TO: All KCQA Members

FR: Vincent Mor, PhD
Robyn Y. Nishimi, PhD
Lisa McGonigal, MD, MPH

RE: KCQA Measure Testing Results

DA: February 16, 2015

NQF's endorsement criteria center on four criteria: Importance to Measure and Report (including a specific performance gap), Scientific Acceptability (reliability and validity of the measure's properties), Usability and Use, and Feasibility. Importance, Usability and Use, and Feasibility are met via the literature review (largely) and the fact that the measures (or similar variants) are used for internal quality improvement and the data are collected during the regular flow of care and are accessible electronically for the vast number of patients.

Addressing the performance gap, reliability, and validity criteria requires testing of the measure specifications. Accordingly, in November 2014, KCQA members approved retrospective testing the specifications for two fluid management measures—***FM2: Post-Dialysis Weight Above or Below Target Weight*** and ***FM7: Avoidance of Utilization of High Ultrafiltration Rate (UFR) (≥13 ml/kg/hour)***. Though not required by NQF, prospective testing also was approved to assess implementation-related issues. The specifications approved for FM2 and FM7 are provided as Attachment A.

SUMMARY
This memorandum:

- provides a high-level review of the retrospective testing approach;
- summarizes the testing results;
- recommends two modifications to the specifications (one for each measure); and
- reviews the measure submission material being provided to NQF by CMS for its UFR measure;
- provides the KCQA Steering Committee's recommendation regarding whether FM2 and FM7 should be submitted to NQF for endorsement consideration.

In summary, testing the **specifications for both FM2 (weight) and FM7 (UFR) identified a performance gap**, with a range of 0 to 100% (lower number is better for both measures), and an average score of 23% for FM2 and 11.9% for FM7. (We believe the 100% is due to low census, which is currently being analyzed further.)

The intra-class correlation for this measure across the three participating dialysis organizations is reasonably high, indicating a reasonable level of reliability within facilities over time—i.e., there is considerable within-facility stability with respect to performance on this measure over the course of 12 months. The estimated between-facility variance is greater than the within-facility variation, suggesting that the measure discriminates between the 4,884 facilities. **Across**

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all groups, there is more variation between facilities than within facilities, which, when considered in light of the relatively high intra-class correlation coefficients, suggests that the measure is reliable and differentiates between facilities.

For both FM2 and FM7, the correlations between performance on each measure and the SMR, SHR, and hospitalization rate are statistically significant and in the expected direction. Facilities with fewer patients deviating from their prescribed target weight post-dialysis have lower mortality and hospitalization, as do facilities that have fewer patients with high UFR. While the size of the correlation in not large, it does reflect the hypothesized underlying relationship between process measures of dialysis quality and the ultimate patient outcome of mortality and hospitalization, and the correlations found are in-line with similar relationships for hospital and nursing home process measures and hospitalization, rehospitalization, and mortality.

Finally, **we recommend two changes to the specifications.** First, based on the very strong recommendation of the testing organizations, **we recommend FM7 exclude patients receiving dialysis > three times/week** because the underlying evidence base drew upon this population. Second, **we recommend FM2 be limited to a calculation period that is defined as the same week that the monthly Kt/V is drawn.** This change significantly reduces burden for manual data submitters and, as importantly, harmonizes it with FM7. One organization tested this construct and found the average score per facility was 2.7% higher (lower score is better performance). Reliability and validity were comparable to the "every session" construct. (Please note that the specifications table has redline to exclude patients with a functioning kidney transplant; this was inadvertently not reflected in the voting version of the table, but was agreed to, so needs to be represented going forward.) **With these changes, the KCQA Steering Committee recommends KCQA members approve submission of FM2 and FM7 to NQF.**

TESTING APPROACH

Following approval of the specifications, we developed a retrospective testing and data analysis protocol designed to use data from three KCQA member dialysis organizations, each with the capacity to provide retrospective analyses from a data warehouse. The protocol was further refined via email and conference calls with individuals[1] from the three providers.

Participating organizations reviewed pertinent data from their data warehouse/ repository systems for all eligible dialysis patients treated at all their facilities across the United States. So as to allow validation of the measures (process and rationale described in a following section) against the most current Standardized Hospitalization Ratio (SHR) and Standardized Mortality Ratio (SMR) scores publicly available on Dialysis Facility Compare (DFC), data spanning the period January 1, 2013 through December 31, 2013 were used.[2]

To acknowledge multiple testing organizations, no data-sharing, and anonymization, data are presented by organization, but with no identifiers.

TESTING RESULTS

NQF requires information on: 1) demographics of the test population, in particular information about denominator exclusions; 2) demonstration of a performance gap; 3) testing and analysis

[1] Steve Brunelli (DVA), Jay-r Lacson (FMC), and Dan Weiner (DCI).
[2] Data from the end of December 2012 may have been necessary to calculate FM7 for some sessions.

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of the measure's reliability and validity; and 4) demonstration that the measures identify statistically significant and meaningful differences in performance.

Demographics

NQF seeks information on the number of measured entities, as well as number of patients included and excluded.

Measured Entities

Since KCQA agreed that the appropriate minimum number of patients per facility would be empirically determined during testing (i.e., we would not *a priori* adopt the CMS threshold of 11 patients nor the KCP threshold of 25 patients), all facilities within each organization (with the exceptions noted below) were included in the study. The following is a composite of the facility demographics:

- 4,884 facilities across the three organizations were included in the study.
- Based on the monthly averages, the mean facility census (i.e., the number of patients receiving care at the facility, weighted and averaged across the three organizations) was 84.11 patients. Facility populations ranged from 1 to 664 patients per month.
- Nine facilities were excluded from the study for the following reasons:
    - The facility had only one adult patient in 2013.
    - Two facilities had on average only one patient per month in 2013.
    - The facility was part of the company for only one month in 2013.
    - All patients within five facilities received <7 treatments in any given month in 2013.

Patients

A total of 412,522 patients across the three organizations met the measures' denominator criteria and were included in the study, with a range of 15,184 to 215,008 patients per organization. In summary:

- Mean patient age = 61.66 years
- Range of patient ages = 18.01 to 104.00 years
- Gender = 56.26% male and 43.74% female
- Race/Ethnicity = 52.37% white, 36.33% African American, 2.82% Asian, 1.16% American Indian/Native Alaska, 0.67% Native Hawaiian/other Pacific Islander, 0.57% other/missing/declined; 15.60% Hispanic (independent of race).

With one exception, the denominator and exclusion definitions are the same for both measures. The following data thus apply to both FM2 and FM7 (*Note: Data on monthly exclusions totals that impact the first two bullets are still pending from one organization)*:

- The total number of annual exclusions across the two organizations that have submitted this information to date was 195,625 patient-months (9.00%), with a range of 14,949 to 180,676 patient-months excluded per organization in 2013.
- The average monthly exclusion count across the two organizations was 16,302 patients (approximately 8.25%), with a range of 1 to 255 patients excluded per facility each month.
- The annual counts for the individual exclusions across the three organizations were:
    - Age <18 years = 32,622 patient-months were excluded, for an annual exclusion rate of 0.66%.
    - Patients in a facility <30 days = 375,201 patients-months were excluded across the year, for an annual exclusion rate of 7.58%.

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- Home dialysis patients = 251,304 patient-months (5.08%).
- <7 hemodialysis treatments in the facility during the reporting month = 378,345 patient-months (7.64%).
- Patients without a completed CMS Medical Evidence Form (Form CMS-2728) in the reporting month = 32,806 patient-months (0.65%).
- Kidney transplant recipients with a functioning graft = not tested, as discussed further below.

Although not provided for in the original protocol, the testing advisors recommended that patients receiving four or more dialysis sessions in the calculation period also be excluded from the FM7 denominator population only. For this data element, the annual exclusion count was 78,077 patient-months, yielding an annual exclusion rate of 1.58%.

As can be seen, with one exception (transplant recipients with functioning graft), the frequency with which the exclusions were encountered during testing is sufficient to demonstrate they are necessary to prevent unfair distortion of performance results; table 4 of Attachment B documents that the variability in their occurrence across providers also supports the need for the exclusions. We note that KCP historically has supported a standardized exclusion of "patients with functioning kidney transplant." KCQA discussed and agreed to include such an exclusion, but it was inadvertently not reflected in the table approved by KCQA in November 2014. The exclusion was, however, included for testing in the protocol. We found it could not be operationalized consistently across providers during the limited time for testing, but have retained it in the current specifications since it remains clinically relevant and appropriate.

Performance Gap[3]

NQF requires evidence of a performance gap demonstrating variation in performance across providers. The KCQA testing results demonstrate a performance gap for both measures; that is, there are opportunities for improvement.

FM2—Post-Dialysis Weight >1 kg Above or Below Target Weight

FM2 assesses the percentage of patients whose average post-dialysis weight is 1 kg or more above or below the prescribed target weight during the reporting period. The intent of the measure is to increase focus on the identification and correction of post-dialysis and target weight discrepancies to help attenuate large fluctuations in fluid balance and blood pressure that contribute to volume overload syndromes, hypertension, and cardiac hypertrophy and decrease associated hospitalizations and mortality.

The ranges and mean annual performance scores across all facilities indicate there is large variation in performance (lower score = better performance):[4]

- Organization A: range 0.93-62.50%, 17.91% average (95% CI = 16.45-19.38; SD = 10.81)
- Organization B: range 0-100%,[5] 21.82 average (95% CI = 21.67-21.98; SD = 12.03)
- Organization C: range 0-100%,[5] 25.13% average (95% CI = 24.62-25.63; SD = 11.56)

[3] Data were analyzed at the level of the individual dialysis session to create a monthly score for each facility for each of the 12 months of 2013; monthly scores were aggregated up to yield an annual score for each facility.

[4] Some data are presented as coming from Organization A, B, and C, but to preserve anonymity, this nomenclature is random and is scrambled throughout the memo and Attachment B, such that Organization A in one section might become Organization B or C in another section.

[5] Participating organizations noted that scores of 100% were secondary to low census and are currently analyzing the data to determine whether these facility-months should be removed from the denominator were a census criterion incorporated into the measure specifications.

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FM7—Avoidance of High Ultrafiltration Rate

FM7 assesses the percentage of patients with an average UFR >13 ml/kg/hour with an average session duration of <240 minutes and who receive less than four treatments in the calculation period. The rationale for the measure is to foster the use of slower, gentler dialysis sessions to reduce hemodialysis-related mortality. After patients with four or more dialysis sessions in the calculation period are excluded from the denominator, the measure criteria can be met by employing either or both of two approaches: 1) dialyzing patients at an average UFR <13 ml/kg/hour and/or 2) dialyzing patients for an average of ≥240 minutes per session during the reporting period. Adherence to these conventions will help attenuate the rapid fluctuations in fluid balance and blood pressure that contribute to cardiovascular morbidity and mortality in hemodialysis patients.

The ranges and mean annual performance scores across all facilities indicate there is significant variation in performance across facilities (lower score = better performance).

- Organization A: range 0-34.46%, 12.45% average (95% CI = 11.57-13.34; SD = 6.56)
- Organization B: range 0-48.00%, 10.68% average (95% CI = 10.39-10.97; SD = 6.60)
- Organization C: range 0-100%,[6] 12.67% average (95% CI = 12.56-12.79; SD = 8.82)

Reliability

The reliability of the measures was assessed using a repeated measures analysis of variance (ANOVA) test. Data were statistically analyzed using the facility and the treatment month as independent variables and the measure scores as dependent variables. Analyses were conducted separately for all the facilities in each of the dialysis organizations. The rationale for using repeated measures ANOVA in these analyses is that there should be relatively little within-facility variation in the monthly proportion of patients' dialysis treatment sessions that do not meet the clinical standard threshold (e.g., are within +/- 1.0 kg of the difference between the observed and desired weight post-treatment). Rather, if these measures are helpful in discriminating high and low performing facilities, the level of variation from month to month should be high between facilities.

Both FM2 and FM7 were analyzed for within- and between-facility variance among patient treatment sessions that did not meet the quality standard specifications. The "within" facility variation is the "error variance" or "noise" that reflects the degree of between-month variation in the measure that occurs within a facility. On the other hand, the "between" facility variation is the explained or "systematic variance" (i.e., the "signal") that is attributable to variation in performance between facilities and represents real differences in performance. We calculated the intra-class correlation coefficient for each of the quality measures which estimate the ratio of the between to the within group variance, standardized for both the level of variation and the numbers of observations facilities examined. The higher the intra-class correlation coefficient, the greater the reliability of the measures. We also examined the ratio of the between- to the within-facility variation in the two measures as a "signal to noise" ratio. When there is more between-facility variation than there is within-facility variation, the measure is discriminating between facilities.

[6] Participating organizations noted that scores of 100% were secondary to low census and are currently analyzing the data to determine whether these facility-months should be removed from the denominator were a census criterion incorporated into the measure specifications.

KCQA WORKING DOCUMENT

FM2—Post-Dialysis Weight ≥1 kg Above or Below Target Weight

In the table below, we report the FM2 intra-class correlation coefficient across the study facilities in each of the three participating organizations, as well as the respective between- and within-group variances and the ratio of between- to within-facility variation:

Dialysis Organization	Intra-Class Correlation	Between-Facility Co-Variance	Within-Facility Co-Variance	Ratio of Between- to Within-
A	.77	.011	.003	3.6
B	.71	123.6	49.2	2.5
C[7]	.63	231.8	116.4	2.0

As can be seen, the intra-class correlation for this measure across the dialysis organizations is reasonably high, indicating a reasonable level of reliability within facilities over time. This means that there is considerable within-facility stability with respect to performance on this measure over the course of 12 months. Additionally, the estimated between-facility variance is greater than the within-facility variation, suggesting that the measure discriminates between the facilities participating. Across all groups, there is more variation between facilities than within facilities, which, when considered in light of the relatively high intra-class correlation coefficients, suggests that the measure is reliable and differentiates between facilities.

FM7—Avoidance of High Ultrafiltration Rate

The FM7 intra-class correlation coefficient across the study facilities in each of the three organizations is presented in the following table, as well as the respective between- and within-group variances and the ratio of between- to within-facility variation:

Dialysis Organization	Intra-Class Correlation	Between-Facility Variance	Within-Facility Variance	Ratio of Between- to Within-
A[8]	.60	321.2	184.0	1.7
B	.70	41.1	17.4	2.3
C	.65	.004	.002	2.0

The intra-class correlation for this measure across the organizations is also reasonably high, indicating a reasonable level of reliability and within-facility stability over the course of 12 months. Additionally, the estimated between-facility variance is greater than the within-facility variation, again suggesting that the measure discriminates between the participating facilities. Across all groups, there is more variation between facilities than within facilities, which when considered in light of the relatively high intra-class correlation coefficients, suggests that the measure is reliable and differentiates between facilities.

Validity

Correlative validity was used to meet NQF's validity testing requirements. Specifically, the validity of the measures was evaluated by correlating facility-specific FM2/FM7 scores with each facility's 2013 Standardized Hospitalization Ratio for Admissions measure (SHR) and Standardized Mortality Ratio measure (SMR)[9] scores, using Pearson's Correlation Coefficient.[10,11] As noted previously, 2013 facility data were used for testing to allow for

[7] Dialysis organization C provided Sums of Squares data that were used to calculate the statistics.
[8] Dialysis organization A provided Sums of Squares data that were used to calculate the statistics.
[9] The SMR specifications are based on a 4-year rolling period.
[10] While flawed in KCP's view, the SHR and SMR are NQF-endorsed and could be reasonably viewed by an NQF Committee as publicly available outcome measures that KCQA's measures could be expected to impact.
[11] The Standardized Readmission Ratio for Dialysis Facilities measure (SRR) also was suggested as a possible alternative to the SHR. However, the SRR is not yet NQF-endorsed and is not publicly available, in contrast to the

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correlation with the most current SHR/SMR scores publicly available on Dialysis Facility Compare (DFC); as noted previously, both the SHR and SMR are NQF-endorsed measures. If available, correlation to 2013 hospitalization rates from DFRs also were analyzed.

FM2—Post-Dialysis Weight >1 kg Above or Below Target Weight
The FM2 Pearson's Correlation Coefficients are summarized as follows:

Dialysis Organization	2013 SHR	2013 hospitalization rate (from DFR)	2013 SMR
A	0.16	0.19	0.10
B	0.17	0.17	0.25
C	0.19		0.15

FM7—Avoidance of High Ultrafiltration Rate
The FM7 Pearson's Correlation Coefficients are summarized as follows:

Dialysis Organization	2013 SHR	2013 hospitalization rate (from DFR)	2013 SMR
A	0.11	0.11	0.07
B	0.12		0.17
C	0.09	0.08	0.03

The correlation between the quality performance measure of the deviation between patients' post-dialysis weight and their prescribed weight and the SMR and SHR is statistically significant and in the expected direction; facilities that have fewer patients deviating from their prescribed weight post-dialysis have lower mortality and hospitalization. Similarly, the correlations between avoidance of high UFR and the SMR and SHR are statistically significant and in the expected direction; facilities that have fewer patients with high UFR have lower mortality and hospitalization.

While the size of the correlation in not large, it does reflect the hypothesized underlying relationship between process measures of dialysis quality and the ultimate patient outcome of mortality and hospitalization. There are many reasons that measures of process and outcome are only minimally correlated. Hospitalizations and death are caused by many factors other than the performance of the dialysis facility and are much broader and complex measures than an indicator of the process of dialysis, which is what the FM2 and FM7 measures are. The literature on the relationship between hospitals' quality performance and 30-day mortality or rehospitalization for selected conditions or the relationship between nursing home quality measures and 30-day rehospitalization rates suggest only low levels of correlation. Thus, relatively speaking, facilities that have better performance on these process quality performance measures have lower standardized hospitalization and mortality.

Statistical/Meaningful Difference
In addition to reliability and validity information, NQF requests "statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities." NQF does not provide detailed guidance, so we reviewed measure submission forms

SHR. Additionally, the SRR does not capture all of a facility's admissions because it looks only at readmissions within 30 days of an index discharge, and thus might not correlate with other measures of quality as strongly as might the SHR, which captures all hospitalizations.

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for five NQF measures across four recent projects. The approach of the Joint Commission was the most straightforward.[12]

Descriptive statistics for the annual performance measure scores for all tested entities were constructed. These statistics include the mean, standard deviation and standard error, 95% confidence interval, median, mode, and range of scores across the measured entities. As did the Joint Commission, we defined meaningful difference as a significant spread (>20%) between minimum and maximum scores or a significant spread between median and minimum or median and maximum scores.

Measure	N	Range of Scores	Mean Score	Median Score	Mode of Scores	Interquartile Range
FM2	2,205 (2 of 3 organizations)	0-100%	24.43% SD =11.68 SE = 0.25 95% CI = 23.95%-25.92%	24.00%	25.00%	16.00
FM7	2,200 (2 of 3 organizations)	0-48%	10.85% SD =6.61 SE = 0.14 95% CI = 10.57-11.13%	10%	8%	8.00

The results for both measures are interpreted as showing a significant spread between both the minimum and maximum scores, as well as the median and minimum and maximum scores, indicating meaningful differences.

REVIEW OF CMS UFR MEASURE

As you are aware, CMS has developed and is submitting an ultrafiltration rate measure to NQF—*Ultrafiltration Rate > 13 ml/kg/hour*—that is similar, but has key differences, from FM7. We have had two conference calls with CMS and UM-KECC regarding harmonizing our measures. There are some small issues (e.g., KCQA is ≥13 vs. CMS is >13), but the greatest discrepancies between the two measures are:

- The CMS measure does not contain a length of session component. To encourage longer dialysis and not create unintended consequences of longer session on the patient(s) that follow on such a treatment day (who may then sign-off early), the KCQA measure accounts for time.
- The CMS measure relies on data from a single session (the session data submitted via CROWNWeb for the Kt/V measure). To avoid potential gaming when a single event is used and create a more accurate representation of performance, the KCQA measure specifies an average rate for the three sessions—the Kt/V measure data and data from the other two sessions during that week. This three-session average also obviates potential uneven-ness in performance that could arise depending on the particular day of the week any given facility is using for the Kt/V data.

We believe it's important for the Steering Committee and all KCQA members to be cognizant of this competing measure as it considers whether to submit FM7. If KCQA opts against submission, the aforementioned key specifications that were judged important during KCQA development will likely be unaddressed and the CMS measure lacking these elements may be endorsed.

[12] Only two of the three participating dialysis organization's results are reflected in these statistics because the data required for all calculations has not yet been received from the third.

The balance of this section provides a brief overview of how CMS meets the major NQF criteria:

- First, we note that we are perplexed by CMS' use of different periods of CROWNWeb data for testing the different NQF-required components and doing so without explanation (May-Sept 2012 for performance gap; Jan, Feb, Apr, May, June 2011 CROWNWeb data for validity; May 2012 for reliability and meaningful difference). Thus, while the directionality of testing results is the same for KCQA and CMS, it is impossible to draw any conclusions except to note that KCQA's measure uses a consistent dataset and is more current.
- As expected, the both measures draw on the same evidence base.
- CMS reports as its performance gap a facility-level mean of 19.6% of patients at a facility with UFR>13 ml/kg/hour (SD 12.3%) with the 25th percentile, median, and 75th percentile as 11.4%, 18.2%, and 26.5%, respectively. CMS also reports the percentage of patients with UFR >13 by race/ethnicity based on May 2012 data: overall=20.4%; Asians=32.8%; American Indians=25.1%; African Americans=18.0%; Other races=24.6%. Other demographic stratification found higher UFR in females=22.1%; Hispanics=25.4%; young adults 18-34=35.9%.
- For reliability testing, CMS found IUR=0.73, which indicates that about 73% of the variation in the UFR>13 can be attributed to the between facility differences and 27% to within facility variation.
- For validity, CMS performed a Poisson regression analysis with "observed mortality by quintile levels of facilities with ultrafiltration >13 ml/kg/hour, ***with the model offset by expected mortality*** [emphasis added]." A facility in the highest quintile of patients with UFR >13 (i.e., poorer performance) for 2011 had an estimated 5.7% higher risk of mortality than the lowest quintile range. We note that no information was provided about the "expected mortality offset" and so cannot assess the CMS validity analysis since the KCQA approach looked at correlation to the publicly available SMR and SHR.

RECOMMENDATION

The Steering Committee recommends the changes to the specifications, and further recommends KCQA members vote to approve both FM2 and FM7 to NQF for endorsement consideration.

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DRAFT MEASURE SPECIFICATIONS TABLE
02/15/15

ID	TITLE	DESCRIPTION	NUMERATOR	DENOMINATOR	EXCLUSIONS
FM2	**Post-Dialysis Weight Above or Below Target Weight**	Percentage of patients with an average post-dialysis weight ≥1 kg above or below the prescribed target weight.	Number of patients[1] from the denominator with an average post-dialysis weight ≥1 kg above or below the prescribed target weight during the ~~reporting~~ calculation period. **Interpretation of Score:** Lower score = better quality **Additional Information:** The average post-dialysis and prescribed target weight difference is calculated for the treatments received in the calculation period. The calculation period is defined as the same week that the monthly Kt/V is drawn.[2]	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis during the ~~reporting~~ calculation period.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Home dialysis patients. 4. <7 hemodialysis treatments in the facility during the month. 5. Facilities treating <XX adult in-center hemodialysis patients during the reporting period.[3] 6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728). ~~6.~~7. Kidney transplant recipients with a functioning graft.
FM7	**Avoidance of Utilization of High UFR (≥13 ml/kg/hour)**	Percentage of adult in-center hemodialysis patients in the facility whose average UFR ≥13 ml/kg/hour.	Number of patients[1] from the denominator whose average UFR ≥13 ml/kg/hour who receive an average of <240 minutes per treatment during the calculation period. **Interpretation of Score:** Lower score = better quality **Additional Information:** The average UFR is calculated for the treatments received in the calculation period. The calculation period is defined as the same week that the monthly Kt/V is drawn. The average UFR for the calculation period is calculated in the following manner: 1. The UFR (in ml/kg/hour) is first calculated for each treatment in the calculation period as: ([{*Pre-Dialysis Weight in kg – Post-Dialysis Weight* in kg} x 1000 ml/kg] ÷ *Post-Dialysis Weight in kg*) ÷ (*Delivered Treatment Time in minutes) x 60 minutes/hour* 2. The average UFR for the calculation period is then calculated by summing the UFRs for each treatment and dividing by the number of treatments in the calculation period: (UFR_1 + UFR_2 … + UFR_X) ÷ (X treatments) The average treatment time is calculated as: (*Total Minutes Dialyzed During the Calculation Period*) ÷ (*Number of Treatments in Calculation Period)*	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis during the calculation period.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Peritoneal dialysis patients. 4. <7 hemodialysis treatments in the facility during the month. 5. Facilities treating <XX adult in-center hemodialysis patients during the reporting period.[3] 6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728). 7. Kidney transplant recipients with a functioning graft. ~~6.~~8. Patients who receive 4 or more dialysis sessions during the calculation period.[4]

[1] To address the fact that patients may contribute varying amounts of time to the annual denominator population, results will be reported using a "patient-month" construction.
[2] Testing advisors suggested that an abbreviated FM2 be evaluated during testing, as reflected in the redlined specifications. Results of both version of the measure will be presented during the conference call.
[3] The Workgroup agreed to determine the appropriate minimum number of patients empirically during testing; this work is ongoing and will be reported to KCQA when available.
[4] Exclusion added for testing per the recommendation of the testing advisers from the three organizations.