

National Consensus Development and Strategic Planning for Health Care Quality Measurement

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

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Executive Summary

This Measure Set Review (MSR) Recommendations Report provides a detailed overview of the interested party consensus recommendations to retain or remove measures from the End-Stage Renal Disease Quality Incentive Program (ESRD QIP). The MSR Recommendation Group based these recommendations on public comments received both verbally and in writing as well as a robust discussion during the hybrid in-person/virtual MSR meeting on October 17, 2023, in Baltimore, MD.

The goal of the MSR process is to optimize the Centers for Medicare & Medicaid Services (CMS) quality programs' measure portfolio via recommendations to retain or remove measures. These recommendations are based on the measure's properties, performance trends, and whether the measure continues to support a given program's needs and priorities. Recommendation Group members also considered how the removal of an individual measure may potentially reduce redundancy or create a measurement gap.

Prior to the MSR meeting, Recommendation Group members received a preliminary analysis of the 15 ESRD QIP measures in the <u>2023 Measure Set Review (MSR): End-Stage Renal Disease</u> <u>Quality Incentive Program (ESRD QIP) Report</u> and were asked to submit initial feedback on potential benefits and risks of retention or removal for each measure to drive discussion questions during the October 17 meeting. Twenty-one of the 23 MSR Recommendation Group members attended the meeting either in person (13) or virtually (8) through the Zoom meeting platform to discuss the measures and vote for recommendations. These members represented the interested parties shown in Figure 1 and were joined by CMS and Partnership for Quality Measurement (PQM) representatives from Battelle, the Institute for Healthcare Improvement, and Rainmakers.

Figure 1. Measure Set Review Meeting Attendance



Members discussed measures in the following ESRD-specific domains: Clinical Care, Reporting, Care Coordination, Patient and Family Engagement, and Patient Safety. Table 1 shows the vote counts by measure. MSR Recommendation Group members had the option to vote to recommend a measure be retained in ESRD QIP or to recommend that it be removed from ESRD QIP. Members voted in real time via the Voteer platform to enable both in-person and virtual attendee votes.

CMIT ID	Measure Title	Retain	Remove	Recusals
00314-01C- ESRDQIP	Hemodialysis Vascular Access Type: Standardized Fistula Rate	2 (10%)	19 (90%)	0
00313-01-C- ESRDQIP	Hemodialysis Vascular Access: Long-term Catheter Rate	18 (90%)	2 (10%)	0
00698-01-C- ESRDQIP	Standardized Transfusion Ratio (STrR)	14 (74%)	5 (26%)	0
00407-01-C- ESRDQIP	Kt/V Dialysis Adequacy (Comprehensive)	16 (84%)	3 (16%)	1
00360-01- CESRDQIP	Hypercalcemia	16 (89%)	2 (11%)	0
00733-01- CESRDQIP	Ultrafiltration Rate (UFR)	1 (5%)	20 (95%)	0
00440-01-C- ESRDQIP	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec)	16 (76%)	5 (24%)	0
00461-02-C- ESRDQIP	National Healthcare Safety Network (NHSN) Dialysis Event	16 (76%)	5 (24%)	0
00672-03-C- ESRDQIP	Clinical Depression Screening and Follow-Up	13 (65%)	7 (35%)	0
00180-01- CESRDQIP	COVID-19 Vaccination Coverage Among Healthcare Personnel	13 (65%)	7 (35%)	0
00697-01- CESRDQIP	Standardized Readmission Ratio (SRR) for dialysis facilities	13 (68%)	6 (32%)	0
00695-01-C- ESRDQIP	Standardized Hospitalization Ratio (SHR)	14 (74%)	5 (26%)	0
00546-01-C- ESRDQIP	Percentage of Prevalent Patients Waitlisted (PPPW)	12 (63%)	7 (37%)	0
00381-02-C- ESRDQIP	CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey	14 (78%)	4 (22%)	0
00458-01-C- ESRDQIP	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients	17 (100%)	0	0

Table 1. MSR Recommendation	Group Vote Counts	per Measure (ESRD QIE	October 2023)
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During the course of the day's discussions, Recommendation Group members voiced interest in seeing progress made in the areas of equity across multiple social determinants of health, flexibility in measure specification to account for patient choice and personalized medicine, risk adjustment and measure exclusions that reflect real-world care scenarios, consideration of the unique needs of rural communities, and exploration of ways to increase measure utility to patients and measured entities.

Chapter 1. Measure Set Review (MSR) Overview

For the 2023 MSR process, Battelle focused on a specific CMS Medicare quality program (i.e., End-Stage Renal Disease Quality Incentive Program) rather than a priority area from the Cascade of Meaningful Measures. This allowed us to pilot our consensus-building approach with the MSR committee through a lens that is more familiar to its members. In future years, we will shift to a more holistic approach as described in the <u>Guidebook of Policies and Procedures</u> for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR).

1.1 ESRD QIP Overview

The ESRD QIP is authorized by section 1881(h) of the Medicare Improvements for Patients and Providers Act (MIPPA).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 in <u>42 CFR 413.177</u> and <u>413.178</u>. The technical specifications for ESRD QIP measures are available for review on the <u>CMS website</u>. 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 ESRD prospective payment system (PPS) proposed rule, which includes several updates for the ESRD QIP, which are presented in Table 1.

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.	

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

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

During CY 2020, measures within ESRD QIP, as well as other CMS quality reporting programs, were part of a measures suppression policy because CMS "determined that circumstances caused by the public health emergency (PHE) due to COVID-19 have significantly affected the measures and resulting performance scores." While measure scores were suppressed, measure rates were displayed with suppressions for specific months relevant to the PHE.³ While the suppression policy impacted the QIP scoring, facilities still reported data to CMS. More information on this measure suppression policy in relation to ESRD QIP can be found in the 2022 Final Rule as well as the <u>ESRD COVID FAQ document</u>.

1.2 MSR Recommendation Group Composition

Battelle staff conducted a public call for nominations and targeted outreach to solicit nominees for Pre-Rule Making Review (PRMR) committees. Battelle prioritized individuals who had previously participated in similar panels/committees or had a demonstrated knowledge of these processes; fit into more than one roster category; and possessed lived experience interacting with the health care system. Battelle considered members with often under-represented voices, including individuals with relevant background and experience who may not have had an opportunity to participate in these processes before. Battelle's goal was to create an inclusive Recommendation Group that balanced experience, expertise, and perspectives. Members were selected to serve on the MSR Recommendation Group from among those chosen to serve on PRMR Recommendation and Advisory Groups based on experience and suitability to the ESRD QIP review.



Figure 2. MSR Recommendation Group Interested Parties

During the October 17 meeting, 21 of the 23 MSR Recommendation Group members attended either in person (13) or virtually (8) through the Zoom meeting platform. Measure developers and stewards of ESRD QIP measures, members of the public, and representatives of relevant

³ End-Stage Renal Disease Quality Incentive Program (ESRD QIP) Frequently Asked Questions: Exceptions for Dialysis Facilities Affected by COVID-19. <u>ESRD QIP COVID 19 FAQs (cms.gov).</u>

federal agencies joined virtually. Representatives from CMS were in attendance in person to contribute to meeting facilitation and virtually to provide program context when needed.

1.3 Prior to ESRD QIP Measure Set Review Meeting

Battelle conducted preliminary assessments (PAs) for each measure within the ESRD QIP. The PAs 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 whether a measure was impactful, meaning it was found to be important, reliable, valid, feasible, and usable across programs and populations based on measure information and data provided. Measures were additionally considered against the eight removal factors used in prior MSR cycles to justify removal from CMS programs. These removal factors were used to guide committee members understanding of historical rationale for removing measures from CMS in years prior but were not used as stand-alone removal criteria for ESRD-QIP in this cycle.

The PA report identified factors supporting and challenging the continued inclusion of each measure in ESRD QIP. The supporting factors included strong evidence in the literature related to a measure's impact on clinical outcomes, high scientific acceptability scores, ease of implementation, and strong evidence of measure usability. The factors challenging continued inclusion in the program included new evidence challenging measure importance, changes to clinical guidelines, low scientific acceptability, implementation challenges, and unintended consequences of use. Members of the MSR Recommendation Group reviewed the MSR Draft Report and completed a worksheet for each of the 15 ESRD QIP measures.

After Battelle completed the preliminary assessment report, it was published on the PQM website for a second public comment period for 15 days. Battelle staff summarized public comment feedback and provided it to MSR Recommendation Group members, CMS, and the general program as an appendix in the final posted preliminary analysis report and part of the material for the meeting discussion.

1.4 ESRD QIP Measure Set Review Meeting

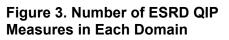
Battelle staff convened the MSR Recommendation Group for the 2023 MSR Meeting on October 17, 2023, in Baltimore, MD, to review the ESRD QIP measure set.

These members represented the interested parties shown in Figure 1 and were joined by CMS and PQM representatives from Battelle, the Institute for Healthcare Improvement and Rainmakers.

Dr. Nicole Brennan, PQM Executive Director, welcomed the attendees to the meeting and introduced her co-facilitator and PQM Technical Director Ms. Brenna Rabel. Recommendation Group co-chairs Mr. Reginald Barnes and Dr. Kamyar Kalantar-Zadeh each shared their relevant patient and clinician perspectives and motivation for serving in this role. Several attendees represented the CMS both in person and virtually, including Dr. Michelle Schreiber, the Deputy Director of the Center for Clinical Standards and Quality for the Centers. Dr. Schreiber noted that CMS was present to serve as a resource and welcomed members and participants.

Members discussed measures in the following domains: Clinical Care (4), Reporting (6), Care Coordination (3), Patient and Family Engagement (1), and Patient Safety (1).

MSR Recommendation Group members could vote to recommend a measure be retained in ESRD QIP or to recommend that it be removed from ESRD QIP. Members voted in real time via the Voteer platform to enable both in-person and virtual attendee votes. The discussion quorum required the attendance of at least 60% of the Recommendation Group members during roll call at the beginning of the meeting.





The voting quorum required at least 80% of active Recommendation Group members who did not recuse themselves from the vote. During the daylong meeting, some members stepped away temporarily, so Battelle collected voting counts for each measure to ensure we retained quorum. A simple majority of greater than 50% of voting members was required for determination of the vote outcome.

At the beginning of each domain discussion, CMS ESRD representative Dr. Stephanie Clark gave an overview of the history of each measure's use in federal reporting programs. Members of the public had the opportunity to provide verbal or written comment via Zoom on any of the measures within that domain for the Recommendation Group's consideration. Throughout the public comment opportunity and subsequent measure discussions, two Battelle moderators coordinated virtual attendees' participation by voicing written comments and organizing a queue of virtual attendees who wished to unmute and contribute verbally.

Chapter 2. ESRD QIP MSR Recommendations

2.1 Clinical Care Domain

2.1.1 Hemodialysis Vascular Access Type: Standardized Fistula Rate (SFR) – <u>CMIT ID:</u> 00314-01-C-ESRDQIP

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

Summary of Written Public Comment⁴: National Kidney Foundation supports removal and suggests that this removal will better align care with the Kidney Disease Outcomes Quality Initiative (KDOQI) Vascular Access Clinical Practice Guideline 2019 Update and implementation tools.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Remove from ESRD QIP.

Vote Count: Retain (2), Remove (19), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 Recommendation Group members reviewed the evidence and history of the "fistula first" approach to hemodialysis vascular access to minimize the use of catheters. Recommendation Group members expressed concern around the evidentiary support of this measure, citing changes in clinical guidelines, lack of randomized controlled trials showing sustained benefit to a fistula first approach, and the endorsement removal in 2020 based on evidence concerns.
Statutorily Required Category	• The Recommendation Group sought clarification from CMS representatives in attendance on the statutory requirement for a vascular access measure in ESRD QIP and discussed the impact of removal.
Validity & Usability	 Recommendation Group members reviewed evidence on the lower infection rate among fistula users compared with long-term catheter use. While infection rates and hospitalizations were lower for patients with an AVF than those with a catheter, attendees also noted that AVF patients often underwent more surgeries over time. Recommendation Group members also noted that the cost to insurers and patients across the types of vascular access varies and that cost containment is an additional secondary consideration.
Equity	• On the topic of equity, multiple members asked for clarity from CMS on the availability of data on the performance of this measure across patient populations and emphasized the role of patient education and choice in addressing equity gaps.

⁴ A complete record of all written public comment received for all ESRD QIP Measures during this MSR cycle can be found in Appendix C of the <u>Final MSR Report</u> at <u>www.p4qm.org</u>

Evaluation Themes	Recommendation Group Member Discussion
Patient Engagement	 Recommendation Group members expressed concern that patient choice was not adequately reflected in the measure. Recommendation Group members noted a frequent lack of patient education and engagement in the decision of vascular access type as well as a failure to consider personal goals and wishes for quality of life.

The Recommendation Group voted to recommend removing this measure from ESRD QIP. They also suggested that any future revision of the measure include fistula or graft to be more responsive to patient choice and personalized medicine.

Potential Impacts of Measure Removal:

The Recommendation Group sought clarification on the statutory requirement for a vascular access measure in ESRD QIP from CMS members in attendance. Members discussed how both this SFR measure and the Long-Term Catheter Rate measure both fulfil this purpose. Recommendation Group members weighed the potential benefits and harms of recommending removal of this measure. While recognizing the importance of a vascular access measure, the group ultimately voted to recommend removal due to concerns around the evidence base and lack of patient choice reflected in the measure.

2.1.2 Hemodialysis Vascular Access: Long-term Catheter Rate – <u>CMIT ID: 00313-01-C-</u> <u>ESRDQIP</u>

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for 3 months or longer for vascular access.

Summary of Written Public Comment: The National Kidney Foundation supports retention.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (18), Remove (2), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	• The Recommendation Group reviewed the benefits and risks of long- term catheter use in hemodialysis, noting the increased risk of infection for this type of vascular access.
Data	 One Recommendation Group member asked about the missing data being assumed to be catheter use. A representative from CMS noted the percentage of missing data is less than 2%.
Feasibility	 A patient member joining virtually asked how high burden data collection is, and it was later confirmed data collection is a low burden. The group discussed feasibility concerns around data collection and staff availability.
Statutorily Required Category	• The Recommendation Group sought clarification from CMS representatives in attendance on the statutory requirement for a vascular access measure in ESRD QIP and discussed the impact of removal.

Evaluation Themes	Recommendation Group Member Discussion
Equity	 A representative who works in a community with limited resources noted that patients often do not realize they have kidney disease until they walk into the facility and there is little time for proper education about the risks of long-term use of the catheter. The group considered the potential for this measure to penalize facilities that serve a greater percentage of marginalized or underserved communities where disease detection may be delayed. Recommendation Group members noted the importance of collecting sociodemographic data and explained the importance of patient choice in care decisions. Several Recommendation Group members encouraged the developer to explore risk adjustment and/or stratification for this measure to best reflect equity concerns.
Quality of Life	• Several Recommendation Group members and attendees shared the patient and caregiver perspective on catheter access and noted that catheters place more constraints on activities of daily living and quality of life.
Patient Engagement	 Recommendation Group members noted educating the patient on the risks of long-term catheter use is critical. Recommendation Group members noted that while a minority of patients may choose catheter access as a first option, these patients tend to be older, have multiple comorbidities, experience complications, and have advanced stages of disease at first detection. Patients and equity experts in attendance agreed that the measure should be risk adjusted and asked the group to consider if patients are ever denied treatment.

The Recommendation Group encouraged CMS and measure developers to explore risk adjustment for this measure to better address equity concerns.

Potential Impacts of Measure Removal:

The Recommendation Group sought clarification on the statutory requirement for a vascular access measure in ESRD QIP from CMS members in attendance. Recommendation Group members weighed the potential benefits and harms of recommending removal of this measure. The group ultimately voted to recommend this measure be retained in ESRD QIP due, in part, to the statutory requirement for a vascular access measure as well as recognition that the benefits of the measure outweigh the potential challenges.

2.1.3 Standardized Transfusion Ratio (STrR) - CMIT ID: 00698-01-C-ESRDQIP

Description: Dialysis facility reporting of data on Medicare claims and in End-stage Renal Disease Quality Reporting System (EQRS) 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.

Summary of Written Public Comment: The National Kidney Foundation supports retention. The National Forum of ESRD Networks recommends that the STrR remain a reporting measure. The National Forum of ESRD Networks Kidney Patients Advisory Council has expressed concern that the current STrR measure may have the unintended consequence of causing harm to patients by incentivizing facilities to avoid transfusing patients suffering from anemia when transfusions may be clinically indicated. In acknowledgment of the statutory requirement for an anemia measure in the QIP, commenter suggests replacing this measure with a measure of percentage of prevalent patients (on hemodialysis for > 90 days) treated with ESAs with hemoglobin (Hgb) 9.0 to 12.0 g/dL.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (14), Remove (5), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	• The Recommendation Group reviewed the clinical importance of anemia management for dialysis patients and the evidence base for the measure.
Measure Exclusions	 One clinician requested clarification on whether measure exclusions consider the circumstances of the transfusion, such as emergency care in the intensive care unit (ICU). A member noted that while these cases may be less frequent, the measure specification currently does not differentiate by transfusion rationale. Recommendation Group members considered what exclusion additions could improve use of the measure in future. One clinician member voiced support for a measure exclusion that considers transfusion volume and rationale.
Statutorily Required Category	 The Recommendation Group noted that ESRD QIP has a statutory requirement for an anemia management measure, and that this measure meets that requirement for the program. The Recommendation Group explored this measure as a "proxy" for anemia management and considered alternative measure targets that may more directly measure anemia, such as iron.
Validity & Reliability	 The Recommendation Group discussed measure validity in past National Quality Form (NQF) maintenance review and asked the developer, attending virtually, to explain validity testing methodology during measure development. The Recommendation Group considered the moderate reliability in available data for this measure and considered sources of variation. Recommendation Group members discussed facility-level variation and encouraged the implementation of anemia protocols at the facility level to improve standardization of care.
Usability	• Recommendation Group members discussed usability of the measure and the potential for unintended consequences including delayed transfusions and a lack of shared clinical decision-making with patient engagement.
Alternative Measures	• In looking for a more direct measure of anemia management, the Recommendation Group briefly discussed the potential utility of iron as a measure target.

Additional Considerations for CMS and Future Directions:

The Recommendation Group explored opportunities for additional exclusions to better reflect the reason for transfusion and considered the potential for conversion to a reporting measure in future. They encouraged CMS to explore the development of new measures that more directly target anemia management and encouraged the implementation of anemia protocols at the facility level to improve standardization of care.

Potential Impacts of Measure Removal:

The Recommendation Group considered the potential impacts of recommending removal of this measure and recognized that it fulfills the anemia management statutorily required measure category. The Recommendation Group discussed concerns that measure removal could impact clinical practice and ultimately voted to recommend measure retention in ESRD QIP.

2.1.4 Kt/V Dialysis Adequacy (Comprehensive) – CMIT ID: 00407-01-C-ESRDQIP

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

Summary of Written Public Comment: The National Kidney Foundation supports removal due to challenging factors identified regarding the importance, scientific acceptability, validity, feasibility, and usability evaluation criteria. Commenter recognizes attainment of Kt/V targets are very high, so there is lack of room for improvement with this measure. The National Kidney Foundation & National Forum of ESRD Networks recommend that CMS establish a technical expert panel (TEP) that includes patient input to explore the current evidence and make specific recommendations that recognize that incident dialysis patients, patients with a recently failed kidney transplants, and prevalent patients with significant residual native renal function might benefit from different spKt/V corrected for residual function thresholds or other appropriate measure of dialysis adequacy. The National Forum of ESRD Networks believes that the use of exclusive HD Kt/V without accounting for residual kidney function (RKF) could adversely impact hemodialysis patients and their outcomes and that perceived contrast between PD and HD dialysis adequacy requirements and reporting could cause confusion. The National Forum of ESRD Networks also recommend endorsing the use of RKF when calculating spKt/V in the hemodialysis population and would otherwise recommend against adopting added weight to the dialysis adequacy measure if RKF is not added out of concern for patient kidney health and the disproportionate impact it has on smaller dialysis facilities.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (16), Remove (3), Recusal (1).

Evaluation Themes	Recommendation Group Member Discussion
	 Patients expressed strong support for this measure, with a recognition of the importance of capturing whether dialysis is occurring at a basic level. The measure was also viewed as important for gathering data on access to care, equity, and treatment adequacy. Attendees explored the relevance of this measure and weighed the need for capturing whether dialysis is occurring with the desire for clinical measures that allow the quality of that dialysis to be examined. CMS shared plans for inclusion of dialysis time alongside this adequacy measure in 2025.
Statutorily Required Category	 The Recommendation Group noted that there is a statutory requirement for a dialysis adequacy measure in ESRD QIP and that this measure meets that requirement for the program.

Evaluation Themes	Recommendation Group Member Discussion
Rural Health	 Representatives for rural health facilities as well as patients and clinicians from traditionally underserved communities shared their perspectives on how this measure could be used to identify care access gaps and move progress on health equity. One member shared the perspective from working in dialysis facilities that serve a small number of patients. They expressed concern that any variability in whether patients were able to access their sessions may skew the rate more strongly given the small number of patients in that facility.
Usability •	 The group engaged in a robust discussion around the consideration of "adequacy" in this measure given that only one session a month is required for the reporting threshold. Several Recommendation Group members expressed interest in seeing this potentially converted to a reporting measure in future due to high reporting rates and current measure specification that captures dialysis on a basic level.
Equity •	Recommendation Group members agreed that, in future, more information on how this measure performs across patient populations and urban/rural settings is needed to address equity concerns.

The Recommendation Group had an extensive conversation about additional considerations for CMS and future direction for this measure. Recommendation Group members expressed interest in seeing this potentially converted to a reporting measure in future. This was based on the recognition that this measure has very high reporting rates but lacks the additional specification to measure true dialysis adequacy beyond whether it occurred on a basic level. Recommendation Group members encouraged developers to consider revisions of this measure that utilize both quantitative and qualitative methods and better reflect patient perspectives on how adequate dialysis is defined.

Potential Impacts of Measure Removal:

The Recommendation Group considered the potential impacts of recommending removal of this measure and recognized that it fulfills the dialysis adequacy statutorily required measure category. The Recommendation Group ultimately voted to recommend measure retention in ESRD QIP.

2.2 Reporting Domain

2.2.1 Hypercalcemia - CMIT ID: 00360-01-C-ESRDQIP

Description: 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.

Summary of Written Public Comment: The National Kidney Foundation supports retention.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (16), Remove (2), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 The Recommendation Group considered some of the evidence around cardiovascular harms that this measure seeks to prevent.
Statutorily Required Category	• The Recommendation Group noted that the measure fulfils the statutorily required bone and mineral disease requirement.
Usability	 While considering benefit and harm trade-offs, attendees discussed the usability of the reporting measure and explored the potential for early detection of cancers through calcium reporting.
Equity	 In discussing equity implications of this measure in practice, a clinician member shared an anecdote from their experience of a facility-level strategy to transfer patients who negatively impacted the measure score due to comorbidities and complications to alternate facilities.
Alternative Measures	 In exploring alternative measurement pathways for this required category, the Recommendation Group recognized the relative neutrality of calcium as a target compared to alternative targets such as phosphorus levels that lack clearly agreed-upon thresholds. After discussion, the Recommendation Group failed to identify alternative measures currently developed that could serve as more meaningful replacements.
Patient Engagement	 Recommendation group members explored patient perspectives to examine whether this was the most meaningful measure for patients for this domain. Recommendation group members encouraged developers and CMS to explore opportunities for measures with greater patient value and engagement for future measures in this category.

The Recommendation Group members were interested in a reexamination of the statute requiring a bone mineral metabolism-based measure in ESRD QIP. Additionally, they encouraged developers to thoughtfully consider alternative measure targets other than calcium to fulfill this requirement more meaningfully as either a clinical or reporting measure. Recommendation group members encouraged developers and CMS to explore opportunities for measures with greater patient value and engagement for future measures in this category.

Potential Impacts of Measure Removal:

The Recommendation Group considered the potential impacts of recommending removal of this measure and recognized that it fulfills the bone and mineral disease management statutorily required measure category. The Recommendation Group failed to identify alternative measures currently developed that could serve as more meaningful replacements and determined that the benefits to inclusion outweighed any challenges. The Recommendation Group ultimately voted to recommend measure retention in ESRD QIP.

2.2.2 Ultrafiltration Rate (UFR) - CMIT ID: 00733-01-C-ESRDQIP

Description: Number of months for which a facility reports all required data elements for ultrafiltration rate (UFR) in EQRS 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).

Summary of Written Public Comment: The National Kidney Foundation supports removal, agrees with concerns raised within the challenging factors for this measure, and believes the UFR measure is inappropriate as a performance measure because there is no randomized controlled trial data showing that limiting the UFR to <13 improves patient outcomes.

Summary of Verbal Public Comment from MSR Meeting 10/17: The developer shared that this measure is being retired and they did not submit for maintenance review.

Measure Review Final Vote: Recommendation to Remove from ESRD QIP.

Vote Count: Retain (1), Remove (20), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 Several Recommendation Group members clarified what this measure assesses from a patient perspective and gave examples of the harms that the measure seeks to prevent. Clinician members and an ESRD QIP representative further elaborated on the potential harms caused by shortened dialysis sessions, leading to a more rapid ultrafiltration rate.
Threats to Validity	 In consideration of the evidence for and the validity of this measure, Recommendation Group members discussed the patient-level factors that influence UFR. A clinician Recommendation Group member explained different patient scenarios that may result in a UFR that was outside the recommended threshold, such as patient weight.
Usability	• Recommendation Group members discussed potential unintended consequences of the "one-size-fits-all" approach to UFR, citing the need for inclusion of patient choice and patient-level factors such as comorbidities.
Equity	 Several members expressed concern for potential equity implications of not including patient choice and desired quality of life in the measure. Through an equity lens, attendees discussed how barriers in access to care and competing demands on patient time may influence this measure's use.
Patient Engagement	• Recommendation Group members discussed the lack of individual patient goals and choice in the measure.

Additional Considerations for CMS and Future Directions:

The Recommendation Group emphasized considering patient perspectives and individualized treatment factors and goals in this or any other measure seeking to address dialysis treatment time.

Potential Impacts of Measure Removal:

The Recommendation Group discussed the implications of recommending removal in detail before voting to remove. The Recommendation Group weighed the harms of high UFR dialysis sessions against the unintended consequences of holding all patients to the same UFR threshold as dictated by the measure's current inclusion in ESRD QIP. Ultimately, the Recommendation Group voted to recommend removal based on the current measure's lack of inclusion of patient choice and individualized clinical decision-making as well as the limited current evidence base.

2.2.3 Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) – <u>CMIT ID: 00440-01-C-ESRDQIP</u>

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

Summary of Written Public Comment: The National Kidney Foundation supports retention with future refinement due to recognition that there is no assessment of whether the medication reconciliation was meaningfully performed or accurate.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Evaluation Themes	Recommendation Group Member Discussion
	 Several Recommendation Group members shared personal experiences as patients or caregivers to emphasize the importance of medication reconciliation for patient safety and quality of life. While the Recommendation Group recognized the vital importance of medication reconciliation, members were concerned that the measure as currently used has become a "checkbox" rather than a measure of a meaningful medication reconciliation process. Recommendation Group members expressed that they want to see this measure revised toward a more meaningful and direct measure of effective medication reconciliation process.
Feasibility	 Many attendees voiced concern that current reconciliation processes are challenged by limited electronic health record (EHR) interoperability between clinical facilities and incomplete data on prescription fulfilment at community pharmacies.
Rural Health	• A Recommendation Group member with experience working in rural communities shared their perspective on how vital medication reconciliation is for patients who may see specialists spread over a large geographic area but cautioned that effective medication reconciliation requires information resources and staff that may not be uniformly available.
	 This measure was widely seen as an opportunity to fill holes in the current safety net for dialysis patients and prevent harms. While the Recommendation group members saw ways to strengthen this measure for increased utility and meaningfulness, its current version was not associated with any negative unintended consequences from use.
Alternative Measures	 The Recommendation Group explored how this measure is harmonized across other programs and found no suitable alternative.
	 Recommendation Group members discussed disparities in performance on this measure and, as one attendee voiced, these disparities "underline rather than undermine" the importance of this measure. Members agreed that harms stemming from a lack of effective medication reconciliation is an equity issue, given the burden of harm on patients with lower health literacy and limited access to patient education resources.

Vote Count: Retain (16), Remove (5), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
•	Recommendation Group members currently working in low-resource communities noted staffing and timing challenges that have led to the abbreviated medication reconciliation processes commonly in use.
• Patient	Recommendation Group members expressed interest in this measure being revised to require patient engagement more directly in the medication reconciliation process as an opportunity for filling gaps in patient education.

The Recommendation Group expressed interest in this measure being revised toward a more meaningful and direct measure of effective medication reconciliation processes. When a CMS representative posed the question, "If there was a way to give this measure more 'teeth' but keep it harmonized, would you want that?" much of the room and virtual voting members raised their hands to indicate support. They also suggested that any revision of this measure in future consider the interoperability challenges that smaller and more rural clinics may experience during medication reconciliation.

Potential Impacts of Measure Removal:

The Recommendation Group did not discuss potential impacts of measure removal in detail.

2.2.4 National Healthcare Safety Network (NHSN) Dialysis Event – <u>CMIT ID: 00461-02-</u> <u>C-ESRDQIP</u>

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.

Summary of Written Public Comment: The National Kidney Foundation supports retention with future refinement and raises strong concerns based on the challenging factors identified for scientific acceptability and validity evaluation criteria.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (16), Remove (5), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance •	The Recommendation Group noted that this measure captures instance of reporting of dialysis event only, comparing it to the clinical NHSN bloodstream infection (BSI) measure also in ESRD, which provides a more detailed assessment of dialysis outcomes. Representatives from the CDC joined the discussion as the measure developer and provided a brief history of this measure and its role in incentivizing the 12-month reporting required for the paired BSI measure. Given that the BSI clinical measure requires complete reporting of event data, CMS implemented the measure to incentivize complete and continuous reporting of the types of infection-related events. Several attendees questioned whether this measure lends meaningful value to patient safety and care without being paired alongside the BSI

Evaluation Themes	Recommendation Group Member Discussion
	measure and asked fellow Recommendation Group members to consider—later in the day—whether alterations to the BSI measure could be explored to meet this goal more efficiently.
Feasibility	 Recommendation Group members with experience in dialysis facility reporting explained how this measure's data collection can add to the staff workload without directly informing patient care. Recommendation Group members evaluated the data collection and reporting burden to staff compared with the current benefits to complete reporting of BSI, a topic that had great importance to both clinical and patient group attendees.
Epidemiological Reporting	• After discussion with CMS and CDC representatives as well as a Recommendation Group member with knowledge of national and state reporting infrastructure, it was clear that if this measure were removed, there would be no national record of the events being tracked by this measure.

The Recommendation Group members expressed interest in exploring ways to incentivize the complete reporting necessary to generate the NHSN BSI measure through standards and other CMS-level tools.

Potential Impacts of Measure Removal:

One attendee questioned whether, without this measure, event data of this type would be collected in a standardized and central system. After discussion with CMS and CDC representatives as well as a Recommendation Group member with knowledge of national and state reporting infrastructure, it was clear that if this measure were removed, there would be no national record of the events being tracked by this measure. While some states would continue to collect at the state and local network level for epidemiological purposes, attendees were concerned that removal of this measure from ESRD QIP would eliminate the record of these infection-related dialysis events at the national level, with downstream implications that have not been fully examined to date.

2.2.5 Clinical Depression Screening and Follow-Up - CMIT ID: 00672-03-C-ESRDQIP

Description: Facility reports in EQRS 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.

Summary of Written Public Comment: The National Kidney Foundation Supports retention and notes that innovative reimbursement models are needed to support depression treatment in this population.

Summary of Verbal Public Comment from MSR Meeting 10/17: A member of the public who has experienced dialysis care shared their journey of care and experience with depression. They encouraged the Recommendation Group, developers, and CMS to consider length of dialysis session alongside other factors that may influence depressive symptoms. They also emphasized the importance of considering and screening for somatic depression symptoms and psychological symptoms.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 Recommendation Group members recognized the importance of detecting and intervening in depressive symptoms for overall patient health and wellbeing. The requirement for follow-up planning was discussed by Recommendation Group members, as they questioned whether this requirement was meaningful, given that the measure is satisfied if a follow-up plan is documented.
Validity	 The discussion largely centered around concerns with validity, noting screening tools such as the PHQ-9 may not be accurately capturing data across patient populations and administration methods. Members also considered bias in self-reporting methods versus reporting with the assistance of a trained social worker. Exclusions for severe mental illness were also discussed, with consideration of potential introduced bias given the comorbidity of depression with other psychiatric conditions.
Feasibility	• Recommendation Group members asked questions concerning the use of CPT and G-Codes. A representative from CMS clarified that the current infrastructure has challenges with the codes, thus requiring manual abstraction and linkage processes.
Patient Engagement	• Recommendation Group members reflected on the public comment received during the meeting, asking if dialysis-specific experiences may be related to depression severity.

Vote Count: Retain (13), Remove (7), No Recusals.

Additional Considerations for CMS and Future Directions: The Recommendation Group encouraged CMS and developers to extend future focus on the critical issue of depression among dialysis patients beyond simple screening to more accurate and meaningful measurement of follow-up plan suitability and implementation.

Potential Impacts of Measure Removal:

The Recommendation Group did not discuss potential impacts of measure removal in detail.

2.2.6 COVID-19 Vaccination Coverage Among Healthcare Personnel – <u>CMIT ID:</u> 00180-01-C-ESRDQIP

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

Summary of Written Public Comment: The National Kidney Foundation supports retention.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (13), Remove (7), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 Recommendation Group members asked to clarify how many vaccines/boosters individuals are required to get to be considered up to date. A CMS representative noted an update of this measure with specifications to accommodate changing federal guidelines was in the proposed (now final) rule. A representative from the CDC noted the concept of "up to date" is revised over time as new vaccines become available. An individual would be considered up to date if they have received the 2023-2024 vaccine. A definition of "up to date" is provided each reporting quarter. The developer recognized the challenge of defining "up to date" and explained providers have the option to report and update the record with the latest vaccine if the data is available. Recommendation Group members noted this measure may have imperfect data.
Feasibility	 A Recommendation Group member expressed some concern about the burden put on staff to keep information revised every time the vaccine is updated and asked if there is a better way to track this data on a seasonal basis, such as the way the flu vaccine is tracked. A representative from CMS noted the measure must be tracked separately from a numerator and denominator perspective.
Patient Safety	 A Recommendation Group member noted COVID-19 infection rates have decreased since the beginning of the pandemic and asked about the relevancy of the measure now that there is no longer a mandate to be vaccinated. A patient member of the Recommendation Group noted that while it may be a provider burden to stay up to date with the latest vaccine, COVID-19 is still a major concern for patients. Death rates for ESRD patients during 2020 and 2021 were discussed. A representative from CMS agreed and explained that even though the pandemic was declared over, COVID-19 is still a concern in the ESRD population. Several members reflected on the importance of this measure to patient safety alongside workforce concerns and acknowledged that this measure will have imperfect and missing data.
Equity	• A Recommendation Group member noted health care workers across the U.S. may be required to pay for the vaccine and that this may be a deterrent.

Evaluation Themes	Recommendation Group Member Discussion
	• Another Recommendation Group member agreed, noting the vaccine could cost as much as \$140 per dose, so having access to employee benefits that cover the cost is important.
Alternative Measures	 When asked about harmonization of this measure across programs, a CMS representative noted there are no other immunization measures in the ESRD QIP program, but a composite measure could be considered in the future. CMS confirmed the COVID vaccine for all health care personnel is in almost all CMS programs.

The Recommendation Group voted to retain this measure within ESRD QIP with a recognition that it is harmonized with all other programs. The Recommendation Group encourages relevant parties to consider how best to work within the missing data challenges unique to this measure.

Potential Impacts of Measure Removal:

A Recommendation Group member asked about the relevance of this measure now that there is no longer a mandate to be vaccinated for COVID-19. Several Recommendation Group members noted COVID-19 is still a concern especially in the ESRD population. Recommendation Group members expressed the need to ensure the workforce is vaccinated to take care of patients. A representative from CMS also confirmed the measure is used to ensure health care personnel are vaccinated in almost all CMS programs.

2.3 Care Coordination Domain

2.3.1 Standardized Readmission Ratio (SRR) for Dialysis Facilities – <u>CMIT ID: 00697-</u> 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 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.

Summary of Written Public Comment: The National Kidney Foundation supports retention with future refinement and raises concerns and suggestions for further improvement in the establishment of higher quality transition of care for patients.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (13), Remove (6), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion	
Importance	 The recommendation group paired this discussion with the discussion of the Standardized Hospitalization Ratio (SHR) measure because of the overlap in measure topic, specification, and implementation. 	

Evaluation Themes	Recommendation Group Member Discussion	
	 A patient member of the Recommendation Group noted their expectation when going to the hospital is to receive the best quality of care possible and this measure is a way to track that. A representative from CMS noted the measure is intended to ensure issues are proactively addressed to keep the patient out of the hospital. 	
Validity	 The measure was not endorsed in 2017 due to issues with validity testing. The developer clarified that when validity testing was done, information on different correlation coefficients was presented to the consensus-based entity (CBE), and they were unable to submit additional data for that measure cycle. A Recommendation Group member asked if the measure should be put back through endorsement to evaluate updated validity data. 	
Risk Adjustment	• The group examined the risk adjustment for this measure with patient-level comorbidities and facility-level factors discussed relative to feasibility and equity concerns.	
Equity	 A CMS representative encouraged participants to look at the measure from a care coordination perspective to determine if the system is designed with measures that reinvest in low-income communities. Representatives from facilities that serve populations with a higher prevalence of advanced kidney disease—such as skilled nursing facilities, long-term care facilities, or populations without proper access to care—expressed concern that they may be penalized for facilitating the initial hospitalization and readmission for a patient population with a greater need. 	
Rural	• Representatives from a rural community encouraged CMS to examine how national norms are generated and how the impact of setting measure thresholds may impact rural communities.	

The Recommendation Group encouraged CMS and developers to consider how national norms for setting thresholds and risk adjustment models relate to equity concerns for traditionally underserved populations and facilities in rural communities. Recommendation Group members encouraged CMS to evaluate how the ratio is calculated to address equity concerns and to consider measuring usability at a facility level across regions and population subgroups.

Potential Impacts of Measure Removal:

Recommendation Group members discussed the importance of retaining a measure that ensures patients are receiving proper care. Although equity and the lack of validity testing were brought up as concerns, Recommendation Group members noted that the benefits outweigh the burdens.

2.3.2 Standardized Hospitalization Ratio (SHR) – CMIT ID: 00695-01-C-ESRDQIP

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

Summary of Written Public Comment: The National Kidney Foundation supports retention.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (14), Remove (5), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 The Recommendation group paired this discussion with the discussion of the SRR measure because of the overlap in measure topic, specification, and implementation. A Recommendation Group member with provider experience explained that, as a provider, they do their best to cover all necessary services in one visit but noted due to the high rate of hospitalizations in dialysis patients, this measure is important to prevent unnecessary hospitalizations.
Usability	 A representative from CMS noted both SHR and SRR measures are used in the long-term care settings. If conversations are happening weekly with patients, care can be coordinated to prevent a hospitalization. The developer noted the readmission ratio is the coordination of care after discharge and the hospitalization ratio is based on overall care. There is not a perfect correlation, but together they are complementary and cover both longitudinal and overall care. A Recommendation Group member suggested measuring usability of the measure at the facility level to determine if actionable data for improvement in care are produced. CMS clarified both the SRR and SHR measures are pay for performance and the associated penalties apply. A Recommendation Group member noted they are in favor of retaining a measure where patients not receiving care is brought to light and noted the benefits outweigh the burden.
Risk Adjustment	 A Recommendation Group member asked when and how patient characteristics are considered for this measure. The developer confirmed there are a list of comorbidities that are adjusted for and the group then discussed suitability of this risk model. The group examined the risk adjustment for this measure with patient-level comorbidities and facility-level factors discussed relative to feasibility and equity concerns.
Rural	 A Recommendation Group member with experience working in rural communities shared examples of common access-to-care barriers for the ESRD population. A member suggested that CMS evaluate how the national ratio for determining thresholds for this measure is calculated with consideration of how that may impact use of the measure in rural communities.

Additional Considerations for CMS and Future Directions:

The Recommendation Group encouraged CMS and developers to consider how national norms for setting thresholds and risk adjustment models relate to equity concerns for traditionally underserved populations and facilities in rural communities. Recommendation Group members encouraged CMS to evaluate how the ratio is calculated to address equity concerns and to consider measuring usability at a facility level across regions and population subgroups.

Potential Impacts of Measure Removal:

Recommendation Group members discussed the importance of retaining a measure that ensures patients are receiving proper care. Although equity and the lack of validity testing were

brought up as concerns, Recommendation Group members noted the benefit outweighs the burden. Recommendation Group members encouraged CMS to evaluate how the ratio is calculated on a national level to address equity concerns and to consider measuring usability at a facility level.

2.3.3 Percentage of Prevalent Patients Waitlisted (PPPW) – <u>CMIT ID: 00546-01-C-</u> <u>ESRDQIP</u>

Description: 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.

Summary of Written Public Comment: The National Kidney Foundation supports retention and notes that waitlisting practices vary widely across transplant centers and are often not within the dialysis facility's control.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (12), Remove (7), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 A Recommendation Group member noted that transplants typically take years to complete because of long waitlist times. One member shared, based on family experience, the challenges of the transplant centers and the knowledge that the process of getting a patient on the waitlist based on certain criteria is important. A Recommendation Group member noted it is an important measure and that there has been substantial work done by CMS to support this measure.
Accountable Entity	 Several attendees voiced concern that this measure may place accountability for waitlist practices solely on the dialysis facilities despite multiple health care entities contributing to waitlist decisions and timing. A representative from CMS noted that, while facilities do not have the final say about if a patient makes it on the transplant list, they do have the opportunity to educate the patient on their options and serve as a link to transplant centers.
Equity	 Several Recommendation Group members expressed equity concerns given disparities seen in transplants. A Recommendation Group member shared a story about a patient who relocated and went from a yearlong wait to a monthlong wait on the transplant list to highlight regional inequities in transplant waitlist times and processes. Recommendation Group members also discussed the need for transplant patients to have reliable housing while they are on the waitlist and how this requirement impacts individuals without stable housing.
Exclusions	• Representatives with experience in SNFs and LTCs asked the developer to explain the rationale behind excluding residents in those facilities. The developer shared that this exclusion was included to account for functional impairment and comorbidities that would make patients unsuitable for transplant.

Evaluation Themes	Recommendation Group Member Discussion	
	 Attendees encouraged the developer to reconsider this approach and use direct measures of function and comorbidity rather than using care facility as a proxy to reduce potential inequities. Attendees gave examples of patient types who may reside temporarily in SNF and LTC facilities due to rehabilitation or unhoused status but would otherwise be suitable candidates for waitlisting and transplant. 	
Patient Engagement	 A participant noted if a patient brings someone with them as a live donor, they may receive a transplant before dialysis is needed. Recommendation Group members expressed concern about what patients are put on the waitlist. 	

A Recommendation Group member encouraged CMS and developers to consider a model for joint accountability that includes transplant facilities and all other relevant entities in the waitlist process. The member encouraged the developer to reconsider current measure exclusions and risk adjustment to best reflect patient waitlist suitability and reduce bias in denominator selection.

Potential Impacts of Measure Removal:

The Recommendation Group agreed the measure is important to ensure patients are properly educated about their transplant options. Although concerns about equity and varying wait times depending on region were discussed, the Recommendation Group agreed the measure is important to retain.

2.4 Patient and Family Engagement Domain

2.4.1 CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (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. (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.

Summary of Written Public Comment: The National Kidney Foundation supports removal due to challenging factors identified regarding the importance, scientific acceptability, validity, feasibility, and usability evaluation criteria. Additionally, commenter believes removal of the measure is warranted due to low response rates and the low number of facilities qualifying for survey scoring.

Summary of Verbal Public Comment from MSR Meeting 10/17: National Kidney Foundation supported the removal of this measure due to challenging factors identified related to measure

importance; scientific acceptability; validity, feasibility, and usability; as well as low response rates and low number of facilities that qualify for survey scoring.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (14), Remove (4), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion
Importance	 Recommendation Group members noted the measure was meaningful and valuable to collect this data, especially from a patient perspective, but acknowledged the challenges and opportunities for improvement. Members questioned the impact on patient care and outcomes, given the lack of evidence to support improvement of patient quality of life.
Feasibility	 On the topic of feasibility, Recommendation Group members considered the data collection method to support retaining the measure, but noted the significant patient burden, low response rate, and cost as challenges. Recommendation Group members suggested using innovative technology to incentivize participation and increase flexibility. A CMS representative commented on the directionality of the survey, noting that the Agency for Healthcare Research and Quality is exploring the inclusion of additional questions about safety and bias, and testing online versions of the survey to be completed by smartphone.
Alternative Measures	 Recommendation Group members discussed implementation of electronic options incentivize participation and increase flexibility.
Equity	 Attendees expressed concern over the unique difficulties patients in low- resource or rural areas faced, specifically, health literacy, internet access, and availability of dialysis facilities.
Patient Engagement	• Patient members of the Recommendation Group noted that they felt burdened by the frequency, difficulty, and length of the survey and that this may impact the reliability of the results.

Additional Considerations for CMS and Future Directions: A Recommendation Group member suggested maintaining mail and telephone surveys along with implementation of electronic options to capture a larger audience. Recommendation Group members felt the patient perspective should be prioritized and flexibility should be considered.

Potential Impacts of Measure Removal:

The Recommendation Group did not have a substantial discussion about potential impacts of measure removal as there was general support for retention during discussion.

2.5 Patient Safety Domain

2.5.1 National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients – <u>CMIT ID: 00458-01-C-ESRDQIP</u>

Description: The Standardized Infection Ratio (SIR) of Bloodstream Infections (BSIs) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.

Summary of Written Public Comment: The National Kidney Foundation supports retention with future refinement but has strong concerns around the inaccuracy of the data being

collected and suggests the BSI component be improved through hospitals reporting BSI to dialysis facilities or directly to NHSN.

Summary of Verbal Public Comment from MSR Meeting 10/17: None.

Measure Review Final Vote: Recommendation to Retain in ESRD QIP.

Vote Count: Retain (17), Remove (0), No Recusals.

Evaluation Themes	Recommendation Group Member Discussion	
Importance	 Recommendation Group members recognized the relevance and importance of patient safety. 	
Feasibility	 A representative from the CDC joining as the measure developer said that this measure allows standardized collection and tracking of BSI rates. Attendees questioned whether lab data such as blood culture results could be utilized in this measure, and CMS shared that work is currently underway to enable this data linkage. 	
Unintended Consequences	 The Recommendation Group examined the potential for unintended consequences of this measure. An attendee said an example of this may be a clinician being reluctant to order blood culture for an eligible patient in ICU due to not wanting to be penalized for any positive testing results. A representative from CMS in attendance shared that they are in the process of examining how testing intensity impacts this outcome measure and that they recognize the role that may play in care decisions. 	
Patient Engagement	 Overall, there was a positive patient Recommendation Group member support for this measure in recognition of the contribution to patient safety. 	

Additional Considerations for CMS and Future Directions:

The Recommendation Group again reflected on the earlier discussion of the NHSN Dialysis Event measure and again encouraged further exploration of additional methods to incentivize complete reporting of this measure through standards and other levers available to CMS.

Potential Impacts of Measure Removal: Recommendation Group members did not discuss the impacts of removal and voted to retain the measure.

Common Themes for Future Consideration:

During the MSR meeting, Recommendation Group members expressed several recurring themes for where they would like to see measures be revised and improved moving forward. Figure 4 shows the topics that members would like to see measure developers and CMS dedicate resources to addressing in future measures for ESRD QIP.





Equity

Embed an equity lens at all points of measurement process, from data collection through reporting and across multiple social determinants of health. During the day's discussions, Recommendation Group members voiced interest in seeing progress made in the areas of equity across multiple social determinants of health. Multiple members asked for clarity from CMS on the availability of data on the performance of measures across patient sociodemographic subgroups and regional variation for facilities. In considering how equity could be progressed, members encouraged developers and CMS to look to ways to pair patient education with measurement targets.



Engage Rural Perspectives

Consider the unique challenges experienced in rural communities in all measure thresholds and reporting requirements. Representatives for rural health facilities as well as patients and clinicians from traditionally underserved communities shared their perspectives on how this measure could be used to identify care access gaps and move progress on health equity. The Recommendation Group encouraged CMS and developers to consider how national norms for setting thresholds and risk adjustment models relate to equity concerns for traditionally underserved populations and facilities in rural communities. Recommendation Group members encouraged CMS to evaluate how the ratio is calculated to address equity concerns and to consider measuring usability at a facility level across regions and population subgroups.



Include Flexibility for Patient Choice

Include flexibility in measure specification to account for patient choice, desired quality of life and personalized medicine. During discussions, Recommendation Group members voiced concern for how patient choice and personalized treatment

plans were not considered by current measures. The lack of patient choice reflected in measures was frequently accompanied by discussions of how that lack of choice may negatively impact patient quality of life in instances where processes or thresholds required for measure satisfaction conflicted with a patient's individualized goals and desired quality of life. Patient and clinician representatives shared examples of how patient education and engagement in clinical decision making are critical to overall quality of care. In future, measure developers and CMS are encouraged to explore ways to include flexibility within measure specification, risk adjustment, or other means to better support the patient choice inherent in personalized medicine.



Reflect Real-World Care

Incorporate measure exclusions and risk adjustment models that reflect real-world patient care scenarios and patient-level factors to increase measure usability. Several measures under discussion for ESRD QIP included exclusions designed to address incomplete data and confounding concerns. In examples of care decisions given by clinician members of the Recommendation Group, attendees heard cases where the clinically appropriate care choice would negatively impact an entity's score on a measure. Measure developers are encouraged to collaborate with TEP members to explore a diverse set of use cases when determining exclusion criteria. Members of the Recommendation Group also expressed concern that some exclusions were functioning as a proxy to the true reason to exclusion to improve ease of data collection—such as excluding residents in long-term care settings under the assumption all may have impaired functional status. Inclusion of patient-level factors that address equity concerns in the risk model or stratifying results by these factors should also be more routinely done to provide the data needed for facilities to advance health equity for the communities they serve.

Appendix A. Measure Set Review Meeting Attendance

Member	Organization	Individual or Organizational Representative
Akinluwa Demehin	American Hospital Association	Organizational
Amir Qaseem	American College of Physicians	Organizational
Ben McGaugh	Mountain-Pacific Quality Health Foundation	Individual
Cary B. Shames	Sharp Health Plan; AHIP	Organizational
Donna Bednarski	American Nephrology Nurses Association	Organizational
Janice Tufte	Hassanah Consulting	Individual
Jean Drummond	HealthCare Dynamics International	Individual
Kamyar Kalantar-Zadeh	Harbor-UCLA Medical Center; National Forum of ESRD Networks	Organizational
Koryn Rubin	American Medical Association	Organizational
Mary Ellen DeBardeleben	Encompass Health	Organizational
Matthew Cerasale	University of Chicago, Society of Hospital Medicine	Organizational
Michelle Doll	VCU Health System	Individual
Reginald Barnes	Autoimmune Registry	Individual
Starlin Haydon-Greatting	SHG Clinical Consulting and Population Health	Individual
Susan Runyan	Runyan Health Care Quality Consulting	Individual
Theresa Schmidt	Real Chemistry	Organizational
Tilithia McBride	Federation of American Hospitals	Organizational
Virgil Dickson	America's Essential Hospitals	Organizational
Virginia Irwin-Scott	ChenMed	Individual
Warren Jones	University of Mississippi Medical Center	Individual
Wei Ying	Blue Cross Blue Shield of Massachusetts	Organizational
Wendy Fitts	University of Pennsylvania Health System (Penn Medicine) - Lancaster General Health	Individual

2023 Measure Set Review Recommendation Group Members

Federal Agencies

Centers for Medicare & Medicaid Services (CMS) Centers for Disease Control and Prevention (CDC) Health Resources and Services Administration (HRSA) Office of the Assistant Secretary for Health (OASH) Office on Women's Health (OWH)

Partnership for Quality Measurement Organizations

Battelle Institute for Healthcare Improvement Rainmakers

