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

CMS thanks the community for their comments and questions about the DFC Star Rating System. All comments have been given serious consideration. This document provides responses to the questions and issues raised by the ESRD community. CMS believes that the Star Rating System 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 ensure that the DFC Star Ratings empower health care consumers with information to make more informed health care decisions, encourage providers to strive for higher levels of quality and drive overall health system improvement.

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.

1. **Concern that the Kidney Community was not consulted properly before designing the ESRD Star Rating**

The kidney community and stakeholders were consulted and informed in the following ways:

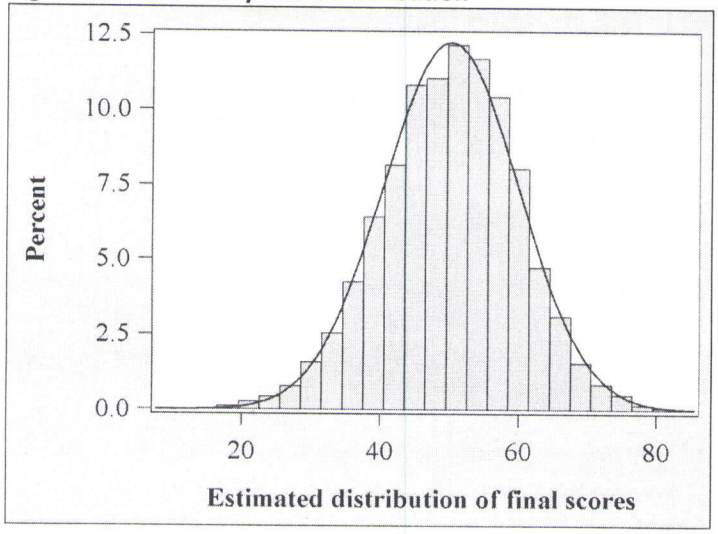
- In June 2014 CMS first announced their intent to implement the Star Rating system in a CMS Blog (http://blog.cms.gov/2014/06/18/star-quality-ratings-coming-soon-to-compare-sites-on-medicare-gov/);
- CMS presented the proposed Star Rating methodology and explanatory information to the public on a National Provider Call (NPC) in July 2014. CMS responded to stakeholder and community comments during the call;
- CMS prepared responses 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 Rating System;
- CMS has met with and is continuing to meet with multiple stakeholders. The measures used to develop the Star Ratings have been, and currently are publicly reported, on Dialysis Facility Compare

The proposed Star Rating System is 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 creates new 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. **Bell curve or symmetric distribution distorts quality performance, is not meaningful or does not show statistical differences between categories**

The Star Ratings were based on a final 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 Facility Score Distribution



As the final facility scores were continuous, discretion was exercised when choosing cut points to categorize facilities. The cut points were chosen and resulted in a 10% 1-star, 20% 2-star, 40% 3-star, 20% 4-star, and 10% 5-star categorization. There are several justifications for choosing these cut points. First, the distribution of final facility scores was approximately symmetric, which justifies assigning 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 Quality Ratings reflect better quality of care, as indicated by higher performance on these quality measures. Third, the Star Rating System allows 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 Facility Scores Between Star Rating Categories

Star Rating 1	Mean Final Score (SE)	Star Rating 2	Mean Final Score (SE)	T-test P-value
★	32.4 (0.192)	★★	41.7 (0.066)	<.0001
★★	41.7 (0.066)	★★★	50.3 (0.063)	<.0001
★★★	50.3 (0.063)	★★★★	58.4(0.059)	<.0001
★★★★	58.4(0.059)	★★★★★	66.7 (0.173)	<.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 Star Rating Categories

Measure	Averages of Individual Measures (SE) by Star Rating				
	★	★★	★★★	★★★★	★★★★★
STrR	1.50 (0.029)	1.20 (0.02)	1.00 (0.01)	0.81 (0.012)	0.63 (0.015)
SHR	1.28 (0.014)	1.12 (0.009)	0.99 (0.005)	0.86 (0.007)	0.75 (0.011)
SMR	1.34 (0.017)	1.11 (0.007)	1.02 (0.004)	0.93 (0.007)	0.84 (0.010)
All Kt/V	75.5 (0.78)	81.8 (0.42)	86.8 (0.20)	89.5 (0.24)	92.3 (0.27)
Hypercalcemia	5.7 (0.18)	4.6 (0.11)	3.4 (0.06)	2.3 (0.07)	1.8 (0.08)
AVF	48.6 (0.42)	56.0 (0.29)	62.1 (0.20)	67.3 (0.28)	73.2 (0.39)
Catheter > 90 days	20.3 (0.35)	14.7 (0.18)	10.6 (0.11)	7.6 (0.13)	5.2 (0.16)

Note: For STrR, SHR, SMR, hypercalcemia, and catheter, lower valuess are better; for all Kt/v and AVF, higher values are better.
Standard error provided in parenthesis.

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 System provides a way to distinguish these facilities based on the DFC measures.

b. Using percentiles would discourage improvement compared to using fixed thresholds; fixed thresholds would allow for targets that facilities could aim to achieve.

There is no gold standard for fixed thresholds in practice. Applying benchmarks in the Star Ratings therefore 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 inflate the Star Ratings. This inflation of ratings might provide misleading information to vulnerable consumers who benefit from an objective and parsimonious system that distinguishes between higher and lower-performing facilities.

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. **The DFC Star Ratings do not match QIP in measures, rating score, and rating distribution; Patients will be confused by the difference in scores**

While QIP and DFC Star Ratings both provide information about quality performance, these programs have clearly distinctive objectives. 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. On the other hand, the DFC Star Rating System provides summary performance information for patients and other consumers to allow comparison of dialysis facilities based on current national-level performance data.

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 Star Rating System will continue to distinguish facility performance compared to the current national average. Specifically, the DFC Star Rating System rates 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).

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 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.

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. In other words, if the QIP payment reduction categories were used as the method for determining the star ratings, there would be virtually no variation among facilities that would provide patients and consumers information on the actual differences in quality of care. For example, using the PY2013 QIP data file, of the 5885 facilities that had a QIP score:

- 5617 facilities (95.45%) would receive 5-Stars,
- 159 facilities (2.70%) would receive 4-Stars,
- 52 facilities (0.88%) would receive 3-Stars,
- 15 facilities (0.25%) would receive 2-Stars,
- 42 facilities (0.71%) would receive 1-Star.

Since more than 95% of facilities would receive a 5-star rating using the QIP score, the star rating would not assist dialysis patients and consumers in comparing dialysis facilities (which is the stated intent of the DFC star rating system.) In addition, using the QIP score would result in three or four star facilities (the average and above average groups) being entirely comprised of those in the lowest 5 percent in QIP performance.

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

We recognize the rating system 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. The methodology is different than other compare sites/consumer rating systems in terms of scoring, tiers, and measures

CMS does not require the same methodology to be used for the different quality rating systems. CMS designs and implements methodologies to serve specific program objectives. For example, consumer research has shown that using symbols, such as stars, helps consumers to interpret information. The intent of using star ratings is to help a consumer differentiate the quality of care provided by a facility. Our data show that there are significant differences in the quality of care provided by dialysis facilities. The proposed system compares facilities to each other relative to the current national average performance rather than to performance from a previous year. The system allows patients and other consumers to see which facilities distinguish themselves from others across categories based on current overall performance on the set of DFC quality measures.

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, as proposed, provide a useful tool for consumers and should be used with other information when choosing a facility.

4. **Concerns about the DFC quality measures**

   a. **Standardized Measures have not been vetted properly**

The standardized measures have all been vetted at different stages of development, have been implemented by CMS and are currently publicly posted on Dialysis Facility Compare. 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 publically 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. **Standardized ratios have confidence intervals and such measures with uncertainty should not be used**

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 Star Rating System and can be used for ranking of 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 at incidence 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.

The adjustment for comorbidities (clinical conditions) prior to the start of treatment is consistent with the NQF and the CMS Measures Management System Blueprint: "Risk factors should be present at the start of care to avoid mistakenly adjusting for factors arising due to deficiencies in care being measured."

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. Standardized measures should be weighted higher.

We appreciate your statement 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 Rating System. 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 patient as reported by CROWNWeb.

h. Concerns about 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. Concern about 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

5 | 10 | 25 | 50 | 100

the rating system. Specifically, 1 or 2 star facilities are not necessarily the facilities that provide poor service; instead, 1-star means "well under national average" and 2-star should be interpreted "under national 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 it is not our intention or expectation that the Star Ratings will become the overriding or sole determinant of dialysis facility selection. 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 System, 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[1]:

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

[1]The following information is not currently visible during the preview period but will be on the website as an update on DFC

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 have 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 chances 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.

New York

Table 3. Final Star Rank Distribution by State

State	Facilities	Final Star Ranks				
		★	★★	★★★	★★★★	★★★★★
AK	8	0.00	0.00	75.00	25.00	0.00
AL	150	7.33	18.67	44.00	18.00	12.00
AR	64	17.19	32.81	39.06	6.25	4.69
AS	1	0.00	100.00	0.00	0.00	0.00
AZ	115	6.09	18.26	37.39	26.09	12.17
CA	565	3.72	13.45	43.72	26.73	12.39
CO	71	1.41	5.63	28.17	33.80	30.99
CT	44	2.27	9.09	38.64	27.27	22.73
DC	22	0.00	18.18	40.91	40.91	0.00
DE	23	13.04	21.74	39.13	13.04	13.04
FL	367	15.53	27.52	40.87	12.53	3.54
GA	300	8.33	20.00	40.67	20.67	10.33
GU	4	0.00	25.00	75.00	0.00	0.00
HI	23	0.00	4.35	21.74	56.52	17.39
IA	64	6.25	7.81	32.81	29.69	23.44
ID	26	0.00	11.54	38.46	30.77	19.23
IL	259	13.90	23.55	39.00	16.99	6.56
IN	141	10.64	24.11	42.55	16.31	6.38
KS	52	9.62	11.54	40.38	11.54	26.92
KY	108	9.26	22.22	46.30	14.81	7.41
LA	153	13.07	29.41	36.60	17.65	3.27
MA	77	3.90	23.38	41.56	25.97	5.19

— 40
35
— 43
37
35
31
— 43
38
64.79
50
74
53
50
38

GA MS —
MT —
NH —
AZ light green
KS MN MASS

NE med green

Table 3. Final Star Rank Distribution by State

State	Facilities	Final Star Ranks				
		★	★★	★★★	★★★★	★★★★★
MD	129	13.95	20.93	44.19	14.73	6.20
ME	17	0.00	0.00	47.06	41.18	11.76
MI	188	14.89	21.81	37.77	20.21	5.32
MN	100	6.00	16.00	46.00	23.00	9.00
MO	146	12.33	13.70	49.32	17.81	6.85
MP	2	0.00	0.00	100.00	0.00	0.00
MS	76	11.84	15.79	47.37	18.42	6.58
MT	12	8.33	8.33	58.33	16.67	8.33
NC	187	4.28	26.74	38.50	21.39	9.09
ND	16	0.00	6.25	37.50	31.25	25.00
NE	36	11.11	19.44	25.00	16.67	27.78
NH	15	6.67	20.00	46.67	13.33	13.33
NJ	137	16.06	17.52	37.96	19.71	8.76
NM	38	7.89	18.42	28.95	21.05	23.68
NV	45	4.44	20.00	33.33	24.44	17.78
NY	253	17.79	17.39	39.13	17.00	8.70
OH	280	14.64	30.00	40.36	8.57	6.43
OK	79	2.53	26.58	35.44	17.72	17.72
OR	55	0.00	16.36	43.64	25.45	14.55
PA	269	15.24	19.33	40.52	18.59	6.32
PR	41	56.10	29.27	14.63	0.00	0.00
RI	17	5.88	17.65	47.06	11.76	17.65

Table 3. Final Star Rank Distribution by State

State	Facilities	Final Star Ranks				
		★	★★	★★★	★★★★	★★★★★
SC	122	11.48	22.95	37.70	19.67	8.20
SD	19	0.00	0.00	36.84	26.32	36.84
TN	166	10.84	24.70	37.95	20.48	6.02
TX	519	5.78	18.11	41.81	20.42	13.87
UT	37	5.41	13.51	35.14	32.43	13.51
VA	147	8.16	21.77	40.14	19.73	10.20
VI	3	0.00	0.00	33.33	66.67	0.00
VT	8	12.50	0.00	37.50	50.00	0.00
WA	77	2.60	10.39	32.47	45.45	9.09
WI	116	6.03	18.97	33.62	25.00	16.38
WV	35	37.14	25.71	22.86	5.71	8.57
WY	9	11.11	22.22	11.11	44.44	11.11
	6033					

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" 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. Star Ratings could cause unintended consequences, e.g, Insurance companies and suppliers could use Star Rating information to penalize facilities

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 Rating Systems 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 Rating System. 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.

9. 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, and implementing the rating system in January 2015 has allowed CMS the opportunity to use their feedback in driving the process forward.

Responses to Questions from Dialysis Patient Citizens

Our understanding is that star ratings are not evenly distributed across the country; we have seen unofficial data indicating that there are a disproportionate number of one- and two-star facilities in the South and Greater Appalachia, and a disproportionate number of four- and five-star facilities in the Pacific Northwest and Upper Midwest.

If the star ratings were properly risk-adjusted, wouldn't they be evenly distributed across the country without regard to regional population health factors?

> **RESPONSE**: CMS has a standing policy not to risk adjust for regional differences in utilization and care. The geographic differences you pinpointed actually reveal that the rating system is able to detect such regional differences. If we identify that a region has an unusually large number of poorly performing facilities, it is appropriate and fair to make that information available to patients and help patients actively engage in dialogues with providers in view of improving quality of health care.

The way the star ratings seem to suggest that beneficiaries are better off receiving care in Washington State is ironic since one purpose of the Medicare ESRD benefit was to eliminate the need to relocate to the Northwest for kidney care. Is it CMS' position that beneficiaries should consider relocating their residences in response to star ratings?

> **RESPONSE**: As we stated above, we maintain a standing policy not to risk adjust for regional differences in utilization and care. We believe it is important that patients, as well as providers, be aware of these differences. We believe that lower rated facilities do not necessarily provide poor quality care. The lower rating suggests that their performance as measured by the DFC measures is below the national norm. It is not our intention or expectation that the star ratings are the sole determinant of dialysis facility selection. We have carefully evaluated the scenario as suggested by you in the process of developing the rating system, and have drafted an official guideline that patients make health care decisions using more than just quality measure data. Below is our guidance to facilitate consumers' understanding of the rating system.
>
> *"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.*

In summary, the star rating system provides an additional tool whereby patients can search by various attributes important to them, for example, distance to facility, shifts shifts beginning after 5pm, whether the facility offers peritoneal dialysis services, and so forth. In the future, we will also explore adding other attributes to the star rating system, such as patients' experience. All these tools, combined, will help patients make more informed decisions when selecting providers."

Can you walk us through some DFC map views in some of the areas with lower overall scores, such as West Virginia or Ohio? What will a consumer see in terms of a spatial distribution of facilities with 3 stars or more alongside those with two stars or less, and distances, drive times, etc. for patients who want to move?

RESPONSE: Dialysis Facility Compare currently allows consumers to conduct a search of facilities through the use of either a map or list view. The list view provides a list of facilities that may be filtered or listed based on a number of characteristics, including the availability of specific services, such as shifts beginning after 5pm, or distance to the facility. We intend to include the Star Ratings among these categories, allowing consumers to limit or prioritize searches based on a facility's rating.

The map view is similar to what would be found on a MapQuest or Google Maps search, identifying dialysis facilities within a selectable radius of the consumer's location. An icon appears on the map to denote location, and patients are able to filter results in similar fashion to that on the list view, using the same characteristics.

There are a variety of ways to present data to consumers. For instance, both Consumer Reports and NCQA use multiple "bubbles" to represent different individual dimensions instead of using a single composite summary score. So for example, consumer satisfaction is one dimension that both Consumer Reports and NCQA report separately. Can you tell us why the composite five star format, encompassing multiple process and outcome measures, was deemed best suited for dialysis patients?

RESPONSE: This was a policy decision. There are a limited numbers of quality measures currently reported on DFC. Multiple component scores are a possibility, but of uncertain value, as the breakdown would probably lead to individual measures receiving their own star rating, and negating the value of providing a summary assessment to patients.

We understand that Hospital Compare will award stars solely based on patient satisfaction. Can you tell us why a different format was selected for DFC than Hospital Compare?

RESPONSE: Hospital Compare is a complex website as compared to DFC, publicly reporting more than 100 quality measures on a regular basis. CMS made an explicit decision to implement Star Ratings on Hospital Compare incrementally, beginning with the critical topic of patient experience of care. We anticipate that Hospital Compare's Star Ratings will expand to include other quality measures in the future.

While we agree that patient experience of care is important for inclusion in the DFC Star Ratings, we decided not to include them in the initial run for two reasons. First, we have not previously publicly reported data from the ICH CAHPS, which is a principal to which we adhered for all other measures included in the Star Ratings. Second, we do not currently have access to sufficient data for dialysis facilities to render a valid assessment for inclusion in the Star Ratings. We anticipate that patient experience of care data will be available to us in CY 2015, and plan to consider ICH CAHPS reporting on DFC and inclusion in the Star Ratings when they are.

Can you show us the language that CMS proposes to post on DFC advising consumers how to use the star system?

RESPONSE: The draft language to be posted on the DFC website is available in the FAQ document at:
https://dialysisdata.org/sites/default/files/content/FAQs/Star%20Rating%20FAQ%20.pdf

Can you show us the language that CMS proposes to post on DFC advising consumers how to interpret differences between star ratings and QIP PSCs in facilities?

RESPONSE: As noted on the previous response, the draft language to be posted on the DFC page is currently available on dialysisdata.org. That language does not address the differential interpretations of the Star Ratings and QIP, in part because we seek to avoid confusion regarding the two programs on the website. However, we are currently working to modify the language included on the QIP PSC to clarify how we view the PSC within the context of Star Ratings.

Overview of consumer testing- what did you want patients to get out of the star ratings, how did you define and test comprehension, and how did consumers react (did they comprehend the meaning of the ratings as CMS intended)?

RESPONSE:

Consumer testing examined consumer:

- Preference for the Dialysis Facility Compare without stars and with stars,
- Desire for a legend that defined the meaning of 1 star vs. 2 stars, etc.,
- Comprehension of star ratings after reading proposed accompanying explanatory content.

Findings from the testing were as follows:

- Participants preferred the site with stars and agreed it could help them in terms of making a decision about which dialysis facility to visit. However, in some instances, availability of certain services may be more important than star ratings.

- Slightly more than half of participants preferred a legend with words to explain the stars than without words.
- Participants agreed on the need for greater technical detail about the stars in order to help them understand how to most appropriately use them to make a decision about a dialysis facility. (CMS is addressing this need through technical guides which will be posted along with the star ratings.)

During consumer testing, was a scenario introduced in which patients were told that the facility they are using was a one- or two-star facility? If so, what was the reaction of patients?

RESPONSE: During consumer testing, participants were not explicitly asked for their reactions to a scenario of using a one- or two- star facility. Participants were asked to share their assumptions of the meaning of stars and they overwhelmingly indicated that more stars indicated higher quality. However, participants were quick to point out that often other factors or the availability of certain services would be more important to them than the overall star rating. Additionally, after reading some of the content that will accompany star ratings, participants were able to articulate that the star rating compares facilities to each other and that a one or two star rating does not mean they will receive poor care from a facility.

Supplementary Online Material

Figure S-1: Geographic locations for Americas 2, 3, and 4.

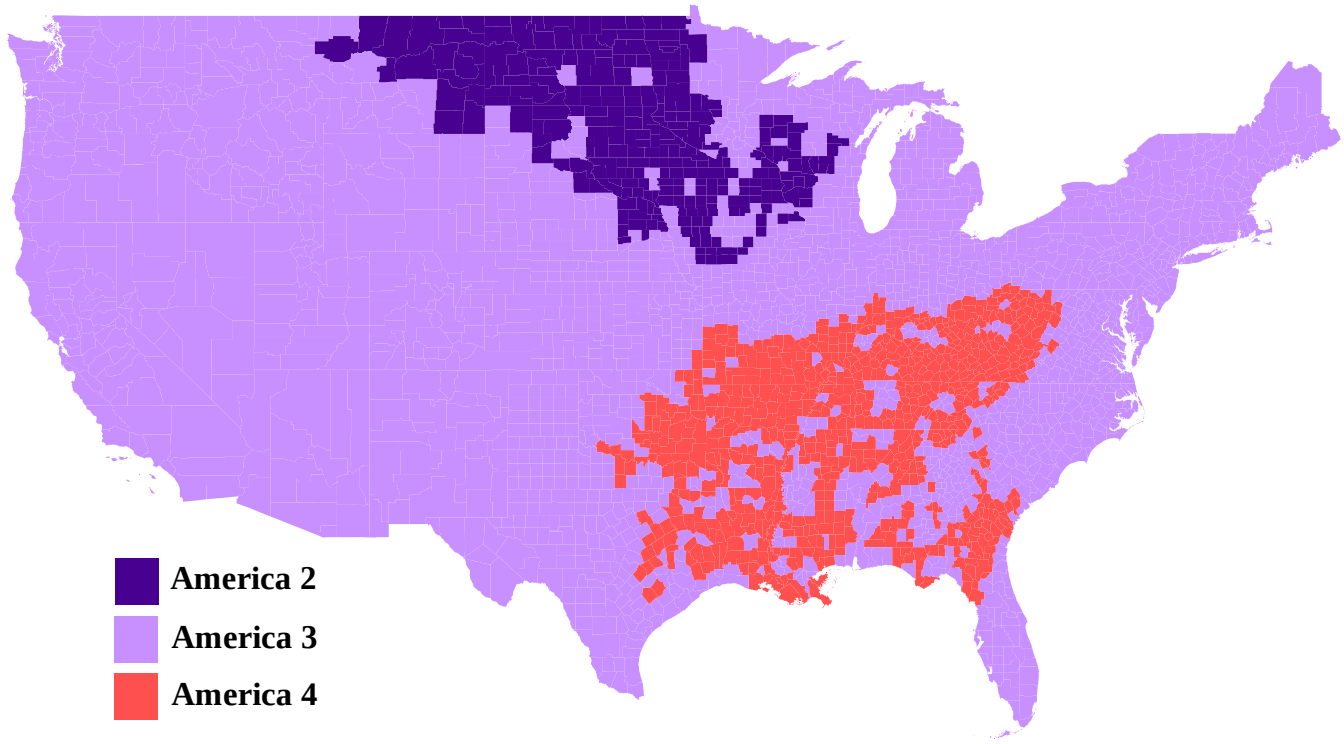


Figure S-2: Geographic locations for Americas 6, 7, and 8