

## PUBLIC COMMENT SUMMARY REPORT

**Project Title:** Dialysis Facility Compare (DFC) Measures

**Dates:** The Call for Public Comment ran from October 11, 2018 to December 31, 2018. The Public Comment Summary was made on available on May 16, 2019.

**Project Overview:** The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to produce the DFC Measures and DFC Star Ratings. The contract name is the Kidney Disease Quality Measure Development, Maintenance, and Support contract. The contract number is 75FCMC18D0041 Task Order No. 75FCMC18F0001.

**Project Objectives:** In October 2017, CMS requested Public Comment on the inclusion of additional measures to Dialysis Facility Compare (DFC) measures in order to:

- Increase transparency in the process and selection criteria
- Allow for increased input from the community on candidate measures
- Increase opportunity for the inclusion of externally developed measures on DFC

**Comments were requested on the following measures:**

- Percentage of Prevalent Patients Waitlisted (PPPW)
- Standardized Waitlist Ratio (SWR)

**Information About the Comments Received:**

Public comments were solicited by email and through a National Provider Call (teleconference). Five responses were received on this topic. The summary of these topics were summarized and posted in May 2018. Following those comments CMS decided to move forward with the process and the two measures were previewed for dialysis facilities only during the summer of 2018. In October 2018 CMS solicited by email and through a National Provider Call comments on inclusion of these measures in the public release of Dialysis Facility Compare beginning in October 2019. Two responses were received on this topic. Many of the issues discussed in the two letters were addressed during the previous year's public comment. They are also restated here.

**Stakeholder Comments—General and Measure-Specific**

### General

One commenter was concerned about the degree to which performance on these measures is under the control of the dialysis facility. Specifically, commenters are concerned that these measures are limited in terms of actionability by the dialysis center, as the ultimate decision on waitlist status is made by the transplant center and the patient.

**Response:** *Waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and*

*optimizing the health of the patient while on dialysis. These efforts depend heavily and in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. For example, interventions could include strong communication with transplant centers and advocacy for patients by dialysis facilities, as well as proper education, encouragement and support of patients during their decision-making about the transplantation option. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.*

One commenter raised a concern about the effect variations in transplant center listing policies may have on dialysis facility performance.

**Response:** *Although there may be some variation in transplant center policies regarding candidacy, dialysis facilities still have the responsibility to advocate for patients they feel would benefit from transplantation, either through discussions with local transplant centers or by facilitating evaluation and listing at transplant centers more geographically distant from the facility. In addition, we did perform analyses relating to the PPPW measure that examined regional variation by using a transplant center rate adjustment based on historical waitlist data weighted by zip code. However, we ultimately decided against including transplant center adjustment for the following reasons:*

- 1. The transplant center rate adjustment was not statistically significant in the model, and was unstable dependent on how a small percent of missing values are handled.*
- 2. The inter-unit reliability (IUR) decreased from 0.82 to 0.79 after adding the effect to the PPPW model, indicating no improvement in reliability of the measure with inclusion of the effect.*
- 3. The C-Index for both the model with and without this adjustment was 0.72.*

One commenter noted a concern about the effect of the changes to the kidney allocation policy in 2014 that may have affected the timing of waitlisting by some transplant centers.

**Response:** *The new allocation policy applies nationally, affecting transplant centers throughout the country similarly, so it would not be expected to disadvantage particular dialysis facilities.*

*In addition, the change in allocation policy does not remove the potential advantage of early wait-listing. Even if patients eventually receive living donor transplants, the availability of a living donor is often not known with certainty until the candidate is fully evaluated, and candidates are almost universally placed on the deceased donor wait list prior to living donation. Further, the SWR measure explicitly credits facilities for the occurrence of living donor transplants. Also, even in the absence of a specific advantage such as a high degree of sensitization, the possibility of a zero antigen mismatch donor kidney becoming available can lead to an earlier than expected transplantation. Thus there remains an advantage for patients to be waitlisted at the earliest possibility. One commenter noted that measures for transplant education or referral may better reflect the role dialysis facilities play in the care of their patients with respect to access to transplantation.*

**Response:** *Although it is true that patient education and referral are important steps towards transplantation, there are practical hurdles currently to implementing measures based on them due to lack of the necessary data capture at the national level. Beyond that concern however, referral may be too low a bar for such measures as it is still quite distant from the goal of kidney transplantation. Studies have shown (e.g. Patzer et al, JAMA 2015;314:582) that only a minority of referred patients are ultimately waitlisted, and that there are racial disparities in the conversion from referral to waitlisting. Dialysis facilities can contribute importantly to access to the waitlist beyond referral, such as assisting patients with completion of necessary evaluation studies and maintaining their good health to help ensure candidacy.*

One commenter noted that some facilities do not have local access to a Transplant Center which makes obtaining a transplant difficult.

**Response:** *Although we acknowledge the challenges some dialysis facilities may face, the importance of transplantation to the health and well-being of their patients with end-stage kidney disease makes access to it imperative. Dialysis facilities are expected to make every effort to assist patients with access to a transplant center for potential evaluation.*

### Additional Comments

One commenter noted a concern with the way that the patient experience (ICH CAHPS) Star Ratings are displayed on the DFC site.

**Response:**

*Thank you for your comment. We will pass this suggestion on to the appropriate group.*

### Overall Analysis of the Comments and Recommendations

CMS and UM-KECC appreciate the time dedicated to reviewing and providing comments on the proposed candidate measures for DFC. The two transplant waitlist measures (SWR and PPPW) will be made available for public reporting on DFC in October 2019.

## Public Comment Verbatim Report

Date Posted	Text of Comments	Name, Credentials, and Organization of Commenter	Type of Organization	Recommendations/Actions Taken
May 16, 2019	See appendix	Sherla Farrell-Sealey	Individual	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.
May 16, 2019	See appendix	Franklin W. Maddux, MD, FACP Chief Medical Officer Executive Vice President for Clinical and Scientific Affairs	Provider Organization	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment themes are provided above.

User: Sherla Farrell-Sealey

Content:

End-Stage Renal Disease Access to Kidney Transplantation Measure Development

(PPPW)

The US Virgin Islands do not have a local transplant center. The patients are referred to transplant centers in the mainland. Many of our patients do not have the financial resource or support to travel to the mainland decreasing the amount of potential listing of candidates.

Patients are encouraged to go to a center in a state where they have family support. Not many of our patients have this options. Which means they would have to pay for transportation and housing, which is very costly.



**FRESENIUS  
MEDICAL CARE**

Kate Goodrich, M.D.  
Director, Center for Clinical Standards and Quality Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

Submitted via email: [dialysisdata@umich.edu](mailto:dialysisdata@umich.edu)

**RE: Updates to the Dialysis Facility Compare Website and the Star Ratings Program**

Fresenius Medical Care North America (FMCNA) appreciates the opportunity to provide input on the candidate measures for Dialysis Facility Compare (DFC). FMCNA is the largest integrated supplier in the country of services and products for individuals undergoing dialysis due to ESRD. Operating over 2,400 outpatient dialysis facilities, FMCNA provides dialysis services to over 180,000 people with kidney failure in the United States.

FMCNA supports the goal of DFC as a tool to facilitate comparison of the quality of care between dialysis facilities. However, we want to ensure that the information presented on DFC is meaningful to those who rely on it to make decisions about their health care. In this regard, we believe it is essential that quality measures that are used to evaluate facility performance are informed by factors that are within the control of or can be reasonably influenced by dialysis facility care.

Below, we highlight concerns with the proposed measures for inclusion on DFC, the Percentage of Prevalent Patients Waitlisted (PPPW) and Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). Namely, we are concerned that the measures do not accurately reflect the quality of dialysis facility care because being placed on the waitlist for kidney transplantation is influenced by numerous factors, many of which are outside of the influence of dialysis facility care or care coordination. We suggest that CMS pursue transplantation measures for DFC that better reflect the dialysis facility's role in the waitlisting process and serve as better indicators of the quality of care provided by the facility.

We also offer brief comments about the newly-introduced ICH CAHPS Star Ratings. While the ICH CAHPS-based star rating is a potentially useful tool, we want to ensure that DFC visitors have complete information so that they can make informed judgements when comparing facilities. We recommend that CMS provide DFC visitors information that clearly delineates the number of facilities with ICH CAHPS star ratings, a method to filter when there is no ICH CAHPS star rating for a facility, and information about each facilities' ICH CAHPS response rate for the performance period.

**Transplant Measures**

CMS is considering the inclusion of two additional measures on DFC: PPPW and SWR.

The transplantation measures under consideration for DFC are problematic because performance is based on transplant waitlisting. Transplant waitlisting decisions are made by transplant centers and

**Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter St Waltham, MA 02451-1457 (781) 699-9000

numerous factors outside of the dialysis facility's control influence the likelihood of transplant waitlisting. These factors include:

- transplant center waitlisting evaluation and selection practices;
- access to transplant evaluation (e.g., proximity and number of transplant centers, transplant center evaluation guidelines);
- pre-existing medical co-morbidities that are contraindications to transplantation (e.g., recent malignancy);
- lack of transportation to the transplant centers for the evaluation process;
- lack of social support; and
- incomplete insurance for transplantation and post-transplant care.

Ultimately, transplant centers decide whether an individual is placed on the kidney transplant waitlist, not dialysis facilities. While dialysis facilities are well-positioned to provide transplant education, refer patients for transplant evaluation and support patients during their transplant work-up, we do not believe the contemplated measures properly capture the quality of health care that is primarily attributable to dialysis facility care.

Quality ratings based on factors outside of a facility's control could deteriorate the value of DFC for patients, families and care givers seeking information. There is significant regional variation across transplant centers throughout the United States in terms of their approach toward evaluation of candidates, including the length of evaluation and the process for waitlisting candidates. Differences in transplant center practices could impact a dialysis facility's performance on the PPPW and SWR measures, creating the appearance of differences in quality across dialysis facilities when in fact the difference relate to the practices of the proximate transplant centers. Such a result would be misleading for individuals that use DFC to make informed health care decisions. Dialysis facility performance should not be artificially lowered or increased due to transplant center practices.

Furthermore, evolving transplant center approaches to wait-listing, in light of recent revisions to OPTN allocation policy, have the potential to exacerbate attribution issues with PPPW and SWR. In 2014, OPTN revised its policies to prioritize candidates based on time spent on dialysis (as opposed to time spent on the wait-list). In response to these policy changes, some centers may change the timing of their evaluation and wait-listing as early evaluation no longer offers any advantage to individuals who do not have a high PRA or a potential living donor.

Considering these concerns, we recommend DFC include measures within the realm of dialysis facility influence that better reflect the quality of dialysis facility care. For example, measures for education of patients about the transplant option or referral of patients to a transplant center for evaluation would more directly reflect dialysis facility care and the role played by facilities in the waitlisting process. We believe measures such as a transplant referral measure would serve CMS' stated goals to encourage facilities to coordinate care with transplant centers without the risk of rewarding or penalizing facilities based on factors beyond their control.

### **ICH CAHPS Star Ratings and Performance**

In October 2018, CMS started publishing star ratings based on ICH CAHPS performance on DFC.

### **Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter St Waltham, MA 02451-1457 (781) 699-9000

We recommend the DFC site provide an explanation for patients, families and caregivers that more than 50 percent of US dialysis facilities do not have patient experience (ICH CAHPS) Star Ratings. This information should be made clearer when presenting star ratings to ensure transparency and to help visitors understand that a “no star” rating does not necessarily imply the lowest possible patient experience rating. We also feel it is important to include an option for “no star rating” in the filter function on the right-side panel of DFC to allow patients to include these facilities in their comparisons.

We also recommend including facility-level response rates when displaying ICH CAHPS Star Ratings or top-box performance. Such information would provide useful context to DFC visitors and help them to understand the percent of eligible survey respondents who completed the survey.

### **Conclusion**

We appreciate the opportunity to provide feedback on DCF. Please do not hesitate to contact Dr. Frank Maddux at [Frank.Maddux@fmc-na.com](mailto:Frank.Maddux@fmc-na.com) or (781) 699-2424 you have questions or would like to discuss these recommendations.

Sincerely,

A handwritten signature in black ink that reads "Franklin W. Maddux MD". The signature is written in a cursive style with a horizontal line under the "x".

Franklin W. Maddux, MD FACP  
Chief Medical Officer  
Executive Vice President for Clinical and Scientific Affairs

**Fresenius Medical Care North America**

Corporate Headquarters: 920 Winter St Waltham, MA 02451-1457 (781) 699-9000