure score (i.e., accountable entity-level) as an indicator of quality or cost/resource use (i.e., the score is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance) be presented for this initial endorsement?

☒ No

☐ Yes

☐ **A.6 Address health equity (optional)**

I will describe how this measure contributes to efforts to address inequities in health care. This is an optional criterion for FMS.

☒ **A.7 Measure's use or intended use ***

I will provide the measure's use or intended use and actions measured entities must take to improve performance on this measure. For a maintenance measure, I will provide a summary of any progress improvement.

A.8 Risk-adjustment or stratification *

☒ No, neither risk-adjusted nor stratified

☐ Yes, risk-adjusted only

☐ **Conceptual model for risk adjustment**

I will present the conceptual model for risk adjustment, including supporting evidence from literature, internal analyses, and/or expert panels, AND

☐ **Risk adjustment approach**

I will present the risk adjustment approach, including the methodology, specifications, results, and interpretation of results

☐ Yes, stratified only

☐ **All information required to stratify the measure results**

I will present all information required to stratify the measure results, including the stratification variables, definitions, specific data collection items/responses, and code/value sets

☐ Yes, both risk-adjusted and stratified

☐ **Conceptual model for risk adjustment**

I will present the conceptual model for risk adjustment, including supporting evidence from literature, internal analyses, and/or expert panels, AND

☐ **Risk adjustment approach**

I will present the risk adjustment approach, including the methodology, specifications, results and interpretation of results, AND

☐ **All information required to stratify the measure results**

I will present all information required to stratify the measure results, including the stratification variables, definitions, specific data collection items/responses, and code/value sets, and the risk-model covariates and coefficients for the adjusted version of the measure

A.9 Quality Measure Developer and Steward Agreement (QMDSA) Form *

☐ I already submitted a [QMDSA Form](#) to Battelle

☐ I would like to submit the QMDSA form now

☐ I will submit the QMDSA form later.

☒ The measure is owned by a government entity; therefore, the QMDSA Form is not applicable at this time.

A.10 Additional and Maintenance Measures Form *

Choose one. Note: Measure stewards with current measures endorsed by Battelle, who wish to add additional measures to their current QMDSA, will need to complete this form.

☐ I have submitted or will submit an [Additional and Maintenance Measures Form](#)

☒ The Additional and Maintenance Measures Form is not applicable at this time.

☒ **A.11 508 Compliance ***

I will ensure that the measure information that will be submitted at FMS, including all attachments, will be prepared in accordance with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194).

Measure Points of Contact Information

The user account completing this form is the Measure Developer Point of Contact (POC)

☐ Do you have a secondary **measure developer** point of contact?

[\[If checked\]](#)

Secondary POC email:

Secondary POC phone number:

Country:

First Name:

Last Name:

Organization:

Street Address:

City, State, Zip:

☐ The measure developer is NOT the same as **measure steward**

[\[If checked\]](#)

Steward POC email:

Steward POC phone number:

Steward organization URL:

Steward Organization [\[choose from drop-down menu\]](#):

Country:

First Name:

Last Name:

Organization:

Street Address:

City, State, Zip:

Steward Organization Copyright

Full Measure Submission

Section 1. Measure Specifications

[NOTE: Items 1.1-1.9, 1.14, and 1.15 were entered in the ITS, and can be edited in the FMS]

1.10 Measure Rationale *

Provide a rationale for why measured entities should report this measure, including how the measure will improve the quality of care for patients and/or any associated health care costs, and what are the benefits or improvements in quality envisioned by use of this measure.

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.

1.11 Measure Webpage *

Provide a URL to a webpage, specific for this measure, containing current detailed specifications, including code lists, risk model details, and supplemental materials. Do not enter a URL to a home page or to general information. The webpage must be publicly accessible. If no URL is available, copy and paste this example: <http://example.com>.

<http://example.com>

1.12 [If the measure is an eCQM] Attach MAT Output

Attach the zipped output from the Measure Authoring Tool (MAT). If you did not use the MAT, please contact [PQM Support](#). Use the measure specification fields (e.g., 1.14a – 1.15c) for the plain-language description of the specifications. One file only; 256 MB limit; Allowed file types: .zip.

1.13 Attach Data Dictionary

Attach a data dictionary, code table, and/or value sets (include variables in the final risk model or stratification plan, if applicable). Attachment should include variables used in the final risk model and/or stratification, if applicable.

One file only; 256 MB limit; Allowed file type: .xls; .xlsx; .csv (please clearly label sheets).

☐ **1.13a Data dictionary not attached**

I attest that all information will be provided in relevant fields where code and/or value sets are needed (e.g., 1.14a – 1.15b).

TBD

1.14a Numerator Details *

Provide details needed to calculate the numerator. All information required to identify and calculate the cases from the target population (denominator) with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If your list of codes with descriptors is greater than will fit in this text box, you must attach an Excel or csv file in the previous question. If the numerator includes a list (or lists) individual codes with descriptors that exceeds one page, please provide this information in an xls; .xlsx; .csv file as part of the data dictionary attachment.

A patient reporting month is defined as the last month of the six month observation period; for example, for the June 2023 reporting month, the hyperphosphatemia value is the average 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. 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 6-month rolling average phosphorus is greater than or equal to 6.5 mg/dL. If there are multiple phosphorus measurements during the month, only the first value in the calendar month will be used for the calculation.

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.

1.15a Denominator Details *

Provide details needed to calculate the denominator. All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If the list(s) of individual codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment.

A patient reporting month is included if the patient is >18 years 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 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). Established ESRD patients 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). Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, Home Hemodialysis, CAPD or CCPD in the most recent month of the reporting period. Patients under the care of the facility for at least 30 days are determined as follows: if the discharge date from the specified facility is missing/null or is after the last day of the most

recent month of the reporting period, then the patient's time under the care of the facility is calculated from the admit date to the last day of the most recent month of the reporting period; if the discharge date is prior to the last day of the most recent month of the reporting period, the patient is excluded from the calculation.

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 claims 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).

1.15b Denominator Exclusions *

Briefly describe exclusions from the denominator cases, if any. Enter "None" if the measure does not have denominator exclusions.

In addition to exclusions that are implicit in the measure definition (age <18 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
- BMI under 18.5

1.15c Denominator Exclusions Details *

Provide details needed to calculate denominator exclusions. Enter "None" if the measure does not have denominator exclusions. All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets. If the list(s) of codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment.

For a given patient reporting month, the exclusion criteria must not be met within the entire 6-month window used to calculation 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.

1.16 Type of Score *

Select the most relevant type of score.

- ☐ Categorical, e.g., yes/no
- ☐ Continuous variable, e.g., average
- ☐ Count

- ☒ Rate/proportion
- ☐ Composite scale
- ☐ Other scoring method

1.16a Describe other scoring method *

1.17 [If Measure Type (1.5) IS NOT “Cost/Resource Use”] Measure Score

Interpretation *

Select the appropriate interpretation of the measure score

- ☐ Better quality = Higher score
- ☒ Better quality = Lower score
- ☐ Better quality = Score within a defined interval
- ☐ Passing score defines better quality
- ☐ Other

1.17a Describe Other measure score interpretation *

1.17 [If Measure Type (1.5) IS “Cost/Resource Use”] Select the type of cost measure *

- ☐ Per capita (population- or patient-based)
- ☐ Per episode
- ☐ Per procedure
- ☐ Other

1.17a Specify other cost measure *

1.18 Calculation of Measure Score *

Diagram or describe the calculation of the measure score as an ordered sequence of steps. Identify the denominator, denominator exclusions (if any), numerator, time period of data collection, risk adjustment and/or stratification, and any other calculations.

Patient reporting months with a 6-month rolling average phosphorus of 6.5 mg/dL or greater are included in the numerator. The number of patient reporting months with a phosphorus average of 6.5 mg/dL or greater 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 (only facilities with greater than 10 patients for the reporting period).

1.18a Attach measure score calculation diagram

Attach a measure score calculation diagram, if desired.

One file only; 256 MB limit; Allowed file types: .pdf; .jpg; .png.

1.19 Measure Stratification Details *

Provide all information required to stratify the measure results, if necessary. Include the stratification variables, definitions, code/value sets, and if appropriate, the risk-model covariates and coefficients for the clinically-adjusted version of the measure. If the list(s) of codes with descriptors exceeds one page, please provide this information in an Excel or .csv file as part of the data dictionary attachment. If the measure is not stratified, please state "The measure is not stratified." If the information is included within the data dictionary attachment, please state "See data dictionary attachment."

The measure is not stratified.

1.20 Testing Data Sources *

Select the data sources for which you have tested and specified the measure. Choose all that apply.

- ☐ Administrative Data
- ☒ Claims Data
- ☐ Electronic Health Records
- ☐ Paper Patient Medical Records
- ☐ Registries
- ☐ Standardized Patient Assessments
- ☐ Patient-Reported Data and/or Survey Data *[Answer questions 1.21-1.24]*
- ☐ Non-Medical Data
- ☒ Other Data Source

1.20a Specify other data source *

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

1.21 *[If "Patient-Reported Data and/or Survey Data" was selected above]* Patient reported data collection tools

Choose one (1.21a or 1.21b). If the measure requires patient-reported data to collect stratification and/or risk adjustment variables, please include this information as well.

1.21a Data Source URL(s)

Provide link to the survey, tool, questionnaire, or scale used as a data source for your measure. This must be an external URL such as <http://example.com>. If no URL is available, copy and paste the example: <http://example.com>. Click "Add Another Item" to enter multiple URLs.

1.21b Attach Data Collection Tool(s)

Attach the survey, tool, questionnaire, or scale used as a data source for your measure. One file only; 256 MB limit; Allowed type: .zip.

1.22 *[If “Patient-Reported Data and/or Survey Data” was selected for 1.20]* **Proxy Responses ***

Are proxy responses allowed?

☐ No ☐ Yes

1.23 *[If “Patient-Reported Data and/or Survey Data” was selected for 1.20]* **Survey Respondent ***

Please indicate the respondent for your survey, tool, questionnaire, or scale. Select all that apply.

☐ Patient
☐ Family or other caregiver
☐ Clinician
☐ Other

1.23a Specify other survey respondent *

1.24 *[If “Patient-Reported Data and/or Survey Data” was selected for 1.20]* **Data Collection and Response Rate ***

For survey/patient-reported data, provide instructions for data collection (e.g., modes of collection, languages of administration), including disclosing minimum response rates and guidance on improving response rates. In addition, specify how to calculate response rates for reporting with performance measure results.

1.25 Data Sources *

Identify the specific data source(s), other than or in addition to any patient-reported data and/or survey data collection instrument(s) indicated for the measure. For example, provide the name of the database, clinical registry, etc. and describe how the data are collected. Please discuss any data feasibility, reliability, and/or validity challenges and how this has been mitigated.

Phosphorus values are sourced from EQRS, a mandatory reporting mechanism for all CMS-certified dialysis facilities.

Data for patient placement are derived from an extensive national ESRD patient database, which is primarily based on the Renal Management Information System (REMIS), 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), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data (primarily outpatient). In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, 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 *

Indicate whether the measure has a minimum sample size to calculate the performance score and provide any instructions needed for obtaining the sample and guidance on minimal sample size.

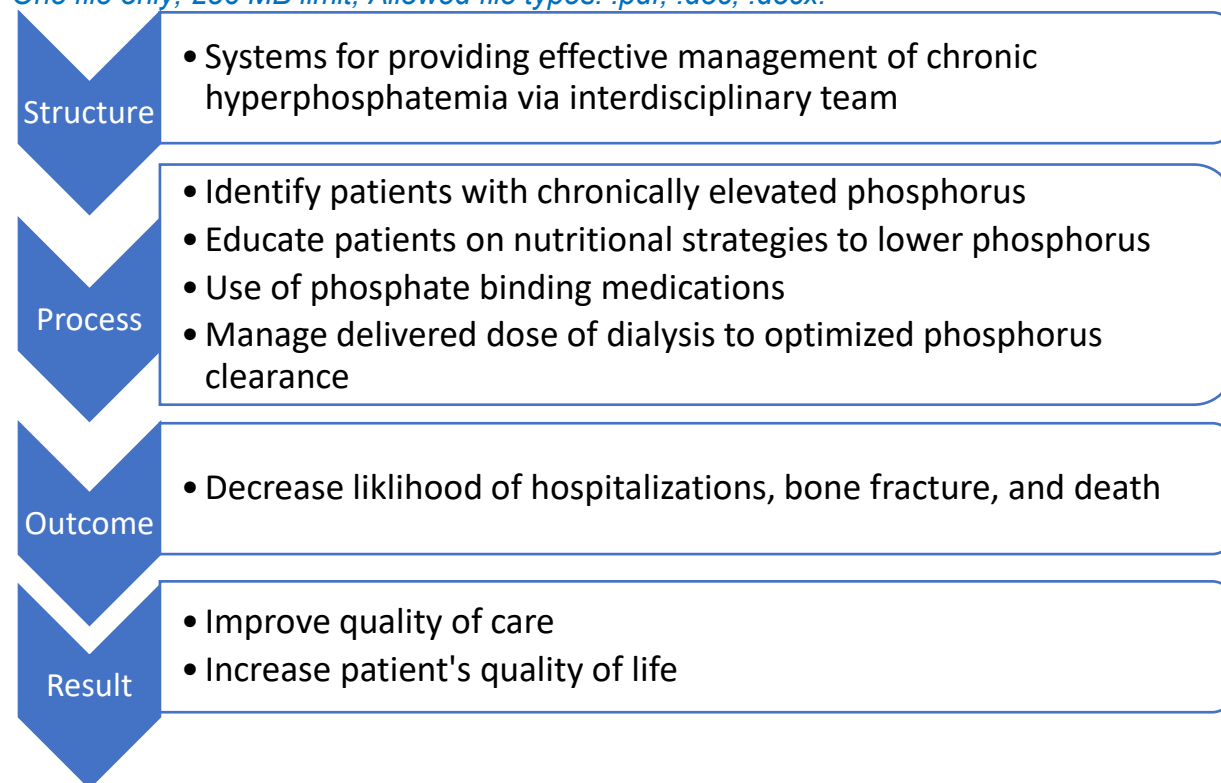
Public reporting of this measure on Care Compare or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction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

Section 2. Importance

2.1 Attach Logic Model *

Attach a logic model depicting the relationship between structures and processes and the desired outcome. Briefly describe the steps between the health care structures and processes (e.g., interventions, or services) and the desired health outcome(s). Identify the relationships among the inputs and resources available to create and deliver an intervention, the activities the intervention offers, and the expected results (i.e., desired outcome). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process, or outcome being measured.

One file only; 256 MB limit; Allowed file types: .pdf; .doc; .docx.



2.2 Evidence of Measure Importance *

Summarize evidence of the measure's importance from the literature, linking the structure/process/intermediate outcome to the desired health outcome. Please provide references for supporting evidence.

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-regulations/dialysis> 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 effect a reduction in mortality, and that avoidance of hypophosphatemia is prudent.

Summary

There is no high-quality direct evidence from prospective interventional clinical trials showing that phosphorus reduction results in better patient outcomes, nor is there evidence supporting one phosphorus lowering technique over others (including phosphorus binder use, GI phosphorus absorption blocker, or dietary/nutritional intervention) as preferred approach in

lowering the risk of mortality in this population. There is, however, 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.

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2.3 [If initial endorsement] Anticipated Impact *

If implemented, what is the measure's anticipated impact on the desired outcomes, such as those listed in the logic model? Please cite evidence to identify adverse events and costs

avoided and provide references. Describe how the benefits of the measure's impact will outweigh any potential unintended consequences.

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 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

If available, provide evidence of performance gap or measurement gap by providing performance scores on the measure as specified at the specified level(s) of analysis. Please include mean, minimum, maximum, and scores by deciles by using the table below or upload an attachment. In the text field here, describe the data source, including number of measured entities, number of patients, dates of data. If a sample was used, provide characteristics of the entities included. If performance scores are unavailable for the measure, please explain.

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 7,497. The total number of patients included in the performance scores was 447,576.

Table 1 Performance Scores by Decile

Enter the overall mean, minimum, and maximum scores, and mean scores by decile. Enter the number of measured entities and persons/encounters/episodes overall and within each decile.

	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Performance 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%
N of Dialysis Facilities	7497	15	749	750	749	751	749	750	750	746	754	749	28
N of Patient Months	3,758,302	2,265	299,891	379,102	403,430	412,333	408,232	409,928	396,900	400,499	366,704	281,283	7,833

There is a significant performance gap: facilities in decile 1 (highest performing group) have only 7.8% of patient months with a 6-month rolling average phosphorus level is ≥ 6.5 mg/dL compared to decile 10 facilities (lowest performing group) at 45.8% of patient months.

2.4a Attach Performance Gap Results

If needed, you may attach additional performance gap results here. If submitting an attachment rather than entering results in Table 1 above, please enter the overall mean, minimum, and maximum scores, and mean scores by decile. Enter the number of measured entities and persons/encounters/episodes overall and within each decile. Please ensure all attachments are 508 compliant, all tables and figures are labeled with alternative text, as appropriate. Please clearly refer to any results within your attachment within the relevant text fields of this measure submission form.
One file only; 256 MB limit; Allowed types: .zip, .pdf, .docx, .xls, .xlsx

2.5 [If initial endorsement] Health Care Quality Landscape *

Please explain why existing measures/quality improvement programs are insufficient for addressing this health care need.

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.

2.6 Meaningfulness to Target Population *

Provide evidence the target population (e.g., patients) values the measured outcome, process, or structure, and finds it meaningful. Please describe how and from whom you obtained input.

Although some patients have symptoms related to chronic hyperphosphatemia such as itching or other dermatologic manifestations, most 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.

Section 3. Feasibility

3.1 Feasibility Assessment *

Describe the feasibility assessment conducted showing you considered the people, tools, tasks, and technologies necessary to implement this measure. For maintenance measures, describe whether feasibility issues due to implementation might have arisen and the near-term (i.e., within one year) mitigation approaches

The feasibility assessment should address:

- *Whether all required data elements are routinely generated and used during care delivery*
- *The extent of any missing data, measure susceptibility to inaccuracies, and the ability to audit data to detect problems*
- *Estimates of the costs or burden of data collection, data entry, and analysis including the impact on clinician workflow, diagnostic thought processes, and patient-physician interaction*
- *Barriers encountered or that could be encountered in implementing the measure specifications, data abstraction, measure calculation, or performance reporting*
- *Ability to collect information without violation of patient confidentiality, including circumstances where measures based on patient surveys or the small number of patients may compromise confidentiality*
- *Identification of unintended consequences*

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). 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.

3.2 [If an eCQM] Attach Feasibility Scorecard *

Attach your completed feasibility scorecard; please create the scorecard using the approved template [\[link\]](#).

One file only; 256 MB limit; Allowed types: .xlsx.

3.3 Feasibility Informed Final Measure *

Describe how the feasibility assessment informed the final measure specifications, indicating any decisions made to adjust the measure in response to feasibility assessment.

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

3.4 Proprietary Information *

Indicate whether your measure or any of its components are proprietary, with or without fees (choose one).

- ☐ Proprietary measure or components (e.g., risk model, codes), without fees
- ☐ Proprietary measure or components with fees
- ☒ Not a proprietary measure and no proprietary components

3.4a [If any proprietary components for 3.4] Fees, Licensing, or Other Requirements *

Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

N/A

Section 4. Scientific Acceptability

4.1 Data and Samples

4.1.1 Data Used for Testing *

Describe the data used for testing (include dates, sources).

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.

4.1.2 Differences in Data *

If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), clearly identify which data source/sample is used for each aspect of testing, including the years of data used in each. If there are no differences to report, enter "None."

None

4.1.3 Characteristics of Measured Entities *

Describe characteristics of measured entities included in the analysis (e.g., number, size, location, type). If you used a sample, describe how you selected measured entities for inclusion in the sample and the representativeness of the sample.

7,497 facilities with 10 or more eligible adult 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.

4.1.4 Characteristics of Units of the Eligible Population *

Describe characteristics of the patients, encounters, episodes, etc., including numbers and percentages by factors such as age, sex, race, or diagnosis. Provide descriptive statistics separately by each specified level of analysis and data source. If you used a sample, describe how you selected the patients for inclusion in the sample and the representativeness of the sample. If there is a minimum case count used for testing, you must reflect that minimum in the specifications in Minimum Sample Size in Section 1.

A total of 447,576 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, 56.3% were white, 34.7% were black, 20.5% were Hispanic, and 46.0% had diabetes as primary cause of ESRD.

4.2 Reliability

4.2.1 Level(s) of Reliability Testing Conducted *

Choose all that apply.

- ☐ Patient- or Encounter-Level (e.g., inter-abstractor reliability)
- ☒ Accountable Entity-Level (e.g., signal-to-noise analysis)
- ☐ Not applicable/reliability testing not conducted

4.2.1a *Please explain why reliability testing was not conducted*

4.2.2 [If reliability testing was conducted] Method(s) of Reliability Testing *

For each level of reliability testing conducted, describe the method(s) of reliability testing and explain what each tests. Describe the steps, do not just name a method. What type of error does it test? Provide the type of statistical analysis used. Describe proportion of missing data, how missing data was analyzed and/or excluded, and any sensitivity analysis conducted.

Note: Testing at the patient- or encounter-level requires that all critical data elements be tested (not just agreement of one final overall computation for all patients). At a minimum, the numerator, denominator, and exclusions must be assessed and reported separately. Prior evidence of reliability of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that: includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

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.

4.2.3 [If reliability testing was conducted] Reliability Testing Results *

Provide the statistical results from reliability testing for each level and type of reliability testing conducted. Where applicable, include results from accountable entity-level reliability testing (e.g., signal-to-noise testing) in the table below.

4.2.3a [If reliability testing was conducted] Attach Additional Reliability Testing

Results

If needed, you may attach additional reliability testing results here. Please ensure all attachments are 508 compliant, all tables and figures are labeled with alternative text, as appropriate. Please clearly refer to any results within your attachment within the relevant text fields of this measure submission form.

One file only; 256 MB limit; Allowed types: .zip, .pdf, .docx, .xls, .xlsx

Table 2 [If accountable entity-level testing was conducted, i.e., if 4.2.1 includes

“Accountable Entity-Level”)] **Accountable Entity-Level Reliability Testing Results**

Enter the overall reliability, minimum, maximum, and mean reliability by decile. Enter the number of measured entities and persons/encounters/episodes overall and within each decile. If a sample, provide characteristics of the entities included. Note that the mean performance score should be the same as what was entered in the performance score table in Section 2 for this level of analysis and year(s).

	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Reliability (IUR)	0.767	0.356	0.476	0.590	0.652	0.694	0.728	0.757	0.783	0.810	0.839	0.883	0.951
N of dialysis facilities	7497	15	745	775	739	696	795	723	763	754	757	750	28
N of patient months	3,758,302	2,265	91,207	159,305	203,405	233,587	318,102	338,400	418,557	495,687	611,919	888,133	7,833

4.2.4 [If reliability testing was conducted] Interpretation of Reliability Results *

Provide your interpretation of the results in terms of demonstrating reliability for each level and type of reliability testing conducted. How do the results support an inference of reliability for the measure?

The overall IUR for the sample dataset was 0.77. The IUR's per deciles of patients ranged from 0.48 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.

4.3 Validity

4.3.1 Level(s) of Validity Testing Conducted *

Choose all that apply.

- ☐ Patient- or Encounter-Level (e.g., sensitivity and specificity)
- ☒ Accountable Entity-Level (e.g., criterion validity)
- ☐ Not applicable/validity testing not conducted

4.3.1a Provide a rationale for why validity testing is not applicable/was not conducted

4.3.2 Type of accountable entity-level validity testing conducted *

Choose all that apply.

- ☒ Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)
- ☐ Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use (i.e., the score is an accurate reflection of the effect of performance on quality or resource use and can distinguish good from poor performance).
- ☐ Not applicable/accountable entity-level validity testing not conducted

4.3.2a [If a maintenance measure] Provide a rationale for why accountable entity-level validity testing was not conducted

4.3.3 [If validity testing was conducted] Method(s) of Validity Testing *

For each level of testing conducted, describe the method(s) of validity testing and what each tests. Describe the steps (do not just name a method) and explain what was tested (e.g., accuracy of data elements compared with authoritative source, relationship to another measure as expected). What statistical analysis did you use? Describe proportion of missing data, how missing data was analyzed and/or excluded, and any sensitivity analysis conducted.

Note: Testing at the patient- or encounter-level requires that all critical data elements be tested (not just agreement of one final overall computation for all patients). At a minimum, the numerator, denominator, and exclusions must be assessed and reported separately. For patient- or encounter-level testing, prior evidence of validity of data elements for the data type specified in the measure (e.g., hospital claims) can be used as evidence for those data elements. Prior evidence could include published or unpublished testing that: includes the same data elements, uses the same data type (e.g., claims, chart abstraction), and is conducted on a sample as described above (i.e., representative, adequate numbers, and randomly selected, if possible).

For empirical accountable entity-level testing, the following should be included:

- *Narrative describing the hypothesized relationships*
- *Narrative describing why examining these relationships (e.g., correlating measures) would validate the measure*
- *Expected direction of the association*
- *Expected strength of the association*

We used January 2022 – December 2022 EQRS clinical data to assess facility level performance scores. 7,497 facilities with 10 or more patients were used for validity testing, which includes 447,576 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.

4.3.4 [If validity testing was conducted] Validity Testing Results *

Provide the statistical results from validity testing for each level and type of validity testing conducted.

Poisson Regression with SMR & SHR

Mortality

Quintile	Performance Score (%)	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq	Rate Ratio (95%CI)
1	10.4	-0.079	0.0079	-0.0942	-0.0633	99.99	<0.0001	1.0 (Reference)
2	17.2	0.026	0.0107	0.0048	0.0468	5.82	0.0468	1.03(95% CI: 1, 1.05)
3	21.7	0.063	0.0107	0.0419	0.0838	34.5	<0.0001	1.06(95% CI: 1.04, 1.09)
4	26.8	0.083	0.0108	0.0614	0.1036	58.71	<0.0001	1.09(95% CI: 1.06, 1.11)
5	38.9	0.168	0.011	0.1466	0.1899	231.82	<0.0001	1.18(95% CI: 1.16, 1.21)

Hospitalization

Quintile	Performance Score (%)	Estimate	Standard Error	Wald 95% Confidence Limits		Wald Chi-Square	Pr > ChiSq	Rate Ratio (95%CI)
1	10.4	-0.0936	0.0012	-0.0959	-0.0913	6429.55	<0.0001	1.0 (Reference)
2	17.2	0.0432	0.0016	0.0402	0.0463	758.66	<0.0001	1.04(95% CI: 1.04, 1.05)
3	21.7	0.0374	0.0016	0.0343	0.0404	560.09	<0.0001	1.04(95% CI: 1.03, 1.04)
4	26.8	0.0635	0.0016	0.0604	0.0666	1616.89	<0.0001	1.07(95% CI: 1.06, 1.07)
5	38.9	0.1181	0.0016	0.1149	0.1212	5312.94	<0.0001	1.13(95% CI: 1.12, 1.13)

4.3.4a [If validity testing was conducted] Attach Additional Validity Testing Results

If needed, you may attach additional validity testing results here. Please ensure all attachments are 508 compliant, all tables and figures are labeled with alternative text, as appropriate. Please clearly refer to any results within your attachment within the relevant text fields of this measure submission form.

One file only; 256 MB limit; Allowed types: .zip, .pdf, .docx, .xls, .xlsx

4.3.5 [If validity testing was conducted] Interpretation of Validity Results *

Provide your interpretation of the results in terms of demonstrating validity for each level and type of validity testing conducted. How do the results support an inference of validity for the measure? For accountable entity-level testing, discuss how the results relate to the hypothesis? If the results are not what were expected, why?

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.

4.4 Risk Adjustment

4.4.1 Methods Used to Address Risk Factors *

What methods or approaches were used to explore the effects of risk factors on this measure? (Note: If you tested for the effects of risk factors and ultimately determined that risk adjustment or stratification was not warranted, please select the method(s) used and provide details of the testing and your rationale in 4.4.2 through 4.4.6; the measure's ultimate status will be reported in 4.4.7).

Choose all that apply.

- ☐ Statistical risk adjustment model with risk factors
- ☐ Stratification by risk factor category
- ☐ Other

4.4.1a Describe other method(s) used

- ☒ No risk adjustment or stratification.

4.4.1b [If Measure Type is outcome or cost/resource]

Provide a rationale for why there is no need to address differences in patient characteristics (i.e., case mix) to achieve fair comparisons across measured entities for your outcome or resource measure.

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.

4.4.2. [If risk factors are addressed by any method (4.4.1)] Conceptual Model

Rationale *

Explain the rationale for the risk approach, including reasons for risk adjustment and/or stratification. Describe the sources that inform the conceptual model, e.g., scientific literature, unpublished findings, TEP. Consider age, gender, race, ethnicity, urbanicity/rurality, Medicare/Medicaid dual eligibility status, indices of social vulnerability (e.g., Centers for Disease Control and Prevention Social Vulnerability Index), and markers of functional status-related risk (e.g., cognitive or physical function) in the conceptual model, using evidence to support the model, with references. If risk factors (e.g., social, functional status-related, clinical) are included in the conceptual model but data are not available for all factors, describe any potential bias, as a result of not including the risk factor(s) in the final risk adjustment model or stratification. Address the validity of the measure in light of this bias.

4.4.2a [If risk factors are addressed by any method (4.4.1)] **Attach Conceptual Model ***
 Attach a figure of the conceptual model that illustrates the hypothesized pathway between the social and/or functional status-related risk factors, patient clinical factors, quality of care, and the measured outcome.

One file only; 256 MB limit; Allowed types: .pdf, .jpg, .png, .zip

4.4.3 [If risk factors are addressed by any method (4.4.1)] **Risk Factor Characteristics Across Measured Entities ***

Provide descriptive statistics showing how the risk variables identified from the conceptual model are distributed across the measured entities. Indicate which risk factors were tested in the risk adjustment model and which were tested for stratifying the measure, as applicable.

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4.4.4 [If risk factors are addressed by any method (4.4.1)] **Risk Adjustment Modeling and/or Stratification Results ***

Describe the statistical results of the analyses used to test and select risk factors for inclusion in or exclusion from the risk model and/or stratification, as applicable. Clearly indicate the risk factors included in the final risk model and/or used in the final stratification approach.

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4.4.4a [If risk factors are addressed by any method (4.4.1)] **Attach Risk Adjustment Modeling and/or Stratification Specifications ***

Provide detailed risk adjustment model and/or stratification specifications, including the method(s), risk factor data sources, and equations, as applicable. Please list all risk factors in your conceptual model, clearly indicating which factors were available/tested and which (if any) were retained in final model and/or stratification plan. Also include the data source, code with descriptor, and coefficient for each risk factor in the final risk adjustment model or stratification plan, as appropriate.

One file only; 256 MB limit; Allowed types: .xls; .xlsx; .csv

4.4.5 [If 4.4.1 includes “Statistical risk adjustment model with risk factors”] **Calibration and Discrimination ***

Describe the approach and results of calibration and discrimination testing. Describe any over- or under-prediction of the model for important subgroups.

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4.4.5a [If 4.4.1 includes “Statistical risk adjustment model with risk factors”] **Attach Calibration and Discrimination Testing Results ***

Attach results of calibration and discrimination testing.

One file only; 256 MB limit; Allowed types: .pdf; .zip

4.4.6. [If risk factors are addressed by any method (4.4.1)] Interpretation of Risk Factor Findings *

Provide your interpretation of the results, in terms of demonstrating adequacy of controlling for differences in patient characteristics (i.e., case mix). Clearly describe the rationale for why each risk factor tested WAS or WAS NOT included in the final model. Describe what the results mean, including what is normally expected in relation to the test conducted.

4.4.7 [If risk factors are addressed by any method (4.4.1)] Final Approach to Address Risk Factors *

*After testing, what methods or approaches were ultimately used to control for the effects of risk factors? (**Note:** the final approach should be supported by the testing and the rationale provided in 4.4.2-4.4.6). Choose all that apply.*

- ☐ Statistical risk adjustment model with risk factors
- ☐ Stratification by risk factor category
- ☐ Other

4.4.1a Describe other method(s) used

- ☐ No risk adjustment or stratification.

Section 5. Equity

5.1 Contributions Towards Advancing Health Equity (optional).

Describe how this measure contributes to efforts to advance health equity. Provide a description of your methodology and approach to empirical testing of differences in performance scores across multiple socio-contextual variables (e.g., race, ethnicity, urbanicity/rurality, socio-economic status, gender, gender identity, sexual orientation, age). Provide an interpretation of the results, including interpretation of any identified differences and consideration of negative impact or unintended consequences on subgroups.

Optional, no response needed.

Section 6. Use & Usability

6.1 Use

6.1.1. Current Status *

Is this new or maintenance measure currently in use?

☒ No ☐ Yes

6.1.2 [If initial endorsement] Current or Planned Use(s) *

Choose all that apply

- ☒ Public Reporting
- ☐ Public Health/Disease Surveillance
- ☒ Payment Program
- ☐ Regulatory and Accreditation Programs
- ☐ Professional Certification or Recognition Program
- ☐ Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
- ☐ Quality Improvement (Internal to the specific organization)
- ☐ Other

6.1.2a Please specify other current or planned use

6.1.3 [If maintenance review] Current Use(s) *

Choose all that apply

- ☐ Public Reporting
- ☐ Public Health/Disease Surveillance
- ☐ Payment Program
- ☐ Regulatory and Accreditation Programs
- ☐ Professional Certification or Recognition Program
- ☐ Quality Improvement with Benchmarking (external benchmarking to multiple organizations)
- ☐ Quality Improvement (Internal to the specific organization)
- ☐ Other

6.1.3a Please specify other use *

☐ Not in use

6.1.3b Provide more information as to why the measure is not in use and whether there

is a near-term (within one year) plan for its use within an accountability application² *

6.1.4 [If Current Status = Yes (6.1.1)] Program Details *

Please provide the following information describing the program(s) in which the measure is currently used:

Name of the program and sponsor

URL of the program

Purpose of the program

Geographic area and percentage of accountable entities and patients included

Applicable level of analysis and care setting

[To add details for another program, click “Add Measure Submission Program” button; To remove a program record entered in error, click “Remove Program” at the top right of the appropriate program details section]

6.2 Usability

6.2.1 Actions of Measured Entities to Improve Performance *

*What are the actions measured entities must take to improve performance on this measure?
How difficult are those actions to achieve and how can measured entities overcome those difficulties?*

Actions that dialysis facilities can take to improve long-term phosphorus control include nutritional counseling to help patients choose low phosphorus foods as part of their nutrition plan, prescription of phosphorus binding agents, and potentially adjustment of dialysis prescription to maximize phosphorus clearance. 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.

² Accountability applications are uses of measure performance results about identifiable, accountable entities to make judgments and decisions because of performance. This can be as confidential reporting, reward, recognition, punishment, payment, or selection (e.g., public reporting, accreditation, performance-based payment, network inclusion/exclusion).

6.2.2 [If maintenance review OR Current Status = Yes (6.1.1)] Feedback on Measure Performance *

Summarize the feedback on measure performance and implementation from the measured entities and others. Describe how you obtained feedback.

6.2.3 [If maintenance review OR Current Status = Yes (6.1.1)] Consideration of Measure Feedback *

Describe how you considered the feedback when developing or revising the measure specifications or implementation, including whether you modified the measure and why or why not.

6.2.4 [If maintenance review OR Current Status = Yes (6.1.1)] Progress on Improvement *

Discuss any progress on improvement (trends in performance results, including performance across sub-populations if available, number and percentage of people receiving high-quality health care, geographic area, number and percentage of accountable entities and patients included). If use of the measure demonstrated no improvement, provide an explanation.

6.2.5 [If maintenance review OR Current Status = Yes (6.1.1)] Unexpected Findings *

Explain any unexpected findings (positive or negative) during implementation of this measure, including unintended impacts on patients.