Partnership for Quality Measurement

National Consensus Development and Strategic Planning for Health Care Quality Measurement

2023 Measure Set Review (MSR): End Stage Renal Disease Quality Incentive Program (ESRD-QIP)

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Executive Summary

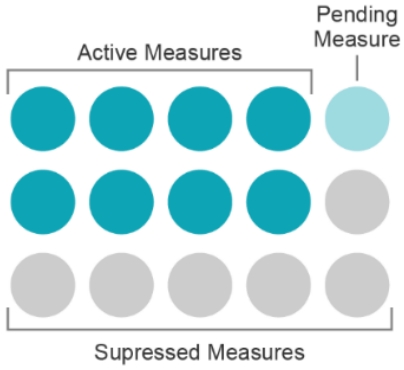
Background and Context

The goal of the Measure Set Review (MSR) processes is to optimize the Centers for Medicare & Medicaid Services (CMS) Medicare quality programs measure portfolio via measure removal recommendations. The recommendations to remove a measure are based on updated information on the measure's properties, performance trends, and whether the measure continues to support the program's needs and priorities.

The focus of the 2023 MSR cycle is the CMS End-Stage Renal Disease Quality Incentive Program (ESRD QIP).

Scope and Limitations

There are 15 measures within the ESRD QIP. Of these measures:



- Six were suppressed during the 2020 and 2021 reporting years due to the COVID-19 Public Health Emergency (PHE).
- One measure, COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), was recently adopted into the program and start with CY 2023 reporting.
- Despite the suppression policy in effect, data collection from facilities resumed in July 2020. The suppression policy effects were on the QIP scoring and payment structures.

Performance data were analyzed at the program level for each of the reporting years. CMS-reported program-level data were analyzed for the subset of measures for which facility-level data were not available.

Preliminary Assessment

The preliminary assessment by Battelle staff focused on evaluating available measure information, historical testing data, and standing committee review from past endorsement and maintenance cycles, as well as current scientific literature and measure performance within the last three reporting years. These evaluations considered each measure's importance, scientific acceptability, feasibility, and usability. Measures were additionally considered against the eight removal factors used in prior MSR cycles to justify measure removal from CMS programs.

Across the fifteen measures assessed, our assessment found several factors across the evaluation criteria supporting and several factors challenging the continued inclusion in ESRD QIP. Supporting factors included strong evidence in the literature related to measure's impact on clinical outcomes, high measure scientific acceptability, ease of implementation, and strong usability. Factors challenging continued inclusion of measures in the program included new evidence challenging measure importance, changes to clinical guidelines, low scientific acceptability, implementation challenges and unintended consequences of use.

Chapter 1. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)1.1 ESRD QIP Overview

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act.[1] The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. ESRD QIP policies are outlined at 42 CFR 413.177 and 413.178. The technical specifications for ESRD QIP measures are available for review on the CMS website. Statutorily required categories of measures include anemia management, dialysis adequacy, and patient satisfaction, among others.[2] On June 30, 2023, CMS issued the calendar year (CY) 2024 end-stage renal disease prospective payment system (PPS) proposed rule, which includes several updates for the ESRD QIP as presented in Table 1.

Table 1. Summary of the ESRD QIP Proposed Rule.

Current Proposed Rule Changes	
Changes	• Codifies definition of "minimum total performance score" as well as measure selection, retention, and removal policies. • Modifies COVID–19 Vaccination Coverage Among Healthcare Personnel reporting measure to align with updated measure specifications developed by the Centers for Disease Control and Prevention. • Updates the Clinical Depression Screening and Follow-Up measure's scoring methodology to convert the measure to a clinical measure.
Additions	• Facility Commitment to Health Equity reporting measure • Social Drivers of Health reporting measure • Screen Positive Rate for Social Drivers of Health reporting measure **beginning PY 2027*
Removals	• Ultrafiltration Rate reporting measure • Standardized Fistula Rate clinical measure

For 2020 to 2021, several measures within ESRD QIP, as well as other CMS quality reporting programs, were part of a measures suppression policy as it was "determined that circumstances caused by the public health emergency (PHE) due to COVID–19 have significantly affected the measures and resulting performance scores." During CY 2020/PY 2022, the following measures were suppressed: Standardized Hospitalization Ratio (SHR) clinical measure, the Standardized Readmission Ratio (SRR) clinical measure, the In-Center Hemodialysis Consumer Assessment

[1] Guidance for explaining the laws and regulations as they pertain to the ESRD Quality Incentive Program. ESRD Quality Incentive Program - Laws & Regulations | Guidance Portal (hhs.gov)

[2] H.R.6331 - 110th Congress (2007-2008): Medicare Improvements for Patients and Providers Act of 2008. (2008, July 15). https://www.congress.gov/bill/110th-congress/house-bill/6331

of Healthcare Providers and Systems (ICH CAHPS) clinical measure, and the Long-Term Catheter Rate clinical measure.

During CY 2021/PY 2023, the following measures were suppressed: SHR clinical measure, SRR clinical measure, ICH CAHPS clinical measure, Long-Term Catheter Rate clinical measure, Percentage of Prevalent Patients Waitlisted (PPPW) clinical measure, and Kt/V Dialysis Adequacy Comprehensive clinical measure and the Standardized Fistula Rate (SFR) clinical measure. While the suppression policy impacted the QIP scoring, data were still being reported to CMS by facilities. More information on this measure suppression policy in relation to ESRD QIP can be found in the 2022 Final Rule. Table 1.2 provides information on ESRD QIP measures including their CMS Measures Inventory Tool (CMIT) ID, Consensus-Based Entity (CDE) number if available, name and their description.

1.2 ESRD QIP Measures

Table 1.2 Current End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Measures.

CMIT ID	CBE ID	Measure Name	Description
Active in ESRD QIP			
00314-01-C-ESRDQIP	CBE 2977	Hemodialysis Vascular Access: Standardized Fistula Rate	Adjusted percentage of adult hemodialysis (HD) patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.
00360-01-C-ESRDQIP	CBE 1454	Hypercalcemia	A proportion of all adult patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing.
00698-01-C-ESRDQIP	CBE 2979	Standardized Transfusion Ratio (STrR)	Dialysis facility reporting of data on Medicare claims and in EQRS (End-stage Renal Disease Quality Reporting System) used to determine the number of eligible patient-years at risk for calculating the risk adjusted facility-level transfusion ratio (STrR) for adult Medicare dialysis patients.
00733-01-C-ESRDQIP[3]	Not endorsed, based on CBE 2701	Ultrafiltration Rate (UFR)	Number of months for which a facility reports all required data elements for ultrafiltration rate (UFR) in CROWNWeb for all HD sessions during the week of the monthly Kt/V draw submitted for that clinical month for each eligible patient (both Medicare and non-Medicare dialysis patients), (based on CBE# 2701).
00440-01-C-ESRDQIP	CBE 2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)	The percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional (based on CBE #2988).

[3] The Ultrafiltration Rate measure was suggested for removal in PY 2026 in the current proposed rule.

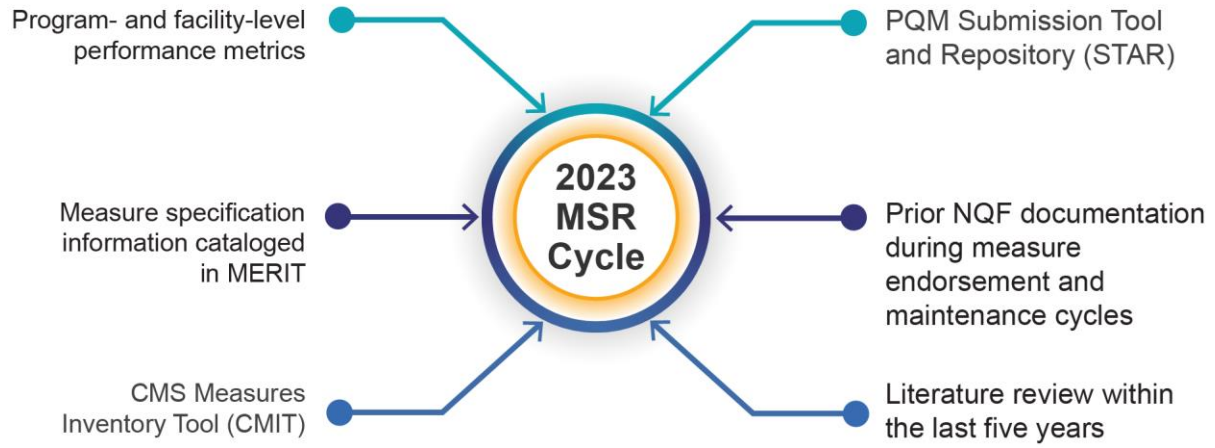
CMIT ID	CBE ID	Measure Name	Description
00461-02-C-ESRDQIP	Not endorsed	National Healthcare Safety Network (NHSN) Dialysis Event	Number of months for which facility reports NHSN Dialysis Event data to the CDC. There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.
00458-01-C-ESRDQIP	Not endorsed, based on CBE 1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients	The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSIs) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
00672-03-C-ESRDQIP	Not endorsed, based on CBE 0418	Clinical Depression Screening and Follow-Up	Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before the close of the December clinical month. 1. Screening for clinical depression is documented as being positive, and a follow-up plan is documented. 2. Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. 3. Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. 4. Screening for clinical depression documented as negative and no follow-up plan required. 5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. 6. Clinical depression screening not documented, and no reason is given.
Active Measures, Suppressed 2020 & 2021			
00697-01-C-ESRDQIP	CBE 2496	Standardized Readmission Ratio (SRR)	The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4 to 30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. Note that the measure is based on Medicare-covered dialysis patients.

CMIT ID	CBE ID	Measure Name	Description
00695-01-C-ESRDQIP	CBE 1463	Standardized Hospitalization Ratio (SHR)	Risk-adjusted standardized hospitalization ratio of observed hospitalizations to expected hospitalizations.
00546-01-C-ESRDQIP	CBE 3695	Percentage of Prevalent Patients Waitlisted (PPPW)	The percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
00381-02-C-ESRDQIP	CBE 0258	In-Center Hemodialysis (ICH) CAHPS Survey	The percentage of patient responses to multiple survey measures to assess their dialysis providers, the quality of dialysis care they receive, and information sharing about their disease. (Survey is administered twice a year). Three Composite Measure Scores: The proportion of respondents answering each response option by item, created from six or more survey questions reported as one measure score. Composites include Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, and Providing Information to Patients. Three Global Items: A scale of 0 to 10 to measure the respondent's assessment of the following: Rating of the Nephrologist, Rating of Dialysis Center Staff, and Rating of the Dialysis Facility.
00313-01-C-ESRDQIP	CBE 2978	Hemodialysis Vascular Access: Long-term Catheter Rate	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.
00180-01-C-ESRDQIP	CBE 3636	COVID-19 Vaccination Coverage among HCP	Percentage of health care personnel (HCP) who receive a complete COVID-19 vaccination course.
00407-01-C-ESRDQIP	Not endorsed	Kt/V Dialysis Adequacy Comprehensive Measure-HD	The percentage of all patient-months for patients whose delivered dose of dialysis (either HD or PD) met the specified threshold during the reporting period.

Chapter 2. Review Methodology

2.1 Data Collection and Sources

Data for the 2023 MSR cycle included program level performance metrics, measure specification information cataloged in the CMS Measures Under Consideration Entry/Review Information Tool (MERIT), the CMS Measures Inventory Tool (CMIT), the PQM Submission Tool and Repository (STAR), and prior National Quality Forum (NQF) documentation during measure endorsement and maintenance cycles when applicable. Staff also conducted a review of published literature within the last 5 years to assess any updates or challenges to the evidence base and clinical framework for each measure.



CMS-reported program-level data[4] were analyzed for 2020, 2021, and 2022 performance years. The reporting facilities were sorted into deciles by performance score and the average performance score was calculated for each decile, which provided information about the distribution of the performance score. Data that were not binomial (such as the ratio number of events per patient-month) were converted to binomial by multiplying the ratio by the number of patients.

Figure 2.1 shows the number of dialysis facilities reporting for ESRD QIP measures during performance years 2020, 2021, and 2022. During this timeframe, some measures had reduced reporting due to the PHE measure suppression policy. Additionally, reporting data on the COVID-19 Vaccination Coverage among HCP was not available during these reporting years as this measure is newly considered for CY 2023 reporting.

[4] Arbor Research Collaborative (2023). ESRD QIP Measure Evaluation Report. Delivered on March 7, 2023 under Contract No. 75FCMC18D0016.

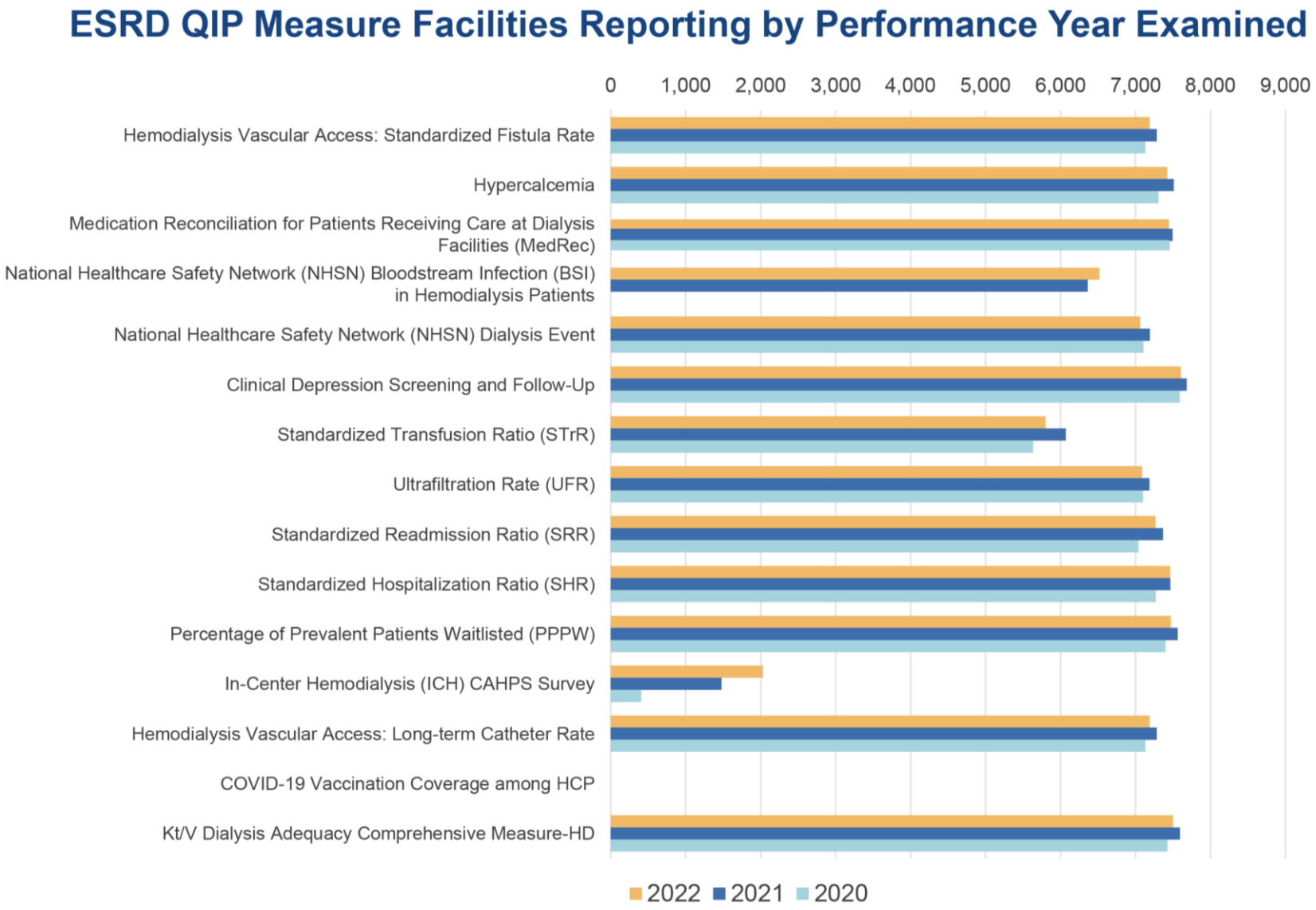


Figure 2.1. Facilities Reporting ESRD QIP Measures by Performance Year Examine

2.2 MSR Evaluation Criteria and Staff Assessment

Table 2.2 shows the evaluation criteria utilized for this review along with their alignment to the ESRD removal factors finalized and discussed in CY 2019 ESRD PPS final rule (83 FR 56983 through 56985). Battelle staff collaborated with subject matter experts in measure science and consulted ESRD QIP key informants when necessary. Staff used the criteria in Table 2.2 to assess each measure, synthesizing across data sources to generate elements both supporting and challenging continued ESRD QIP use for consideration of the MSR committee. Review of performance and reliability data was conducted with consideration of the potential impacts of the PHE within the reporting years examined.

Table 2.2 MSR Preliminary Assessment Evaluation Criteria

Criteria	CMS Removal Factor
Importance: Evidence shows causal link between measure targets and health outcomes; measure performance gap considered.	**Factor 1.** Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made. **Factor 2.** Performance or improvement on a measure does not result in better or the intended patient outcomes.
Scientific Acceptability **Reliability:** Data show an acceptable level of reliability at analysis level. **Validity:** Measure aligns with current guidelines and practice; threats to validity are minimized.	**Factor 3.** A measure no longer aligns with current clinical guidelines or practice.
Feasibility: People, tools, tasks, and technologies necessary to implement this measure are reasonable for chosen care settings.	**Factor 7.** It is not feasible to implement the measure specifications. **Factor 8.** The costs associated with a measure outweigh the benefit of its continued use in the program.
Usability: Unintended consequences are minimized; measure is implemented across the patient journey as intended.	**Factor 6.** Collection or public reporting of a measure leads to negative or unintended consequences.
ESRD QIP Program-Level Consideration	
Alternative Measures: Measure remains appropriate for inclusion when compared with alternative measures.	**Factor 4.** A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the topic becomes available. **Factor 5.** An alternative measure more strongly associated with desired patient outcomes for the topic becomes available.

Chapter 3. Measure Review Findings

We present the information found by criteria but will not make a recommendation on a measure's continued use in the program. For each measure, an evaluation table is provided to outline evidence supporting and challenging continued ESRD QIP use of the measure. Additionally, measure score performance aggregated for all reporting facilities is shown graphically across CY 2020 to 2022 for each measure. Measure evaluation was conducted using the criteria outlined in Chapter 2 and relied on review of multiple information sources. When possible, relevant recent literature was consulted to inform reviewers' understanding of the clinical importance and impact of each measure. Alternative measures within current CMS programs and/or those having received prior CBE endorsement were examined.

Appendix A contains program-level performance data for measures reporting during the CY 2020-2022.

3.2.1 00314-01-C-ESRDQIP Hemodialysis Vascular Access: Standardized Fistula Rate

CMIT ID: 00314-01-C-ESRDQIP

Measure description: Adjusted percentage of adult hemodialysis (HD) patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

Measure Type: Intermediate Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims Data

Table 3.2.1a. Preliminary Assessment of 00314-01-C-ESRDQIP Hemodialysis Vascular Access: Standardized Fistula Rate

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Literature associates the use of AVF for hemodialysis access with lower rates of infection compared with both arteriovenous grafts (AVG) and long-term catheters. • Recent studies and systematic reviews also find lower risk of mortality or hospitalization from use of AVF relative to other access or with early conversion from catheter to AVF. • The 2020 maintenance submission found disparities in AVF use based on age, sex, race/ethnicity, and socio-economic status (SES). • Overall mean measure score of 61.1%, ranging from mean of 35.6% in decile 1 to mean of 78.8% in decile 10 (2021 analysis). • Statutorily required category.	• Evidence base does not include randomized controlled trials (RCTs). • Measure was not recommended for endorsement in 2020 due to lack of evidence. • Literature suggests AVF may not be the best option for all patients with comorbidities given confounding influence of these conditions; 2020 prior CBE committee expressed concern that at the measure's already high scores, the opportunity for improvement might be primarily among patients for whom AVF is not recommended. • While distribution of performance scores and the presence of disparities indicate a gap, performance data also show a decline in scores overall and by decile from 2020 to 2022.
Scientific Acceptability, Reliability	• The 2020 maintenance submission tested reliability using data from January-December 2018, and reported an IUR of .755.	• None identified

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• Measure aligns with current clinical practice guidelines. • Risk adjusted for patient characteristics (age, BMI, nursing home status, incident and prevalent comorbidities and other factors) affecting suitability of patients for AVF vs. AVG. • Measure is intended to be reported jointly with CBE #2978, Hemodialysis Vascular Access: Long-term Catheter Rate, which is intended to encompass all three access methods. • The 2019 maintenance submission tested validity using data from January 2017 – December 2018, and found a negative correlation between the measure score and risk of both mortality and hospitalization, as expected.	• Evidence for the guideline was downgraded prior to 2020 maintenance submission, and evidence is currently rated as low or expert opinion. • During 2020 maintenance review, the committee expressed concern about downward pression on clinicians to order AVFs even when they might not be the most patient-centered option. • Patient choice is a confounding factor. • Reasons for beginning hemodialysis with a catheter include acute onset of ESRD and non-working or immature AV access, which are not accounted for in risk adjustment model.
Feasibility	• Required data elements are routinely captured during patient care and are in defined fields in electronic sources. • Per the 2020 maintenance submission, comments about inaccurate or missing data were rare.	• Data elements are coded by someone other than the person collecting original information.
Usability	• No unintended consequences were reported in the 2020 maintenance submission. • Facilities can preview performance results prior to posting and submitting questions and comments about their results. • Mechanisms for collecting feedback from measured entities include QIP helpdesk, a preview period, and public comment.	• This measure was suppressed for PY 2023 due to the determination that the COVID-19 public health emergency significantly affected the performance score; in addition, performance scores declined overall and across all quantiles from 2020-2022.

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
ESRD QIP Program-Level Consideration		
Alternative Measures	• A related measure, CBE #2594, Optimal End Stage Renal Disease (ESRD) Starts, does not address dialysis facilities or dialysis providers.	• None identified

Additional Published Literature Consulted:

Celik S, Gok Oguz E, Ulusal Okyay G, Selen T, Ayli MD. (2021) The impact of arteriovenous fistulas and tunneled cuffed venous catheters on morbidity and mortality in hemodialysis patients: A single center experience. Int J Artif Organs;44(4):229-236.

Federal Register, 42 CFR Parts 413 and 512. Vol. 87, No. 214. Nov 7, 2022. https://www.govinfo.gov/content/pkg/FR-2022-11-07/pdf/2022-23778.pdf [accessed 8/18/23]

Jhee JH, Hwang SD, Song JH, Lee SW. (2019) The Impact of Comorbidity Burden on The Association between Vascular Access Type and Clinical Outcomes among Elderly Patients Undergoing Hemodialysis. Sci Rep. 3;9(1):18156.

Li J, Lu H, Xie Z, Li Q, Shi H. (2023) Outcomes of arteriovenous graft vs. fistula for haemodialysis access in the elderly: A systematic review and meta-analysis. Exp Ther Med. 26(2):399. doi: 10.3892/etm.2023.12098. PMID: 37522056; PMCID: PMC10375446.

Liebman SE, Chang EY. (2019) An analysis of central venous catheter-based hemodialysis starts. Clin Nephrol;92(1):9-14.

Raimann JG, Chu FI, Kalloo S, Zhang H, Maddux F, Wang Y, Kotanko P. (2020) Delayed conversion from central venous catheter to non-catheter hemodialysis access associates with an increased risk of death: A retrospective cohort study based on data from a large dialysis provider. Hemodial Int. (3):299-308.

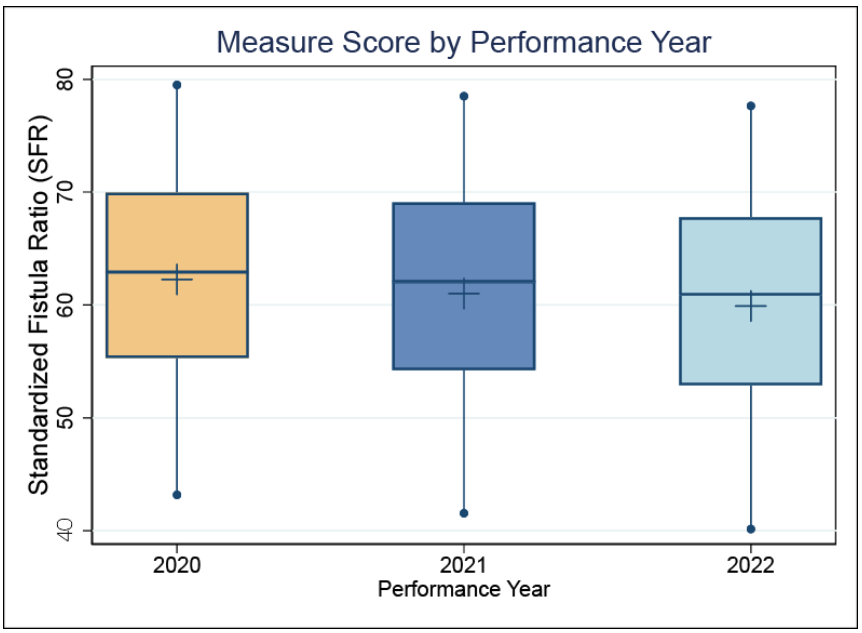


Figure 3.2.1 Measure Score for Hemodialysis Vascular Access: Standardized Fistula Rate[5]

[5] Guidance on interpretation for this and subsequent plots: For each performance year, the dots indicate the lower 5th and upper 95th percentiles and the vertical line is the range between these values. The box spans the lower 25th to the upper 75th percentile. The horizontal line in the box indicates the median, and the "+" indicates the mean.

Table. 3.2.1b. MSR Measure Information Sheet from CMIT for 00314-01-C-ESRDQIPHemodialysis Vascular Access: Standardized Fistula Rate

	Description
Measure Name	Hemodialysis Vascular Access: Standardized Fistula Rate
CMIT ID	00314-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Healthcare Priority: Safety Goal: Reduced Preventable Harm
Measure type	Intermediate Outcome
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Endorsement Removed
History	Initial Endorsement: December 9, 2016 Last Endorsement: December 9, 2016 Endorsement removed: November 15, 2020 The NQF Renal Standing Committee did not recommend the measure for continued endorsement on September 22, 2020. This measure did not reach consensus on evidence, a must-pass criterion, during the spring 2020 cycle measure evaluation meetings held on June 16 and 18, 2020. The Committee re-voted on the measure during the September 22, 2020 post-comment web meeting and did not recommend the measure for endorsement. Rationale: The Committee expressed concern that the current fistula rate of 64% may be indicative that the remaining opportunities for improvement include many patients for whom fistula may not be the best route, such as those in hospice care, with end-stage liver disease, or cancer.
Measure description	Adjusted percentage of adult hemodialysis (HD) patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

	Description
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Claims Data
Numerator	Adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last HD treatment session of the month.
Denominator	All patient-months where the patient is at least 18 years old as of the first day of the reporting month who are determined to be maintenance HD patients (in-center and home HD) for the entire reporting month at the same facility.
Denominator exclusions, if applicable	Facility Exclusion 1. Facilities treating fewer than 11 eligible patients during the calendar year of assessment. 2. For new facilities only, the month in which the CCN becomes effective and the following three months. 3. Calculations will exclude the months covered by a granted ECE. Patient Exclusions 1. Pediatric patients (<18 years old). 2. Patient-months not on HD. 3. Patient-months with in-center or home HD for less than a complete reporting month at the same facility. 4. Patient-months where a patient with a catheter has a limited life expectancy, defined as: a. Patients under hospice care in the current reporting month. b. Patients with metastatic cancer in the past 12 months. c. Patients with end stage liver disease in the past 12 months. d. Patients with coma or anoxic brain injury in the past 12 months. 5. 5. Patients not on ESRD treatment.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	Yes

	Description
Performance data	Appendix A
Related measures in other programs	2594 Optimal End Stage Renal Disease (ESRD) Starts
Summary of measure's feasibility	CBE measure submission, 2020: Data elements are generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score). Coded by someone other than the person obtaining original information (e.g., DRG, ICD-9 codes on claims). All data elements are in defined fields in a combination of electronic sources. Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors. Measures reported on DFC are reviewed on a regular basis by dialysis facility providers. Review of comments and questions received in the past for the Standardized Fistula Rate showed only rare instances of concern expressed about inaccurate or missing data. Details on the measure's scientific acceptability is available upon request.
Scientific acceptability: validity testing	NQF Scientific Methods Panel (SMP) vote for validity – Moderate (H-1; M-7; L-1; I-0) The SMP reviewed this measure and expressed concerns related to the comorbidity conditions, namely that the measure is not adjusted. The committee agreed with the SMP's concerns and noted the relationship between facility-level quintiles of performance scores and the SMR and standardized hospitalization rate (SHR) using Poisson regression. The Committee noted that the risk adjustment is based on a multivariate logistic regression model. The adjustment is made for age, BMI at incident, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD, comorbidities, and two binary indicators, including missing a CMS-2728 form; and an indicator for if at least one of the comorbidities were present. The Committee expressed concern about 23% of the data being missing. The Committee considered the loss of information as a part of seeking balance in measuring an entire population and ensuring accuracy in the risk model and the presence of an adjustor in the model for those without comorbidity data.
Scientific acceptability: reliability testing	This measure was reviewed by the NQF SMP. SMP vote for reliability – Moderate (H-4; M-5; L-0; I-0) Committee noted very little change in the specifications since its last submission. The testing was conducted at the measure score level by calculating an IUR with bootstrapping, IUR = 0.76 with no PIUR provided.

3.2.2 00360-01-C-ESRDQIP Hypercalcemia

CMIT ID: 00360-01-C-ESRDQIP

Description: Proportion of all adult patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing.

Measure Type: Intermediate Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims Data

Table 3.2.2a. Preliminary Assessment of 00360-01-C-ESRDQIP Hypercalcemia

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• There exists ample evidence in the literature demonstrating that hypercalcemia is associated with poor health outcomes, including all-cause mortality, cardiovascular events, and vascular/valvular calcification.	• Evidence base for this measure does not include randomized control trials. • Mean performance is high (1.31% overall in 2021) with negligible variation across facilities, showing little room for improvement.
Scientific Acceptability, Reliability	• 2019 maintenance submission used data from Jan-Dec 2017 to assess reliability and calculated an annual IUR of 0.87.	• In addition, the developer notes in their 2019 maintenance submission that the IUR result should be interpreted with caution given the skewed performance scores.
Scientific Acceptability, Validity	• This measure aligns with current clinical guidelines. • An algorithm for addressing hypercalcemia has been proposed (Fong et al., 2023). • Measure performance scores provided in 2019 maintenance submission were predictive of mortality as measured by the standardized mortality ratio.	• Current clinical guidelines are rated as low quality or expert opinion, and none provides recommendations for managing hypercalcemia. • Available research on clinical management of recalcitrant hypercalcemia is sparse and limited to case reports.
Feasibility	• Required data elements are routinely captured during patient care and available from CROWNWeb and EHRs.	• None identified

Hypercalcemia

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Usability	• No unintended consequences were reported in the 2019 maintenance submission. • Facilities can preview performance results prior to posting and submitting questions and comments about their results. • Mechanisms for collecting feedback from measured entities include QIP helpdesk, a preview period, and public comment.	• None identified
ESRD QIP Program-Level Consideration		
Alternative Measures	• None identified	• None identified

Additional Published Literature Consulted:

Fong, J.M.N., Chia, E.C., Zhang, M. and Malakar, R.D., (2023), March. Recalcitrant hypercalcemia in a dialysis patient: Case report, literature review, and proposed management algorithm. In Seminars in Dialysis (Vol. 36, No. 2, pp. 170-174).

Mahmoud, S., Mitwally, H., El Zeer, H.S., El Madhoun, I. and Khatib, M., (2018). Use of pamidronate to treat hypercalcemia in an oncology dialysis patient: A case report. The American Journal of Case Reports, 19, p.1087.

Pratt, R.M., West, M.L. and Tennankore, K.K., (2020). Use of denosumab to treat refractory hypercalcemia in a peritoneal dialysis patient with immobilization and tertiary hyperparathyroidism. Peritoneal Dialysis International, 40(1), pp.103-106.

Shen, Y. and Fei, P., (2019). Refractory hypercalcemia due to an ectopic mediastinal parathyroid gland in a hemodialysis patient: a case report. BMC nephrology, 20, pp.1-4.

Uehara, A., Yazawa, M., Kawata, A., Hachisuka, R. and Shibagaki, Y., (2017). Denosumab for treatment of immobilization-related hypercalcemia in a patient with end-stage renal disease. CEN Case Reports, 6, pp.111-114.

Yamada, S., Arase, H., Tokumoto, M., Taniguchi, M., Yoshida, H., Nakano, T., Tsuruya, K. and Kitazono, T., (2020). increased Risk of infection-Related and All-cause Death in Hypercalcemic patients Receiving Hemodialysis: the Q-cohort Study. Scientific reports, 10(1), p.6327.

Zaitoun, M.F., Al-Alsheikh, K.A. and Elnazer, W., (2021). Use of high-dose denosumab in the management of immobilization-related hypercalcemia in an end-stage renal disease patient on hemodialysis: A case report and review of the literature. Clinical Nephrology, 96(6), p.353.

Hypercalcemia

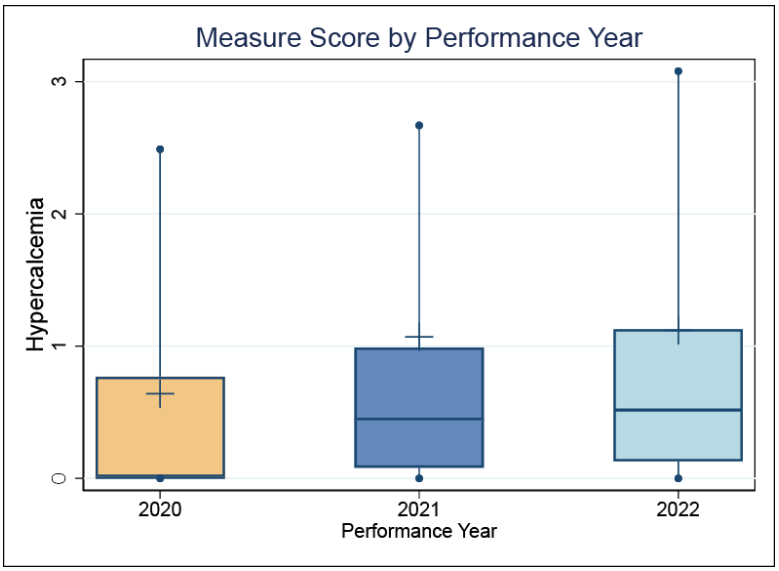


Figure 3.2.2 Measure Score for Hypercalcemia

Table 3.2.2b MSR Measure Information Sheet from CMIT for 00360-01-C-ESRDQIP Hypercalcemia

	Description
Measure Name	Hypercalcemia
CMIT ID	00360-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Healthcare Priority: Chronic Conditions Goal: Improved Disease-Specific Outcomes
Measure type	Intermediate Outcome
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Endorsed with Reserve Status
History of endorsement	Initial Endorsement: August 16, 2011 Last Endorsement: October 2, 2015
Measure description	Proportion of all adult patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Claims Data
Numerator	Number of patient-months in the denominator with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing.
Denominator	Number of patient-months at the facility during the measurement period. Includes both Medicare and non-Medicare patients.
Denominator exclusions, if applicable	Facility Exclusion 1. Facilities treating fewer than 11 eligible patients during the calendar year of assessment. 2. Facilities with fewer than 3 months of data reported in EQRS1. 3. Calculations will exclude the months covered by a granted ECE. Patient Exclusions 1. Patients younger than 18 years 2. Patients present at the facility for fewer than 30 days during the 3-month study period. 3. Patients

Hypercalcemia

	Description
	on ESRD treatment for fewer than 90 days as of the first day of the reporting month. 4. Patients not on ESRD treatment as defined by a completed 2728 form or an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims. 5. Patients who have died or been discharged prior to the last day of the reporting month. 6. Patients for whom the facility reported fewer than 3 months of calcium values in EQRS during the measurement period, plus the two months prior (i.e., November and December of the previous year will be used in calculating the three-month rolling average for January and February of the baseline and performance period).
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures in other programs	N/A
Summary of measure's feasibility	The data elements required are routinely measured as part of patient care and can be derived from CROWNWeb and electronic health records.
Scientific acceptability: validity testing	Validity was assessed using Poisson regression models to identify the predictive strength of facility-level performance scores for the measure, on mortality, using the 2017 SMR. We anticipate a positive correlation with the SMR, since hypercalcemia is a marker of poor overall health. For the Spring 2019 Maintenance submission, the results again suggest the measure performance scores were predictive of mortality as measured by the 2017 SMR. The facility-level relative risk of mortality for a 10% increase in percent of patients with hypercalcemia, is 1.08 ($p<0.0001$).
Scientific acceptability: reliability testing	The developer used January 2017- December 2017 CROWNWeb data to calculate facility-level monthly and annual performance scores. 6,824 facilities that had at least 11 eligible patients were included in the testing. The annual IUR across the 12 reporting months was 0.87, which indicates that 87% of the variation in the yearly based measure can be attributed to the between facility variation.

3.2.3 00698-01-C-ESRDQIP Standardized Transfusion Ratio (STrR)

CMIT ID: 00698-01-C-ESRDQIP

Description: Dialysis facility reporting of data on Medicare claims and in EQRS that are used to determine the number of eligible patient years at risk for calculating the risk adjusted facility-level transfusion ratio (STrR) for adult Medicare dialysis patients.

Measure Type: Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims Data

Table 3.2.3a. Preliminary Assessment of 00698-01-C-ESRDQIP Standardized Transfusion Ratio

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• The relationship between measure target and patient health outcomes is well supported in the literature and current clinical guidelines. • This measure allows for detection of transfusion patterns as an evidence-based indicator of the quality of anemia management for dialysis patients. • Statutorily required category.	• Literature suggests there may be clinical decision making around using a measure solely on anemia management vs. the clinical step of transfusion, which is a signal of anemia management. Measure targets as part of full transfusion pathway could be considered.
Scientific Acceptability, Reliability	• Moderately high inter unit reliability in submitted testing data during endorsement for 2014-2017 as shared during 2020 maintenance review. • The developer tested score-level reliability at the facility level using bootstrapping to evaluate inter-unit reliability (IUR) and found IURs for the one-year STrR have a range of 0.63-0.68 across the years 2014, 2015, 2016, and 2017.	• None identified

Standardized Transfusion Ratio (STrR)

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• During 2020 maintenance review of this measure, the standing committee voted to pass on validity with a majority vote of moderate. Data from 2021 show a continuation of mid-level performance.	• Facility-level attribution may not adequately reflect provider level factors that contribute to STrR. • Not all comorbidities of relevance are reflected in the current statistical risk model.
Feasibility	• Uses claims-based data and codes collected in routine care.	• May not adequately reflect emerging home-based dialysis options
Usability	• STrR is actionable measure for facility-level review of transfusion patterns alongside Erythropoiesis-Stimulating Agents (ESA) for addressing anemia and can lead to practice change.	• Annual reporting may limit the ability of facilities to course-correct and implement improvements as they would if reported quarterly. • Facility-level of attribution could fail to detect clinician or unit level patterns that need to be monitored.
ESRD QIP Program-Level Consideration		
Alternative Measures	• None identified	• None identified

Additional Published Literature Consulted:

Fuller, D.S., Bieber, B.A., Pisoni, R.L., Li, Y., Morgenstern, H., Akizawa, T., Jacobson, S.H., Locatelli, F., Port, F.K. and Robinson, B.M., (2016). International comparisons to assess effects of payment and regulatory changes in the United States on anemia practice in patients on hemodialysis: the dialysis outcomes and practice patterns study. Journal of the American Society of Nephrology: JASN, 27(7), p.2205.

Wetmore, J.B., Tzivelekis, S., Collins, A.J. and Solid, C.A., (2016). Effects of the prospective payment system on anemia management in maintenance dialysis patients: implications for cost and site of care. BMC nephrology, 17, pp.1-9.

Gilbertson, D. T., Yan, H., Xu, H., Sinsakul, M., Peng, Y., Wetmore, J. B., Liu, J & Li, S. (2021). Development and Validation of a Transfusion Risk Score for Patients Receiving Maintenance Hemodialysis. Kidney360, 2(6), 948.

Peters, C.B., Hansen, J.L., Halwani, A., Cho, M.E., Leng, J., Huynh, T., Burningham, Z., Caloyeras, J., Matsuda, T. and Sauer, B.C., (2019). Validation of algorithms used to identify red blood cell transfusion related admissions in veteran patients with end stage renal disease. eGEMs, 7(1).

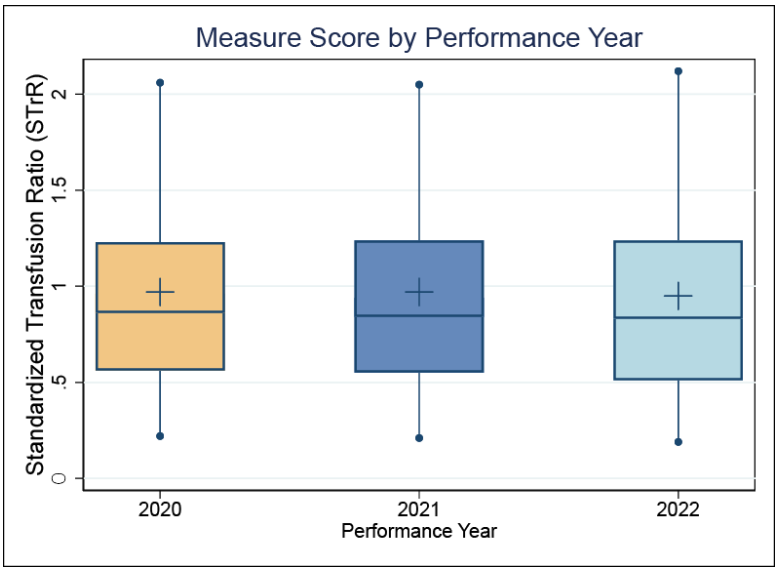


Figure 3.2.3 Measure Score for Standardized Transfusion Ratio

Table 3.2.3b. MSR Measure Information Sheet from CMIT for 00698-01-C-ESRDQIP Standardized Transfusion Ratio

	Description
Measure Name	Standardized Transfusion Ratio (STrR)
CMIT ID	00698-01-C-ESRDQIP
CMS program in which the measure is used	ESRD QIP
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Healthcare Priority: Chronic Conditions Goal: Improved Disease-Specific Outcomes
Measure type	Outcome
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Endorsed
History	Initial Endorsement: December 9, 2016 Last Endorsement: November 20, 2020 The NQF Renal Standing Committee recommended the measure for endorsement. The CSAC expressed no concerns with the Committee's evaluation or recommendation and voted unanimously to endorse the measure.
Measure description	Dialysis facility reporting of data on Medicare claims and in EQRS that are used to determine the number of eligible patient years at risk for calculating the risk adjusted facility-level transfusion ratio (STrR) for adult Medicare dialysis patients.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Claims Data
Numerator	Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the inclusion episodes of the reporting period. Inclusion episodes are those that do not have any claims pertaining to the

	Description
	comorbidities identified for exclusion, in the one year look back period prior to each observation window.
Denominator	Number of eligible red blood cell transfusion events (as defined in the numerator statement) that would be expected among patients at a facility during the reporting period, given the patient mix at the facility. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.
Denominator exclusions, if applicable	Facility Exclusions 1. Facilities with less than 10 patient-years at risk during the calendar year of assessment. 2. Calculations will exclude the months covered by a granted ECE. Patient Exclusions 1. Patients less than 18 years old. 2. Patients on ESRD treatment for fewer than 90 days. 3. Patients on dialysis at the facility for fewer than 60 days 4. Time during which patient has a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant). 5. Time during which a patient is enrolled in Medicare Advantage according to Medicare Enrollment database. 6. Patients who have not been treated by any facility for a year or longer. 7. Patients with a Medicare claim (Part A inpatient, home health, hospice, and skilled nursing facility claims or Part B outpatient and physician supplier) for one of the following conditions in the past year: hemolytic and aplastic anemia, solid-organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, or sickle cell anemia. 8. Patient-months not within two months of a month in which a patient has $1200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. 9. Patients are excluded beginning 60 days after they recover renal function or withdraw from dialysis.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	Yes
Performance data	Appendix A

Ultrafiltration Rate (UFR)

	Description
Related measures in other programs	N/A
Summary of measure's feasibility	All data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry. The data is generated, collected, and used by healthcare personnel during provision of care.
Scientific acceptability: validity testing	During the measure evaluation meeting in January 2020, the Standing Committee did not accept the SMP's rating on validity and determined their discussion warranted a vote. Standing Committee vote for validity: H-1; M-10; L-3; I-2. The developer provided face validity assessment using a TEP. The developer conducted score-level empirical testing using a Poisson regression model and indicated significant association of the STrR with hospitalization, mortality, and percent of patients with low hemoglobin levels. The Committee noted that removal of Medicare Advantage patients from the denominator resulted in more patients being excluded from the measure.
Scientific acceptability: reliability testing	During the measure evaluation meeting in January 2020, the Standing Committee did not accept the SMP's rating on reliability and determined their discussion warranted a vote. Standing Committee vote for reliability: Reliability: H-0; M-13; L-2; I-1. The developer tested score-level reliability at the facility level using bootstrapping to evaluate inter-unit reliability (IUR) and found IURs for the one-year STrR have a range of 0.63-0.68 across the years 2014, 2015, 2016, and 2017.

3.2.4 00733-01-C-ESRDQIP Ultrafiltration Rate (UFR)

CMIT ID: 00733-01-C-ESRDQIP

Description: Percentage of adult in-center hemodialysis patients in the facility whose average ultrafiltration rate (UFR) is >=13 ml/kg/hour AND who receive an average of <240 minutes per treatment during the calculation period.

Measure Type: Process

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims)

Table 3.2.4a. Preliminary Assessment of 00733-01-C-ESRDQIP Ultrafiltration Rate

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Evidence reviewed supports that high UFR and/or shorter dialysis sessions place undue strain on the cardiovascular system and can result in increased risk of negative health outcomes. • Statutorily required category.	• Evidence published since endorsement has shown that UFR is influenced by additional factors such as patients' interdialytic weight gain and that the patient risks associated with high UFR are related to the frequency or number of sessions with high UFR rather than the UFR independently.
Scientific Acceptability, Reliability	• During prior endorsement review, the committee noted the reliability of the measure was moderate based on the (ICCs) from the developer's analysis. An ICC was calculated to estimate the ratio of the between-to-the within-facility variance, standardized for the level of variation and the number of observations examined. Dialysis Provider A ICC – 0.60; Dialysis Provider B ICC – 0.65; Dialysis Provider C ICC – 0.70 The Standing	• Noted during initial endorsement "significant performance variation remains between dialysis facilities" and remains in recent data.
Scientific Acceptability, Validity	• Data from 2021 reporting year, the measure demonstrated acceptable	• Threats to validity identified include confounding factors not accounted for in statistical risk model and review of

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
	level of validity and aligned with clinical guidelines. The mean score for 2021 year was 0.86.	evidence suggests that a patient's UFR measurements may not necessarily indicate the quality of a patient's ESRD treatment once accounting for additional patient-level treatment considerations.
Feasibility	• Data elements collected routinely in EHR with no additional abstraction burden.	• Potential unintended consequences to patient care related to blood pressure goals. Studies have indicated that the UFR reporting measure may not result in the intended patient outcomes due to potential confounding factors.
Usability	• Acceptable usability demonstrated in dialysis care settings.	• Tracking the ultrafiltration rate as a quality indicator may influence decision-making regarding dialysis treatment.
ESRD QIP Program-Level Consideration		
Alternative Measures	• None identified	• None identified

Additional Published Literature Consulted:

Assimon, M.M., Wenger, J.B., Wang, L. and Flythe, J.E., (2016). Ultrafiltration rate and mortality in maintenance hemodialysis patients. American Journal of Kidney Diseases, 68(6), pp.911-922.

Kramer, H., Yee, J., Weiner, D.E., Bansal, V., Choi, M.J., Brereton, L., Berns, J.S., Samaniego-Picota, M., Scheel Jr, P. and Rocco, M., (2016). Ultrafiltration rate thresholds in maintenance hemodialysis: an NKF-KDOQI controversies report. American Journal of Kidney Diseases, 68(4), pp.522-532.

Kim, J.K., Song, Y.R., Park, G., Kim, H.J. and Kim, S.G., (2017). Impact of rapid ultrafiltration rate on changes in the echocardiographic left atrial volume index in patients undergoing haemodialysis: a longitudinal observational study. BMJ open, 7(2), p.e013990.

Slinin, Y., Babu, M. and Ishani, A., (2018), November. Ultrafiltration rate in conventional hemodialysis: Where are the limits and what are the consequences? In Seminars in Dialysis (Vol. 31, No. 6, pp. 544-550).

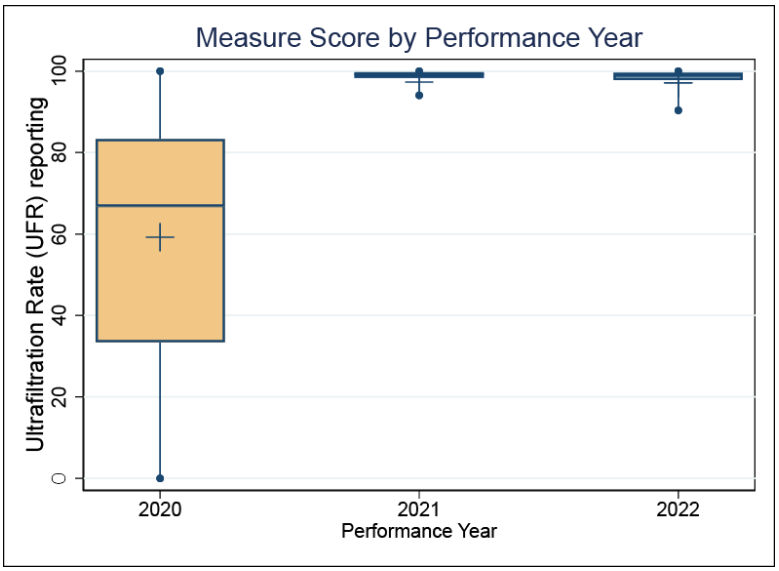


Figure 3.2.4 Measure Score for Ultrafiltration Rate

Table 3.2.4b. MSR Measure Information Sheet from CMIT for 00733-01-C-ESRDQIP Ultrafiltration Rate

	Description
Measure Name	Ultrafiltration Rate (UFR)
CMIT ID	00733-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	N/A
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Health care Priority: Chronic Conditions Goal: Evidence-Based Healthcare
Measure type	Process
Measure developer	Kidney Care Quality Alliance (KCQA)
CBE endorsement status	Endorsed
History	N/A
Measure description	Percentage of adult in-center hemodialysis patients in the facility whose average ultrafiltration rate (UFR) is >=13 ml/kg/hour AND who receive an average of <240 minutes per treatment during the calculation period.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims)
Numerator	Number of patients* from the denominator whose average UFR is >=13 mg/kg/hr (NOT just >13) hour AND who receive an average of <240 minutes per treatment during the calculation period.** *To address the fact that patients may contribute varying amounts of time to the annual denominator population, results will be reported using a “patient-month” construction. ** The calculation period is defined as the same week that the monthly Kt/V is drawn.
Denominator	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis during the calculation period.

Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

	Description
Denominator exclusions, if applicable	The following patients are excluded from the denominator population: 1. Patients <18 years of age (implicit in denominator definition). 2. Home dialysis patients (implicit in denominator definition). 3. Patients in a facility <30 days. 4. Patients with >4 hemodialysis treatments during the calculation period. 5. Patients with <7 hemodialysis treatments in the facility during the reporting month. 6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728) in the reporting month. 7. Kidney transplant recipients with a functioning graft. 8. Facilities treating <=25 adult in-center hemodialysis patients during the reporting month.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures	CBE #0258 Consumer Assessment of Healthcare Providers and Systems (CAHPS) In-Center Hemodialysis Survey (ICH CAHPS) CBE #2977 Hemodialysis Vascular Access: Standardized Fistula Rate CBE #2978 Hemodialysis Vascular Access: Long-Term Catheter Rate CBE #0249 Delivered Dose of Hemodialysis Above Minimum CBE #0256 Minimizing Use of Catheters as Chronic Dialysis Access CBE #0257 Maximizing Placement of Arterial Venous Fistula (AVF) CBE #1460 Bloodstream Infection in Hemodialysis Outpatients

Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

	Description
Summary of measure's feasibility	From 2020 Renal CDP Report: The Standing e Committee noted this measure as one that draws on readily available data sources and passed it on feasibility with little discussion. Feasibility vote-19; H-11; M-7; L-1; I-0.
Scientific acceptability: validity testing	The Standing Committee noted that the tests provided by the developer for the validity of the measure were appropriately conducted and the results were directionally expected. The measure developer tested score level validity using convergent validity, a common approach to score level testing. Validity vote-20; H-0; M-19; L-1; I-0.
Scientific acceptability: reliability testing	Reliability testing was conducted at 4,252 dialysis facilities from three dialysis providers. An ICC was calculated to estimate the ratio of the between-to-the within-facility variance, standardized for the level of variation and the number of observations examined. Dialysis Provider A ICC – 0.60; Dialysis Provider B ICC – 0.65; Dialysis Provider C ICC – 0.70 The Standing Committee noted that the reliability of the measure was moderate based on the (ICCs) from the developer's analysis. Reliability vote- 20; H-1; M-19; L-0; I-0.

3.2.5 00440-01-C-ESRDQIP Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

CMIT ID: 00440-01-C-ESRDQIP

Description: The percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.

Measure Type: Process

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Paper Medical Records

Table 3.2.5a. Preliminary Assessment of 00440-01-C-ESRDQIP MedRec

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Evidence suggests wide variability in performance and room for improvement related to ESRD patient medication management Prioritization of medication reconciliation has the potential to positively impact rates of medication-related problems, healthcare costs, and quality of life. Further, Wigneswaran et al. (2019) proposed a "kidney pharmacy-focused quality pyramid that is intended to provide a framework to guide dialysis organizations, health care providers, and/or clinicians with respect to an optimal medication management approach for dialysis patients."	• There is very limited recent literature on medication management related to dialysis. • The Measure Information Form notes two publications tangentially discussing disparities, with just one specific to the dialysis setting. Specifically, Manley et al. (2003) published an observational study reporting a negative correlation between age and the number of drug record discrepancies identified ($r = -0.27$, $p = 0.04$) in hemodialysis patients. The authors noted this was a reversal from previous reports on medication adherence, and speculated sample size, follow-up period, or random phenomenon may apply. The other publication reported findings from a small 2014 Duquesne University study at an urban indigent primary care clinic, wherein medication discrepancies were more likely to persist in Caucasian subjects when compared to African Americans, despite pharmacist-led medication reconciliation. The authors theorized this finding might stem from variations in providers' communication styles with the two patient groups, but noted additional

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
		investigations in this area are needed.
Scientific Acceptability, Reliability	• The Patient Safety Report concluded that the recent Standing Committee vote on reliability yielded 9 High and 10 Moderate votes. • Rationale: The developer tested the measure at the score level using beta-binomial testing. The mean reliability score is 0.9935.	• None identified
Scientific Acceptability, Validity	• The most recent Standing Committee vote on validity yielded a Moderate rating, with 0 High, 17-Moderate, and 2 Low votes. • There was a systematic assessment of face validity by experts. Two groups of field experts in the field of ESRD/dialysis care. • 88.9% of the 9-member panel agreed it is highly likely or likely that the measure score provides an accurate reflection of medication reconciliation quality. • 77.8% of the panel agreed it is highly likely or likely that the measure can be used to distinguish good from poor quality.	• The most recent Patient Safety Report captured two comments: • One comment expressed that medication reconciliation as a quality measure becomes too burdensome for providers without actually demonstrating that meaningful reconciliation has taken place. • Another comment noted that the measure may not be harmonized with existing measures.

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Feasibility	• All data elements are defined in fields in electronic health records. This measure is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score).	• When developing the measure specifications and operationalizing the specifications for testing, it was noted while all three dialysis organizations that participated in testing have identified and engage in the same three components of medication management—i.e., documentation, reconciliation, and review—one organization defined reconciliation and review in reverse to those detailed in the KCQA measure specifications. • When developing the measure specifications and operationalizing the specifications for testing, variations between the electronic medical record systems of the three large dialysis organizations that participated in testing were identified.
Usability	• Variants of the measure are currently in use member dialysis organizations for internal quality improvement, prompting the developer to develop this measure to standardize the specifications and definitions for accountability purposes.	• The Measure Information Form indicated this new measure is not yet in use. Variants of the measure are currently in use by KCQA member dialysis organizations for internal quality improvement, prompting KCQA to develop this measure to standardize the specifications and definitions for accountability purposes. • Given the variability among electronic systems and because some medications are prescribed by other entities for which “indication” may be unknown, for instance, it was determined that “unknown” must be an allowable response to many data elements so as to maintain the measure’s feasibility.
ESRD QIP Program-Level Consideration		
Alternative Measures		• The three related or competing measures (selected from NQF-endorsed measures) included: ▪ 0097: Medication Reconciliation Post-Discharge- The percentage of discharges for patients 18 years of age and older for whom the

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
		discharge medication list was reconciled with the current medication list in the outpatient medical record by a prescribing practitioner, clinical pharmacist or registered nurse. ▪ 0554: Medication Reconciliation Post-Discharge (MRP)- The percentage of discharges during the first 11 months of the measurement year (e.g., January 1–December 1) for patients 66 years of age and older for whom medications were reconciled on or within 30 days of discharge. ▪ 2456: Medication Reconciliation: Number of Unintentional Medication Discrepancies per Patient-This measure assesses the actual quality of the medication reconciliation process by identifying errors in admission and discharge medication orders due to problems with the medication reconciliation process. The target population is any hospitalized adult patient. The time frame is the hospitalization period. • This measure is harmonized with existing NQF-endorsed medication reconciliation measures in that all similarly specify that the medication reconciliation must address ALL prescriptions, over-the-counters, herbals, vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency, and route.

Additional Published Literature Consulted:

Frament, J., Hall, R. K., & Manley, H. J. (2020). Medication Reconciliation: The Foundation of Medication Safety for Patients Requiring Dialysis. American Journal of Kidney Diseases: The official journal of the National Kidney Foundation, 76(6), 868–876. https://doi.org/10.1053/j.ajkd.2020.07.021

Manley, H. J., Drayer, D. K., McClaran, M., Bender, W., and Muther, R. S. (2003). Drug Record Discrepancies in an Outpatient Electronic Medical Record: Frequency, Type, and Potential Impact on Patient Care at a Hemodialysis Center. Pharmacotherapy, 23(2), 231-239. https://doi.org/10.1592/phco.23.2.231.32079

van der Nat, D. J., Huiskes, V. J. B., Taks, M., Pouls, B. P. H., van den Bemt, B. J. F., & van Onzenoort, H. A. W. (2022). Usability and perceived usefulness of patient-centered medication reconciliation using a personalized health record: A multicenter cross-sectional study. BMC Health Services Research, 22(1), 776. https://doi.org/10.1186/s12913-022-07967-7

Wigneswaran, J., St Peter, W. L., Nissenson, A. R., Krishnan, M., Faris, R., Becker, B., & Lorch, J. (2019). Redefining Medication Management in Dialysis: A Kidney Pharmacy Quality Pyramid. Kidney Medicine, 1(5), 307–314. https://doi.org/10.1016/j.xkme.2019.06.008

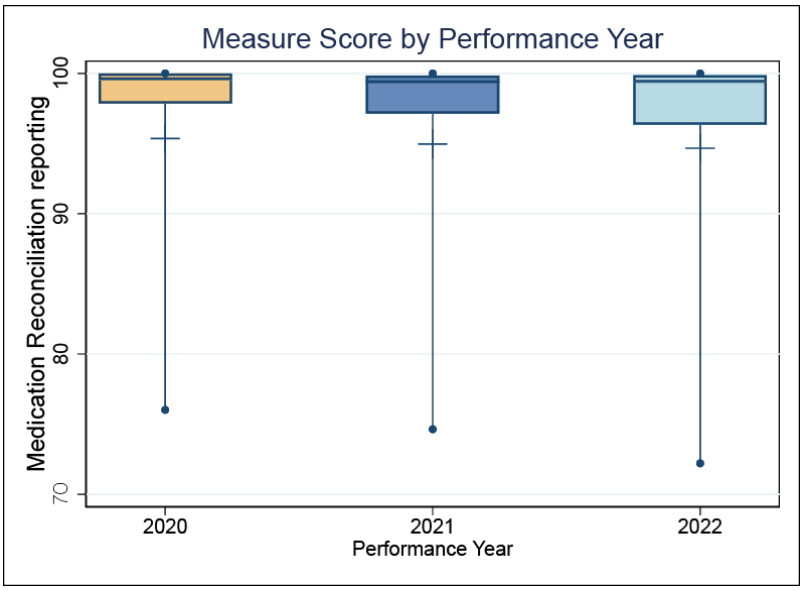


Figure 3.2.5 Measure Score for Medication Reconciliation for Patients Receiving Care at Dialysis Facilities

Table 3.2.5b MSR Measure Information Sheet from CMIT for 00440-01-C-ESRDQIP MedRec

	Description
Measure Name	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)
CMIT ID	00440-01-C-ESRDQIP
CMS program in which the measure is used	ESRD QIP
Additional programs in which the measure is used	N/A
Measure steward	Kidney Care Quality Alliance (KCQA)
Cascade of Meaningful Measures (CoMM) Domain	Health care Priority: Seamless Care Coordination Goal: Optimal Interoperability and Data Availability/Reconciliation
Measure type	Process
Measure developer	Kidney Care Quality Alliance (KCQA)
CBE endorsement status	Endorsed
History	Initial Endorsement: January 26, 2017 Last Endorsement: Spring 2021
Measure description	The percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional (based on CBE #2988).
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Paper Medical Records
Numerator	Number of patient-months in the denominator for which the facility reported the following required data in CROWNWeb: • Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: ○ physician ○ nurse ○ ARNP ○ PA ○ pharmacist

Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)

	Description
	○ pharmacy technician personnel • Name of eligible professional
Denominator	Total number of eligible patient-months for all patients assigned to a dialysis facility during the performance period.
Denominator exclusions, if applicable	• In-center patients who receive < 7 HD treatments in the facility during the reporting month. • Patients who are not assigned to the facility for the entire reporting month. • Patients not on ESRD treatment as defined by a completed 2728 form, a REMIS/CROWNWeb record, or a sufficient amount of dialysis reported on dialysis facility claims • Facilities with a CCN certification date on or after October 1 of the year prior to the performance period. • Calculations will exclude the months covered by a granted ECE.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Related measures in other programs	N/A
Summary of measure's feasibility	All data elements are defined in fields in electronic health records. Data is generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score).
Scientific acceptability: validity testing	There was a systematic assessment of face validity by experts. Two groups of field experts in the field of ESRD / dialysis care. 88.9% of the 9-member panel agreed it is highly likely or likely that the measure score provides an accurate reflection of medication reconciliation quality. 77.8% of the panel agreed it is highly likely or likely that the measure can be used to distinguish good from poor quality. Standing Committee vote on validity: 0-H; 17-M; 2-L; 0-I
Scientific acceptability: reliability testing	From 2017 CBE Technical Report: Standing Committee vote on reliability: 9-H; 10-M; 0-L; 0-I The developer tested the measure at the score level using beta-binomial testing. The mean reliability score is 0.9935. Standing Committee vote on validity: 0-H; 17-M; 2-L; 0-I

3.2.6 00461-02-C-ESRDQIP National Healthcare Safety Network (NHSN) Dialysis Event

CMIT ID: 00461-02-C-ESRDQIP

Description: Number of months for which facility reports NHSN Dialysis Event data to the CDC. There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.

Measure Type: Structure

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims)

Table 3.2.6a. Preliminary Assessment of 00461-02-C-ESRDQIP NHSN Dialysis Event

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Evidence supports a causal link with this measure and an impact on positive health outcomes. Infections of the vascular access site cause substantial morbidity and mortality. After cardiovascular/ cerebrovascular diseases and malignancies, infections are the fourth most common cause of death in hemodialysis (HD) patients.	• A recent study found that only 64% of cultures were reported accurate and complete, and 36% were incomplete, inaccurate, or reported a BSI culture when a different infection type occurred (Shah et al 2021). The most common error was incomplete reporting, affecting 22.5% of cultures.
Scientific Acceptability, Reliability	• Reliability assessment was not available from prior Standing Committee review as this measure is not endorsed by a CBE.	
Scientific Acceptability, Validity	• This measure currently aligns with clinical guideline and standard of care. Evidence supports that there are actionable interventions that can be undertaken at the facility level to influence outcome. Dialysis event rates are stratified by vascular access type and expressed per 100 patient-months.	• This report-only measure potentially misses confounding factors that could be used to improve patient care at the facility level. Evidence shows that hemodialysis catheter-associated bloodstream infections continue to occur at unacceptable rates, indicating a need for novel preventative approaches. • Additionally, there was no data or information available on discrimination or calibration of the risk adjustment model.

National Healthcare Safety Network (NHSN) Dialysis Event

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Feasibility	• Measure uses standard NHSN forms and/or the definitions for data collection and reporting protocol.	• Manual data collection burden limits feasibility.
Usability	• This measure has articulated tools to improve performance or to receive feedback on performance. Evidence shows that implementing an intervention and surveillance program and by using a dedicated checklist and readymade kit for handling the vascular access we were able to significantly lower the access-related infection rates, even in the presence of a high proportion of tunneled central venous catheters.	• None identified
ESRD QIP Program-Level Consideration		
Alternative Measures	• National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients is also in the ESRD but these measures are significantly different.	• None identified

Additional Published Literature Consulted:

Shah, A., Jassal, V. and Bowman, B.T., (2021). Accuracy of Hemodialysis Bloodstream Infection Pathogen Reporting to the National Healthcare Safety Network: Results of an Academic Dialysis Program Audit. Kidney Medicine, 3(4), pp.683-685.

Nguyen, D.B., Shugart, A., Lines, C., Shah, A.B., Edwards, J., Pollock, D., Sievert, D. and Patel, P.R., (2017). National Healthcare Safety Network (NHSN) dialysis event surveillance report for 2014. Clinical journal of the American Society of Nephrology: CJASN, 12(7), p.1139.

Mohamed, H., Ali, A., Browne, L.D., O'Connell, N.H., Casserly, L., Stack, A.G. and Hussein, W.F., (2019). Determinants and outcomes of access-related blood-stream infections among Irish haemodialysis patients; a cohort study. BMC nephrology, 20, pp.1-9.

Lyman, M., Nguyen, D.B., Shugart, A., Gruhler, H., Lines, C. and Patel, P.R., (2020). Risk of vascular access infection associated with buttonhole cannulation of fistulas: data from the National Healthcare Safety Network. American Journal of Kidney Diseases, 76(1), pp.82-89.

Hasanoglu, I., Guner, R., Sahin, S., Yılmaz Karadag, F., Parmaksiz, E., Atalay, H.V., Alısır Ecder, S., Arslan Gulen, T., Atan Ucar, Z., Karabay, O. and Sipahi, S., (2022). Surveillance of hemodialysis related infections: a prospective multicenter study. Scientific Reports, 12(1), p.22240.

Gork, I., Gross, I., Cohen, M.J., Schwartz, C., Moses, A.E., Elhalel, M.D. and Benenson, S., (2019). Access-related infections in two haemodialysis units: results of a nine-year intervention and surveillance program. Antimicrobial Resistance & Infection Control, 8(1), pp.1-7.

Fisher, M., Golestaneh, L., Allon, M., Abreo, K. and Mokrzycki, M.H., (2020). Prevention of bloodstream infections in patients undergoing hemodialysis. Clinical journal of the American Society of Nephrology: CJASN, 15(1), p.132.

Brown, R.S., Brickel, K. and Davis, R.B., (2018). Two-year observational study of bloodstream infection rates in hemodialysis facility patients with and without catheters. Clinical Journal of the American Society of Nephrology: CJASN, 13(9), p.1381.

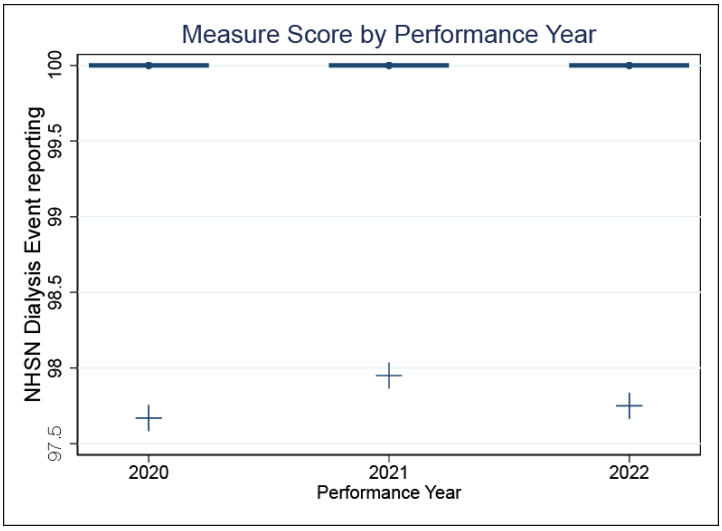


Figure 3.2.6 Measure Score for NHSN Dialysis Event

Table 3.2.6b. MSR Measure Information Sheet from CMIT for 00461-02-C-ESRDQIP NHSN Dialysis Event

	Description
Measure Name	National Healthcare Safety Network (NHSN) Dialysis Event
CMIT ID	00461-02-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	N/A
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Health care Priority: Safety Goal: Reduced Preventable Harm
Measure type	Structure
Measure developer	Unknown
CBE endorsement status	Not Endorsed
History	Number of months for which facility reports NHSN Dialysis Event data to the CDC. There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.
Measure description	Facility/Hospital/Agency
Level of analysis	Administrative Data (non-claims)
Data sources	N/A
Numerator	N/A
Denominator	1. Facilities which do not treat in center hemodialysis patients. 2. Facilities with a CMS open date on or after January 1, 2017.
Denominator exclusions, if applicable	N/A
Numerator exceptions, if applicable	N/A
Risk adjustment, if applicable	No

National Healthcare Safety Network (NHSN) Dialysis Event

	Description
Performance data	Appendix A
Related measures in other programs	No information available
Summary of measure's feasibility	No information available
Scientific acceptability: validity testing	No information available
Scientific acceptability: reliability testing	No information available

3.2.7 00458-01-C-ESRDQIP National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients

CMIT ID: 00458-01-C-ESRDQIP

Description: Number of months for which facility reports NHSN Dialysis Event data to the CDC. There are three types of dialysis events reported by users: IV antimicrobial start; positive blood culture; and pus, redness, or increased swelling at the vascular access site.

Measure Type: Structure

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims)

Table 3.2.7a. Preliminary Assessment of CBE 00458-01-C-ESRDQIP NHSN BSI in Hemodialysis

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Importance	• Evidence supports a causal link with this measure and an impact on positive health outcomes. Infections of the vascular access site cause substantial morbidity and mortality. After cardiovascular/ cerebrovascular diseases and malignancies, infections are the fourth most common cause of death in hemodialysis (HD) patients.	• A recent study found that only 64% of cultures were reported accurate and complete, and 36% were incomplete, inaccurate, or reported a BSI culture when a different infection type occurred (Shah, et al., 2021). The most common error was incomplete reporting, affecting 22.5% of cultures.
Scientific Acceptability, Reliability	• Reliability assessment was not available from prior Standing Committee review as this measure is not endorsed by a CBE.	
Scientific Acceptability, Validity	• This measure currently aligns with clinical guidelines and standard of care. Evidence supports that there are actionable interventions that can be undertaken at the facility level to influence outcome.	• This report-only measure potentially misses confounding factors that could be used to improve patient care at the facility level. Evidence shows that hemodialysis catheter-associated bloodstream infections continue to occur at unacceptable rates, indicating a need for novel preventative approaches. • Additionally, there was no data or information available on

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
		discrimination or calibration of the risk adjustment model.
Feasibility	• Measure uses standard NHSN forms and/or the definitions for data collection and reporting protocol.	• Manual data collection burden limits measure feasibility.
Usability	• This measure has articulated tools to receive feedback on performance. Evidence from the literature shows that implementing an intervention and surveillance program access-related infection rates can be lowered, even in the presence of a high proportion of tunneled central venous catheters.	• None identified
ESRD QIP Program-Level Consideration		
Alternative Measures	• National Healthcare Safety Network (NHSN) Dialysis Event is also within the same program. Some, but acceptable level of overlap between measures.	• None identified

Additional Published Literature Consulted:

Shah, A., Jassal, V. and Bowman, B.T., (2021). Accuracy of Hemodialysis Bloodstream Infection Pathogen Reporting to the National Healthcare Safety Network: Results of an Academic Dialysis Program Audit. Kidney Medicine, 3(4), pp.683-685.

Nguyen, D.B., Shugart, A., Lines, C., Shah, A.B., Edwards, J., Pollock, D., Sievert, D. and Patel, P.R., (2017). National Healthcare Safety Network (NHSN) dialysis event surveillance report for 2014. Clinical journal of the American Society of Nephrology: CJASN, 12(7), p.1139.

Mohamed, H., Ali, A., Browne, L.D., O'Connell, N.H., Casserly, L., Stack, A.G. and Hussein, W.F., (2019). Determinants and outcomes of access-related blood-stream infections among Irish haemodialysis patients; a cohort study. BMC nephrology, 20, pp.1-9.

Lyman, M., Nguyen, D.B., Shugart, A., Gruhler, H., Lines, C. and Patel, P.R., (2020). Risk of vascular access infection associated with buttonhole cannulation of fistulas: data from the National Healthcare Safety Network. American Journal of Kidney Diseases, 76(1), pp.82-89.

Hasanoglu, I., Guner, R., Sahin, S., Yılmaz Karadag, F., Parmaksiz, E., Atalay, H.V., Alısır Ecder, S., Arslan Gulen, T., Atan Ucar, Z., Karabay, O. and Sipahi, S., (2022). Surveillance of hemodialysis related infections: a prospective multicenter study. Scientific Reports, 12(1), p.22240.

Gork, I., Gross, I., Cohen, M.J., Schwartz, C., Moses, A.E., Elhalel, M.D. and Benenson, S., (2019). Access-related infections in two haemodialysis units: results of a nine-year intervention and surveillance program. Antimicrobial Resistance & Infection Control, 8(1), pp.1-7.

Fisher, M., Golestaneh, L., Allon, M., Abreo, K. and Mokrzycki, M.H., (2020). Prevention of bloodstream infections in patients undergoing hemodialysis. Clinical journal of the American Society of Nephrology: CJASN, 15(1), p.132.

Brown, R.S., Brickel, K. and Davis, R.B., (2018). Two-year observational study of bloodstream infection rates in hemodialysis facility patients with and without catheters. Clinical Journal of the American Society of Nephrology: CJASN, 13(9), p.1381.

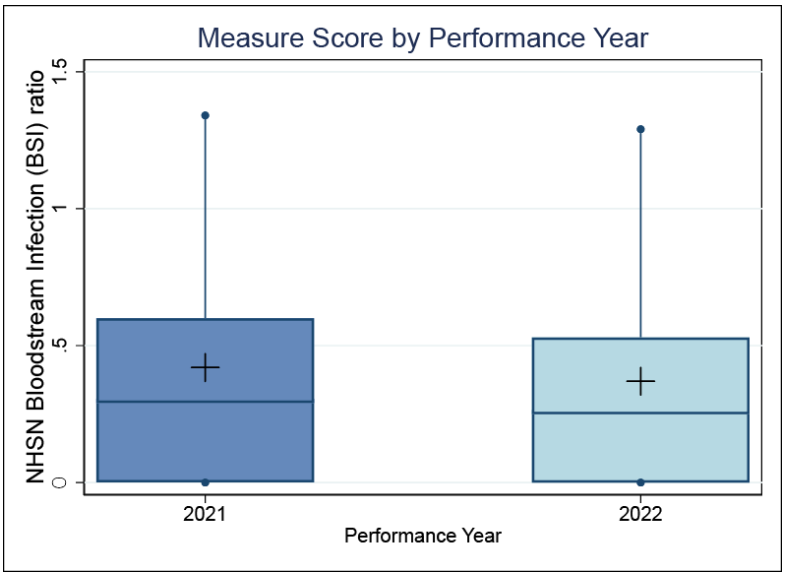


Figure 3.2.7 Measure Score for NHSN BSI

Table 3.2.7b. MSR Measure Information Sheet from CMIT for 00458-01-C-ESRDQIP NHSN BSI in Hemodialysis

	Description
Measure Name	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients
CMIT ID	00458-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Disease Control and Prevention (CDC)
Cascade of Meaningful Measures (CoMM) Domain	Health care Priority: Safety Goal: Reduced Preventable Harm
Measure type	Outcome
Measure developer	Not Specified in CMIT
CBE endorsement status	Endorsed
History	Initial Endorsement: August 16, 2011 Last Endorsement: October 2, 2015 In the absence of detailed specifications and methodology on the Adjusted Ranking Metric (ARM), the Committee did not recommend the measure, as currently submitted, for continued endorsement. Members of the Committee encouraged developers to use a broad standardization methodology rather than using access type alone. Taking into account the Committee's concerns about the ARM aspect of the measure, the developer removed it from the measure. After this update, the Committee changed its decision and recommended this measure for endorsement.
Measure description	The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims)
Numerator	The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission.

National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients

	Description
Denominator	Number of maintenance HD patients treated in the outpatient HD center on the first two working days of the month.
Denominator exclusions, if applicable	Facility Exclusions 1. Facilities that do not offer in-center HD as of December 31 of the performance period. 2. Facilities with a CCN open date on or after October 1 of the year prior to the performance year. 3. Facilities that treat fewer than 11 in-center HD patients during the performance period. 4. Facilities with approved Extraordinary Circumstances Exception (ECE). Patient Exclusions 1. Patients receiving only inpatient HD during the reporting month. 2. Patients receiving only home HD or peritoneal dialysis during the reporting month. 3. Patients not on ESRD treatment as defined by a completed 2728 form, an EQRS record, or a sufficient amount of dialysis reported on dialysis facility claims.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures in other programs	N/A
Summary of measure's feasibility	All data elements are defined in fields in electronic health records.
Scientific acceptability: validity testing	Standing Committee vote on validity: 2-H; 15-M; 1-L; 0-I Committee members expressed concerns about validity being reassessed now that NHSN is available. The developer was encouraged to provide more current data in order to accurately review many aspects of this measure, including reliability and validity. During their post-comment call, the Committee decided to reconsider this measure and agreed the measure was reliable and valid once the ARM was removed from the measure. It was noted that with this revision, the measure is much more closely aligned to the originally endorsed specification, with the only revision being the addition of SIR.
Scientific acceptability: reliability testing	Standing Committee vote on reliability: 0-H; 4-M; 3-L; 14-I, Reconsideration vote on reliability: 1-H; 17-M; 0-L; 0-I

National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients

	Description
	This measure was reviewed by the Renal Standing Committee during the measure evaluation meeting in June 2015. Committee members noted the analysis of performance was completed almost a decade ago and that all analyses completed showed a substantial variation in the rates of reported blood stream infections. While the SIR component of the measure is well established, and has clear specifications, the ARM portion of the measure was identified as not well specified. Committee members stated it was challenging to evaluate a measure with the level of specificity on methodology provided by the developer and requested updated data. Members of the Committee encouraged developers to use a broader standardization methodology rather than using access alone. Overall, committee members did not find the specifications on the methodology proposed for the Adjusted Ranking Metric (ARM) portion of the measure and data provided by the developer to be insufficient and the measure failed at reliability. Based on these comments, the developer removed the ARM aspect of the measure.

3.2.8 00672-03-C-ESRDQIP Clinical Depression Screening and Follow-Up

CMIT ID: 00672-03-C-ESRDQIP

Description: Facility reports in CROWNWeb one of the six conditions for each qualifying patient once before the close of the December clinical month.

1. Screening for clinical depression is documented as being positive and a follow-up plan is documented.
2. Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible.
3. Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given.
4. Screening for clinical depression documented as negative and no follow-up plan required.
5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible.
6. Clinical depression screening not documented, and no reason is given.

Measure Type: Process

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data; Claims Data; Registry Data

Table 3.2.8a. Preliminary Assessment of 00672-03-C-ESRDQIP Clinical Depression Screening & Follow Up

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Depression screening has been associated with several positive outcomes for patients, with evidence indicating “early recognition and treatment of behavioral health disorders can prevent complications, improve quality of life, and help reduce health care costs” (Mulvaney-Day et al., 2018).	• There is limited recent data on morbidity and usefulness of the screening tool most commonly used for depression screening, the PHQ-9 scale. However, recent evidence suggests “The PHQ-9 seems to be similarly sensitive but may be less specific for younger patients than for older patients; a cut-off score of 10 or above can be used regardless of age” (Levis et al., 2019). • Further, in a clinical trial of patients with chronic conditions “there were no differences in quality-adjusted life-years or depression-free days in those who were and were not screened for depression, even when depression

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
		screening was followed by enhanced depression care" (Kronish et al., 2020).
Scientific Acceptability, Reliability	• During prior endorsement review, the Standing Committee vote on reliability yielded the following votes: High (8); Moderate (14); Low (1). • In the previous review (2008), the measure developer provided data on the inter-rater reliability testing of the data elements on a random sample of 275 Medicare claims, resulting in 89.7% agreement for the numerator, 100% agreement for the denominator, and 66.5% agreement for exclusions. The Committee noted good results in the updated reliability testing –using a signal-to-noise analysis at the score level, the developer reported a mean reliability statistic of 0.99 for both claims and registry.	• None identified
Scientific Acceptability, Validity	• There is considerable and consistent patient-oriented research evidence, in addition to clinical recommendation statements, documenting the prevalence and burden of depression among individuals with chronic illness and a history of major medical events, the importance of screening for depression, and the availability of depression screening tools.	• A threat to validity noted by the previous review committees during measure maintenance was that excluding people who refuse screening might impact accuracy as people who are experiencing depressive symptoms might be more inclined to refuse to engage in such activity. • Committee members additionally expressed concern about other exclusions including the emergent nature of a visit, noting that the emergent visit might be the result of a risk-taking behavior related to depression and about excluding individuals with bipolar disorder because the assumption that they are in treatment may not be true.

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Feasibility	• Data consists of administrative claims and clinical database/registry. Further, data elements are in defined fields in a combination of electronic sources. • No implementation challenges noted by developer. • The developer emphasized HCPCS codes are used for reporting. • Data are generated or collected by and used by health care personnel during the provision of routine care. • The developer did not encounter any difficulties related to data availability.	• Data are coded by someone other than the person obtaining original information (e.g., DRG, ICD-9 codes on claims). Although this may reduce bias, this approach requires two staff to handle data.
Usability	• Incentive available: The Measure Information Form reported this measure is part of The Physician Quality Reporting System (PQRS), sponsored by CMS, is a national reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals (EPs).	• The Measure Information Form reported the average performance rate fluctuated substantially over time as uptake of measure increased. • Facilities should pair screening and follow-up with appropriate linkage to treatment as needed to avoid unintended consequences.
ESRD QIP Program-Level Consideration		
Alternative Measures	• The measure has been broadly applied. CMIT website captures several measure variation titles: • Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Active)	• While this measure has been widely used across programs and served as a blueprint for additional age-specific measures, this use suggests that condition-specific measures addressing depression screening targets should be examined.

Clinical Depression Screening and Follow-Up

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
	• Clinical Depression Screening and Follow-Up - (Active) • Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Active) • Screening for Depression and Follow-Up Plan: Ages 12-17 (CDF-CH) (Active) • Screening for Depression and Follow-Up Plan (CDF-HH) • Preventive Care and Screening: Screening for Depression and Follow-Up Plan (CDF-AD) (Active) • Screening for Depression and Follow-Up Plan: Ages 12 to 17 (CDF-CH) (Active) • Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Active) • Screening for Clinical Depression and Follow-Up Plan: Ages 12 - 17 (Active)	

Additional Published Literature Consulted:

Kronish, I. M., Moise, N., Cheung, Y. K., Clarke, G. N., Dolor, R. J., Duer-Hefele, J., Margolis, K. L., St Onge, T., Parsons, F., Retuerto, J., Thanataveerat, A., & Davidson, K. W. (2020). Effect of Depression Screening After Acute Coronary Syndromes on Quality of Life: The CODIACS-QoL Randomized Clinical Trial. JAMA Internal Medicine, 180(1), 45–53. https://doi.org/10.1001/jamainternmed.2019.4518

Levis, B., Benedetti, A., Thombs, B. D., & DEPRESsion Screening Data (DEPRESSD) Collaboration (2019). Accuracy of Patient Health Questionnaire-9 (PHQ-9) for screening to detect major depression: Individual participant data meta-analysis. BMJ (Clinical research ed.), 365, l1476. https://doi.org/10.1136/bmj.l1476

Mulvaney-Day, N., Marshall, T., Downey Piscopo, K., Korsen, N., Lynch, S., Karnell, L. H., Moran, G. E., Daniels, A. S., & Ghose, S. S. (2018). Screening for Behavioral Health Conditions in Primary Care Settings: A Systematic Review of the Literature. Journal of General Internal Medicine, 33(3), 335–346. https://doi.org/10.1007/s11606-017-4181-0

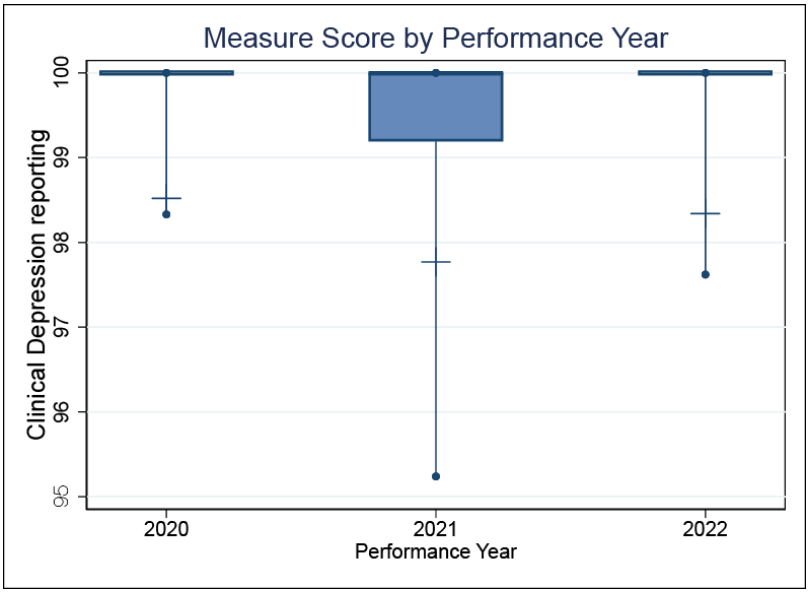


Figure 3.2.8 Measure Score for Clinical Depression Screening and Follow-Up

Table 3.2.8b. MSR Measure Information Sheet from CMIT for 00672-03-C-ESRDQIP Clinical Depression Screening and Follow-Up

	Description
Measure Name	Clinical Depression Screening and Follow-Up
CMIT ID	00672-03-C-ESRDQIP
CMS program in which the measure is used	ESRD QIP
Additional programs in which the measure is used	Merit-Based Incentive Payment System Program (CQM & eCQM); Medicare Shared Savings Program (CQM & eCQM) ; Medicaid: Adult Core Set (CQM & eCQM); Medicaid: Health Home Core Set (CQM & eCQM); Medicaid: Child Core Set (CQM & eCQM); Maryland Total Cost of Care Model; Integrated Care for Kids Model
Measure steward	CMS; Mathematica
Cascade of Meaningful Measures Domain	Health care Priority: Behavioral Health Goal: Mental Health Disorders Screening and Treatment
Measure type	Process
Measure developer	CMS/University of Michigan Kidney Epidemiology and Cost Center
CBE endorsement status	Endorsement removed
History	Initial Endorsement: July 31, 2008 Last Endorsement: June 28, 2017 Endorsement Removal: September 20, 2020 This measure was last endorsed in 2017 under a different CBE number, #3148.
Measure description	Facility reports in CROWNWeb one of the six conditions below for each qualifying patient once before the close of the December clinical month. 1. Screening for clinical depression is documented as being positive and a follow-up plan is documented. 2. Screening for clinical depression documented as positive, a follow-up plan is not documented, and the facility possesses documentation that the patient is not eligible. 3. Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given. 4. Screening for clinical depression documented as negative and no follow-up plan required.

	Description
	5. Screening for clinical depression not documented, but the facility possesses documentation stating the patient is not eligible. 6. Clinical depression screening not documented, and no reason is given.
Level of analysis	Facility/Hospital/Agency
Data sources	N/A
Numerator	Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized tool AND, if positive, a follow-up plan is documented on the date of the eligible encounter.
Denominator	Patients 12 years or older who have been treated at the facility for 90 days or longer
Denominator exclusions, if applicable	1. Patients who are younger than 12 years 2. Patients treated at the facility for fewer than 90 days 3. Facilities with a CCN open date on or after July 1, 2017 4. Facilities treating fewer than 11 eligible patients during the performance period
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	Patients with a Documented Reason for not Screening for Depression: -Patient refuses to participate. -Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status. -Situations where the patient's functional capacity or motivation to improve may impact the accuracy of results of standardized depression assessment tools. For example: certain court appointed cases or cases of delirium.
Risk adjustment, if applicable	N/A
Performance data	Appendix A
Related measures in other programs	CBE 518 Depression Assessment Conducted
Summary of measure's feasibility	Data elements are routinely collected in electronic sources and there have been no implementation challenges noted. The developer emphasized that for this claims/registry measure, they use HCPCS codes for reporting.

Clinical Depression Screening and Follow-Up

	Description
Scientific acceptability: validity testing	Standing Committee vote on validity: M-18; L-3; I-2 Committee members expressed concerns about excluding people who refuse screening, noting that people who are depressed might be more inclined to refuse to engage in such activity. Committee members expressed concern about other exclusions including the emergent nature of a visit, noting that the emergent visit might be the result of a risk-taking behavior related to depression and about excluding individuals with bipolar disorder because the assumption that they are in treatment may not be true. One Committee member expressed concern about emergency room physicians' evaluation on this measure. The Committee further expressed concern about the frequency of screenings, asking if the screening should occur at each visit.
Scientific acceptability: reliability testing	Standing Committee vote on reliability: H-8; M-14; L-1; I-0 In the previous review (2008), the developer provided data on the inter-rater reliability testing of the data elements on a random sample of 275 Medicare claims, resulting in 89.7 percent agreement for the numerator, 100 percent agreement for the denominator, and 66.5 percent agreement for exclusions. The Committee noted good results in the updated reliability testing –using a signal-to-noise analysis at the score level, the developer reported a mean reliability statistic of 0.99 for both claims and registry.

3.2.9 00697-01-C-ESRDQIP Standardized Readmission Ratio (SRR)

CMIT ID: 00697-01-C-ESRDQIP

Description: The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge, to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm.

Measure Type: Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Claims Data; Registry Data

Table 3.2.9a. Preliminary Assessment of CBE 00697-01-C-ESRDQIP Standardized Readmission Ratio

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Evidence supports appropriate interventions can be undertaken to reduce the risk of unplanned readmissions and that a gap in care exists, warranting a national performance measure.	• None identified
Scientific Acceptability, Reliability	• During endorsement review, the IUR was 0.35 and the PIUR was 0.61. The Standing Committee passed the measure on reliability based on the PIUR.	• The Standing Committee considered the differences between these two reliability statistics, noting that the IUR is less than 0.5.

Standardized Readmission Ratio (SRR)

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• Aligns with current clinical guidelines and standard of care and the statistical risk model, considers SDOH through area deprivation index among other indicators.	• During endorsement review, the SMP found that the results did not adequately demonstrate measure score validity and did not pass the measure on validity. The SMP's concerns centered on the adequacy of the measure correlations presented for measure score validity testing. This all-cause measure potentially misses patient-level indicators for readmission among ESRD subtypes, treatment plans, or specific comorbidities. Additionally, readmission method/source not differentiated between ED or other setting.
Feasibility	• Claims and administrative data are collected and accessible as part of routine facility operation, no additional reporting burden.	• This criterion was not originally considered during endorsement as the measure failed scientific acceptability.
Usability	• Measure produces high-level all cause readmission ratio that is risk standardized for easy facility review and use for quality improvement initiatives.	• Measure does not differentiate between patient population types and as such produces a broad, general ratio that facilities may have trouble using to guide specific changes to clinical practice.
ESRD QIP Program-Level Consideration		
Alternative Measures	• Standardized Hospitalization Ratio is a related measure within the ESRD program but not a suitable replacement.	• None identified

Additional Published Literature Consulted:

Lin, Y., Yang, C., Chu, H., Wu, J., Lin, K., Shi, Y., Wang, H., Kong, G. and Zhang, L., (2019). Association between the Charlson Comorbidity Index and the risk of 30-day unplanned readmission in patients receiving maintenance dialysis. BMC nephrology, 20(1), pp.1-8.

Liu, L.G., Rogers, J.R., Reeder, R., Walsh, C.G., Kansagara, D., Vawdrey, D.K. and Salmasian, H., (2021). Published models that predict hospital readmission: a critical appraisal. BMJ open, 11(8), p.e044964.

Gallagher, D.M., Zhao, C. and Goldstein, B.A., (2022). A Readmission Risk Model for Hospitalized Patients Receiving Dialysis: Evaluation of Predictive Performance. Kidney Medicine, 4(8).

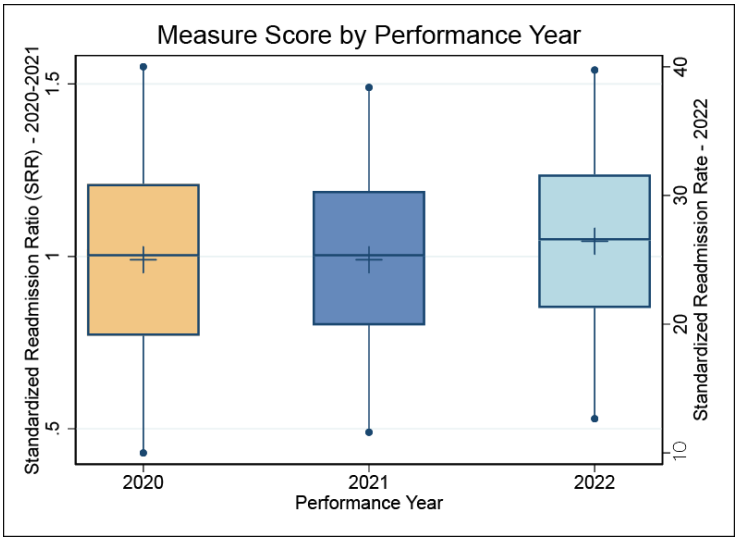


Figure 3.2.9 Measure Score for Standardized Readmission Ratio & Rate[6]

[6] During Performance year 2022, the calculation of this measure converted the SRR into a rate. Prior years have this shown as a ratio. Y axis scales are adjusted accordingly.

Table 3.2.9b MSR Measure Information Sheet from CMIT for 00697-01-C-ESRDQIP Standardized Readmission Ratio

	Description
Measure Name	Standardized Readmission Ratio (SRR) for dialysis facilities
CMIT ID	00697-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Priority: Person-Centered Care Goal: Optimal Patient Experience
Measure type	Outcome
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Endorsement Removed
History	Initial endorsement: 12/23/2014 Endorsed: 12/9/2016 Endorsement Removed: 11/16/2020 The NQF All-Cause Admissions and Readmissions committee did not recommend the measure for continued endorsement on June 22, 2020.
Measure description	The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. Note that the measure is based on Medicare-covered dialysis patients.
Level of analysis	Facility/Hospital/Agency
Data sources	Claims Data Registries
Numerator	The observed number of index hospital discharges that are followed by an unplanned hospital readmission within 4-30 days of discharge.

Standardized Hospitalization Ratio (SHR)

	Description
Denominator	The expected number of index discharges followed by an unplanned readmission within 4-30 days in each facility, which is derived from a model that accounts for patient characteristics, the dialysis facility to which the patient is discharged, and the discharging acute care or critical access hospitals involved.
Denominator exclusions, if applicable	Facility Exclusions 1. Facilities with less than 11 index hospital discharges during the calendar year of assessment. 2. Calculations of index discharges will exclude the months covered by a granted ECE.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	Yes, statistical risk model
Performance data	Appendix A
Related measures in other programs	N/A
Summary of measure's feasibility	The Standing Committee did not vote on this criterion because the measure did not pass scientific acceptability.
Scientific acceptability: validity testing	SMP vote for Validity: H-1; M-5; L-3; I-0 The SMP's concerns centered on the adequacy of the measure correlations presented for measure score validity testing. The developers provided a detailed response to the panel's concerns. However, the SMP still found that the results did not adequately demonstrate measure score validity and did not pass the measure on validity. The Standing Committee agreed to uphold the SMP's rating on validity (Y-18, N-0), which was to not pass the measure on validity.
Scientific acceptability: reliability testing	This measure was deemed as complex and was evaluated by the NQF Scientific Methods Panel (SMP) in spring 2020. Consensus was not reached on reliability. Standing Committee vote on Reliability: H-1; M-15; L-2; I-0 NQF's policy states that measures that do not pass SMP review are still eligible to be pulled for review by a Standing Committee, as long as the rationale for not passing the measures does not include inappropriate methodology or inadequate testing. The measure was eligible to be pulled so the Standing Committee pulled the measure for reconsideration and voted on the measure. The Standing Committee considered the SMP's discussion on the standards of acceptable reliability for IUR, as well

Standardized Hospitalization Ratio (SHR)

	Description
	as its comparison to profile PIUR. The IUR was 0.35 and the PIUR was 0.61. The Standing Committee passed the measure on reliability based on the PIUR. The Standing Committee considered the differences between these two reliability statistics, noting that the IUR is less than 0.5. The Standing Committee discussed how this measure may be used, considering that this is a new measure and the PIUR reflects how well the measure reliably flags outliers rather than between provider variation. While several considerations were noted on the reliability, the Standing Committee agreed to pass the measure on reliability.

3.2.10 00695-01-C-ESRDQIP Standardized Hospitalization Ratio (SHR)

CMIT ID: 00695-01-C-ESRDQIP

Description: Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations.

Measure Type: Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims Data

Table 3.2.10a. Preliminary Assessment of 00695-01-C-ESRDQIP Standardized Hospitalization Ratio

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Evidence shows interventions can be undertaken to reduce the risk of unplanned hospital visits and that a gap in care exists that warrants a national performance measure.	• None identified
Scientific Acceptability, Reliability	• The measure demonstrated moderate reliability during prior standing committee review. During endorsement review of reliability, the PIUR in data provided ranged from 0.75 – 0.85.	• During endorsement review, the SMP raised interoperability concerns: Because the PIUR is not in general interpretable as an IUR and because it does not appear to have another simple or direct interpretation, this raises the question of how to determine what PIUR value corresponds to “acceptable reliability.”

Standardized Hospitalization Ratio (SHR)

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• Aligns with current clinical guidelines. Evidence supports social risk factors that may confound renal care quality, patient outcomes, and hospitalization associations; However, these factors were considered, analyzed, and added to the risk model if appropriate.	• This all-cause measure potentially misses patient-level indicators for hospitalization among ESRD subtypes, treatment plans, or specific comorbidities. • During endorsement review, the Standing Committee expressed concern that social risk factors were excluded from the risk model. The Standing Committee acknowledged that although the developer identified several social factors, when added into the risk adjustment model, there was minimal impact to the measure score. The Standing Committee noted that the right social factors may not be considered for risk adjustment due to data limitations.
Feasibility	• Claims and administrative data are collected and accessible as part of routine facility operation, no additional reporting burden.	• None identified
Usability	• Measure produces high-level all cause hospitalization ratio that is risk standardized for easy facility review and use for quality improvement initiatives.	• Measure does not distinguish between patient population types and produces a broad, general ratio that facilities may have trouble using to guide specific changes to clinical practice.
ESRD QIP Program-Level Consideration		
Alternative Measures	• Standardized Readmission Ratio is a related measure within the ESRD program but not a suitable replacement.	• None identified

Additional Published Literature Consulted:

Lin, Y., Yang, C., Chu, H., Wu, J., Lin, K., Shi, Y., Wang, H., Kong, G. and Zhang, L., (2019). Association between the Charlson Comorbidity Index and the risk of 30-day unplanned readmission in patients receiving maintenance dialysis. BMC nephrology, 20(1), pp.1-8.

Liu, L.G., Rogers, J.R., Reeder, R., Walsh, C.G., Kansagara, D., Vawdrey, D.K. and Salmasian, H., (2021). Published models that predict hospital readmission: a critical appraisal. BMJ open, 11(8), p.e044964.

Gallagher, D.M., Zhao, C. and Goldstein, B.A., (2022). A Readmission Risk Model for Hospitalized Patients Receiving Dialysis: Evaluation of Predictive Performance. Kidney Medicine, 4(8).

Fuller, D.S., Bieber, B.A., Pisoni, R.L., Li, Y., Morgenstern, H., Akizawa, T., Jacobson, S.H., Locatelli, F., Port, F.K. and Robinson, B.M., (2016). International comparisons to assess effects of payment and regulatory changes in the United States on anemia practice in patients on hemodialysis: the dialysis outcomes and practice patterns study. Journal of the American Society of Nephrology: JASN, 27(7), p.2205.

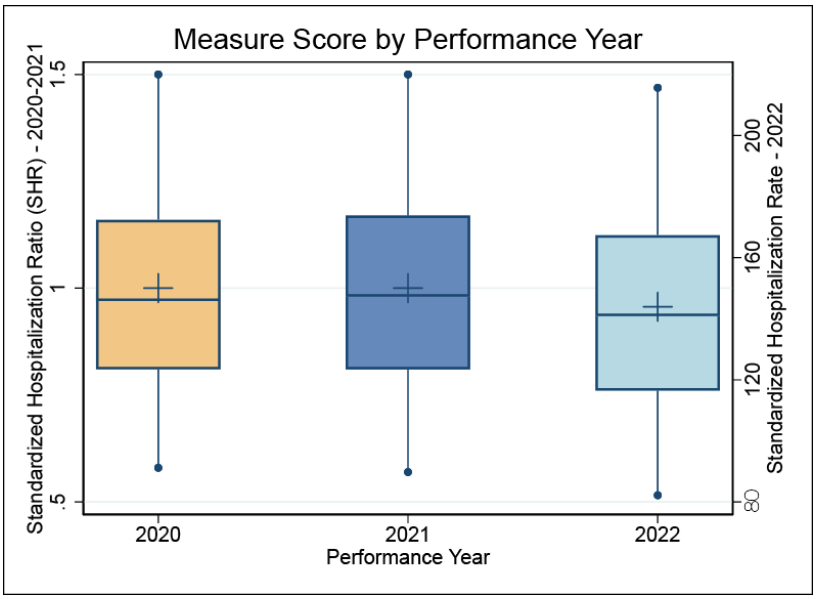


Figure 3.2.10 Measure Score for Standardized Hospitalization Ratio[7]

[7] During Performance year 2022, the calculation of this measure converted the SHR into a rate. Prior years have this shown as a ratio. Y axis scales are adjusted accordingly.

Table 3.2.10b. MSR Measure Information Sheet from CMIT for 00695-01-C-ESRDQIP Standardized Hospitalization Ratio

	Description
Measure Name	Standardized Hospitalization Ratio (SHR)
CMIT ID	00695-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	N/A
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Not specified in CMIT
Measure type	Outcome
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Endorsed
History	Initial Endorsement: 08/16/2011 Last Endorsed: 11/20/2020
Measure description	Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Claims Data
Numerator	Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
Denominator	Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.
Denominator exclusions, if applicable	Facility Exclusions 1. Facilities with less than 5 patient-years at risk during the calendar year of assessment. 2. Calculations will exclude the months covered by a granted ECE. Patient Exclusions 1. First 89 days of ESRD treatment. 2. Time during which patient has a functioning kidney transplant (exclusion begins 3 days prior to the date of transplant). 3. Patients treated at the facility for fewer than 60 days. 4. Patients are excluded beginning 60 days after they recover renal function or withdraw from

	Description
	dialysis. 5. Patients who have not been treated by any facility for a year or longer. 6. Months which are not within or in the two months following a month in which the patient has $900 of Medicare-paid dialysis claims or at least one Medicare inpatient (hospital and skilled nursing facilities) claim.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	Yes, Statistical risk model
Performance data	Appendix B
Related measures	CBE #2496 Standardized Readmission Ratio (SRR) for Dialysis Facilities CBE #0369 Standardized Mortality Ratio (SMR) for Dialysis Facilities
Summary of measure's feasibility	Feasibility vote: H-13; M-5; L-0; I-0 (18/18 – 100%, Pass) The Standing Committee agreed that the measure uses claims data that can be generated or collected during the provision of care and that no fees, licensing, or requirements are needed to use the measure.
Scientific acceptability: validity testing	Committee members requested clarification on the use of inpatient claims only for Medicare Advantage (MA) beneficiaries. In their discussion, the Standing Committee attributed the use of inpatient claims for MA beneficiaries to the outpatient claims being unavailable for most qualifying patients. Therefore, the developer used inpatient claims to adjust for comorbidities for both fee-for-service and MA. The Standing Committee expressed concern that social risk factors were excluded from the risk model. The Standing Committee acknowledged that although the developer identified several social factors, when added into the risk adjustment model, there was minimal impact to the measure score. The Standing Committee noted that the right social factors may not be considered for risk adjustment due to data limitations. Validity vote: H-3; M-5; L-1; I-0 (SMP) 8/9 – 89%, Pass While these considerations were noted on the validity of the measure, the Standing Committee agreed to uphold the SMP's rating on validity (Y-18, N-0).
Scientific acceptability: reliability testing	This measure is deemed complex and was evaluated by the NQF Scientific Methods Panel. SMP vote for Reliability: H-2; M-6; L-1; I-0.

Percentage of Prevalent Patients Waitlisted (PPPW)

	Description
	The developer assessed reliability using data among Medicare ESRD dialysis patients from 2015-2018. For each year of the four years from 2015-2018 there were 7,045, 7,316, 7,590 and 7,890 facilities, respectively. Patients who were treated at a facility for < 60 days and Therefore, could not be assigned a facility were not included in the IUR calculation. IUR- 2015: 0.59, 2016: 0.57, 2017: 0.53, 2018: 0.53 The IUR ranged from 0.53 – 0.59. The developer also computed an additional metric of reliability, termed the profile IUR (PIUR). PIUR- 2015: 0.85, 2016: 0.84, 2017: 0.78, 2018: 0.75 The PIUR ranged from 0.75 – 0.85. The SMP raised interoperability concerns: Because the PIUR is not in general interpretable as an IUR and because it does not appear to have another simple or direct interpretation, this raises the question of how to determine what PIUR value corresponds to "acceptable reliability". The Standing Committee agreed to uphold the SMP's rating on reliability (Y-18, N-0).

3.2.11 00546-01-C-ESRDQIP Percentage of Prevalent Patients Waitlisted (PPPW)

CMIT ID: 1100546-01-C-ESRDQIP

Description: Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.

Measure Type: Process

Level of Analysis: Facility/Hospital/Agency

Data Source: Claims Data

Table 3.2.11a. Preliminary Assessment of 00546-01-C-ESRDQIP* Percentage of Prevalent Patients Waitlisted

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Empirical evidence reference in the 2022 submission indicates that patients are more likely to be waitlisted if they are referred to a transplant center or if they are informed by their dialysis providers about transplantation; furthermore, waitlisting is associated with improved survival and quality of life. • The 2020 submission reported disparities in PPPW based on sex, race, and ethnicity. • Both the 2022 submission (using 2019 data) and data reported by ESRD QIP (2021) demonstrate a gap; for example, in 2019, there was an overall mean measure score of 19.1%, ranging from a mean of 6.1% in decile 1 to a mean of 35.1% in decile 10.	• Available evidence is observational. • While distribution of performance scores and the presence of disparities indicate a gap, improvement in performance scores from 2020 to 2022 was negligible in terms of the overall mean and by decile.
Scientific Acceptability, Reliability	• The 2022 submission reports IUR of 0.941 using 2019 data from dialysis practitioner group practices.	• None identified

Percentage of Prevalent Patients Waitlisted (PPPW)

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation is cited in the 2022 submission as a comprehensive resource to help clinicians evaluate patients' candidacy for transplant. • Risk adjusted for age, area deprivation index (ADI), dual eligibility, diabetes as primary cause of ESRD, comorbidities at ESRD incidence including tobacco and drug use, prevalent comorbidities, and transplant center characteristics; it is noted that adjustment for ADI and dual eligibility is necessary because transplant centers use these factors as criteria for candidacy. • The 2022 measure submission tested validity using data from 2019 (dialysis providers) and found a positive correlation between the measure score and transplant rate, and a negative correlation between the measure score and mortality, as expected.	• KDIGO resource cited contains more than 100 distinct recommendations with varying grades. • The 2022 Committee expressed concern about the effects of unmeasured confounders and patient preference; the scientific methods panel did not reach consensus on validity.
Feasibility	• All data elements are collected by health care personnel during the provision of care and are stored in defined fields in electronic resources.	• Data elements are coded by someone other than the person collecting original information.
Usability	• No unintended consequences were reported in the 2022 submission. • Feedback from 2022 TEP was majority supportive; they noted that waitlisting is a critical step for transplantation and that dialysis practitioners can directly contribute to waitlisting through patient education, assistance with documentation, and referrals.	• Physician group results had not been shared with measured entities at the time of the 2022 submission and no feedback on measure performance or implementation is available (measure not in use).
ESRD QIP Program-Level Consideration		
Alternative Measures	• Endorsed measure CMIT 01702-01-C-MIPS, CBE #3695, Percentage of	• None identified

Percentage of Prevalent Patients Waitlisted (PPPW)

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
	Prevalent Patients Waitlisted (PPPW).	

*The ESRD QIP CY 2024 proposed rule does not list CBE #3695 for the Percentage of Prevalent Patients Waitlisted (PPPW) (See Table 12, p. 42488, CMS–1782–P, June 30, 2023). However, CBE #3695 Percentage of Prevalent Patients Waitlisted (PPPW) was endorsed on December 12, 2022. For the purpose of this review, we have used the CBE 2022 measure information submission materials and the 2020 MUC/MERIT submission materials. The CBE 2022 evidence and test attachments were not available for review.

Additional Published Literature Consulted: Evidence provided in 2022 submission used for review

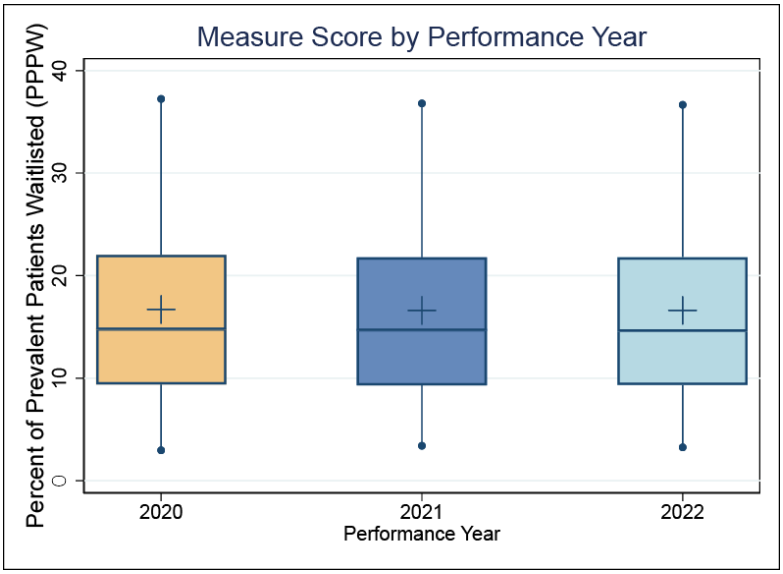


Figure 3.2.11 Measure Score for Percentage of Prevalent Patients Waitlisted

Table 3.2.11b. MSR Measure Information Sheet from CMIT for 00546-01-C-ESRDQIP Percentage of Prevalent Patients Waitlisted

	Description
Measure Name	Percentage of Prevalent Patients Waitlisted (PPPW)
CMIT ID	00546-01-C-ESRDQIP
CMS program in which the measure is used	ESRD QIP
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Health care Priority: Person-Centered Care Goal: Optimal Patient Experience
Measure type	Process
Measure developer	University of Michigan Kidney Epidemiology and Cost Center (UMKECC)
CBE endorsement status	Not Endorsed
History	Not Specified
Measure description	Percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
Level of analysis	Facility/Hospital/Agency
Data sources	Claims Data
Numerator	Number of patient-months in which the patient at the dialysis facility is on the kidney or kidney-pancreas waitlist as of the last day of each month during the performance period.
Denominator	All patient-months for patients who are under the age of 75 on the last day of each month and are assigned to the dialysis facility according to each patient s treatment history as of the last day of each month during the reporting year.
Denominator exclusions, if applicable	Facility Exclusions 1. Facilities treating fewer than 11 eligible patients during the calendar year of assessment. 2. Calculations will exclude the months covered by a granted ECE. Patient Exclusions 1. Patients 75 years old and older on the last day of each month during the performance period. 2. Patients admitted to a skilled nursing facility (SNF) or hospice during the evaluation month are

In-Center Hemodialysis (ICH) CAHPS Survey

	Description
	excluded from that month. 3. Patients admitted to SNF at incidence or previously were excluded, according to Question 17u and 22 on the CMS Medical Evidence Form.
Numerator exceptions, if applicable	NA
Denominator exceptions, if applicable	NA
Risk adjustment, if applicable	NA
Performance data	See below
Related measures in other programs	CBE 3695 Percentage of Prevalent Patients Waitlisted (PPPW) and Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW).
Summary of measure's feasibility	Information not available
Scientific acceptability: validity testing	Information not available
Scientific acceptability: reliability testing	Information not available

3.2.12 00381-02-C-ESRDQIP In-Center Hemodialysis (ICH) CAHPS Survey

CMIT ID: 00381-02-C-ESRDQIP

Description: The percentage of patient responses to multiple survey measures to assess their dialysis providers, the quality of dialysis care they receive, and information sharing about their disease.

Measure Type: Patient-Reported Outcome-Based Performance Measure (PRO-PM)

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Patient Reported Data and Surveys

Table 3.2.12a. Preliminary Assessment of 00381-02-C-ESRDQIP In-Center Hemodialysis CAHPS Survey

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Dialysis has been shown to affect patients across a wide variety of outcomes, including but not limited to, identity and perceptions of health. Reid et al. (2016) conducted a systematic review synthesizing the experiences of patients receiving in-center hemodialysis (n=576 patients). Thematic analyses identified four key themes related to patient experience: 1) New dialysis-dependent self (capturing identity and perception of self, resulting from dialysis dependence), 2) Restricted life (capturing physical and emotional constraints as consequences of dependence), 3) Regaining control (capturing strategies aimed at regaining optimism), 4) Relationships with HPs (capturing connection with providers and its influence on perceptions of power and support).	• Disparities (racial, language, and disabilities) for six ICH CAHPS outcome measures were found via multivariate regression analysis, employing 2016 ICH CAHPS Spring Survey patient-level data (N=107,582). • Racial disparities were found at the dialysis facility-level for the percentage of a dialysis facility's patients who are Black. This variable showed consistently statistically significant and negative coefficients across five of the six regression models for the response categories for the dialysis facilities with the higher percentages of patients who are Black. These facility-level racial disparities were found after controlling for Black race at the individual patient level. • Racial disparities were also found at the patient level for three other racial groups. The regression models found statistically significant and negative coefficients for American

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
	• Further, dialysis has been shown to affect quality of life. Budhram et al., (2020) conducted randomized controlled trials and cohort studies (N=3,711 patients) to gain insight into quality of life (QOL). Differences in specific QOL domains between dialysis modalities were identified (e.g., favoring in-center hemodialysis (ICHD) in the domains such as "support from staff," "health status," and "body image") that may aid in patient decision-making based on individual priorities.	Indian or Alaska Native patients (for all six ICH CAHPS outcomes measures), Asian patients (five of the six outcome measures), and mixed-race patients (four of the six outcome measures). • Disabilities disparities were found at the patient level. These included four types of disabilities that showed statistically significant and negative coefficients, including difficulty remembering (for all six ICH CAHPS outcomes measures), difficulty dressing (for all six ICH CAHPS outcomes measures), blindness (five of the six outcome measures), and deafness (four of the six outcome measures) patients.
Scientific Acceptability, Reliability	• Based on the semiannual administration of the ICH CAHPS survey to ESRD patients meeting eligibility criteria, three modes of administration 1) mail only, 2) telephone only, and 3) mixed mode (mail followed by telephone) were reported. • The Final Report indicated unanimous agreement among The Committee that the measure passed the evidence criterion, noting the importance of patient-centered care in facilities that people may frequent several times a week.	• The Final Report indicated Committee agreement that the measure demonstrates a moderate performance gap but noted disparities and trends could be better elucidated without the added adjustment of many social risk factors. Although the Scientific Methods Panel rated the measure moderate for reliability and validity, the Committee expressed the need to see more empiric validity testing demonstrated in future maintenance cycles. The Committee thoroughly deliberated its concern about two out of the five denominator exclusions (hospice patients and non-English speaking patients), noting implications on the assessment and delivery of population-sensitive care and the perception of culturally competent care.
Scientific Acceptability, Validity	• The results of this measure provide facilities with an opportunity to monitor and improve quality and therefore patient outcomes. Survey aspects assessed in this measure align with current standards of care and best practices for patient care.	• None identified

Feasibility	• Most CAHPS surveys, such as Hospital CAHPS and Home Health CAHPS, do not survey a chronic population. The only unexpected finding for ICH CAHPS is that patients have complained about having to answer the same survey twice a year. We have had feedback suggesting shortening the questionnaire. We are looking into the implications of doing this for Dialysis Facility Compare and for the QIP. • The ICH CAHPS survey collects information directly from ESRD patients receiving in-center hemodialysis via one of three modes of administration: mail only, telephone only and mixed mode with mail and telephone follow-up of non-respondents. Since this measures patient experiences, it would not be available from electronic sources. Proxies are not allowed because questions are only answerable by patients. • No data elements are in defined fields in electronic sources.	• In the Final Report, the developer discussed the impractical and insensitive nature of survey application towards hospice patients and explained the way in which facilities account for language barrier. Committee members assessed the developer's reasoning for these exclusions as acceptable. Developers explained that the variations in response rate are not as vast as was noted by the Committee and that mixed-mode survey administration has proven to secure the highest response rate across vendors. Developers also added that very small facilities or facilities that are unable to reach the threshold for completed surveys are excluded from the assessment. • Although the measure is in use, the Committee was unable to reach consensus concerning feasibility due to the burden and cost of survey implementation for providers. Feasibility is not an NQF must-pass criterion. The measure is currently used in the End-Stage Renal Disease Quality Improvement Program and therefore passed use. The Committee raised questions about the comparison of dialysis units with respect to size and response rates. • Difficulties reported: One difficulty in the "sampling" is that there are a large number of ICH facilities in the study (over 6,000) and the number of patients at these sites tend to be small. The median is approximately 50. Therefore, we have to conduct a census for nearly every facility. The challenge is obtaining enough completed surveys to be able to publicly report the results. We are currently working on the possibility of conducting the survey using the Web. CMS is testing web administration of other CAHPS surveys with a view to creating a protocol and guidelines for web administration of the survey.

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Usability	• As part of the Patients Over Paperwork program, the developer is considering options regarding the frequency of administration of the survey and analyzing data to determine how shortening the questionnaire will impact measures. The developer is also investigating the possibility of electronic administration of several CAHPS surveys, including ICH CAHPS. No decisions have been made. • Additional context from Final Report asserts that the Committee raised no significant concerns about usability and agreed that the measure meets the usability criterion.	• Focus groups with in-center hemodialysis patients were conducted for CMS in February 2016 (Baltimore) and April 2016 (San Antonio). Feedback was also collected from telephone conference calls and in-person meetings with provider groups throughout the year. • Feedback Summary: The focus group report concluded that: “Current dialysis patients, in particular, emphasized that the survey questions and reported multi-item measures captured exactly the kind of information that was important to know and that they would look for about dialysis centers.” Feedback from informal meetings with patient groups reflect high interest in the survey. Suggestions for improvement include using the web to collect survey data, shortening the questionnaire, and conducting the survey annually instead of twice a year. • The average score for the multi-item measures increased over time (nephrologists’ communication and caring, quality of dialysis center care and operations, and providing information to patients) while the average scores for the three ratings questions (rating of the nephrologist, rating of the dialysis center staff, and rating of the dialysis facility) dropped from 2015 to 2016 and then increased in 2017. • Additional context from final report: The Standing Committee recommended the measure for continued endorsement. One comment was received during the post-evaluation comment period, raising concerns around the burden on patients for the ICH CAHPS survey, which could potentially cause reliability or validity issues due to low response rates. The Committee discussed this comment and the response submitted by the developer

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
		during the post comment call. The Committee agreed burden is an issue and requested the developer submit additional information on usability and response rates at the time of the next maintenance review. The Committee elected to recommend the measure for continued endorsement.
ESRD QIP Program-Level Consideration		
Alternative Measures	• The CMIT database identified several CAHPS related measures; however, none were specific to In-Center Hemodialysis (ICH). • Examples: ▪ Measure 153: Consumer Assessment of Health care Providers and Systems Home Health Care Survey (HHCAHPS) ▪ Measure 154: Consumer Assessment of Health care Providers and Systems (CAHPS) Hospice Survey ▪ Measure 158: CAHPS for MIPs Clinician/Group Survey	• Related measures indicated in the final report included: NQF #0005, #0166, #0258, #0517, #1741, #2548, and #2967.

Additional Published Literature Consulted:

Reid, C., Seymour, J., & Jones, C. (2016). A Thematic Synthesis of the Experiences of Adults Living with Hemodialysis. Clinical Journal of the American Society of Nephrology, CJASN, 11(7), 1206–1218. https://doi.org/10.2215/CJN.10561015

Budhram, B., Sinclair, A., Komenda, P., Severn, M., & Sood, M. M. (2020). A Comparison of Patient-Reported Outcome Measures of Quality of Life By Dialysis Modality in the Treatment of Kidney Failure: A Systematic Review. Canadian journal of kidney health and disease, 7, 2054358120957431. https://doi.org/10.1177/2054358120957431

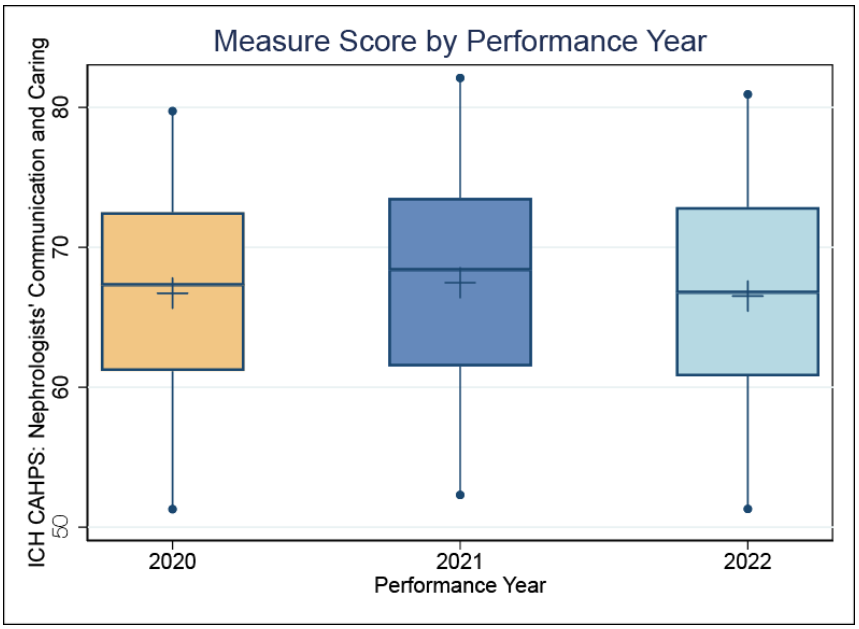


Figure 3.2.12a Measure Score for Nephrologists' Communication and Caring

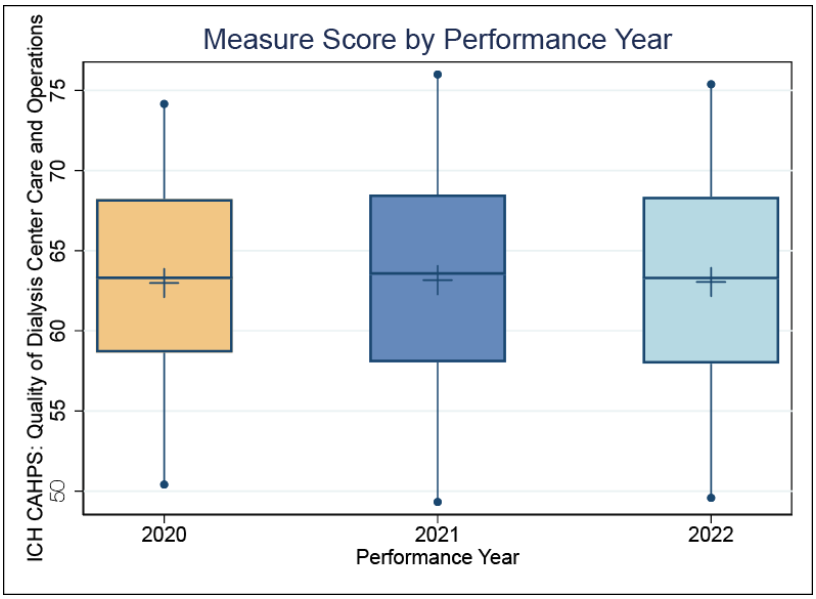


Figure 3.2.12b Measure Score for Quality of Center Care and Operations

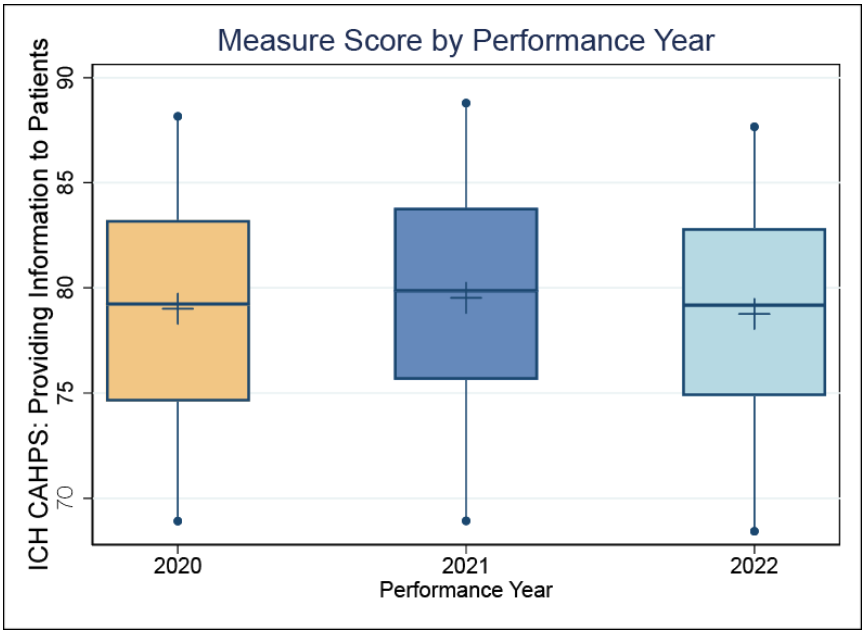


Figure 3.2.12c Measure Score for Providing Information to Patients

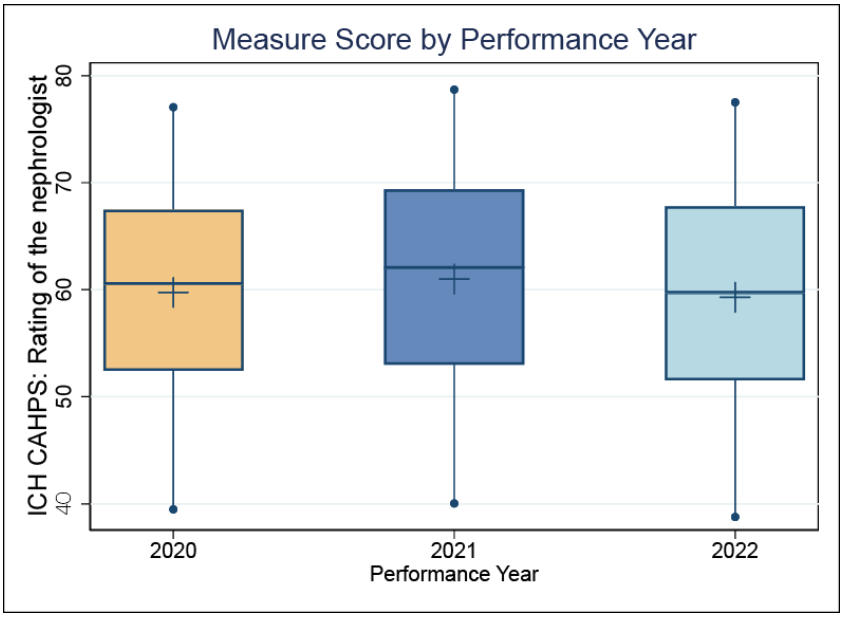


Figure 3.2.12d Measure Score for ICH CAHPS: Nephrologist Rating

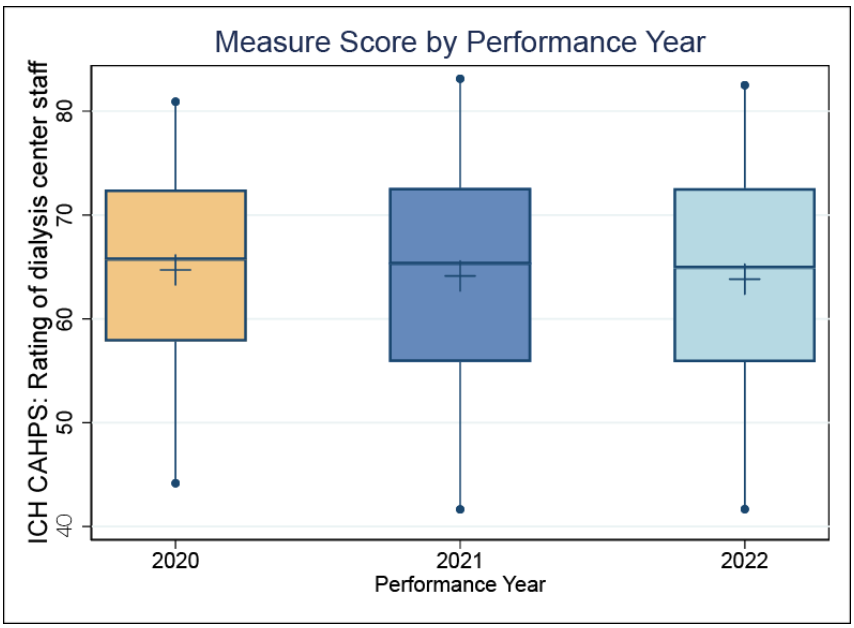


Figure 3.2.12e Measure Score for ICH CAHPS: Center Staff

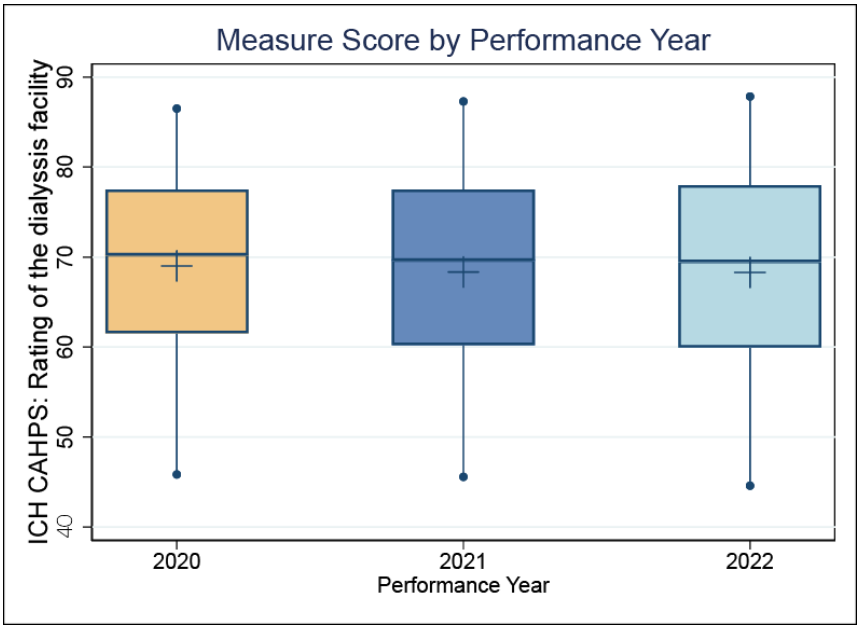


Figure 3.2.12e Measure Score for ICH CAPHS: Dialysis Facility

Table 3.2.12b. MSR Measure Information Sheet from CMIT for 00381-02-C-ESRDQIP In-Center Hemodialysis CAHPS Survey

	Description
Measure Name	CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration
CMIT ID	00381-02-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	N/A
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Priority: Person-Centered Care Goal: Optimal Patient Experience
Measure type	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
Measure developer	Centers for Medicare & Medicaid Services
CBE endorsement status	Endorsed
History	Initial Endorsement: 11/14/2007 Endorsed: 10/25/2019 The NQF Patient Experience and Function Standing Committee recommended the measure for endorsement on 07/01/2019.
Measure description	This survey-based measure is one of the family of surveys called CAHPS Surveys (Consumer Assessment of Healthcare Providers and Systems) that focused on patient experience. The questionnaire asks End Stage Renal Disease (ESRD) patients receiving in-center hemodialysis care about the services and quality of care that they experience. Patients assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease. The survey is conducted twice a year, in the spring and fall with adult in-center hemodialysis patients. Publicly reported measures focus on the proportion of survey respondents at each facility who choose the most favorable responses. Three multi-item measures: a.M1: Nephrologists' Communication and Caring (NCC) b.M2: Quality of Dialysis Center Care and Operations (QDCCO)

	Description
	c.M3: Providing Information to Patients (PIP) Three Global items: a.M4: Rating of the nephrologist b.M5: Rating of dialysis center staff c.M6: Rating of the dialysis facility The first three measures are created from six or more questions from the survey that are reported as one measure score. The three global items are single-item measures using a scale of 0 to 10 to report the respondent's assessment. The percentage of patient responses to multiple survey measures to assess their dialysis providers, the quality of dialysis care they receive, and information sharing about their disease. (Survey is administered twice a year). Three Composite Measure Scores: The proportion of respondents answering each response option by item, created from six or more survey questions reported as one measure score. Composites include Nephrologists Communication and Caring, Quality of Dialysis Center Care and Operations, and Providing Information to Patients. Three Global Items: A scale of 0 to 10 to measure the respondent s assessment of the following: Rating of the Nephrologist, Rating of Dialysis Center Staff, and Rating of the Dialysis Facility.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Patient Reported Data and Surveys
Numerator	The measures score averages the proportion of those responding to each answer choice in all questions. Each global rating will be scored based on the number of respondents in the distribution of top responses, e.g., the percentage of patients rating the facility a 9 or 10 on a 0 to 10 scale (with 10 being the best).
Denominator	Patients with ESRD receiving in-center hemodialysis (HD) at the facility for the past 3 months or longer are included in the initial population. The denominator for each question is the number of patients that responded to the particular question.
Denominator exclusions, if applicable	Facility Exclusions 1. Facility attests in EQRS1 that it treated fewer than 30 eligible in-center HD adult patients during the eligibility period, which is defined as the year prior to the performance period. 2. Facilities that treat 30 or more eligible in-center HD adult patients during the eligibility period but are unable to obtain at least 30 completed surveys during the performance period.

	Description
	3. Facilities with a CCN certification date on or after October 1 of the year prior to the performance year. 4. Facilities not offering In-Center HD as of December 31 of the performance year. Patient Exclusions 1. The following patients are excluded in the count of 30 eligible patients: a. Patients less than 18 years on the last day of the sampling window for the semiannual survey. b. Patients receiving HD from their current facility for less than 90 days. c. Patients receiving hospice care. d. Patients currently residing in an institution, such as a residential nursing home or other long-term care facility, or a jail or prison.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures in other programs	N/A
Summary of measure's feasibility	From the Spring 2019 Patient Experience and Function CDP Report: The Committee was unable to reach consensus concerning feasibility due to the burden and cost of survey implementation for providers. Feasibility is not an NQF must-pass criterion.
Scientific acceptability: validity testing	Although the Scientific Methods Panel rated the measure moderate for validity, the committee expressed the need to see more empiric validity testing demonstrated in future maintenance cycles. The Committee thoroughly deliberated its concern about two out of the five denominator exclusions (hospice patients and non-English speaking patients), noting implications on the assessment and delivery of population-sensitive care and the perception of culturally competent care. In this regard, the developer discussed the impractical and insensitive nature of survey application towards hospice patients and explained the way in which facilities account for language barrier. Committee members assessed the developer's reasoning for these exclusions as acceptable.
Scientific acceptability: reliability testing	The Standing Committee voted to accept the Methods Panel's moderate rating for reliability.

3.2.13 00313-01-C-ESRDQIP Hemodialysis Vascular Access: Long-term Catheter Rate

CMIT ID: 00313-01-C-ESRDQIP

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

Measure Type: Intermediate Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims

Table 3.2.13a. Preliminary Assessment of 00313-01-C-ESRDQIP Hemodialysis Vascular Access Long-term Catheter Rate

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• A substantial evidence base associates long-term catheter use in hemodialysis with higher rates of infection and hospitalization compared with AVF, yet a majority of patients were still using long-term catheters 90 days after starting chronic hemodialysis. • Recent studies and systematic reviews also find higher risk of infection and hospitalization associated with catheter use compared with AVF, or with delayed conversion of catheter to AVF. • 2020 maintenance submission found disparities in AVF use based on age, sex, race/ethnicity, and SES. • Overall mean measure score of 15.6%, ranging from a mean of 4.2% in decile 1 to a mean of 35.2% in decile 10 (2021 analysis). • Statutorily required category.	• Evidence base does not include RCTs. • The 2020 committee noted that catheter lock and catheter cap solutions were not included in the evidence review; a 2022 review reveals reduced risk of catheter-associated infection and dysfunction with appropriate countermeasures. • While distribution of performance scores and the presence of disparities indicate a gap, performance scores also more than doubled in overall mean and by decile from 2020 to 2022 (lower score means better quality).

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Scientific Acceptability, Reliability	• The 2020 maintenance submission tested reliability using data from January-December 2018, and reported an IUR of .76.	• None identified
Scientific Acceptability, Validity	• Measure aligns with current clinical practice guidelines. • Measure is intended to be reported jointly with CBE #2977, Hemodialysis Vascular Access: Standardized Fistula Rate, which is intended to encompass all three access methods. • The 2019 maintenance submission tested validity using data from January 2017 – December 2018, and found a positive correlation between the measure score and risk of both mortality and hospitalization, as expected.	• Evidence for the guideline was downgraded prior to 2020 maintenance submission, and evidence is currently rated as low or expert opinion. • Patient choice is a confounding factor. • The 2020 Committee argued that while catheters are generally the least desirable vascular access, with certain patient characteristics and scenarios it may be the most appropriate option; reasons for beginning hemodialysis with a catheter include acute onset of ESRD and non-working or immature AV access. • The 2020 committee also expressed concern that missing information for vascular access is assumed to be catheter use, which the developer explained was intended to encourage complete documentation of vascular access; consideration should be given to whether this partially explains the declining performance in both this measure and CBE #2977 observed between 2020 and 2022.
Feasibility	• Required data elements are routinely captured during patient care and are in defined fields in electronic sources. • Per the 2020 maintenance submission, comments about inaccurate or missing data were rare.	• Data elements are coded by someone other than the person collecting original information.
Usability	• No unintended consequences were reported in the 2020 maintenance submission.	• The 2020 maintenance submission lists feedback received, including requests for the measure to account for patient choice, comments about the possibility of double penalties for

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
	• Facilities can preview performance results prior to posting and submitting questions and comments about their results. • Mechanisms for collecting feedback from measured entities include QIP helpdesk, a preview period, and public comment.	low AVF and high catheter rates, and comments about risk adjustment factors and exclusions related to exhausting other vascular access option.
ESRD QIP Program-Level Consideration		
Alternative Measures	• A related measure, CBE #2594, Optimal End Stage Renal Disease (ESRD) Starts, does not address dialysis facilities or dialysis providers.	• None identified

Additional Published Literature Consulted:

Celik, S., Gok Oguz, E., Ulusal Okyay, G., Selen, T. and Ayli, M.D., (2021). The impact of arteriovenous fistulas and tunneled cuffed venous catheters on morbidity and mortality in hemodialysis patients: A single center experience. The International Journal of Artificial Organs, 44(4), pp.229-236.

Fisher, M., Golestaneh, L., Allon, M., Abreo, K. and Mokrzycki, M.H., (2020). Prevention of bloodstream infections in patients undergoing hemodialysis. Clinical journal of the American Society of Nephrology: CJASN, 15(1), p.132.

Jhee, J.H., Hwang, S.D., Song, J.H. and Lee, S.W., (2019). The impact of comorbidity burden on the association between vascular access type and clinical outcomes among elderly patients undergoing hemodialysis. Scientific Reports, 9(1), p.18156.

Liebman, S.E. and Chang, E.Y.,(2019). An analysis of central venous catheter-based hemodialysis starts. Clinical nephrology, 92(1), p.9.

Raimann, J.G., Chu, F.I., Kalloo, S., Zhang, H., Maddux, F., Wang, Y. and Kotanko, P., (2020). Delayed conversion from central venous catheter to non-catheter hemodialysis access associates with an increased risk of death: a retrospective cohort study based on data from a large dialysis provider. Hemodialysis International, 24(3), pp.299-308.

Wang, Y. and Sun, X., (2022). Reevaluation of lock solutions for Central venous catheters in hemodialysis: a narrative review. Renal Failure, 44(1), pp.1502-1519.

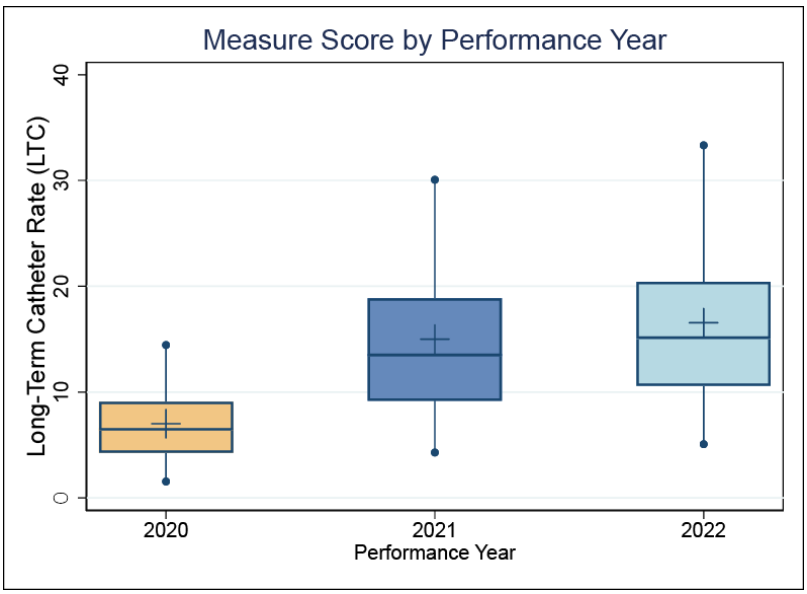


Figure 3.2.13 Measure Score for Hemodialysis Vascular Access: Long-Term Catheter Rate

Table 3.2.13b. MSR Measure Information Sheet from CMIT for 00313-01-C-ESRDQIP Hemodialysis Vascular Access: Long-term Catheter Rate

	Description
Measure Name	Hemodialysis Vascular Access: Long-term Catheter Rate
CMIT ID	00313-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	Care Compare Setting: Dialysis facilities
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures (CoMM) Domain	Priority: Person-Centered Care Goal: Optimal Patient Experience
Measure type	Intermediate Outcome
Measure developer	Not specified in CMIT
CBE endorsement status	Endorsed
History	Endorsed: 11/20/2020 Initial Endorsement: 12/09/2016 The NQF Renal Standing Committee recommended this measure for endorsement in June 2020.
Measure description	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims) Claims Data
Numerator	The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.
Denominator	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility. When used for public reporting, the measure calculation will be restricted to facilities with at least 11 patients in the reporting month. This restriction is required to ensure patients cannot be identified due to small cell size.
Denominator exclusions, if applicable	Exclusions that are implicit in the denominator definition include: • Pediatric patients (<18 years old) • Patients on Peritoneal Dialysis • Patient-months on in-center or home hemodialysis for less than a complete reporting month at the same facility In addition, these exclusions are applied to the denominator:

	Description
	• Patients with a catheter that have limited life expectancy • Patients under hospice care in the current reporting month • Patients with metastatic cancer in the past 12 months • Patients with end stage liver disease in the past 12 months • Patients with coma or anoxic brain injury in the past 12 months.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures in other programs	N/A
Summary of measure's feasibility	Data collection was noted to be conducted via claims and CROWNWeb with no concerns expressed by the Committee related to feasibility.
Scientific acceptability: validity testing	SMP vote for validity – Moderate (H-1; M-6; L-2; I-0) In the discussion on validity, the Committee noted the relationship between facility-level quintiles of performance scores and the SMR and SHR using Poisson regression. The Committee noted that any missing vascular access information in the performance data is assumed to be catheter use. The developer clarified that this is to encourage providers to ensure vascular access route is documented, noting that this is a relatively small portion of providers representing less than 2% of those measured. The Committee expressed some concerns related to the comorbidity conditions, namely that the measure is not adjusted. The Committee generally agreed that the exclusion of comorbidities and lack of risk adjustment is correct. The Committee also discussed that the identification of differences in population needs related to vascular access may need stratification. The developer noted that the factors related to risk adjustment are primarily due to appropriateness of fistula use, thus risk adjustment would be appropriate for the fistula measure and that exclusions are more appropriate for a catheter measure. The exclusions are for pediatrics, hospice care, and comorbidities associated with limited life expectancy. The Committee also discussed missing data and its impact on validity, as well as the impact of patient choice in the presence of known risks. The severity of cardiovascular disease and heart failure was also discussed as a potential inclusion in modelling, but the developer noted that they have not been successful in acquiring appropriate ICD-10 codes with sufficient detail to allow for this.
Scientific acceptability: reliability testing	This measure was deemed complex and was evaluated by the NQF SMP.

Vaccination Coverage Among HCP

	Description
	SMP vote for reliability – Moderate (H-4; M-5; L-0; I-0) Reliability testing conducted at the measure score level by calculating an IUR with bootstrapping; IUR = 0.76. No PIUR was provided.

3.2.14 00180-01-C-ESRDQIP COVID-19 Vaccination Coverage Among HCP

CMIT ID: 00180-01-C-ESRDQIP

Description: Percentage of healthcare personnel (HCP) who receive a complete COVID-19 vaccination course.

Measure Type: Process

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Electronic Clinical Data (non-EHR); Electronic Health Record; Paper Medical Records; Registries

Note: This is a new measure developed during the COVID-19 PHE and as such, does not have data available from all performance years within the lookback period.

Table 3.2.14a. 00180-01-C-ESRDQIP Preliminary Assessment of 00180-01-C-ESRDQIP Vaccination Coverage Among HCP

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Recent evidence notes significant occupational risk (i.e., exposure to COVID-19) for health care personnel, with health care exposures being shown at higher incidence than household and community exposures (Billock et al., 2022).	• As of April 2021, US-based vaccination status and intent research indicates although over half of health care personnel received ≥1 dose of a COVID-19 vaccine (68.2%), 7.1% were unsure, and 14.9% would probably/definitely not get vaccinated (Razzaghi et al., 2022). Influenza vaccination status in 2020–2021 and age (≥60 years) positively influenced COVID-19 vaccination status. Non-Hispanic Black health care personnel, nurse practitioners/physician assistants, assistants/aides, and nonclinical health care personnel were less likely to be vaccination for COVID-19. Reasons for vaccination included protecting self, family and friends, and patients from COVID-19 infection. Authors reported the “most common reason for non-vaccination was

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
		concern about side effects and safety of COVID-19 vaccine." Thus, addressing concerns related to effectiveness, side effects, and safety, as well as seeking understanding of barriers, may improve vaccination incidence among health care personnel.
Scientific Acceptability, Reliability	• The most recent reliability votes awarded a Moderate rating. • The Pearson Correlation Coefficient assessing the strength of association (as the number of HCP vaccinated is close to a continuous variable and the expected relationship between the number of vaccinations measured using NHSN and PPP is a linear one) was high (r=0.846). • Prior reliability testing involved individual-level data element testing for the numerator data element of health care personnel (HCP) COVID-19 vaccination was conducted in 869 CMS-certified nursing homes (NHs) based on data collected from December 2020 – January 2021. Immediately following the authorization of the first COVID-19 vaccines in December 2020, NHSN released COVID-19 reporting modules for tracking vaccination coverage among residents and staff of long-term care facilities.	• Data for the measure are aggregated (not collected at an individual level) and not collected by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. • The overall Pearson Correlation Coefficient between the between Quarterly COVID-19 coverage measure for Q3 (July, August, September) 2021 and annual influenza vaccination coverage measure NQF 0431 for facilities that reported both measures indicate "medium" correlation (generally accepted range for medium correlation, 0.30 – 0.49) between the proposed and previously endorsed coverage measure. This medium correlation was consistent when stratified by facility size (number of health care personnel [HCP]). • There are factors outside of the facilities' control which impact HCP COVID-19 vaccination coverage which are independent of influenza vaccination. With additional time for the new COVID-19 vaccines to gain acceptance and for implementation of vaccination programs to address COVID-19 vaccination hesitancy, coverage rates of COVID-19 and influenza vaccination are likely to correlate more strongly.

Vaccination Coverage Among HCP

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Scientific Acceptability, Validity	• Updated validity data was not generated for this measure as facility-level data was not available for the 2021 year. • Validity testing computed performance measure scores for the proposed quarterly COVID-19 vaccination measure for Q3 of 2021 (July – September) and were compared to the NQF endorsed measure scores for influenza vaccination of HCP for the 2020-2021 influenza season for 1,807 CMS-certified NHs. The overall Pearson correlation coefficient between the quarterly COVID-19 coverage measure for Q3 2021 and annual influenza vaccination coverage (CBE #0431) was 0.4169 ($p<0.0001$ [1,654 facilities]), indicating a "medium" correlation using the generally accepted range for medium correlation: 0.30–0.49.	• None identified

Feasibility	• Feasibility votes awarded a High-Moderate rating (High 10; Moderate 7; Low 0). • The rationale for the shorter data collection period for the proposed measure is to reduce the reporting burden.	• During endorsement committee review, difficulties reported included: 1. There may be lack of access to vaccine and one dose vaccine products were not equally available across all states and so some facilities may be disadvantaged because of the 4-week waiting period between doses of the 2-dose vaccination products. 2. There may be unintended consequences and legal risks to their organization if HCP experience an adverse event related to vaccination. 3. A concern was expressed of staff intimidation if they elect not to receive the vaccine, and that facilities do not have control over the vaccination status of their employees. 4. Request to consider including all HCP in the denominator, at least for an initial reporting period and to allow for consistent cross-provider reporting and accurate measurement and comparisons. 5. Noted the measure was not aligned with the Influenza Vaccination Coverage among HCP (NQF #0431) measure and includes “eligible” workers. 6. There should be flexibility in defining contraindications and contraindications are in flux. 7. The measure for one quarter should not be combined with the next quarter because the most up-to-date data should be available. 8. There is burden of reporting due to difficulty of tracking vaccine status contraindications and declinations and reporting vaccinations 1 week per month, rather than one time per quarter.

Vaccination Coverage Among HCP

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Usability	• Usability votes awarded the measure a High-Moderate rating (High 8, Moderate 8) • A number of commenters wrote in support of the measure's concept and the need to encourage widespread vaccination for HCP. • The measure would help assess the degree to which facilities are taking steps to limit the spread of COVID-19 and reduce the risk of transmission within their facilities. • Public reporting of COVID-19 vaccinations among HCP would provide consumers with important information with which to make informed decisions about the safety of a facility. • The measure would provide greater transparency for federal officials and other stakeholders seeking to effectively target vaccine hesitancy, as well as provide resources related to the COVID-19 vaccines.	• During endorsement committee review, concerns expressed included: ▪ The measure specifications and testing data should be submitted for NQF endorsement. ▪ It is unknown whether a booster vaccination will be necessary. How will vaccine recommendations and potential recommendations for booster doses be accounted for in reporting requirements? ▪ Concern that the vaccinations have not received full FDA approval.

ESRD QIP Program-Level Consideration		

Alternative Measures	• The CMIT website shows eight program-specific version titles of the measure. Thus, it has been applied and used in the last 3 years.
	• Alternative measures identified:
	  ▪ CBE ID 0431: Influenza Vaccination Coverage Among Healthcare Personnel
	  ▪ CBE ID: 390: Healthcare Personnel Influenza Vaccination Reporting Measure
	• The proposed measure is harmonized to use the same denominator categories as CBE 0431. The target population of both NQF 0431 and the proposed measure is health care personnel (HCP) who may be encountered by other HCP and patients during the reporting period.	

Additional Published Literature Consulted:

Billock, R. M., Groenewold, M. R., Sweeney, M. H., de Perio, M. A., Gaughan, D. M., & Luckhaupt, S. E. (2022). Reported exposure trends among healthcare personnel COVID-19 cases, USA, March 2020-March 2021. American Journal of Infection Control, 50(5), 548–554. https://doi.org/10.1016/j.ajic.2022.01.007

Dooling K, McClung N, Chamberland M, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1857-1859. DOI: http://dx.doi.org/10.15585/mmwr.mm6949e1external icon

ACIP Evidence Table for COVID-19 Vaccines Allocation in Phase 1a of the Vaccination Program is available at: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/evidence-table.html

Maltezou, H. C., Panagopoulos, P., Sourri, F., Giannouchos, T. V., Raftopoulos, V., Gamaletsou, M. N., Karapanou, A., Koukou, D. M., Koutsidou, A., Peskelidou, E., Papanastasiou, K., Souliotis, K., Lourida, A., Sipsas, N. V., & Hatzigeorgiou, D. (2021). COVID-19 vaccination significantly reduces morbidity and absenteeism among healthcare personnel: A prospective multicenter study. Vaccine, 39(48), 7021–7027. https://doi.org/10.1016/j.vaccine.2021.10.054

Razzaghi, H., Masalovich, S., Srivastav, A., Black, C. L., Nguyen, K. H., de Perio, M. A., Laney, A. S., & Singleton, J. A. (2022). COVID-19 Vaccination and Intent Among Healthcare Personnel, U.S. American journal of preventive medicine, 62(5), 705–715. https://doi.org/10.1016/j.amepre.2021.11.001

Table 3.2.14b. MSR Measure Information Sheet from CMIT for 00180-01-C-ESRDQIP Vaccination Coverage Among HCP

	Description
Measure Name	COVID-19 Vaccination Coverage among HCP
CMIT ID	00180-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	PCHQR, HIQR, HOQR, HVBP, HACRP, ASCQR, SNFVBP, LTCHQR, IRFQR, SNFQRP, IPFQR
Measure steward	Centers for Disease Control and Prevention (CDC)
Cascade of Meaningful Measures Domain	Not specified in CMIT
Measure type	Process
Measure developer	Not specified in CMIT
CBE endorsement status	Endorsed
History	Initial Endorsement: 07/26/2022 The NQF Patient Safety Standing Committee recommended the measure for endorsement on 02/16/2022
Measure description	Percentage of health care personnel (HCP) who receive a complete COVID-19 vaccination course
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Electronic Clinical Data (non-EHR); Electronic Health Record; Paper Medical Records; Registries
Numerator	The numerator for this measure consists of the cumulative number of HCP in the denominator population who are considered up to date with recommended COVID-19 vaccines. Facilities should refer to the definition of up to date as of the first day of the quarter. https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-May2022-508.pdf As of April 1, 2022, up to date includes individuals who received their second dose in a two-shot primary vaccination series (Pfizer-BioNTech or Moderna vaccines) less than 5 months ago, individuals who received a J&J/Janssen as their primary vaccination less than 2 months ago, individuals who have received a primary series and one booster dose when recommended.

Vaccination Coverage Among HCP

	Description
Denominator	The target population is the number of health care personnel (HCP) eligible to work in the health care facility for at least one day during the one-week data collection reporting period, excluding persons with contraindications to COVID-19 vaccination. This measure includes at least one week of data collection a month for each of the 3 months in a quarter. The denominators are reported by aggregating the categories. There are four categories of HCP: 1. Employees: includes all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll). 2. Licensed independent practitioners (LIPs): This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility. 3. Adult students/trainees and volunteers: This includes all students/trainees and volunteers aged 18 or over who do not receive a direct paycheck from the reporting facility. 4. Other contract personnel: Facilities may also report on individuals who are contract personnel. However, reporting for this category is optional. Contract personnel are defined as persons providing care, treatment, or services at the facility through contract who do not fall into any of the above-mentioned denominator categories.
Denominator exclusions, if applicable	Denominator-eligible individuals with contraindications to COVID-19 vaccination. Medical contraindications are listed in a vaccine's FDA authorization or labeling and include severe allergic reaction. The current list of contraindications as well as exclusions may be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html and includes: 1. Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine. 2. Known diagnosed allergy to a component of the COVID-19 vaccine.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No

Vaccination Coverage Among HCP

	Description
Performance data	Appendix A
Related measures in other programs	CBE #04–1 - Influenza Vaccination Coverage Among Healthcare Personnel
Summary of measure's feasibility	From the 2021 Patient Safety CDP Report: The Standing Committee noted that the data source is not specified because it may vary by facility. Data may be collected from electronic sources or paper-based sources, or it may be obtained from existing records, or a system specifically designed for COVID-19 vaccination tracking. The data are then reported to the NHSN. The Standing Committee discussed whether collecting data for this measure was more feasible amid the pandemic when it was critically relevant and whether it would pose a reporting burden at a later date when the threat may have waned. The developer explained that they chose quarterly reporting to mitigate extremes and make reporting less burdensome than weekly, which is the current practice among many institutions, but more immediately useful than annually. The Standing Committee passed the measure on feasibility. Feasibility vote-17; H-10; M-7; L-0; I-0
Scientific acceptability: validity testing	The Standing Committee expressed some concerns with the optional reporting category of contract personnel included in the denominator, stating that it seems facilities would report this category when it improves their score and not report it when it does not. The developer clarified that the denominator was created to mirror the denominator of CBE #0431, the currently CBE-endorsed influenza vaccination of HCP measure, which also does not require the reporting of contract personnel. The Standing Committee stressed that contract personnel have become a much greater percentage of HCP since the pandemic began and urged the developer to consider making this reporting category a requirement in the future. The Standing Committee noted that the developer conducted validity testing at the accountable-entity level. The overall Pearson correlation coefficient between the quarterly COVID-19 coverage measure for Q3 2021 and annual influenza vaccination coverage (CBE #0431) was 0.4169 ($p<0.0001$ [1,654 facilities]), indicating a "medium" correlation using the generally accepted range for medium correlation: 0.30–0.49.

	Description
	The Standing Committee also noted the data presented represent a medium correlation when stratified by facility size (0.457 for the third quartile [94-131 HCP] and 0.450 for the fourth quartile [>132 HCP]). The Standing Committee had no concerns regarding the validity testing of the measure or how the developer addressed any potential threats to validity and passed the measure on this criterion. Validity vote-18; H-8; M-10; L-0; I-0
Scientific acceptability: reliability testing	The Standing Committee noted the developer conducted reliability testing at the patient/encounter level, and the overall Pearson correlation coefficient for the number of HCP who received COVID-19 vaccinations as reported to the NHSN (measure numerator) compared to the number of COVID-19 vaccinations administered by the Pharmacy Partnership for Long-Term Care Program (PPP) (independent comparator) was 0.846 ($p<0.0001$ [869 Facilities]). The Standing Committee passed the measure on reliability. Reliability vote-18; H-N/A; M-15; L-2; I-1.

3.2.15 00407-01-C-ESRDQIP Kt/V Dialysis Adequacy Comprehensive Measure-HD

CMIT ID: 00407-01-C-ESRDQIP

Description: Percentage of all patient-months for patients whose delivered dose of dialysis (either HD or PD) met the specified threshold during the reporting period.

Measure Type: Intermediate Outcome

Level of Analysis: Facility/Hospital/Agency

Data Source: Administrative Data (non-claims); Claims Data

Table 3.2.15a. Preliminary Assessment of 00407-01-C-ESRDQIP Kt/V Dialysis Adequacy Comprehensive Measure -HD

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
Importance	• Kt/V is a widely accepted measure of dialysis adequacy in the ESRD community. Evidence shows that Kt/V is associated with survival among dialysis patients. • Statutorily required category.	• Kt/V dialysis adequacy measures exhibit limited variation in performance. • There are other tests - more expensive - which would be better indicators of dialysis adequacy than Kt/V. • There are limitations to the accuracy of estimation of V which call into question the validity of applying a single threshold Kt/V value as indicative of adequate dialysis. • Incident hemodialysis patients with substantial residual kidney function (RKF) do not exhibit the expected better survival at higher hemodialysis doses. • Kt/V, urea and related parameters neither reflect the severity of uremic symptoms nor predict long-term outcomes.
Scientific Acceptability, Reliability	• Measure demonstrates moderate to high reliability in 2021 data set.	• None identified

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	**Challenge Factors**
Scientific Acceptability, Validity	• Thresholds reflect the best evidence-based minimum threshold for adequate dialysis for the described patient groups. • The facility has responsibility to continue reaching out to non-compliant patients for the purpose of improving their quality of care. • "Comprehensive" specifications (adult/pediatric, hemodialysis/peritoneal dialysis) allow program to evaluate the care provided to a greater proportion of ESRD patients, particularly pediatric ESRD patients.	• Concern about the strength of evidence supporting the pediatric hemodialysis and peritoneal dialysis Kt/V thresholds established under this measure. • Concern about the impact of peritoneal dialysis patients' noncompliance with treatment protocols on facility performance. • Incremental hemodialysis is a viable option for initiating dialysis in selected pediatric patients. • Incremental PD was beneficial for preserving RRF and showed similar patient survival when compared to conventional full-dose PD. • The dialysis patient might benefit more if, instead, the nephrology community concentrates in the future on pursuing the optimal dialysis dose that conforms with adequate quality of life and on factors that are likely to affect outcomes more than Kt/V. • Pediatric ESRD status may be a "moderator" for entities with low volume of pediatric patients because these facilities may be less familiar with how to best manage dialysis treatments for pediatric patients. • The "pooling" approach does not account for differences across groups in the effort to achieve adequate dialysis. • Transparency provided for pediatric and home dialysis metrics will be lost and the larger adult and hemodialysis populations.
Feasibility	• Data elements needed for this measure are collected using End-stage Renal Disease Quality Reporting System (EQRS).	• There are other tests - more expensive - which would be better indicators of dialysis adequacy than Kt/V.

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
	• Facilities are already familiar with the use and functionality of EQRS because they are using it to report data for other measures in the ESRD QIP.	
Usability	• Adopting standardized protocols based on evidence-based guidelines can help in ensuring that patients receive adequate dialysis. These can include protocols on the duration of dialysis, frequency, and flow rates. • Modern dialysis facilities often use data management systems that collect, analyze, and present data on patients' treatments. This data can be used to adjust treatment protocols for individual patients and ensure they are receiving an adequate dose of dialysis. • Periodic assessments using metrics like Kt/V (a measure of the efficacy of dialysis) can help in ensuring that patients receive adequate dialysis.	• A recent audit of hemodialysis adequacy best practices found that most audit criteria were less than 77% at baseline. Opportunities to improve the compliance rates for nurses included receiving education regarding hemodialysis, checking the prescription order for each patient at each session, and using the prescribed dialyzer for every session. Other opportunities included completing pre-hemodialysis checks, using a sterile technique when inserting an arteriovenous catheter, matching a blood flow rate with the prescription, and maintaining a blood flow rate throughout the treatment session. • Having residual kidney function should lessen the requirement for hemodialysis. However, major barriers hinder reducing hemodialysis time, frequency, or both for patients with residual kidney function, including the difficulty of the required dosing calculations. Recent mobile phone applications (app) may simplify estimating the treatment time required to reach target Kt/V. In principle, the QIP does not pose a barrier to reducing treatment frequency, because adequacy reporting is not required for patients dialyzed twice weekly. However, twice-weekly treatment may prove costly for facilities through reduced revenue from Commercial insurers. • An alternative approach would require continued measurement of stdKt/V. Low values would

Evaluation Criteria	Continued ESRD QIP Use	
	Supporting Factors	Challenge Factors
		suggest that symptoms such as fatigue and poor appetite were due to inadequate toxin removal and alert physicians to poor vascular access function. In many patients, treatment time and frequency would still be determined by the need to remove fluid and inorganic ions. Others might find by experimentation that they feel better with longer treatment, more frequent treatment, or both. However, individual patients who feel well and have adequate volume and inorganic ion control would not be obliged to spend more time on dialysis to achieve a target stdKt/V.
ESRD QIP Program-Level Consideration		
Alternative Measures	• None identified	• None identified

Additional Published Literature Consulted:

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Silva, R.E., Santos, E.C., Justino, P.B., Santos, M.P., Galdino, G., Gonçalves, R.V. and Novaes, R.D., (2021). Cytokines and chemokines systemic levels are related to dialysis adequacy and creatinine clearance in patients with end-stage renal disease undergoing hemodialysis. International Immunopharmacology, 100, p.108154.

Hernandez-Agudelo, S.Y., Musso, C.G., González-Torres, H.J., Castro-Hernández, C., Maya-Altamiranda, L.P., Quintero-Cruz, M.V., Corradino, C., Terrasa, S.A., Aroca-Martínez, G.J. and Cadena-Bonfanti, A., (2021). Optimizing dialysis dose in the context of frailty: an exploratory study. International Urology and Nephrology, 53, pp.1025-1031.

Davies, S.J. and Finkelstein, F.O., (2020). Accuracy of the estimation of V and the implications this has when applying K t/V urea for measuring dialysis dose in peritoneal dialysis. Peritoneal Dialysis International, 40(3), pp.261-269.

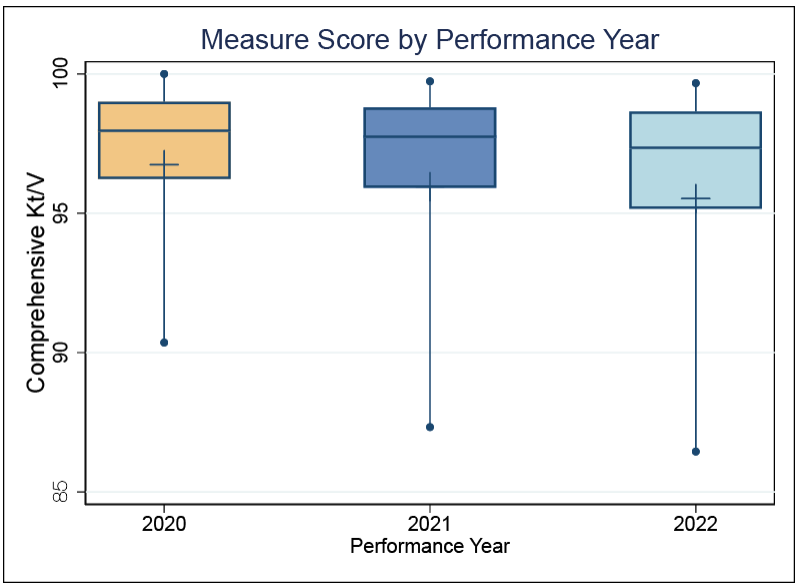

Figure 3.2.15 Measure Score for Kt/V Dialysis Adequacy Comprehensive Measure-HD

Table 3.2.15b. MSR Measure Information Sheet from CMIT for 00407-01-C-ESRDQIP Kt/V Dialysis Adequacy Comprehensive Measure-HD

	Description
Measure Name	Kt/V Dialysis Adequacy Comprehensive
CMIT ID	00407-01-C-ESRDQIP
CMS program in which the measure is used	End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
Additional programs in which the measure is used	N/A
Measure steward	Centers for Medicare & Medicaid Services (CMS)
Cascade of Meaningful Measures Domain	Priority: Chronic Conditions Goal: Improved Disease-Specific Outcomes
Measure type	Intermediate Outcome
Measure developer	Not specified in CMIT
CBE endorsement status	Not Endorsed
History	N/A
Measure description	Percentage of all patient-months for patients whose delivered dose of dialysis (either HD or PD) met the specified threshold during the reporting period.
Level of analysis	Facility/Hospital/Agency
Data sources	Administrative Data (non-claims); Claims Data
Numerator	Number of patient-months in the denominator for patients whose delivered dose of dialysis met the specified thresholds. The thresholds are as follows: 1. Adult HD: spKt/V greater than or equal to 1.2 (calculated from the last measurement of the month using UKM or Daugirdas II). 2. Pediatric In-center HD: spKt/V greater than or equal to 1.2 (calculated from the last measurement of the month using UKM or Daugirdas II). 3. Adult Peritoneal dialysis: Kt/V greater than or equal to 1.7 (dialytic + residual, measured within the past 4 months). 4. Pediatric Peritoneal dialysis Kt/V greater than or equal to 1.8 (dialytic + residual, measured within the past 6 months).
Denominator	• All adult HD patients who received dialysis greater than two and less than four times a week (adults, greater than or equal to 18 years old), and all pediatric in-center HD patients who received dialysis

	Description
	greater than two and less than four times a week (pediatric, less than 18 years old), and the claim or CROWNWeb did not indicate frequent dialysis. • All patients (both HD and PD) who are assigned to the facility for the entire month and have had ESRD for 90 days or more. • Note, patient age is determined as of the first of the month when Kt/V is reported in CROWNWeb, and as of the claim-from date when Kt/V is obtained from claims.
Denominator exclusions, if applicable	• For new facilities only, the month in which the CCN becomes effective and the following three months (see Section 3.5). • Adult HD patients and pediatric in-center HD patients receiving dialysis less than or equal to 2 times weekly or greater than or equal to 4 times weekly (see Section 3.1.4). • Pediatric home HD patients. When Kt/V is reported in CROWNWeb, pediatric patients are defined as patients less than 18 years old as of the first day of the reporting month. If Kt/V is obtained from claims, pediatric patients less than 18 years old as of the claim-from date are excluded. • Patient-months on ESRD treatment for fewer than 90 days at the beginning of the reporting month when using CROWNWeb as the Kt/V data source. If claims are used as the data source, the 90 days on ESRD treatment is determined based on the claim-from date, representing the start of when care was provided. • Patients who changed dialysis modality during the month. Note: For adult HD patients, a change from in-center to home HD (or vice versa) is not considered a modality change. Modality determination is described in Section 3.1.1. • Patients who were not assigned to the facility for the entire month due to death or discharge for one of the following reasons: discontinued, involuntary discharge, transplant, or other reasons for leaving dialysis (see Section 3.1.5). • Patients who were not assigned to the facility for the entire month due to transfer to a different facility. • Criteria for selecting claims and their Kt/V values: A HD claim is considered eligible if it is for an in-center HD (adult or pediatric) or adult home HD patient and meets all three of the following conditions: • The patient has had ESRD for at least 90 days as of the claim-from date; • The home HD patient is at least 18 years old as of the claim-from date; and • The claim is neither a "frequent" dialysis claim nor an "infrequent" dialysis claim, as described in Section 3.1.4.

	Description
	A PD claim is considered eligible if it is from a PD patient who had ESRD for at least 90 days. If there are multiple claims for a patient during a month, the last valid claim is the eligible claim with the latest claim-from date. For a HD patient, if multiple Kt/V values are reported on the last eligible claim, then these decision rules are used to select the Kt/V value: • First, select the highest numeric Kt/V value that is not 8.88 or 9.99. • Second, select 8.88 if reported and no other valid value is reported. • Third, select 9.99 if reported and no other value is reported. For HD patients, the reported spKt/V should not include residual renal function. For a PD patient, the last eligible claim with a Kt/V value that is not expired (i.e., the Kt/V occurrence date is less than or equal to four months prior to the end of the claim for an adult, six months prior to the end of the claim for pediatric) is selected when there are multiple claims reported in a month. If multiple eligible claims are submitted for a patient in the same month and there is at least one Kt/V=9.99 and at least one Kt/V not equal to 9.99 then the claims with Kt/V 9.99 are considered ineligible. Claims reported during ECE months will not be used in calculations.
Numerator exceptions, if applicable	N/A
Denominator exceptions, if applicable	N/A
Risk adjustment, if applicable	No
Performance data	Appendix A
Related measures in other programs	Information not available.
Summary of measure's feasibility	Information not available
Scientific acceptability: validity testing	N/A
Scientific acceptability: reliability testing	N/A

Data for performance years 2020–2022 in Appendix A.

Appendix A: Performance Data for ESRD Measures

Table A.1. ESRD QIP Measure rate performance trends, Performance Year (PY) 2020-2022

Measure Rate	Performance Year	Number of Facilities Reporting	Mean	Std Dev	Percentile						
					5th	10th	25th	Median	75th	90th	95th
Standardized Fistula Ratio (SFR)	2020	7,131	62.27	11.33	43.17	47.98	55.29	62.82	69.97	76.09	79.5
	2021	7,282	61.03	12.17	41.55	46.84	54.23	61.97	69.09	74.94	78.51
	2022	7,189	59.91	11.96	40.15	45.44	52.85	60.84	67.78	73.95	77.63
Standardized Transfusion Ratio (STrR)[8]	2020	5,635	0.97	0.68	0.22	0.33	0.56	0.86	1.23	1.68	2.06
	2021	6,069	0.97	0.67	0.21	0.31	0.55	0.84	1.24	1.7	2.05
	2022	5,799	0.95	0.68	0.19	0.28	0.51	0.83	1.24	1.75	2.12
Hypercalcemia reporting[9]	2020	7,306	0.64	2.05	0	0	0	0	0.77	1.69	2.49
	2021	7,509	1.07	3.91	0	0	0.08	0.44	0.99	1.8	2.67
	2022	7,424	1.12	3.44	0	0	0.13	0.51	1.13	2.06	3.08
NHSN Bloodstream Infection (BSI) ratio	2020	0	.	.	.	.	.	.	.	.	.
	2021	6,363	0.42	0.51	0	0	0	0.29	0.6	1.03	1.34
	2022	6,517	0.37	0.49	0	0	0	0.25	0.53	0.91	1.29

[8] Converted to clinical measure for PY 2026.

[9] Converted to reporting measure PY 2025.

NHSN Dialysis Event reporting	**2020**	**7,104**	**97.67**	**13.42**	**100**	**100**	**100**	**100**	**100**	**100**	**100**
	2021	7,190	97.95	11.97	100	100	100	100	100	100	100
	2022	7,060	97.75	12.8	100	100	100	100	100	100	100
Ultrafiltration Rate (UFR) reporting	2020	7,102	59.2	31.24	0	16.67	33.33	66.67	83.33	100	100
	2021	7,185	97.32	10.02	94.06	96.84	98.34	99.17	99.61	99.88	100
	2022	7,087	97.09	8.56	90.38	94.91	97.77	99.1	99.6	99.92	100
Medication Reconciliation reporting	2020	7,456	95.36	13.66	76.02	89.52	97.83	99.53	100	100	100
	2021	7,495	94.97	13.76	74.64	88.54	97.13	99.34	99.85	100	100
	2022	7,445	94.66	13.72	72.22	86.56	96.32	99.35	99.88	100	100
Clinical Depression reporting[10]	2020	7,589	98.52	10.55	98.33	100	100	100	100	100	100
	2021	7,684	97.77	11.38	95.24	97.44	99.19	100	100	100	100
	2022	7,605	98.34	10.73	97.62	98.86	100	100	100	100	100
Comprehensive Kt/V	2020	7,427	96.74	5.02	90.36	93.51	96.23	97.91	99	99.65	100
	2021	7,592	95.95	7.01	87.33	92.5	95.91	97.7	98.8	99.45	99.73
	2022	7,500	95.53	7.16	86.45	91.49	95.16	97.3	98.65	99.39	99.67
Standardized Readmission Ratio (SRR)[11]	2020	7,038	0.99	0.34	0.43	0.57	0.77	1.00	1.21	1.41	1.55
	2021	7,367	0.99	0.31	0.49	0.60	0.80	1.00	1.19	1.36	1.49
	2022	7,265	26.44	8.35	12.66	16.18	21.27	26.5	31.63	36.48	39.74
Percent of Prevalent Patients Waitlisted (PPPW)	2020	7,399	16.7	10.7	2.97	5.27	9.38	14.68	22.02	30.44	37.23
	2021	7,563	16.62	10.51	3.40	5.36	9.30	14.61	21.79	30.13	36.79
	2022	7,472	16.61	10.51	3.26	5.41	9.34	14.54	21.8	30.06	36.66

[10] Converted to clinical measure PY 2025.

[11] SHR and SRR changed from ratio to rate in PY 2024 (Performance Year 2022).

Standardized Hospitalization Ratio (SHR)	2020	7269	1.00	0.29	0.58	0.66	0.81	0.97	1.16	1.37	1.50
	2021	7,466	1.00	0.29	0.57	0.66	0.81	0.98	1.17	1.37	1.50
	2022	7,462	143.91	41.16	82.24	95.3	116.45	140.88	167.36	196.06	215.6
Long-Term Catheter Rate (LTC)	2020	7,131	7.02	4.15	1.56	2.56	4.23	6.37	9.09	12.22	14.44
	2021	7,282	15.01	9.13	4.3	6.05	9.18	13.4	18.89	25.09	30.07
	2022	7,189	16.55	9.26	5.07	7.13	10.58	15.03	20.43	27.5	33.33
ICH CAHPS[12]: Nephrologists' Communication and Caring	2020	407	66.73	8.78	51.29	56.01	61.15	67.25	72.51	77.84	79.74
	2021	1,478	67.47	9.17	52.31	55.73	61.48	68.33	73.55	78.59	82.11
	2022	2,031	66.52	9.01	51.31	54.84	60.77	66.72	72.88	77.65	80.94
ICH CAHPS: Quality of Dialysis Center Care and Operations	2020	407	62.98	7.41	50.41	52.27	58.64	63.23	68.22	72.44	74.16
	2021	1,478	63.16	7.93	49.32	52.64	58.02	63.5	68.51	73.21	76.00
	2022	2,031	63.05	7.71	49.58	52.72	57.95	63.22	68.37	72.83	75.38
ICH CAHPS: Providing Information to Patients	2020	407	79.01	5.95	68.91	71.29	74.6	79.18	83.23	86.59	88.16
	2021	1,478	79.53	6.04	68.93	71.75	75.63	79.81	83.81	87.03	88.79
	2022	2,031	78.76	5.91	68.43	70.81	74.86	79.13	82.84	85.89	87.66
ICH CAHPS: Rating of the nephrologist	2020	407	59.74	11.47	39.48	45.85	52.42	60.47	67.48	73.75	77.05
	2021	1,478	61.00	11.75	40.03	45.37	52.99	61.97	69.40	75.43	78.69
	2022	2,031	59.30	11.76	38.77	43.73	51.52	59.64	67.82	74.30	77.5
ICH CAHPS: Rating of dialysis center staff	2020	407	64.71	11.32	44.17	49.47	57.83	65.66	72.47	77.79	80.91
	2021	1,478	64.13	12.52	41.65	47.24	55.86	65.24	72.61	79.62	83.13
	2022	2,031	63.83	12.45	41.67	47.12	55.83	64.86	72.59	78.86	82.51

[12] ICH CAHPS scores reported here by domain but discussed in evaluation as composite.

ICH CAHPS: Rating of the dialysis facility	**2020**	**407**	**69.02**	**11.82**	**45.84**	**52.26**	**61.52**	**70.16**	**77.52**	**83.03**	**86.50**
	2021	1,478	68.34	12.77	45.59	50.20	60.20	69.56	77.52	83.66	87.29
	2022	2,031	68.30	13.00	44.61	50.28	59.91	69.42	78.00	84.09	87.85


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