CMS Responses to Questions and Comments about the Dialysis Facility Compare (DFC) Star Ratings

Throughout the formulation of the DFC Star Ratings methodology, CMS has invited and welcomed questions and comments from the dialysis community. We are committed to a transparent and responsive process and have given all comments serious consideration.

This document provides responses to the questions and issues raised by the ESRD community.

CMS believes that the star ratings will empower consumers with additional quality information. It will also encourage providers to continuously achieve higher quality care. With future releases and enhancements to the DFC website, we will continue fostering an open dialogue to facilitate providing better care for all patients receiving chronic dialysis.

We look forward to working with the ESRD community over the coming months to refine and improve the DFC Star Ratings. As we move forward in further exploring the issues raised by stakeholders in the ESRD community, please do not hesitate to contact us with any additional issues or information that you feel is relevant for CMS to consider.

Questions received on consultation with the community relative to the July 10, 2014, National Provider Call: Dialysis Facility Compare Star Rating System

1. Consultation with the Kidney Community

CMS went to great lengths to consult and inform the kidney community:

- In June 2014 CMS first announced their intent to implement the star ratings in a CMS Blog (http://blog.cms.gov/2014/06/18/star-quality-ratings-coming-soon-to-compare-sites-on-medicare-gov/);
- CMS presented the proposed Star Rating methodology and explanatory information to the public on a National Provider Call (NPC) in July 2014. CMS responded to stakeholder and community comments during the call;
- CMS responded to comment letters from providers, as well as other stakeholders in the kidney community since the NPC;
- CMS sought feedback from the Consumer Purchaser Alliance, and several ESRD patients selected for focus group participation to solicit feedback on the DFC Star Ratings;
- CMS has met with and continues to meet with multiple stakeholders.

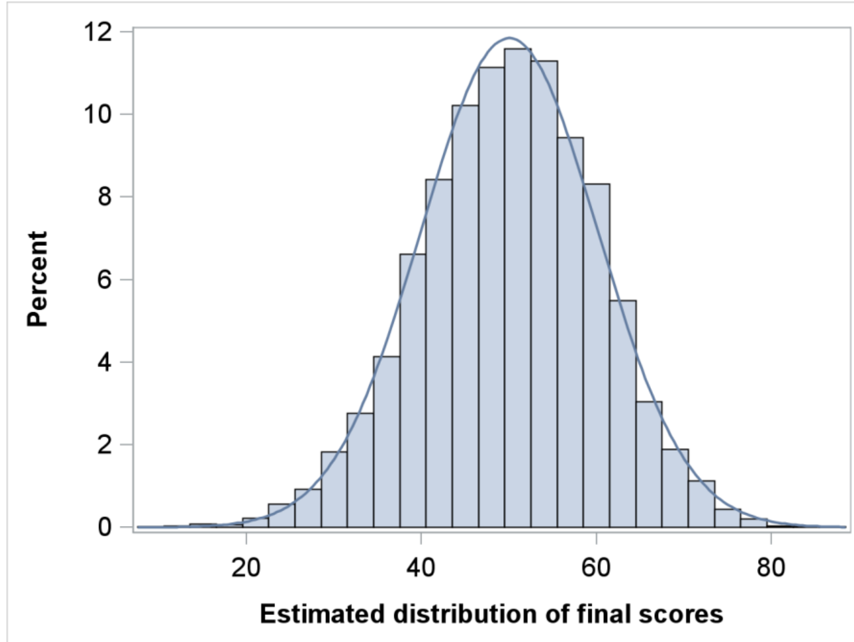
The measures used to develop the star ratings have been, and currently are publicly reported, on Dialysis Facility Compare (DFC).The proposed star ratings are an important initiative, responding to the call for transparent, easily understood and widely available public reporting initiatives as required by the Affordable Care Act (ACA). The ACA requires consumer information on factors such as cost and quality and satisfaction for the Health Insurance Marketplace. This raises expectations of transparency for all CMS programs since consumers often access multiple CMS public and quality reporting sites. In addition, the ACA expanded the Compare sites, creating Physician Compare and new reporting requirements for both Nursing Home Compare and Hospital Compare.

2. Methodological Concerns

a. Use of a Symmetric Distribution.

The DFC Star Ratings were based on a final dialysis facility score that incorporates several individual DFC measures. The final scores yielded an approximately symmetric distribution (as shown in Figure 1) and revealed that the 6000+ facilities nationwide do differ in the quality of care they provide.

Figure 1: Final Dialysis Facility Score Distribution



and the cut points resulted in the following breakdown:

- 10% 1-star
- 20% 2-star
- 40% 3-star
- 20% 4-star, and
- 10% 5-star

We believe these cut points provide a valid and reliable breakdown for patients to assess. Since the distribution of final facility scores was approximately symmetric, it made sense to assign equal percentages to the two tails of the distribution (1- and 2-star; 4- and 5-star). Second, such cut points were able to distinguish facilities in terms of the final score and individual measure components. Specifically, the analysis showed that each star category distinguishes itself from the rest. In other words, each tier has significantly different mean final scores from the other tiers and all the p-values are highly statistically significant at less than 0.0001 in all comparisons. Higher DFC Star Ratings reflect better quality of care, as indicated by higher performance on these quality measures. Third, the DFC Star Ratings allow for approximately equal differences in final scores (roughly 9 points) between adjacent star ratings and yields percentiles that are easily interpretable (5-star facilities are in the top 10%, 4-star facilities are the next 20%, etc.); see Table 1.

Table 1. Comparison of Average Final Dialysis Facility Scores Between Star Rating Categories

Star Rating 1	Mean Final Score (SE)	Star Rating 2	Mean Final Score (SE)	T-test P-value
★	31.8 (0.191)	★★	41.4 (0.066)	<.0001
★★	41.4 (0.066)	★★★	50.2 (0.064)	<.0001
★★★	50.2 (0.064)	★★★★	58.7(0.059)	<.0001
★★★★	58.7(0.059)	★★★★★	67.7 (0.168)	<.0001

We further note that higher DFC Star Ratings are associated with better mean values of individual measure scores. There are highly statistically significant and clinically meaningful differences between these mean values in adjacent tiers, with a p-value of less than 0.0001 in all cases; see Table 2.

Table 2. Comparisons of Averages of Individual Measures between DFC Star Rating Categories

Measure	★	★★	★★★	★★★★	★★★★★
STrR	1.52	1.19	0.98	0.82	0.62
SMR	1.34	1.11	1.01	0.93	0.83
SHR	1.28	1.12	0.99	0.87	0.76
All Kt/V	79.10	85.24	89.26	92.38	94.45
Hypercalcemia	4.63	3.34	2.28	1.24	0.83
AVF	50.24	57.95	63.35	68.97	74.69
Catheter > 90 days	20.21	14.26	10.22	7.27	5.12

Note: For STrR, SMR, SHR, hypercalcemia, and catheter, lower values are better; for all Kt/V and AVF, higher values are better.

In summary, our analysis has confirmed that there are significant differences in terms of the quality of care measured across over 6000 dialysis facilities nationwide. The proposed star rating provides a way to distinguish these facilities based on the DFC measures.

b. Use of Percentiles Instead of Fixed Thresholds.

Applying benchmarks in the DFC Star Ratings has several drawbacks. First, establishing future benchmarks based on previous years' data may mislead patients by using the previous years' criteria to rate facilities' performance in future years. Second, any applications of benchmarks runs the risk of ignoring gradual shifts in facility performance over time and, consequently, may artificially inflate the Star Ratings.

On the other hand, the proposed relative ranking system makes it feasible to compare facilities to each other relative to the national average of current performance rather than performance from a previous year. The system provides an objective tool for patients and other consumers to see which facilities

distinguish themselves from others across the rating categories, based on a set of DFC quality measures. From the providers' perspectives, a relative ranking encourages facilities to remain competitive and strive for continuous quality improvement, in order to retain their current ranking or reach a higher ranking. Otherwise, if the majority of facilities earn a 5- star rating based on a fixed performance benchmark set during a previous year, there would be little encouragement for continuous quality improvement.

3. The DFC Star Ratings do not align with other programs

a. Alignment with QIP.

While DFC Star Ratings and the QIP both provide information about quality performance, these programs have different objectives. DFC Star Ratings provide summary performance information for patients and other consumers to allow comparison of dialysis facilities based on current national-level performance data. On the other hand, the QIP, a value based purchasing program mandated by the 2008 Medicare Improvements for Patients and Providers Act (MIPPA), incentivizes achievement and improvement by linking quality scores to payment

The star ratings that will be reported on DFC will provide additional, useful quality information for consumers. The final score is calculated based on DFC measures and the distribution of these scores is used to assign the star ratings. By annually updating what is considered average performance with national performance data, the DFC Star Ratings will continue to distinguish facility performance compared to the current national average. Specifically, the DFC Star Ratings rate quality of care relative to other facilities in the current year, rather than using benchmarks established in a previous year (e.g., QIP, other QA types of programs). In contrast, if the QIP payment reduction categories were used to determine DFC Star Ratings, 95% of facilities with no payment reduction (based on their Total Performance Score) would receive a 5-star rating. Since more than 95% of facilities would receive a 5-star rating using the QIP score, the star rating based on QIP benchmarks would not assist dialysis patients and consumers in comparing facilities.

DFC Star Ratings also differ from the QIP in the measures used to calculate the star rating. For example, standardized outcomes measures, which are not currently included in the QIP, will be used in DFC Star Ratings. These objective, standardized outcome measures provide important additional information on quality of care and outcomes that are meaningful to consumers.

In summary, the analysis showed that any star rating system based on the QIP benchmarks and scoring methodology would ultimately not be helpful in distinguishing performance for patients and their families.

b. There is variation in measure specifications that CMS is using and/or proposes to use (DFC Five Star, PY 2016 QIP, PY 2017 QIP, and NQF endorsed measure specifications) that suggest little consistency among measures used in these same or other quality programs.

The DFC Star Ratings is still in the development stage. Measures and specifications may need to be revised as part of any updates to measures during the comprehensive re-evaluation that occurs every three years. In some cases, differences in specifications are due to a program-specific implementation in the QIP.

c. **Methodology and Relationship to Other Compare sites.**

CMS recognizes and appreciates that there are different methodologies that can be considered for developing a rating system. The ultimate choice of methodology depends on the context and the purpose of the program. It may not be clinically or statistically appropriate to force consistency across all methodologies. The DFC Star Ratings provides a useful tool for consumers and should be used with other information when choosing a facility.

4. Concerns about the DFC quality measures

a. **Vetting of Standardized Measures.**

The standardized measures have all been vetted at different stages of development, have been implemented by CMS and are currently publicly posted on DFC. The SMR and SHR are NQF-endorsed (2007 and 2011, respectively) and the STrR is in the process of being submitted for NQF endorsement. The SMR has been reported on DFC and available for facility preview and comment every year since 2001. The SHR and STrR have been reported on DFC since January 2013 and January 2014 respectively and similarly have been available for facility preview prior to release on DFC. All three measures were developed with input from a technical expert panel and the specifications were posted by CMS for public comment.

The measure specifications and methodology for all of the measures on DFC have been publicly available on the Methodology tab at www.dialysisdata.org (previously these were available on www.dialysisreports.org). Please see the Guide to the Quarterly Dialysis Facility Compare Report. More detailed information on the SMR and SHR can also be found in Technical Notes on the Standardized Mortality Ratio and Technical Notes on the Standardized Hospitalization Ratio on this tab. The public can also review the detailed methodology for the STrR in the methodology report at: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSTrRMeasure.pdf

In addition, the measure specifications for SMR and SHR were posted for public comment prior to NQF-endorsement. The specifications were also included in the respective NQF final voluntary consensus standards recommendation reports published by NQF in 2008, http://www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_End_Stage_Renal_Disease_Care.aspx and in http://www.qualityforum.org/Publications/2011/10/National_Voluntary_Consensus_Standards_for_End_Stage_Renal_Disease_%28ESRD%29__A_Consensus_Report.aspx.

As a quality measure concept, standardized outcome measures have been implemented for quality reporting and value-based purchasing programs for hospitals, nursing homes, long-term care hospitals, inpatient rehabilitation facilities, and home health agencies.

b. **Confidence Intervals.**

All measures, regardless of standardization, are essentially point estimates that may have various degrees of uncertainty. These measures are all obtained as the maximum likelihood estimates (MLE) and represent the most optimal statistical estimates given the observed data. They represent valid components of the DFC Star Ratings and can be used for ranking of dialysis facilities. In addition, the

standardized measures also represent clinically meaningful outcomes, further justifying their inclusion in our system.

We recognize and agree on the need to characterize the possible statistical uncertainty for the Star Rating computed for each facility. For this purpose, we plan to investigate the variations of scores and will conduct more analysis.

c. Inadequacy of risk adjustment in standardized measures.

There are a number of issues related to risk adjusting appropriately for these measures, including availability of information, appropriateness of adjustment for specific comorbid conditions, and timing of the determination of comorbid conditions.

The CMS-2728 form gives a clear indication (check box) of whether each comorbid condition is present at start of ESRD. However, some have suggested that the comorbid conditions collected on the form do not accurately and completely reflect the clinical condition of the patient. The 2728 form information is collected on and available for all ESRD patients regardless of Medicare eligibility. There is an expectation that dialysis facilities and all providers carefully and accurately complete the 2728 form for each patient, to ensure the development of optimal treatment plans as well as to serve as a valid source of data to support CMS programs.

We will conduct more analysis in future iterations to address some of the current limitations with the risk adjustment process with these outcome measures. However, use of the current risk adjustment methodology is appropriate and has been endorsed as part of the NQF endorsed measures (SMR, SHR; STrR will be submitted to NQF).

d. Concern that dialysis facilities should not be held responsible for the STrR.

Under CMS regulations, dialysis facilities and treating nephrologists are jointly responsible for management of anemia in the facility's chronic dialysis patients. Dialysis facilities accept responsibility under the ESRD Conditions for Coverage, the expanded Medicare ESRD Prospective Payment System, and QIP, for achieving small solute adequate outcomes. This is despite the fact that physicians prescribe dialysis. Similarly, facilities and physician-providers have shared responsibility for anemia management outcomes.

Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, and since there is a strong association between achieved hemoglobin and subsequent transfusion events, the dialysis facility does have a shared responsibility for transfusion events. We acknowledge that dialysis providers are frequently not involved in the immediate decision to transfuse blood products and that the transfusions occur outside of the dialysis facility. We recognize that these transfusions are often in response to acute events such as gastrointestinal bleeding or trauma. However, multiple researchers have identified, in both patient level and facility level risk-adjusted models, achieved hemoglobin is the strongest predictor of subsequent transfusions. Since dialysis facilities do have a direct role in determining achieved hemoglobin as a result of their anemia management practices, there is a shared responsibility in subsequent transfusion events. The responsibility of the dialysis facility for achieved hemoglobin outcomes, and related transfusion risk, is strengthened by applying an extensive list of exclusions for comorbid conditions that are associated with decreased ESA responsiveness, increased transfusion risk, and increased risk of ESA complication.

Avoiding unnecessary transfusions is consistent with the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, though these recognize that in some cases, the risks of ESA therapy may outweigh its benefits.

The methodology used to identify transfusion events from inpatient and outpatient Medicare claims has been used by multiple investigators to identify transfusion events. As described in the detailed methodology report for the STrR (http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/MeasureMethodologyReportfortheProposedSTrRMeasure.pdf) this approach provides a conservative estimate of blood transfusion events occurring in both inpatient and outpatient venues.

The STrR will provide valuable feedback for dialysis facilities and nephrologists regarding their coordinated anemia management practices and bring increased transparency especially vital for small and independent facilities as they continue to provide care to dialysis patients, striving to prevent unnecessary transfusions.

e. SHR measure has a correlation of 0.4 with the STrR, suggesting the measures are capturing the same thing.

Factor analysis was used to group correlated measures for this specific reason. A correlation of 0.4 is not high enough to warrant removal of a measure from the rating system. It is important to group measures that are more correlated with each other. By equally weighting groups containing more correlated measures, we ensure that we do not overweight the characteristics being measured by any one group of measures, simply because that group includes more measures.

f. Weighting of Standardized measures.

We appreciate that the standardized measures provide valuable information in weighting facility scores. While the argument has been made that these measures are more important, other stakeholders have different opinions and some even have suggested they not be included in the star ratings. With the lack of consensus across opinions, it seems best to equally weight domains of similar measures. However, we will continue searching for clear evidence that suggests alternative weighting strategies.

g. Majority of measures used in the Star Rating are comprised of Medicare-sourced measures.

Most of the measures included in the Star Rating are limited to Medicare-only patients. The two exceptions are the Standardized Mortality Ratio and the Hypercalcemia measure. These measures assess all dialysis patients. We anticipate transitioning these measures over to the use of data that encompasses the universe of US ESRD patients as reported by CROWNWeb.

h. Validity of CROWNWeb data for hypercalcemia measure.

We continue to monitor quality data submitted to CROWNWeb for completeness and validity. We have met with stakeholders to discuss the validity of hypercalcemia data specifically, and conduct reliability and validity assessments of the administrative and clinical data submitted to us via CROWNWeb, including the hypercalcemia data.

5. **Patient perception of star ratings**
   a. **Anxiety of patients going to a 1 or 2 star facility; perception of low performance when it is not actually low.**

Our results have confirmed that providers differ in the quality of care they give. Quality ratings can help consumers make more informed health care decisions and may actually reduce patients' anxiety when comparing and selecting facilities. We have given guidelines to facilitate consumers' understanding of the rating system. Specifically, 1 or 2 star facilities are not necessarily the facilities that provide poor service; instead, 1-star means "much below average" and 2-star should be interpreted "below average." While we recognize that patients may experience concern regarding a facility's quality performance that falls below the national average, it is our hope that this will lead patients to take an active role in discussing quality of care with their providers.

   b. **Consumer testing indicates that patient experience is more important than outcomes, assume ratings include patient feedback on quality of care; other aspects of facilities are important that are not included in the Star Rating.**

We recognize that patients make health care decisions using more than just quality measure data, and we recommend that patients use a variety of indicators when choosing a provider. It is intended to be additional information available to patients. We anticipate that as the methodology evolves over time, we will have the opportunity to incorporate other aspects of facility quality, subject to data availability and appropriateness. A non-exhaustive list of other information that may be incorporated includes survey deficiencies, grievances, staffing information, patient safety, and patient experience of care. The methodology presented here is the first step of a meaningful star rating, not its ultimate form. As we consider future updates, we welcome stakeholder suggestions and feedback regarding additional information that should be included in the Star Ratings.

6. **Patient confusion between Star Ratings and QIP.**

We developed four separate technical guidance documents of varying levels of complexity, from a broad basic overview to more detailed technical guides for consumers wanting more information on the measures. CMS believes in serving the needs of patients with varying levels of knowledge and experience. To avoid confusion on the part of the consumer, CMS will also provide the following official consumer guidance on the DFC website for the Initial release:

> ***Star Ratings***
>
> Dialysis facility star ratings are based on information about the quality of care provided at actual dialysis facilities.
>
> To get the stars, information from one facility is compared to information from another facility. More stars indicate higher quality. The stars are one way of comparing one facility with another.
>
> ***Why is this Important?***

Dialysis facilities differ in the quality of care and services they provide to patients. Dialysis Facility Compare shows information about dialysis facilities, including, for example, location, services, their use of best treatment practices, and how often patients go to the hospital.

Use the Dialysis Facility Star Rating Together with Other Information

The Dialysis Facility Compare Star Rating is one of many pieces of information you should use to decide which facility to go to for your care. Use the information on Dialysis Facility Compare to learn about the quality of facilities and the services they offer, compare dialysis facilities side-by-side, and get questions to ask when visiting a dialysis facility.

You should also talk to your doctor about your choices, visit the dialysis facilities you are considering, talk to the staff, and talk to people you know who may be on dialysis. We recommend that you discuss the Star Ratings and other quality information on the Dialysis Facility Compare website when you talk with your doctor about where to get dialysis care, and when you visit dialysis facilities.

Important Things to Remember

Here are some things to think about as you compare dialysis facilities.

- The Star Rating is based on the quality of care information that is reported on Dialysis Facility Compare.
- Dialysis Facility Compare shows results of a facility's performance on certain important measures of quality dialysis care.
- Positive results may mean that a facility is delivering good care. However, there may be other information important to you, like what other patients have to say about the care they receive at a facility that is not included in the Star Rating.

Additionally, the Star Rating compares facilities to each other. A one star rating does not mean that you will receive poor care from a facility. It means that the results of one dialysis facility were below average compared to other dialysis facilities. For this reason, we suggest that you use the Star Rating together with other quality information, your personal preferences and needs for services that different facilities offer, and the information you get when you talk to your doctor or visit dialysis facilities."

7. Concern about national comparisons being used rather than stratification by state/ region/ comparable facilities.

National comparisons of performance are consistent with facility performance measures implemented in many quality programs at CMS for other settings. Several measures used in the construction of the final facility score have been risk adjusted, which has accounted for the differences in the underlying health of populations served by particular facilities**.** We conducted further analyses and found that the distributions of Star Ratings are fairly comparable across states (see Table 3), though there may exist some geographic variations. We will investigate whether these variations are due to random chance or due to any un-studied or unobserved confounders. We will also investigate whether or how further adjustments can be made while we refine the rating system.

Table 3. Star Rating Distribution by State

		Star Rating				
State	Facilities	★	★★	★★★	★★★★	★★★★★
AK	8	0.00	0.00	62.50	37.50	0.00
AL	143	5.59	18.18	40.56	25.17	10.49
AR	61	16.39	40.98	31.15	4.92	6.56
AS	1	0.00	0.00	0.00	100.00	0.00
AZ	110	6.36	22.73	38.18	18.18	14.55
CA	518	6.18	14.86	41.51	24.13	13.32
CO	66	1.52	9.09	28.79	30.30	30.30
CT	42	0.00	14.29	40.48	19.05	26.19
DC	19	0.00	10.53	52.63	26.32	10.53
DE	22	13.64	18.18	40.91	27.27	0.00
FL	350	17.71	28.29	35.14	15.71	3.14
GA	291	5.50	20.62	46.74	21.31	5.84
GU	4	0.00	25.00	75.00	0.00	0.00
HI	22	0.00	9.09	40.91	40.91	9.09
IA	61	4.92	16.39	32.79	27.87	18.03
ID	26	0.00	15.38	38.46	19.23	26.92
IL	229	13.97	20.09	34.93	20.96	10.04
IN	134	8.96	25.37	40.30	17.16	8.21
KS	47	4.26	14.89	31.91	27.66	21.28
KY	102	5.88	27.45	43.14	17.65	5.88
LA	152	13.16	25.00	42.11	15.13	4.61
MA	68	5.88	25.00	42.65	22.06	4.41
MD	124	17.74	14.52	43.55	20.16	4.03
ME	17	0.00	0.00	52.94	23.53	23.53
MI	182	12.64	25.82	34.07	15.38	12.09
MN	95	3.16	17.89	44.21	16.84	17.89
MO	136	11.03	16.91	45.59	18.38	8.09

Table 3. Star Rating Distribution by State

		Star Rating				
State	Facilities	★	★★	★★★	★★★★	★★★★★
MP	2	0.00	100.00	0.00	0.00	0.00
MS	74	8.11	16.22	54.05	12.16	9.46
MT	12	0.00	16.67	41.67	25.00	16.67
NC	181	4.97	18.78	46.41	22.10	7.73
ND	15	6.67	6.67	53.33	13.33	20.00
NE	35	11.43	20.00	42.86	5.71	20.00
NH	14	7.14	14.29	71.43	7.14	0.00
NJ	130	10.77	20.77	38.46	22.31	7.69
NM	36	8.33	11.11	30.56	27.78	22.22
NV	42	9.52	14.29	30.95	35.71	9.52
NY	239	17.15	17.15	40.59	17.57	7.53
OH	257	16.34	30.35	33.46	15.56	4.28
OK	72	1.39	19.44	41.67	13.89	23.61
OR	51	1.96	17.65	47.06	17.65	15.69
PA	256	13.67	27.34	38.67	14.06	6.25
PR	38	60.53	36.84	2.63	0.00	0.00
RI	14	0.00	0.00	64.29	28.57	7.14
SC	117	17.95	16.24	37.61	19.66	8.55
SD	20	0.00	10.00	20.00	25.00	45.00
TN	157	10.19	21.02	43.95	14.65	10.19
TX	496	5.04	16.94	42.74	24.60	10.69
UT	36	2.78	8.33	36.11	36.11	16.67
VA	140	10.71	19.29	40.71	20.00	9.29
VI	3	0.00	0.00	33.33	33.33	33.33
VT	8	12.50	12.50	50.00	25.00	0.00
WA	75	0.00	9.33	40.00	34.67	16.00
WI	110	10.00	12.73	38.18	24.55	14.55

Table 3. Star Rating Distribution by State

		Star Rating				
State	Facilities	★	★★	★★★	★★★★	★★★★★
WV	33	42.42	12.12	30.30	9.09	6.06
WY	8	0.00	12.50	37.50	25.00	25.00
	5701					

8. Other comments and concerns.

a. Cherry picking of patients because of rating.

The measures used in the construction of the final facility score that might cause "cherry picking" by facilities have all been risk adjusted to account for patients' characteristics. This should disincentivize "cherry-picking". Risk adjustment of these measures will provide a fair comparison for facilities treating patients with different characteristics.

b. Impact on small facilities.

Small facilities will naturally be subject to more variation and can be impacted by extreme values. Our relative ranking system, which relies on ranks, can help reduce the impact of extreme values or outliers. Furthermore, minimum patient month criteria have been set for all DFC measures with respect to reporting, in order to increase stability of measures. Finally, if a facility has all measures missing for one of three groupings of measures, a Star Rating is not calculated due to insufficient information.

c. Special care of home dialysis patients.

We recognize that our current measure set does not focus on care issues specific to home dialysis and other modality types. We are interested in developing measures that address these issues, and will continue to consider how to incorporate all modality types into quality measures.

d. Potential unintended consequences,

We believe consumers need an easy-to-understand rating system to inform their choice of providers. We are constantly working to improve our methodologies on all of our Compare sites and will do so with the star ratings as well. CMS considers the opportunity to respond to stakeholder concerns vital to the development process. We will examine this concern and appreciate your bringing it to our attention. We envision that this can be a potential consequence of any rating methodology that distinguishes facility performance, which is not only restricted to the field of ESRD care. While this is a valid concern or point that we will seriously consider, it should not be deemed specific to the star rating methodology we have developed.

e. Are pediatric facilities included in the Star Rating?

Facilities that only treat pediatric patients are not currently rated by the star ratings. Such facilities have limited quality measure information available with which to establish a Star Rating, in part because pediatric patients are systematically excluded from certain quality measures on DFC. This is an issue of particular concern because of the vulnerable nature of this population, and we will continue to investigate ways in which quality measures and other sources of information may be used to provide a rating for these facilities in the future that adequately reflects the quality of care provided for their patients.

Questions received in consultation with the community as part of the October 6, 2014 Special Open Door Forum: Coming Soon- Star Ratings on Dialysis Facility Compare Star Rating System and February 4, 2015 Special Open Door Forum: Understanding Dialysis Facility Compare: Driving Informed Decision Making

1. Methodological Concerns

a. Are scores rounded at each level of the methodology?

We do not round scores at any level of the methodology. However, a set of measure ranks only contains 100 unique values. For this reason, measure values that are not exactly the same are sometimes assigned the same ranking. Measure values that are given the same measure rank are not determined by decimal places, but by order rank of the measure as specified by the default PROC RANK settings in SAS. The default order rank ties are assigned the average of the order ranks they encompass.

b. Did you rank "scores" vs. facilities? In other words, for the former, only 1 rank exists for many facilities with the same score while in the latter, if 5 facilities had the same scores, they could be tied for 50th to 54th rank.

If five facilities had the same measure value, they would be given the same order rank for the measure specified in the default SAS PROC RANK procedure. Since measure values are continuous, there are rarely ties for values other than 0% or 100% on a measure value.

After the final score is obtained, we rate the facilities based on the final scores. As the final score is continuous and widely spread, there are essentially no ties.

2. Concerns about the DFC quality measures

a. Concerns that measures that are included in the star rating calculation are things that are not modifiable by the dialysis facility.

The clinical quality measures used for the DFC Star Rating all relate to facility practices for which dialysis facilities do have control. Measures are based on evidence and clinical practice guidelines. The measures have been reviewed by TEPs and undergone public comment

b. Are the ICH-CAHPS results included in the star rating calculation?

The ICH-CAHPS results are not currently reported on DFC, and ICH-CAHPS is not part of the star rating.

c. Should transient patients be included in the measure?

Facilities are expected to provide the same quality of care and clinical monitoring for all patients regardless of transient status. However, we believe the measure specifications appropriately account for patients seen at a facility for a limited period of time by implementing exclusion criteria specific to quality measures as deemed appropriate. For example, the STrR measure excludes all patients who have not received treatment at a facility for 60 days. The Hypercalcemia measure includes months for patients only once the patient has received treatment at the facility for 30 days.

Other comments and concerns

d. Are there Star Ratings for other services and or care settings or are there plans to do?

Providing summary information to consumers about provider quality of care is an effort that extends to all of our Compare websites. Star ratings are currently available on Compare websites for Nursing Homes and Physicians. We are working to add star ratings to Dialysis Facility Compare, Hospital Compare and Home Health Compare.

e. Are the number and magnitude of deficiency reports from health department inspections considered in the Star Ratings?

At this time health department inspections from state surveyors are not part of the DFC Star Rating. CMS will consider including these data in future releases of the Star Rating system.

f. Are there any plans to consider dialysis treatment tolerability or treatment safety (concepts of clinical tolerance or hemodynamic intolerance/instability) as a future concept for the Star Rating program?

Measures specific to dialysis treatment safety and tolerability are not currently reported on DFC, but we will consider these suggestions as we continue to refine the methodology.

g. Some patient organizations oppose rolling out Star Ratings without including measures that are meaningful to them (such as attentiveness of the dialysis facility staff) are resolved. How does CMS plan to take concerns and recommendations into account before launching the DFC Star Ratings?

CMS recognizes that our quality measure set is not entirely comprehensive of all quality issues that are meaningful to patients and other stakeholders. For example, we consider the ICH CAHPS measure to be a priority for inclusion in the star ratings when those data become available. As we previously announced, we delayed implementation of the star ratings until January 2015. In the interim, we are taking the time to consider stakeholder comments about the star ratings, and their implications for the appropriateness of our methodology, and any resulting modifications. Additionally, we are considering ways in which stakeholders may provide input into the star ratings in future iterations, which would potentially include feedback on including new measures, the removal of existing measures, and the scoring methodology.

h. Will facilities be able to view their raw scores as compared to other facilities on the outcomes and domains?

Yes, facilities will be able to view their facility's raw scores in order to facilitate comparison with other facilities. Table 4 in the preview report (shown below) will showcase the components of the star rating. This table will include the raw score for each measure as well as the normalized scores, domain scores, and the final score. While the facility raw score is available in the report there are not currently comparisons by state or region but we will consider these suggestions as we continue to refine the methodology.

Quarterly Dialysis Facility Compare - Preview for October 2014 Report

DFC Dialysis Facility State: XX Network: 99 CCN: SAMPLE

TABLE 4: Facility Star Rating Calculation *1

The rating is based on the measures reported in the Quarterly DFC-Preview for October report and updated annually each October on DFC.

Calculation Definition	This Facility
Standardized Outcomes Domain	
4a **Standardized Outcomes Score** (average of 4c, 4e, and 4g) *2	45.2
4b 2010-2013 Standardized Mortality Ratio (SMR) *3	1.16
4c Normalized rank: SMR *4	37.8
4d 2013 Standardized Hospitalization Ratio (Admissions) (SHR) *3	0.94
4e Normalized rank: SHR *4	51.2
4f 2013 Standardized Transfusion Ratio (STrR) *3	0.99
4g Normalized rank: STrR *4	46.8
Other Outcomes 1 Domain *5	**2013**
4h **Other Outcomes 1 Score** (average of 4j and 4l) *2	57.0
4i Percentage of patients with arteriovenous fistulae in place (AVF)	53%
4j Normalized rank: AVF *4	31.1
4k Percentage of patients with vascular catheter reported >90 days	2%
4l Normalized rank: Catheter *4	82.9
Other Outcomes 2 Domain	**2013**
4m **Other Outcomes 2 Score** (average of 4r and 4t) *2	40.3
4n Adult HD: Percentage of patients with Kt/V >= 1.2 *6	91%
4o Adult PD: Percentage of patients with Kt/V >= 1.7 *6	86%
4p Pediatric HD: Percentage of patients with Kt/V >= 1.2 *6	Not Available
4q Overall: Percentage of patients with Kt/V >= specified threshold *7	90%
4r Normalized rank: Kt/V *4	51.2
4s Percentage of patients with serum calcium > 10.2 mg/dL	5%
4t Normalized rank: Hypercalcemia *4	29.5
Final Score	
4u **Final score** (average of 4a, 4h, 4m) *8	47.5
4v **Overall Star Rating** *9	★★★☆☆

[*1] See *Guide, Section VIII.*
[*2] The Domain Score is between 0 and 100 and is the average of the normalized ranks for the measures within that domain. If there is at least one measure in the domain, all missing measures in that domain are imputed with the average rank of 50 to limit the non-missing measures from being too influential. If all measures in a domain are missing, then the domain score is not calculated.
[*3] Calculated as a ratio of observed deaths (or admissions/transfusions) to expected deaths (or admissions/transfusions); not included in star rating calculation if there are fewer than 3 expected deaths or fewer than 5 or 10 patient-years at risk for admissions or transfusions, respectively.
[*4] If a measure is Not Available, its normalized rank will be imputed with the average rank of 50 to limit the non-missing measures from being too influential in calculation of the domain score.
[*5] Facilities that service only PD patients will not have any measures in this domain since their patients do not have fistulae or catheters. For these facilities, this domain was not included in the star rating calculation.
[*6] Percentages based on 10 or fewer patients are shown in this table but will be reported as 'Not Available' on DFC.
[*7] For improved ability to compare Kt/V in facilities with different types of patients in terms of modality or pediatric status, the adult and pediatric HD and adult PD Kt/V measurements were pooled into one measure. The percentage of patients that achieve Kt/V greater than the specified thresholds for each of the three respective patient types (adult PD patients, adult HD patients, and pediatric HD patients), was weighted based on the number of patient-months of data available. If the overall Kt/V percentage is based on 10 or fewer patients, then it is reported as 'Not Available' in this table.
[*8] Final score is the average of the 3 domain scores. If all measures in a given domain are missing, then there is no final score and no star rating computed with the exception of PD only facilities. The PD only facilities are missing the Other Outcomes 1 domain so the other two domains (if both have a domain score) are averaged to get the final score.
[*9] The final score was ranked as follows to get the star rating: top 10% got 5 stars, next 20% highest got 4 stars, middle 40% got 3 stars, next 20% lowest got 2 stars, bottom 10% got 1 star.

SAMPLE

i. Why did my star rating change from my preview report made available during the July-August 2014 preview period if you kept the same data and methodology?

Following the 30-day comment period for QIP this year, CMS determined that claims processing manual guidance regarding the submission of Kt/V data on claims may have been misinterpreted by some providers under certain circumstances. Recognizing this, CMS recalculated the Kt/V values for both the QIP and the DFC Star Ratings in order to maintain consistency and fairness in assessment. The majority (77%) of facilities saw very little change in Kt/V (2% or less). In addition, a minor change was made to the calculation of the DFC catheter greater than 90 days measure to ensure the 90-day look back period was applied properly. The resulting impact of this change was very small, with 80% of facilities having a 2%

or less change in the percentage of patients with catheter greater than 90 days. Implementing the recalculation of both the Kt/V and catheter measures changed the rating for approximately 380 facilities, with the majority (98%) due to the Kt/V recalculation alone.

Summary

We appreciate all the concerns and suggestions put forth by the ESRD community. We will continue to meet with the various stakeholder and patient groups to collect their concerns and answer questions related to the DFC Star Ratings. Implementing the rating system in January 2015 has allowed CMS the opportunity to use their feedback in driving the process forward.