Measure Justification Form and Instructions

Project Title: ***Effective Availability and Utilization of Home Dialysis Modalities***

Date:

Information included is current on *February 14th 2022*

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has contracted with the University of Michigan Kidney Epidemiology and Cost Center to develop facility-level measures in the area of modality education for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001. As part of its measure development process, the University of Michigan Kidney Epidemiology and Cost Center convenes groups of stakeholders who contribute direction and thoughtful input to the measure developer during measure development and maintenance.

Measure Name/Title (NQF Measure Submission Form sp.01)

Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

1. Type of Measure

☐process
☐process: appropriate use
☒outcome
☐cost/resource use
☐experience with care
☐efficiency
☐outcome: PRO/PRO-PM
☐structure
☐outcome: intermediate outcome
☐composite

2. Importance (NQF Importance to Measure and Report)

2.1 Evidence to Support the Measure Focus (for reference only) NQF Measure evaluation criterion 1a.

2.1.1 This is a Measure of

☐process:
☐process: appropriate use:
☒outcome:

☐outcome: PRO:
☐cost/resource use:
☐experience with care:
☐efficiency:
☐structure:
☐intermediate outcome:
☐composite:

2.1.2 Logic Model (NQF Measure Submission Form, Importance to Measure and Report: Evidence 1a.01)

Dialysis modality is a health status as it impacts other clinical outcomes (e.g., anemia, cardiovascular related outcomes, infection) and patient reported outcomes (e.g., experience of care). The SMoSR measure reports on the modality outcome of in-center hemodialysis patients who in their first year of treatment switch to a home dialysis modality. Switches to home dialysis in the first year reflect robust education, effective presentation of modality educational materials (facility process), and facilitation of patient decision making by the dialysis unit (facility process). Both are processes owned by the dialysis facility and codified in CMS Regulations (Conditions for Coverage). Additionally, the Advancing American Kidney Health Initiative and the current ESRD Treatment Choices and Kidney Care Choices models place uptake of home dialysis modality (along with transplantation) as one of the metrics on which facilities will be evaluated.

The basic premise of the Standardized Modality Switch Ratio measure is that patients consented to changing their treatment modality to a home modality after initially starting on in-center hemodialysis, as a result of on-going education efforts and effective decision support by the dialysis facility. These processes can lead to helping patients select a home dialysis modality that may best fit with their personal goals and values:

Facility identifies incident patients who are on in-center hemodialysis modality → Facility provides effective education to facilitate patient decision making for a home modality →Improves alignment between patients' goals of care and values and their dialysis modality→Increase rate in switches from in-center to home dialysis modality

2.1.3 Value and Meaningfulness (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Outcomes] 1a.02)

A Technical Expert Panel was convened in spring 2021 to obtain feedback on a draft measure of modality switches from in-center to home dialysis (UM-KECC, 2021). The TEP was co-chaired by a clinical nephrologist and a patient. The TEP was made up of 6 ESRD patients that had experience with in-center and/or home dialysis, and 8 clinicians (nephrologists and nephrology nurses) that treat ESRD dialysis patients. Over the course of the discussion there was strong consensus that 1) rates of home dialysis are very low in the U.S., and 2) that there needs to be greater emphasis on on-going and effective education by nephrologists and the facility care team to allow more patients to make an informed choice for home dialysis. It was also recognized that well over a majority of switches to home dialysis occur within the first year of beginning chronic dialysis.

- Physicians play a critical role in providing dialysis education. If physicians are knowledgeable about home dialysis, then they are more likely to provide balanced education to the patient while considering co-morbidities that may impact a modality selection. Some patient TEP members described bias (toward in-center HD) in the education they experienced, where the risks of home dialysis were highlighted and over-emphasized and those of in-center dialysis downplayed.

- Modality education and decision making ideally should occur in the pre-dialysis stages. However, since many patients start dialysis abruptly, and may have had little or no pre-dialysis education, this process should continue in the dialysis facility after initiating chronic dialysis. Modality education should be an iterative process since patients new to dialysis may not be ready to absorb information or make a modality decision immediately after starting in-center HD.

Overall there was broad consensus that home dialysis is underutilized and that a quality measure to monitor facility performance would be useful to patients, providers, and other stakeholders. The TEP supported the basic construct of the Standardized Modality Switch Ratio (SMoSR) Measure.

University of Michigan Kidney Epidemiology and Cost Center. Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report, Prepared for The Centers for Medicare and Medicaid Services. June, 2021.

2.1.4 Empirical Data (for outcome measures) – as applicable (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Outcomes] 1a.03)

Home dialysis rates remain low in the United States compared with many other countries, hovering around 12% (Briggs 2019). Because there are not formal randomized controlled trials of modality uptake, the evidence for SMoSR is based on a large body of observational studies in the U.S. as well as outside the U.S. such as Canada, several European countries, and Australia and New Zealand.

We evaluated studies that examined the epidemiology and characteristics of home dialysis uptake; educational interventions and processes to support shared-decision making; and studies comparing or assessing outcomes (mortality; hospitalization) between a home dialysis modality (i.e., peritoneal dialysis) and in-center hemodialysis, or the association of home modalities with comorbidities and other health outcomes.

Clinical, operational, economic and patient factors have been identified as barriers to uptake of home dialysis modalities (Chan 2019). Clinical factors include lack of physician competency in prescribing home dialysis modalities; operational include lack of clinician and staff training; economic obstacles include lack of sufficient housing or storage space for dialysis supplies; and patient barriers include lack of adequate education. Studies also have identified demographic characteristics of black race, male sex, older age, and comorbidities as predictors of low uptake of home dialysis; while small dialysis facility size and low physician and nurse experience with home dialysis are facility level barriers.

Studies that examine the role and impact of education on home modality uptake show that about 30% of chronic dialysis patients have reported their modality selection was not really their choice or did not

feel as though they made an informed choice, and that this percentage is higher among in-center hemodialysis (ICHD) patients (Dahlerus 2016; Van Biesen 2014; Song 2013; Winterbottom 2012). Studies have also found that there is a mismatch between stated preference for dialysis modality (i.e., home dialysis) and the actual modality on which patients start. The preferred modality was a home therapy but in many cases patients started on in-center hemodialysis (Pyart 2018; Keating 2014; Liebman 2012). This suggests existing educational efforts fall short of supporting decision making by the patient. Specifically, decision-making efficacy and satisfaction of modality selection has been reported as greater among PD vs in-center HD patients (Zee 2018)

Because of the lack of RCTs comparing dialysis modalities and outcomes, the current evidence is observational in nature. Some studies have shown a survival advantage associated with PD as an initial modality however evidence is mixed about the longer term outcomes and survival benefit for PD versus in-center hemodialysis. As such, in-center and home dialysis are generally considered equivalent with respect to hospitalization rates and mortality. In one meta-review, some differences were observed in physical and mental quality of life domains between patients on PD versus in-center hemodialysis (Budhram 2020)

The evidence indicates that persistently low rates of home dialysis use are associated with both patient and facility level factors. Education and shared decision making interventions suggest an opportunity to improve uptake of home dialysis. Moreover, home modalities offer patients potential flexibility and independence.

Collectively these studies support the construct of the SMoSR which is an indicator of successful education by the facility to facilitate a decision to switch to a home modality, through on-going educational efforts after a patient starts on in-center hemodialysis.

References:

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Zee J, Zhao J, Subramanian L, Perry E, Bryant N, McCall M, Restovic Y, Torres D, Robinson BM, Pisoni RL, Tentori F. Perceptions about the dialysis modality decision process among peritoneal dialysis and in-center hemodialysis patients BMC Nephrol. 2018 Oct 29;19(1):298. doi: 10.1186/s12882-018-1096-x.

2.1.5 Systematic Review of the Evidence (for intermediate outcome, process, or structure quality measures, include those that are instrument-based) – as applicable (Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.02)

N/A

2.1.6 Other Source of Evidence – as applicable (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.13)

N/A

2.1.6.1 Briefly Synthesize the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.14)

N/A

2.1.6.2 Process Used to Identify the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.15)

N/A

2.1.6.3 Citation(s) for the Evidence (NQF Measure Submission Form, Importance to Measure and Report: Evidence [Process] 1a.16)

N/A

2.2 Performance Gap – Opportunity for Improvement (NQF Measure evaluation criterion 1b)

2.2.1 Rationale (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.01)

Home dialysis rates remain low in the United States compared with many other countries (as of 2019, 10.8% PD, 1.8% HHD). This measure will allow one to compare the effectiveness of facility modality education and/or effective utilization of home dialysis modalities. This will be a facility outcome metric for comparison across the US including longitudinal monitoring. It is patient centered in that it is intended to facilitate on-going education that may result in patients choosing a home modality, particularly if there was no pre-dialysis modality education provided. The quality of care will be improved by better alignment between patients' goals and values and their dialysis modality. The focus is on incident patients since most modality changes occur during the first year and likely reflect robust education, effective presentation, and facilitation by the dialysis unit.

2.2.2 Performance Scores (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.02)

After applying all exclusion criteria, we evaluated all Medicare-certified dialysis facilities (n=6,039) treating incident patients (n=316,382) that had at least 1 expected patient modality switch in the reporting years. The distribution of the Standardized Modality Switch Ratio (SMoSR) across these facilities is shown in the table below. The mean value was 1.07 and the standard deviation was 1.00.

Q1	Median	Q3	Mean	Std Dev
0.37	0.84	1.52	1.07	1.00

Deciles of Standardized Modality Switch Ratio

Decile 1: N=933, Mean=0, Std Dev = 0

Decile 2: N=274, Mean=0.21, Std Dev = 0.04

Decile 3: N=604, Mean=0.37, Std Dev = 0.05

Decile 4: N=604, Mean=0.55, Std Dev = 0.05

Decile 5: N=604, Mean=0.74, Std Dev = 0.06

Decile 6: N=604, Mean=0.95, Std Dev = 0.07

Decile 7: N=604, Mean=1.21, Std Dev = 0.08

Decile 8: N=604, Mean=1.53, Std Dev = 0.10

Decile 9: N=604, Mean=1.97, Std Dev = 0.17

Decile 10: N=604, Mean=3.26, Std Dev = 1.12

2.2.3 Summary of Data Indicating Opportunity (NQF Measure Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.03)

N/A.

2.2.4 Disparities (NQF Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.04)

Race and ethnicity have been shown to be predictors of switch to a home modality. Using data from 2016-2019 (described above in 1b.02), we observed that black, Native American and Asian/Pacific Islander patients had lower hazard of modality switch (0.59, 0.67 and 0.86, respectively) compared to white patients. Hispanic patients had lower hazard of modality switch (HR = 0.67) compared to non-Hispanic patients. The hazard of modality switch were not statistically significant between male and female patients (HR=0.99, 95% CI: 0.96, 1.02). Further, patients employed 6 months prior the onset of ESRD had a higher hazard of modality switch (HR=2.00) than patients that were unemployed; Medicare dual eligible patients had a lower hazard of modality switch (HR=0.57) than other patients.

Refer to Risk Adjustment section (2b.24)) for further analyses on race, ethnicity, sex and socioeconomic status.

2.2.5 Provide summary of data if no or limited data (NQF Submission Form, Importance to Measure and Report: Gap in Care/Disparities 1b.05)

N/A

3. Scientific Acceptability (NQF Scientific Acceptability)

3.1 Data Sample Description (NQF Measure evaluation criterion 2)

3.1.1 What Types of Data Were Used for Testing? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.01)

☐abstracted from paper record
☒administrative claims
☒clinical database/registry

☐abstracted from electronic health record (EHR)
☐electronic clinical quality measure (eCQM) Health Quality Measure Format (HQMF) implemented in EHRs
☐other (specify) Click or tap here to enter text.

Measure tested with data from

☐abstracted from paper record
☒administrative claims
☒clinical database/registry
☐abstracted from EHRs
☐eCQM (HQMF) implemented in EHRs
☐other (specify) Click or tap here to enter text.

3.1.2 Identify the Specific Dataset (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.02)

National CROWNWeb data from January 2016-December 2019 and Medicare outpatient dialysis claims data from January 2016 – December 2019.

Data are derived from an extensive national ESRD patient database, which is primarily based on the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data (primarily outpatient). In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC). Hospice information is obtained from Medicare Part A hospice care claims submitted by Hospice providers.

3.1.3 What Are the Dates of the Data Used in Testing? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.03)

01-01-2016 to 12-31-2019

3.1.4 What Levels of Analysis Were Tested? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.04)

Provide testing for all levels specified and intended for measure implementation (e.g., individual clinician, hospital, health plan).

Measure specified to measure performance of (NQF Measure Submission Form, Measure Specifications sp.07)

☐individual clinician
☐group/practice
☒hospital/facility/agency
☐health plan

☐other (specify) Click or tap here to enter text.

Measure tested at level of

☐individual clinician
☐group/practice
☒hospital/facility/agency
☐health plan
☐other (specify) Click or tap here to enter text.

3.1.5 How Many and Which Measured Entities Were Included in the Testing and Analysis? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.05)

Patients on both home (less than 30 days) and in-center hemodialysis during January 2016-December 2019 and starting chronic dialysis within the prior 12 months were included in the analyses. The number of facilities per month ranged from 6,779-7,220 and the total number of patients per year ranged from 115,929 - 117,942

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 1 expected modality switch throughout the reporting period for the measure. We have applied this restriction to all the reliability and validity testing reported here.

3.1.6 How Many and Which Patients Were Included in the Testing and Analysis? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.06)

Baseline Patient Characteristics	*
Body Mass Index Categories	*
BMI < 18.5	9,810 (3.1%)
18.5 ≤ BMI < 25	87,078 (28%)
25≤ BMI < 30	87,624 (28%)
BMI≥30	131,870 (42%)
Gender	*
Female	132,354 (42%)
Male	184,028 (58%)
Age Categories	*
18 < age <= 25	2,809 (0.9%)
25 < age <= 35	10,822 (3.4%)
35 < age <= 45	21,533 (6.8%)

Baseline Patient Characteristics	*
45 < age <= 55	45,781 (14%)
55 < age <= 65	77,920 (25%)
65 < age <= 75	87,094 (28%)
75 < age <= 85	56,799 (18%)
age > 85	13,624 (4.3%)
Race	*
White	210,902 (67%)
Native American/Alaskan Native	3,170 (1.0%)
Asian/Pacific Islander	17,045 (5.4%)
Black	84,388 (27%)
Other race	877 (0.3%)
Ethnicity	*
Hispanic	49,270 (16%)
Non-Hispanic	267,103 (84%)
Unknown	9 (<0.1%)
Medicare Status	*
Dual Eligible	64,264(20.3%)
Medicare Primary Only	93,259 (29.5%)
Medicare Secondary	34,591(10.9%)
Medicare Advantage/HMO	74,825 (23.7%)
Other	49,443 (15.6%)
*	*
Cause of ESRD	*
Diabetes	157,496 (50%)
Non-Diabetes	158,886 (50%)

3.1.7 Sample Differences, if applicable (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.07)

N/A

3.1.8 What Were the Social Risk Factors That Were Available and Analyzed? (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.08)

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare coverage*

**Assessed at a specific time point (e.g., at a home modality switch event). The final variable for Medicare coverage in the model was recoded as:*

1. Medicare as primary and Medicaid (dual eligible)

2. Non-dual Eligible

Area level:

ZIP code level – Area Deprivation Index (ADI) from Census data (2015). Based on patient zip-code.

3.2 Reliability Testing **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a)

3.2.1 Level of Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.09

☐critical data elements used in the measure (e.g., inter-abstractor reliability; data element reliability must address all critical data elements)
☒performance measure score (e.g., signal-to-noise analysis)

3.2.2 Method of Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.10)

The reliability of the SMoSR was assessed using data from adult ESRD dialysis patients during 2016-2019. If the measure were a simple average across individuals in the facility, the usual approach for determining measure reliability would be a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. The SMoSR, however, is not a simple average and instead estimates the IUR using a bootstrap approach, which

utilizes a resampling procedure to estimate the within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

Here we describe our approach to calculating IUR. Let $T_1,\ldots,T_N$ be the SMoSR for N facilities. For each facility, we randomly draw B bootstrap samples of subjects with replacement, each having the same number of subjects as the facility. Our numerical experiments reveal that B=100 is sufficient to reach estimation stability. That is, if the ith facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find the corresponding $SMoSR_i$ and repeat the procedure B (say, 100) times. Thus, for the ith facility, we have obtained 100 bootstrapped SMoSRs, $T_{i1}^*,\ldots, T_{i100}^*$. Let S_i^* be the sample variance of this bootstrap sample for facility i, given by

$$s_{t,w}^2 = \frac{\sum_{i=1}^{N}[(n_i - 1)S_i^{*2}]}{\sum_{i=1}^{N}(n_i - 1)}$$

which is a bootstrap estimate of the within-facility variance in the SMoSR, namely, $\sigma_{t,w}^2$. Calling on formulas from the one-way analysis of variance, an estimate of the overall variance of T_i is

$$s_t^2 = \frac{1}{n'(N-1)} \sum_{i=1}^{N} n_i (T_i - \bar{T})^2$$

where

$$\bar{T} = \sum n_i T_i \,/\, \sum n_i$$

is the overall mean of the observed SMoSR and

$$n' = \frac{1}{N-1}\left(\sum n_i - \sum n_i^2 / \sum n_i\right)$$

is approximately the average facility size (number of patients per facility). Note that s_t^2 is the total variation of SMoSR and is an estimate of $\sigma_b^2 + \sigma_{t,w}^2$, where σ_b^2 is the between-facility variance, the true signal reflecting the differences across facilities. Thus, the estimated IUR, which is defined by

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{t,w}^2}$$

can be estimated with $(s_t^2 - s_{t,w}^2)/s_t^2$.

To assess more directly the value of the measure in identifying providers with extreme outcomes, we also computed an additional metric, termed the profile IUR (PIUR). This was to address the challenge that the IUR could be small in the situation where many providers have outcomes around the national norm, even though the measure may still be able to identify facilities with extreme outcomes. The PIUR,

based on the measure's ability to consistently flag extreme providers, was computed with a two-step approach: first, we evaluated the ability of a measure to consistently profile facilities with extreme outcomes; second, we mapped this reflagging ability to an IUR value computed by assuming no outlier facilities. This resulting value was defined to be the PIUR. The difference between the PIUR and the IUR indicates the extent to which the measure identifies outliers.

The SMoSR calculation only included facilities with at least 1 expected modality switch.

3.2.3 Statistical Results from Reliability Testing (NQF Measure Submission Form, Scientific Acceptability: Reliability - Testing 2a.11)

Overall, we found that IUR for SMoSR has a value of 0.605, which indicates that over 60% of the variation in the SMoSR can be attributed to the between-facility differences and less than 40% to the within-facility variation.

The PIUR is 0.606.

3.2.4 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Reliability – Testing 2a.12)

The IUR is moderate and indicates that the measure can detect differences in performance scores across facilities.

As noted above, the PIUR measures reliability in terms of reflagging rates but is placed on the same scale as IUR. A PIUR that is larger than the IUR indicates that the measure has a higher reliability for identifying extreme values. In this case, the IUR and PIUR are nearly the same, so the IUR also is descriptive of the measures usefulness in identifying extreme values.

3.3 Validity Testing **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Testing 2b)

3.3.1 Level of Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.01)

☐critical data elements (Note: Data element validity must address all critical data elements.)
☒Accountable Entity Level (e.g. hospitals,clinicians)
☒empirical validity testing
☐systematic assessment of face validity of quality measure score as an indicator of quality or resource use (i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance)

3.3.2 Method of Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.02)

Validity of the Standardized Modality Switch Ratio was assessed using several different statistical tests to examine the relationship with other facility level quality measures: Standardized Mortality Ratio (SMR), First-Year Standardized Mortality Ratio (FYSMR), Standardized Hospitalization Ratio (SHR),

Standardized Waitlist Ratio-Incident Dialysis Patients (SWR), ICH-CAHPS "Providing information to patients", and the percentage of home dialysis patients at the facility.

Spearman's rho Correlations with Quality Outcome Performance Measures:

We started by calculating Spearman's rho coefficient to examine the correlation of SMoSR with SMR, FYSMR, SHR, and SWR. Spearman's correlation coefficient, which is a rank-based correlation metric, was chosen for its robustness against potential extreme providers and tied providers. The peer-reviewed literature is mixed in regard to whether home dialysis compared to in-center dialysis offers better survival or lower hospitalization rates. Therefore, we hypothesized no or weak correlations of SMoSR with SMR, FYSMR, and SHR. However, facility processes of care that support robust modality education should result in higher referral for transplant evaluation and subsequent waitlisting. Therefore, we hypothesized a positive correlation between SMoSR and SWR. Table 1 reports the estimated Spearman's rho correlations.

Gamma Tests for Concordance Analysis with Performance Classification:

Next, we performed gamma tests to examine the concordance of facility level SMoSR flagging classifications ("Better than Expected", "As Expected", and "Worse than Expected") with 2019 SWR. The choice of gamma tests in the analysis is due to the fact that these performance categories are naturally ordered in a descending order.

A positive Gamma coefficient would indicate a concordance in flagging categories between SMoSR and an existing performance measure. In contrast, a negative Gamma signifies a discordant relationship. The null hypothesis of Gamma=0 is set up to test for a significant correlation. The higher a Gamma value the stronger the relationship. We hypothesized that there would be moderate agreement in facility classification of performance between the SMoSR and the first year SWR. The estimated magnitude of concordance is provided in Table 2.

Association with patient reported outcomes: ICH-CAHPS "Providing information to patients":

The In-Center Hemodialysis Consumer Assessment of Healthcare Provider and Systems (ICH-CAHPS)[1] is a patient reported experience of care survey to measure in-center hemodialysis patients' perspectives on the care they receive at dialysis facilities. This measure is reported on Dialysis Facility Care Compare. We computed a Pearson correlation (rho) to assess the association between the ICH-CAHPS mean scores for the 9 question composite measure on "providing information to patients"[1] and SMoSR performance classifications of "better than expected", "as expected", and "worse than expected."

[1] Please see https://ichcahps.org/Survey-and-Protocols for the list of questions included in the composite measure which include: "In the last 12 months, did either your kidney doctors or dialysis center staff talk to you about peritoneal dialysis?" and "In the last 12 months, were you as involved as much as you wanted in choosing the treatment that is right for you?"

Collectively the ICH-CAHPS linearized top box score for "providing information" indicates how well the facility is doing providing information on safety as well as all renal replacement modalities, including home dialysis and transplant. Since this facility process of modality education is a critical step for many patients to understand their treatment choices, we expect a higher proportion of patients reporting "yes" on facilities "always providing information" will be associated with a better performance classification on SMoSR. Please see Table 3 below for this association and the Pearson's correlation r statistic.

Association between the percentage of home dialysis patients and performance on SMoSR:

We computed a Pearson correlation rho to assess the association between the different SMoSR performance classifications and the percentage of home dialysis patients at a facility. The proportion of home dialysis patients at a facility reflects the processes that are in place to provide effective modality education and then facilitate a transfer from in-center to home dialysis. We expect a better SMoSR performance classification to be associated with a higher percentage of patients on home dialysis at a facility. Table 4 reports these results and the Pearson correlation r statistic.

Two-part Semi-continuous Model:

A challenge with the analysis for the association between SMoSR and the percentage of home dialysis patients at a facility is that some facilities have no home program resulting in zero patients on home dialysis. This cluster of "zero-patient" facilities will distort the correlation calculation due to the significant amount of ties. One option is to delete these facilities from the calculation. However, such an approach would then be based on a selective sub-sample which may introduce bias. To avoid this, we used a two-part semi-continuous regression model that accommodates data that have both a spike at zero and continuous values over the nonzero part (Atchison 1995). In the first part, we used a logistic regression model to predict the propensity of observing facilities with zero (vs. nonzero) percentage of home dialysis patients as a function of the SMoSR, adjusted for a set of facility characteristics. For the second part of the model, a linear regression is fit only among the subset of facilities with non-zero number of home dialysis patients using SMoSR as the predictor for the percentage of home dialysis patients. We adjusted for the same set of facility characteristics as the binary part. The two models are connected formally through a mixture structure, where the mixing proportion is estimated from the data.

For the logistic model, we expect a higher SMoSR value to be associated with lower odds of facilities having zero home dialysis patients; whereas for the linear model, we expect a positive association between SMoSR and the percentage of home dialysis patients. These results are presented in Table 5 below.

In addition to the above mentioned statistical tests, the validity of the measure is also based on face validity. The SMoSR was reviewed by a TEP in 2021 which supported the measure construct and provided input on the SMoSR risk adjustment and exclusion methodology.

References:

Aitchison J. On the distribution of a positive random variable having a discrete probability mass at the origin. Journal of The American Statistical Association 1955; 50: 901–908.

University of Michigan Kidney Epidemiology and Cost Center. Effective Availability and Utilization of Home Dialysis Technical Expert Panel Summary Report, Prepared for The Centers for Medicare and Medicaid Services. June, 2021.

3.3.3 Statistical Results from Validity Testing (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.03)

Table 1. Spearman Correlation between SMoSR and other Quality Measures, 2016 - 2019

Measure	Spearman's rho	p-value
SMR (2016-2019)	0.030	0.038
FYSMR(2016-2019)	-0.030	0.022
SHR (2019)	-0.060	<0.0001
SWR (2016-2019)	0.120	<0.0001

Table 2: Concordance of SWR and SMoSR (Gamma: 0.29; p<0.0001)

*	*	**SMR**	*	*
*	Worse than Expected	As Expected	Better than Expected	*
SMoSR	*	*	*	*
Worse than Expected	46 (1.2%)	187 (4.7%)	21 (0.5%)	254 (6.4%)
As Expected	174 (4.4%)	2,980 (75%)	191 (4.8%)	3,345 (85%)
Better than Expected	14 (0.4%)	314 (7.9%)	28 (0.7%)	356 (9.0%)
Total	234 (5.9%)	3,481 (88%)	240 (6.1%)	3,955 (100%)

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Table 3: Association of facility performance on SMoSR with ICH-CAHPS score - The Linearized Top Box Score of "Providing Information To Patients" (Pearson's r = 0.191)

*	*	SMoSR	*
Facility Performance	Worse than Expected	As Expected	Better than Expected
The Linearized Score Of Providing Information To Patients	77.60	80.77	82.60

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Table 4: Association of facility performance on SMoSR with percentage of Patients on Home Dialysis Modality (Pearson's r = 0.398)

*	*	SMoSR	*
Facility Performance	Worse than Expected	As Expected	Better than Expected
Percentage of Home dialysis patients at the end of 2019	9.50%	17.55%	26.96%

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Table 5: Association between SMoSR and Percentage of Home Dialysis Patients – Two Part Semi-Continuous Model

*	*	Logistic Regression	*	*	Linear Regression	*
Covariates	OR	95% CI	p-value	Coefficient	95% CI[1]	p-value
SMoSR	0.7	0.62, 0.80	<0.001	2.9	2.6, 3.2	<0.001

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3.3.4 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity – Testing 2b.04)

Table 1 reports the results of the Spearman correlations testing the association between SMoSR and the SMR, FYSMR, SHR, and SWR. SMoSR is associated with SWR (Spearman's rho=0.12, p<.0001), in the expected direction. This suggests that facilities that do well facilitating education on transplant that results in patient waitlisting within the first year, are also performing well providing effective education on home dialysis that results in switches from in-center to home dialysis within the first year. As expected, all other associations between SMoSR and SMR, FYSMR, and SHR were very weak (Table 1) based on the Spearman correlation coefficients. This lack of association is supported by the peer-reviewed literature that has failed to demonstrate a clear relationship between dialysis modality and hospitalization or mortality.

Due to the positive correlation between SMoSR and SWR found in Table 1, we expect moderate agreement in facility classification of performance between the SMoSR and first year SWR. The positive Gamma coefficient 0.29 was statistically significant ($p<0.0001$) indicating that facilities that perform significantly better helping patients switch to home dialysis also do significantly better in helping patients in the referral and waitlisting process for transplant.

Facilities that have processes in place to support effective modality education for kidney failure are more likely to have both higher rates of transplant waitlisting as well as higher switch rates to home dialysis. Therefore, as hypothesized, we found concordance in flagging of facility performance based on the positive gamma values for this test. The Gamma statistic reflects moderate agreement in facility performance categories.

For ICH CAHPS (Table 3), as hypothesized, facilities with a better SmoSR performance have a higher ICH-CAHPS score for providing information to patients. The correlation was only moderate likely due to the ICH-CAHPS composite score also containing questions about general safety in the dialysis clinic that are not specific to modality education.

The average percentage of patients on home dialysis is 9.50%, 17.55% and 26.96% among facilities with the SMoSR classifications “Worse than Expected”, “As Expected” and “Better than Expected”, respectively. In addition, we observed a moderate correlation (Pearson’s rho = 0.398). As hypothesized, among facilities with patients on a home dialysis modality, a better modality switch performance category is associated with a higher proportion of patients on home dialysis as of the end of 2019 (Table 4), which indicates these facilities provided more effective modality education that resulted in a switch to home dialysis. Because this analysis was only on a subset of facilities, those that had at least one patient on a home modality, we estimated a model on the full population of facilities that takes into account whether facilities have 0 or >0 home dialysis patients. Table 5 has findings from two parts of the zero-inflated semi-continuous model that are consistent. The logistic regression part asserts that each unit increase in SMoSR is associated with a 30% decrease in odds of observing a facility with zero home-dialysis patients (p-value < 0.001). The linear regression part of the model indicates that for facilities with non-zero number of home dialysis patients, the proportion of home dialysis patients is positively associated with the SMoSR (beta coefficient=2.9, $p<.0001$) reaffirming the earlier findings in Table 5. As a bottomline, facilities providing more effective modality switch education have higher SMoSRs.

3.4 Exclusions Analysis **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b)

3.4.1 Method of Testing Exclusions (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.16)

The following exclusions are applied to the denominator:

- Patients time at risk under hospice care

- Nursing home patients on home hemodialysis

We calculate the number and percent of patient-time at risk and unique patients for the current (base) measure (exclusions applied) and without the exclusions.

We also compare facility performance classification between SMoSR with and without the exclusions applied. See section 2b.05 for a description of the method used to calculate the p-value for facility flagging and how facilities are classified.

3.4.2 Statistical Results from Testing Exclusions (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.17)

The following tables show the percent of patient-year at risk and the number of unique patients excluded as a result of the above mentioned exclusion strategy. For more details regarding the methodology of the denominator exclusions, please refer to section sp.17. The sensitivity models with and without each exclusion are compared.

Table 5: Percent of patient-year at risk excluded, 2016-2019 data

Exclusion	Before Exclusion	After Exclusion	Percent
Nursing Home	256,100	255,662.7	0.170%
Hospice care	257,500.4	255,662.7	0.732%

Table 6: Number and percent of unique patients excluded, 2016-2019 data

Exclusion	Before Exclusion	After Exclusion	Percent
Nursing Home	317,985	316,382	0.504%
Hospice	317,935	316,382	0.488%

Table 7: Comparing sensitivity models with and without the hospice exclusion, 2016-2019 data

Facility Performance	*	**Current SMoSR**	*	*
*	Better than expected	As expected	Worse than expected	**Total**
SMoSR without the hospice exclusion	*	*	*	*
Better than expected	462 (7.7%)	6 (<0.1%)	0 (0%)	468 (7.7%)
As expected	3 (<0.1%)	5,302 (88%)	1 (<0.1%)	5,306 (88%)
Worse than expected	0 (0%)	5 (<0.1%)	260 (4.3%)	265 (4.4%)
Total	465 (7.7%)	5,313 (88%)	261 (4.3%)	6,039 (100%)

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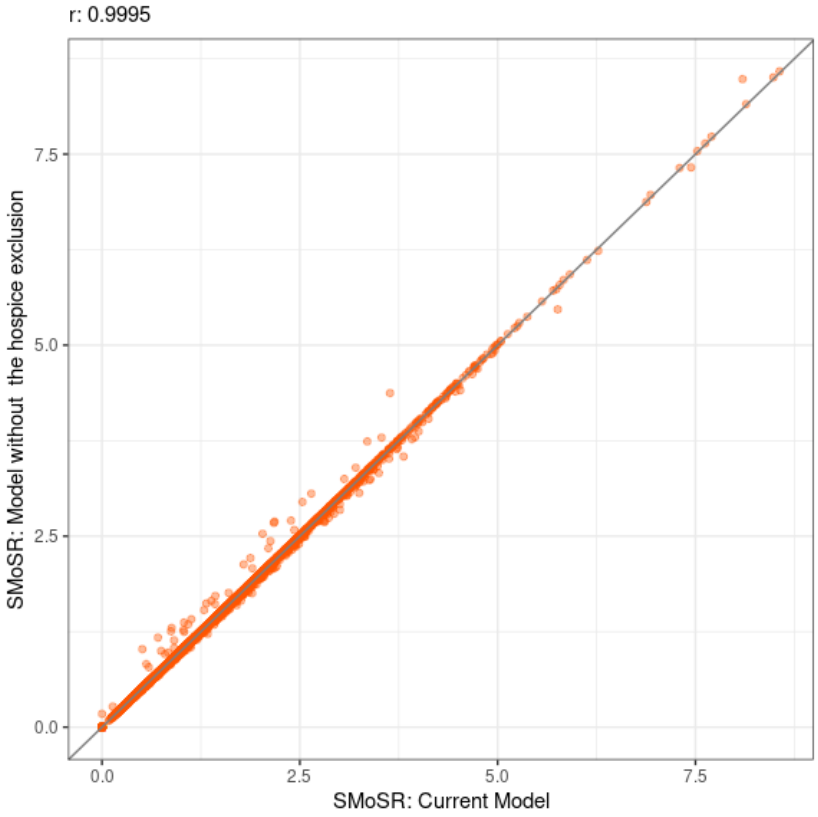
Figure 1: Comparing the SMoSR models with and without excluding the time at risk for hospice stays



Comparing the SMoSR models with and without excluding the time at risk for hospice stays, 15 (<0.2%) facilities changed performance categories. After the exclusion criterion applied, 7(<0.1%) facilities moved to a lower performance category, and 8 (<0.1%) facilities moved to a higher performance category. The SMoSR measure with and without the hospice exclusion are highly correlated (r=0.999).

Table 8: Comparing sensitivity models with and without the nursing home exclusion, 2016-2019 data

Facility Performance	*	**Current SMoSR**	*	*
*	**Better than expected**	**As expected**	**Worse than expected**	**Total**
SMoSR without the nursing home exclusion	*	*	*	*
Better than expected	432 (7.2%)	17 (0.3%)	1 (<0.1%)	450 (7.5%)
As expected	33 (0.5%)	5,264 (87%)	4 (<0.1%)	5,301 (88%)
Worse than expected	0 (0%)	32 (0.5%)	256 (4.2%)	288 (4.8%)
Total	465 (7.7%)	5,313 (88%)	261 (4.3%)	6,039 (100%)

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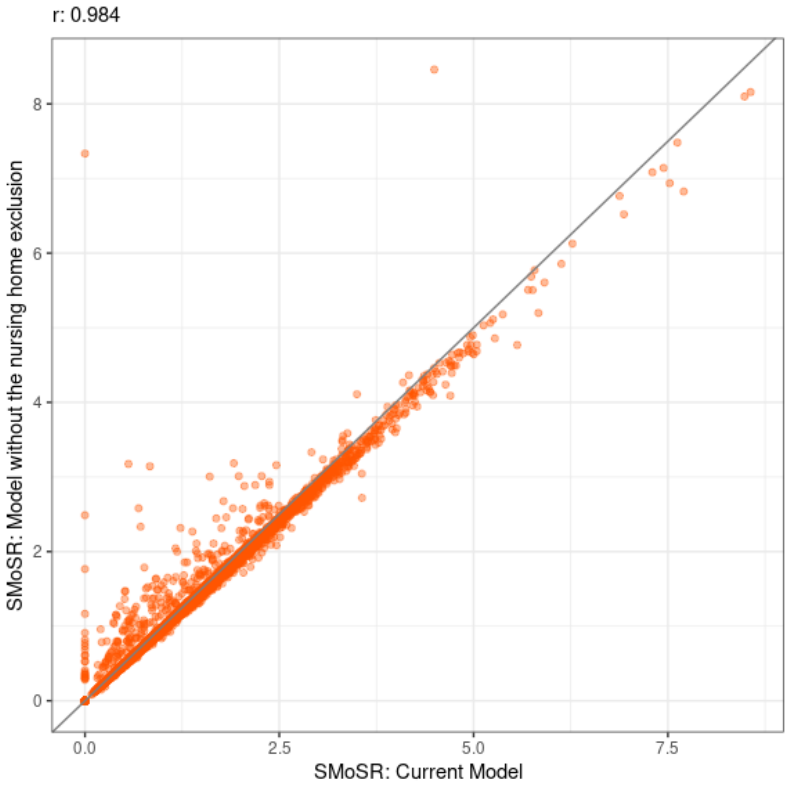
Figure 2: Comparing the SMoSR models with and without excluding nursing home patients that switched to home hemodialysis



Comparing the SMoSR models with and without excluding nursing home patients that switched to home hemodialysis, 87 (1.5%) facilities changed performance categories. After the exclusion criterion applied, 65 (1.0%) facilities moved to a higher performance category, and 22 (0.5%) facilities moved to a lower performance category. SMoSR with and without the exclusion of nursing home patients that switched to home hemodialysis were highly correlated (r=0.984).

3.4.3 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.18)

These analyses indicate that excluding time at risk at hospice stay had minimal or no effect on facility performance on the SMoSR. Similarly, excluding nursing home patients that switch to home hemodialysis had minimal or no effect on facility performance.

The exclusions are needed because the number of patients under hospice care or nursing home patients that switch to home hemodialysis are not distributed evenly across all facilities. While the numbers are generally small it would not be appropriate to include patients under hospice care that may switch to home dialysis as part of end of life care at home.

Nursing home patients that switch to home hemodialysis do so typically as a result of an administrative decision by the nursing home to deliver "home hemodialysis" in the nursing home. This does not reflect shared decision making by the patient.

3.5 Risk Adjustment or Stratification for Outcome or Resource Use Measures **(for reference only)** (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b)

3.5.1 Method of Controlling for Differences (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.19)

The method of controlling for differences in case mix is

☐no risk adjustment or stratification
☒statistical risk model with (specify number) risk factors
☐stratification by (specify number) risk categories
☐other (specify) Click or tap here to enter text.

3.5.2 Rationale for Why There Is No Need for Risk Adjustment (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.21)

N/A

3.5.3 Conceptual, Clinical, and Statistical Methods (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.20)

A two-stage Cox model is used with the first stage being a patient model stratified by facility to avoid bias caused by different covariate distributions across facilities. In this model, covariates are taken to act multiplicatively on the modality switch rate and the adjustment model is fitted with facility defining strata in order to provide valid estimates even if the distribution of adjustment variables differs across facilities. Relevant references are Cox (1972) and Kalbfleisch and Prentice (2002). All analyses are performed using SAS.

The denominator of SMoSR for a facility is the expected number of switches from the patient-records

a facility is then the summation of expected probabilities of modality switch from all the patients assigned to that facility.

The patient characteristics included in the stage 1 model as covariates are:

- Age: Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 18-25 years old, 26-35 years old, 36-45 years old, 46-55 years old, 56-65 years old, 66-75 years old, 76-85 years old, or 85+ years old.
- Diabetes as cause of ESRD
- BMI at ESRD incidence:
    - BMI < 18.5
    - 18.5 ≤ BMI < 25
    - 25≤ BMI < 30
    - BMI ≥30
- Comorbidities at ESRD incidence:
    - Atherosclerotic heart disease
    - Other cardiac disease
    - Diabetes other than as primary cause of ESRD (all types including diabetic retinopathy)
    - Congestive heart failure
    - Inability to ambulate
    - Chronic obstructive pulmonary disease
    - Inability to transfer
    - Malignant neoplasm, cancer
    - Peripheral vascular disease
    - Cerebrovascular disease, CVA, TIA
    - Tobacco use (current smoker)
    - Alcohol dependence
    - Drug dependence
    - At least one of the comorbidities listed
- Calendar year

In general, adjustment factors for the SMoSR were selected based on several considerations, specifically clinical criteria, technical panel expert input, and data availability. We began with a large set of patient characteristics, including demographics, comorbidities at ESRD incidence, and other characteristics. Factors considered appropriate were then investigated with statistical models to determine if they were related to modality switch. Factors related to the SMoSR were also evaluated for face validity before being included. Finally, SDS/SES factors were evaluated based on appropriateness (whether related to disparities in care), and empirical association with the outcome. Based on input from the 2021 TEP, and because of known disparities based on race, ethnicity, sex, and SES, these factors were not included in the final model.

Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.

Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.

3.5.4 Conceptual Model of Impact of Social Risks (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.22)

☒published literature
☒internal data analysis
☐other (specify) Click or tap here to enter text.

3.5.5 Statistical Results (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.24)

Table 9: SMoSR Model Coefficients, Data Years 2016–2018.

Category	Covariates	Hazard Ratio	95% CI	p-value
Age	*	*	*	*
*	18 < Age <= 25	2.082	1.894, 2.287	< 0.001
*	25 < Age <= 35	1.919	1.813, 2.032	< 0.001
*	35 < Age <= 45	1.689	1.611, 1.77	< 0.001
*	45 < Age <= 55	1.249	1.198, 1.301	< 0.001
*	55 < Age <= 65	Reference	*	*
*	65 < Age <= 75	0.83	0.8, 0.862	< 0.001
*	75 < Age <= 85	0.58	0.553, 0.61	< 0.001
*	Age > 85	0.376	0.337, 0.418	< 0.001
BMI	*	*	*	*
*	BMI < 18.5	0.875	0.801, 0.955	0.003
*	18.5 ≤ BMI < 25	Reference	*	*
*	25≤ BMI < 30	1.141	1.102, 1.182	< 0.001
*	BMI≥30	1.05	1.016, 1.086	0.005
Cause of ESRD	*	*	*	*
*	Diabetes	0.973	0.934, 1.014	0.224
*	Missing	0.473	0.151, 1.481	0.202

Category	Covariates	Hazard Ratio	95% CI	p-value
Incident Comorbidities	*	*	*	*
*	Atherosclerotic heart disease	1.082	1.035, 1.132	0.001
*	Malignant neoplasm, cancer	1.083	1.024, 1.143	0.004
*	Other cardiac disease	1.031	0.994, 1.071	0.106
*	Peripheral vascular disease	0.91	0.863, 0.96	< 0.001
*	Chronic obstructive pulmonary disease	0.887	0.844, 0.934	< 0.001
*	Tobacco use (current smoker)	0.886	0.838, 0.935	< 0.001
*	Congestive heart failure	0.857	0.829, 0.886	< 0.001
*	Diabetes	0.838	0.799, 0.878	< 0.001
*	Cerebrovascular disease, CVA, TIA	0.818	0.776, 0.862	< 0.001
*	Inability to transfer	0.796	0.692, 0.914	0.001
*	Alcohol dependence	0.661	0.583, 0.749	< 0.001
*	Inability to ambulate	0.484	0.44, 0.533	< 0.001
*	Drug dependence	0.367	0.312, 0.432	< 0.001
*	At least one incident comorbidity	0.882	0.844, 0.923	< 0.001
Year	*	*	*	*
*	2016	0.791	0.767, 0.817	< 0.001
*	2017	0.874	0.847, 0.902	< 0.001
*	2018	Reference	*	*

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3.5.6 Analyses and Interpretation in Selection of Social Risk Factors (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.25)

The table below shows the parameter estimates for patient-level SDS/SES variables based on a Cox model for modality switch that included these variables along with the original covariates adjusted for in SMoSR.

Table 10: Comparing coefficients between sensitivity models with and without SDS/SES adjustors, 2016-2019: SMoSR Model coefficients

*	**Baseline SMoSR**	*	**SDS/SED-adjusted SMoSR**	*
Covariates	**Hazard Ratio**	**p-value**	**Hazard Ratio**	**p-value**
Gender	*	*	*	*
Female	NA	NA	0.99	0.447
Race	*	*	*	*
White	NA	NA	Reference	*
Black	NA	NA	0.592	< 0.001
Asian/Pacific Islander	NA	NA	0.858	< 0.001
Native American / Alaskan Native	NA	NA	0.667	< 0.001
other race	*	*	0.836	0.195
Ethnicity	*	*	*	*
Non-Hispanic	NA	NA	Reference	*
Hispanic	NA	NA	0.666	< 0.001
Dual Eligible Status	*	*	*	*
Non-Dual eligible	NA	NA	Reference	*
Dual Eligible	NA	NA	0.57	< 0.001
Area Level SES Deprivation	*	*	*	*
ADI	NA	NA	0.694	< 0.001
Employment status 6 months prior to ESRD	*	*	*	*
Employed	NA	NA	1.993	< 0.001
Retired/Other/Unknown	NA	NA	1.234	< 0.001
Unemployed	NA	NA	Reference	*
Age	*	*	*	*
18 < Age <= 25	2.082	< 0.001	2.195	< 0.001
25 < Age <= 35	1.919	< 0.001	2.065	< 0.001

*	**Baseline SMoSR**	*	**SDS/SED-adjusted SMoSR**	*
Covariates	**Hazard Ratio**	**p-value**	**Hazard Ratio**	**p-value**
35 < Age <= 45	1.689	< 0.001	1.761	< 0.001
45 < Age <= 55	1.249	< 0.001	1.265	< 0.001
55 < Age <= 65	Reference	*	Reference	*
65 < Age <= 75	0.83	< 0.001	0.825	< 0.001
75 < Age <= 85	0.58	< 0.001	0.57	< 0.001
Age > 85	0.376	< 0.001	0.367	< 0.001
Body Mass Index	*	*	*	*
BMI < 18.5	0.875	0.003	0.911	0.041
18.5 ≤ BMI < 25	Reference	*	Reference	*
25≤ BMI < 30	1.141	< 0.001	1.111	< 0.001
BMI≥30	1.05	0.005	1.015	0.403
Cause of ESRD	*	*	*	*
Diabetes	0.973	0.224	0.991	0.677
Missing	0.473	0.202	0.53	0.274
Incident Comorbidities	*	*	*	*
Atherosclerotic heart disease	1.082	0.001	1.048	0.043
Malignant neoplasm, cancer	1.083	0.004	1.02	0.474
Other cardiac disease	1.031	0.106	1	0.992
Peripheral vascular disease	0.91	< 0.001	0.908	< 0.001
Chronic obstructive pulmonary disease	0.887	< 0.001	0.902	< 0.001
Tobacco use (current smoker)	0.886	< 0.001	0.914	0.001
At least one incident comorbidity	0.882	< 0.001	0.919	< 0.001
Congestive heart failure	0.857	< 0.001	0.887	< 0.001

*	**Baseline SMoSR**	*	**SDS/SED-adjusted SMoSR**	*
Covariates	**Hazard Ratio**	**p-value**	**Hazard Ratio**	**p-value**
Diabetes	0.838	< 0.001	0.877	< 0.001
Cerebrovascular disease, CVA, TIA	0.818	< 0.001	0.868	< 0.001
Inability to transfer	0.796	0.001	0.826	0.007
Alcohol dependence	0.661	< 0.001	0.674	< 0.001
Inability to ambulate	0.484	< 0.001	0.516	< 0.001
Drug dependence	0.367	< 0.001	0.433	< 0.001
Year	*	*	*	*
2016	0.791	< 0.001	0.797	< 0.001
2017	0.874	< 0.001	0.879	< 0.001
2018	Reference	*	Reference	*

*This cell is intentionally left blank.

Figure 3: Comparison of SMoSR Model with and without SES/SDS

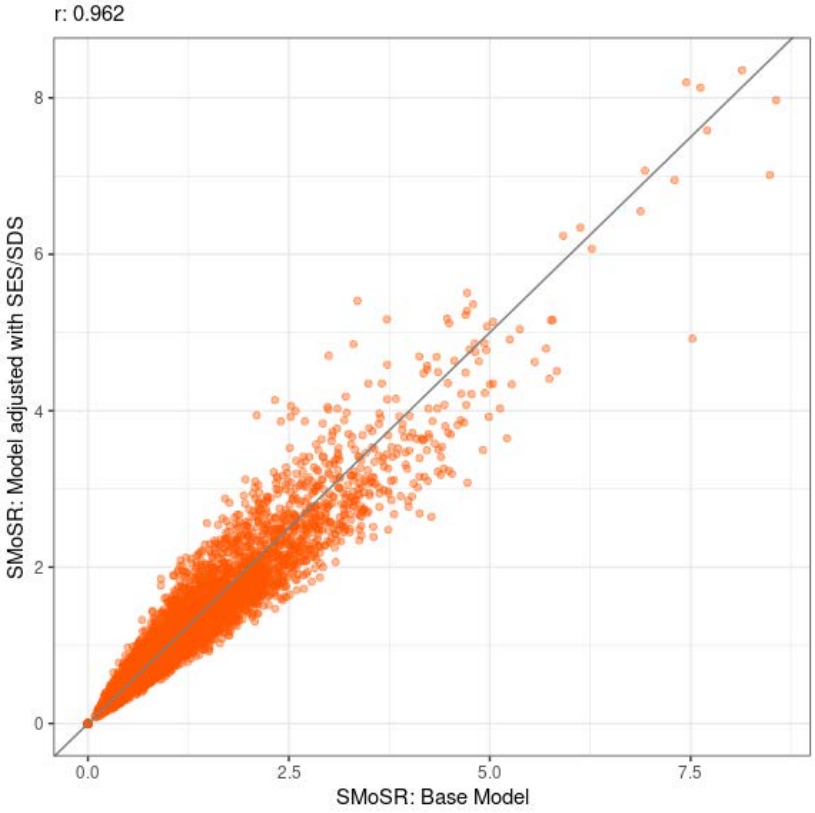


Table 11: Comparison of SMoSR Model with and without SES/SDS

Facility Performance	*	**SMoSR Without SES/SDS (current model)**	*	**Total**
*	Better than expected	As expected	Worse than expected	*
SMoSR With SES/SDS	*	*	*	*
Better than expected	374 (6.3%)	62 (1.0%)	0 (0%)	436 (7.4%)
As expected	87 (1.5%)	5,090 (86%)	87 (1.5%)	5,264 (89%)
Worse than expected	0 (0%)	51 (0.9%)	174 (2.9%)	225 (3.8%)
Total	461 (7.8%)	5,203 (88%)	261 (4.4%)	5,925 (100%)

(Pearson's r=0.962). *This cell is intentionally left blank.

Table 10 reports results of the SMoSR model that includes adjustment for social risk factors of race, ethnicity, sex, dual eligible status, employment status, and area deprivation. Black patients, Asian/Pacific Islander, Native American/Alaskan Native patients had a 40%, 15%, and 33%, respectively, lower hazard of switching from in-center dialysis to a home modality in their first year of dialysis (all $p<0.001$). Patients of Hispanic ethnicity also had a 34% lower hazard ($p<0.001$) of switching modality from in-center to home dialysis, while the impact on females was no different than males. These findings are consistent with the published literature (e.g., Shen 2020; Mehrotra 2015). Among SES factors, employment status at incidence, dual eligible status and area level SES deprivation (ADI) were associated with modality switch events. Employment at ESRD incidence was associated with 99% higher hazard ($p<0.001$) of switching from in-center to home dialysis treatment while patients with Medicare dual eligible status or in areas with higher SES deprivation had lower hazard of modality switch (43%, 31%, respectively, all $p<0.001$). This is consistent with the literature (e.g., Perez 2018; Thorsness 2021) that suggest people with lower SES have lower uptake of a home dialysis modality. The lower uptake is potentially based on an assumption that patients with lower SESE do not have the material and social resources needed to support dialysis at home. Similarly, facilities may generally not encourage home dialysis for patients that they feel may not be able to successfully do dialysis at home due to limited social and economic resources.

Table 11 and figure 3 show results that compare facility performance between the base model that does not adjust for social risk factors, to a model that includes adjustment for race, ethnicity, sex, dual eligible status, employment status at ESRD incidence, and area deprivation. After adjustment for these social risk factors, 287 facilities (4.8%) changed performance categories. One-hundred thirty-eight (2.3%) facilities moved to a lower performance category, and 149 (2.5 %) moved to a higher performance category. SMoSR with and without adjustment for patient SDS/SES were highly correlated (Pearson's $r=0.962$).

There are known disparities in uptake of home dialysis modalities among people of Black race, Hispanic ethnicity, and lower socioeconomic status. This was further highlighted in a recent study examining the association of social risk factors and uptake of home dialysis (Thorsness et al 2021). Overall the study reported that facilities with higher percentages of patients with social risk factors of race, ethnicity, or Medicaid coverage were less likely to offer peritoneal dialysis and had lower rates of initiation of home dialysis. These findings are generally consistent with other peer-reviewed literature that has reported lower uptake of home dialysis in these populations (e.g., Shen 2020; Mehrotra 2015). Thorsness et al (2021) suggested consideration of risk adjustment to assure a fair assessment of facilities with higher proportions of patients with social risk factors. However, there was no examination whether the source of these differences was related to disparities in care and access to home modalities, in which case adjustment would not be appropriate.

Race, Hispanic ethnicity, female sex, and SES factors are not included in the final risk adjusted model for SMoSR. While these factors are associated with decreased uptake of home dialysis in patient-level analyses, the impact is largely attenuated at the facility-level analysis of flagging. That is, 95.2% of facilities performance category will not change with or without adjustment for these social risk factors.

Furthermore, among the 4.8% of facilities whose performance category does change with SES/SDS adjustment, the 2.5% of facilities who move to a higher performance category are offset by the 2.3% of facilities that move to a lower performance category. Further work is needed to demonstrate that differences based on these factors are not related to facility processes of care and differences in the education provided to patients about home dialysis, in order to prevent disparities in care. While there is a push to include social risk factors as adjustments in performance measures, this has potential unintended consequences that may exacerbate disparities. In the absence of definitive evidence demonstrating risk adjustment for these social factors does not result in differential access to care, the most appropriate decision is not to risk adjust for these SDS/SES factors. The primary goal should be to implement quality measures that result in the highest quality of patient care and equitable access for all patients to that care.

Finally, the 2021 Technical Expert Panel consensus was there are known disparities between social risk factors and uptake of home dialysis. TEP members expressed concern that adjusting for social risk factors of race, ethnicity, sex, and SES could potentially further disadvantage patients based on their race, ethnicity, or lack of SES-based resources (UM-KECC, 2021). During the TEP, CMS noted potential legal challenges with implementing race and ethnicity adjustment factors in Federal Payment Programs.

3.5.7 Method Used to Develop the Statistical Model or Stratification Approach (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.26)

Risk factors were selected for the final model based on the magnitude of the coefficients, evaluation of their statistical significance, and the model C-statistic. The C-statistic measures the discriminative power of the regression model with considered risk factors.

3.5.8 Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R^2) (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.27)

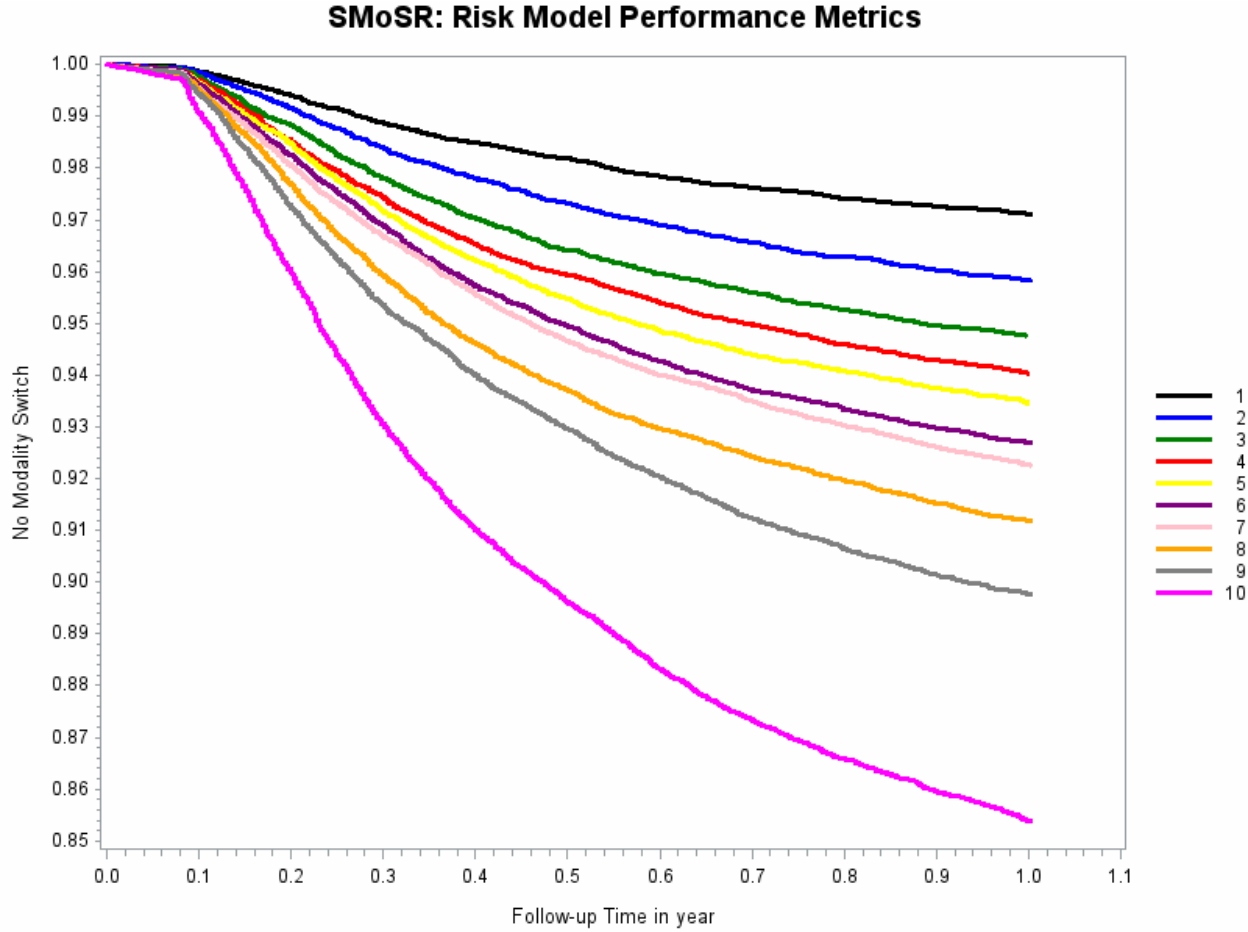
In this model, the C-Statistic=0. 674, which suggests good predictive ability of the risk model.

3.5.9 Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic) (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.28

N/A

3.5.10 Statistical Risk Model Calibration—Risk decile plots or calibration curves (NQF Measure Submission Form: Other Threats to Validity [Exclusions, Risk Adjustment] 2b.29)

Figure 4. Decile plot for SMoSR



3.5.11 Results of Risk Stratification Analysis (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity (Exclusions, Risk Adjustment) 2b.30)

N/A

3.5.12 Interpretation (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.31)

Figure 4 is the decile plot showing estimates of cumulative rates with no modality switch by follow-up time. The plot shows that the risk factors in the model are discriminating well between patients. There is good separation among all 10 groups and the ordering is as predicted by the model (patients predicted to be at higher risk of not switching to home dialysis have the lowest modality switch rates). The absolute differences between the groups is also large at one year ranging from 98% for those patients predicted to have the lowest modality switch rates (group 1) down to 85% for those predicted to have the highest rates of modality switch (group 10).

3.5.13 Optional Additional Testing for Risk Adjustment (NQF Measure Submission Form, Scientific Acceptability: Validity - Other Threats to Validity [Exclusions, Risk Adjustment] 2b.32)

N/A

3.6 Identification of Meaningful Differences in Performance **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b)

3.6.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.05)

The p-value for a given facility is a measure of the strength of the evidence against the hypothesis that the modality switch rate for this facility is identical to that seen nationally overall, having adjusted for the patient mix. Thus, the p-value is the probability that the facility's SMoSR would deviate from 1.00 (national rate) by at least as much as the facility's observed SMoSR. In practice, the p-value is computed using a Poisson approximation under which the distribution of the number of switches to a home modality in the facility is Poisson with a mean value equal to E, the expected number of switches as computed from the Cox model. Accordingly, if the observed number, O, is greater than E, then p-value = 2 * Pr(X>=O) where X has a Poisson distribution with mean E. Similarly, if O<E, the p-value = 2 * Pr(X <=O) where X has a Poisson distribution with mean E.

If the facility SMoSR is less than 1.00 and statistically significant (p<0.05), the classification is "Worse than Expected". This classification is based on the measure ratio, not the rate. If the ratio is greater than 1.00 and statistically significant (p<0.05), the classification is "Better than Expected". Otherwise, the classification is "As Expected". Please note that the facility is not included here if the facility had less than 1 expected modality switch during the reporting period.

3.6.2 Statistical Results (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.06)

Table 3: Proportion of facilities with statistically significant differences

Proportion of facilities with statistically significant differences (p-values < 0.05) is shown as follows:

Better than Expected	As Expected	Worse than Expected	Total
465 (7.7%)	5,313 (88%)	261 (4.3%)	6039

3.6.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.07)

Facilities are flagged if they have outcomes that are extreme when compared to the variation in national modality switch rates adjusted for patient case-mix.

Across all facilities, for the 2016-2019 SMoSR, the majority of facilities had modality switch scores that were "As Expected." Approximately 7.7% of facilities had a SMoSR that was "Better than expected," while 4.3% of facilities had a SMoSR that was "Worse than expected."

3.7 Comparability of Multiple Data Sources/Methods **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b)

3.7.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.12)

N/A

3.7.2 Statistical Results (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.13)

N/A

3.7.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.14)

N/A

3.8 Missing Data Analysis and Minimizing Bias **(for reference only)** (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data])

3.8.1 Method (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.08)

Many data elements can be obtained from multiple sources and missing data occurs rarely for covariates included in this measure.

Age is calculated using the date of birth and reporting month. Date of birth is required in our Standard Analysis Data Files, therefore no missing values were identified in the patient population. We assessed missing data for the CMS-2728 form which is used to determine incident comorbidities.

3.8.2 Missing Data Analysis (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.09)

Summary findings:

Patients with missing primary cause of ESRD on Form CMS-2728 is 0.02% and missing BMI on 2728 is 0.31% of the all patients.

Table 4. Frequency of missing data elements, 2018 data

Data Element	Missing (%)
Patients with missing primary cause of ESRD on Form CMS-2728	0.02%

Data Element	Missing (%)
Patient without BMI reported on Form CMS-2728	0.31%

3.8.3 Interpretation (NQF Measure Submission Form: Scientific Acceptability: Validity - Threats to Validity [Statistically Significant Differences, Multiple Data Sources, Missing Data] 2b.10)

There is a very low frequency of patients with missing primary cause of ESRD and BMI from the CMS form 2728. Missing primary cause of ESRD was adjusted through inclusion of a missing indicator in the regression model, and missing BMI was included as BMI 30+ category (the group with the highest frequency). Given such a small percent of missing (0.31% for BMI and 0.02% for primary cause of ESRD on CMS 2728 form), the impact of missing data on performance scores is negligible and unlikely to be a source of bias in the measure.

4. Feasibility (NQF Feasibility Criterion 3)

4.1 Data Elements Generated as Byproduct of Care Processes (NQF Measure Submission Form, Feasibility 3.01)

Data used in the measure are (check all that apply)

☒generated or collected by and used by healthcare personnel during provision of care (e.g., blood pressure, laboratory value, diagnosis, depression score)
☒coded by someone other than the person obtaining original information (e.g., Diagnosis-Related Group [DRG], International Classification of Diseases, 10th Revision, Clinical Modification/Procedure Coding System [ICD-10-CM/PCS] codes on claims)
☐abstracted from a record by someone other than the person obtaining original information (e.g., chart abstraction for quality measure or registry)
☐other (specify) Click or tap here to enter text.

4.2 Electronic Sources

4.2.1 Data Elements Electronic Availability (NQF Measure Submission Form, Feasibility 3.02.)

To what extent are the data elements needed for the measure available electronically (i.e., needed elements to compute quality measure scores are in defined, computer-readable fields)?

☐All data elements are in defined fields in EHRs.
☐All data elements are in defined fields in electronic claims.
☐All data elements are in defined fields in electronic clinical data such as clinical registry, nursing home MDS, and home health OASIS.
☒All data elements are in defined fields in a combination of electronic sources.
☐Some data elements are in defined fields in electronic sources.
☐No data elements are in defined fields in electronic sources.
☐Data are patient/family reported information; may be electronic or paper.

4.2.2 Path to Electronic Capture (NQF Measure Submission Form, Feasibility 3.03)

N/A

4.2.3 eCQM Feasibility (NQF Measure Submission Form, Feasibility 3.05)

N/A

4.3 Data Collection Strategy

4.3.1 Data Collection Strategy Difficulties (optional) (Measure Submission Form, Feasibility 3.06)

None identified.

4.3.2 Fees, Licensing, Other Requirements (NQF Measure Submission Form, Feasibility 3.07)

N/A

5. Usability and Use (NQF Usability and Use Criterion 4)

5.1 Use (NQF Measure evaluation criterion 4a)

5.1.1 Current and Planned Use (NQF Measure Submission Form, Use 4a.01 and 4a.02)

☐public reporting
☐public health or disease surveillance
☐payment program
☐regulatory and accreditation programs
☐professional certification or recognition program
☐quality improvement with external benchmarking to multiple organizations
☐quality improvement internal to a specific organization
☒not in use
☐use unknown

5.1.1.1 Reasons for Not Publicly Reporting or Use in Other Accountability Application (NQF Measure Submission Form, Use 4a.03)

The measure is undergoing initial endorsement review.

5.1.1.2 Plan for Implementation (NQF Measure Submission Form, Use 4a.04)

CMS will determine if/when to report this measure in a public reporting/payment program. Potential applications for the measure include the ESRD Quality Incentive Program (ESRD QIP) or the Dialysis Facility Care Compare website.

5.1.2 Feedback on the Measure by Those Being Measured or Others (NQF Measure Submission Form, Use 4a.05)

5.1.2.1 Technical Assistance Provided During Development or Implementation (NQF Measure Submission Form, Use 4a.06)

N/A

5.1.2.2 Technical Assistance with Results (NQF Measure Submission Form, Use 4a.06)

N/A

5.1.2.3 Feedback on Measure Performance and Implementation (NQF Measure Submission Form, Use 4a.07)

N/A

5.1.2.4 Feedback from Measured Entities (NQF Measure Submission Form, Use 4a.08)

N/A

5.1.2.5 Feedback from Other Users (NQF Measure Submission Form, Use 4a.09)

N/A

5.1.2.6 Consideration of Feedback (NQF Measure Submission Form, Use 4a.10)

N/A

5.2 Usability (NQF Measure evaluation criterion 4b)

5.2.1 Improvement (NQF Measure Submission Form, Usability 4b.01)

See Importance to Measure and Report for data on performance gap and disparities.

SMoSR is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this measure after endorsement review. Once implemented, facility performance on this measure can be evaluated to determine if the measure has supported and detected quality improvement in home dialysis rates.

5.2.2 Unexpected Findings (NQF Measure Submission Form, Usability 4b.02)

N/A

5.2.3 Unexpected Benefits (NQF Measure Submission Form, Usability 4b.03)

N/A

6. Related and Competing Measures (NQF Related and Competing Criterion 5)

6.1 Relation to Other NQF-Endorsed Measures (NQF Measure evaluation criterion 5)

Are there related measures or competing measures?

☐yes
☒no

6.2 Harmonization (NQF Measure Submission Form, Related and Competing 5.04 and 5.04)

N/A

6.3 Competing Measures (NQF Measure Submission Form, Related and Competing 5.06)

N/A

Additional Information (NQF Measure Submission Form, Additional)

Appendix

Available in attached files.

Other Additional Information

Derek Forfang *(TEP Co-Chair),* Patient Advocate

Brigitte Schiller MD *(TEP Co-Chair*), Nephrologist, Chief Medical Officer, Satellite Healthcare

Rodney Carter, Patient Advocate

Michelle Cassin RN, CPDN, DaVita Kidney Care

Glenn Chertow MD, MPH, Nephrologist, Professor of Medicine and Professor of Epidemiology and Population Health, Stanford University School of Medicine

Paul T. Conway BA, Chair of Policy and Global Affairs- American Association of Kidney Patients

Richard Knight MBA, President, American Association of Kidney Patients

April McGraw BSN, RN, CNN, Patient Advocate and Dialysis Nurse, DaVita Kidney Care

Rajnish Mehortra MD, Nephrologist, University of Washington

Matthew Oliver MD, MHS, FRCPC, Nephrologist, University of Toronto; Sunnybrook Health Sciences Centre; ISPD- North American Chapter

Amber Pettis, BS, Biochemistry; MBA, Patient Advocate, National Kidney Foundation

Cheri Rodriques Jones, Patient Advocate

Martin Schreiber MD, Nephrologist, Chief Medical Officer Home Modalities, DaVita Kidney Care

Stacy Cigliana RN, CNN, VP Clinical Services- Home Therapies, US Renal Care

Isaac Teitelbaum MD, Nephrologist, University of Colorado, Anschutz Medical Center

Eric Weinhandl PhD, Epidemiologist, Chronic Disease Research Group

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2. First Year of Measure Release

2022

Ad.3. Month and Year of Most Recent Revision

01/2022

Ad.4. What is your frequency for review/update of this measure?

Annual

Ad.5. When is your next scheduled review/update for this measure?

4/2023

Ad.6. Copyright Statement

N/A

Ad.7. Disclaimers

N/A

Ad.8. Additional Information/Comments

N/A

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