Public Comment Summary Report

Project Title: ***Practitioner Level Measurement of Effective Access to Kidney Transplantation.***

Dates:

The Call for Public Comment ran from **March 1, 2022** to **March 30, 2022**.

Project Overview:

The Centers for Medicare & Medicaid Services (CMS) has the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop practitioner-level measures in the area of access to kidney transplantation for dialysis patients. The contract name is Kidney Disease Quality Measure Development, Maintenance, and Support. The contract number is 75FCMC18D0041, task order number 75FCMC18F0001.

Information About the Comments Received:

The measure developer solicited public comments by email.

We received 5 responses on this topic, which are detailed in the Public Comment Verbatim Report.
Stakeholder Comments

General Stakeholder Comments:

1.1 Support for Measures

Several commenters recognize the importance of improving transplantation rates for patients with End-Stage Renal Disease. One commenter directly supports the creation and implementation of practitioner-level measurement of effective access to kidney transplantation, noting that kidney transplantation is the optimal treatment modality for most End-Stage Kidney Disease (ESKD) patients. Commenters acknowledge that there are few clinician-level quality measures to encourage access to kidney transplantation. One commenter adds that dialysis centers and nephrologists who deliver care to ESKD patients should be accountable and measured for their role in the transplantation process, citing evidence of stagnant waitlisting rates, especially among socially vulnerable populations, despite policy efforts to increase waitlisting. One comment references the CMS statement of shared accountability between dialysis facilities and transplant centers in enabling patients receiving dialysis to be placed on a kidney or kidney-pancreas waitlist. The commenter agrees that dialysis facilities can work with transplant centers to coordinate care so that patients can traverse the many steps between transplant referral and waitlisting, including starting the transplant evaluation and undergoing the multiple tests and consultations necessary to complete the evaluation. Additionally, the commenter believes that practitioners have a vital role in this responsibility.

> **Response:** The developer agrees that dialysis practitioner groups have a significant role in the coordination of care of dialysis patients in support of access to transplantation, the optimal

treatment modality for most ESKD patients. The measures fill a void in practitioner level quality measures that incentivize improving access to kidney transplantation.

One commenter writes that the measures should also be included under the Merit-Based Incentive Payment System (MIPS).

Response: The developer agrees with the comment. Ultimately, CMS decides which measures to include in its programs.

1.2 Attribution of Waitlisting Measures to Dialysis Practitioners and Facilities

One commenter writes that although transplant centers are the ultimate entity with the power to waitlist a patient, nephrologists and dialysis centers should be held accountable for their role in ensuring that a patient is waitlisted; the comment explains that it is appropriate in order to ensure coordination across the range of stakeholders in the transplant system. In contrast, several commenters express concern that waitlisting is a decision made by the transplant center and is beyond the locus of control of any of the providers targeted in these measures; the measures largely focus on aspects of the patient's status that are beyond the control of the nephrology practitioner or dialysis facility and should not be attributed to dialysis facilities, individual practitioners, or group practices.

Response: Being waitlisted for kidney transplantation is the culmination of a variety of preceding preparatory activities. These include, but are not limited to, education of patients about the option of transplantation, 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 practitioner groups. Although some aspects of the waitlisting process may not entirely depend on dialysis practitioner groups, 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 practitioner groups. For example, through coordination of care, strong communication with transplant centers, and advocacy for patients by dialysis practitioner groups, as well as comprehensive education, encouragement, and support of patients during their decision-making about the transplantation option. The practitioner level access to transplant waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis practitioner groups. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis practitioner groups can be, and are already, making towards access to transplantation, to the benefit of the patients under their care.

1.3 Patient Choice

One comment references the importance of patient choice in transplant access and urges the developer to adjust for patient preference.

Response: The developer acknowledges the importance of patient autonomy to make decisions about transplantation; however, we note that it is important that patients make informed

decisions about their health. Many patients may refuse transplantation due to fears and anxieties that could be allayed with comprehensive education and support about the benefits of transplantation, which can be provided by dialysis facilities and practitioners. In this manner, dialysis practitioner groups can have a substantial influence on decision-making by patients, and it would therefore be inappropriate to adjust for patient preference in the measures.

1.4 Accounting for Comorbidities and transplant Center Eligibility Criteria

Two commenters note that there is variation in transplant center eligibility criteria and exclusions by location, which must be considered. Another comment specifically references that the measures do not exclude patients with criteria considered by transplant centers when they evaluate potential recipients, including severe cardiovascular disease, patients with severe pulmonary disease or other comorbidities, such as obesity, untreated psychiatric illness, and frailty.

Response: We agree that there is variation across transplant centers in eligibility criteria and that underlying patient comorbidities may affect their candidacy. All three waitlisting measures accordingly include adjustment for a wide range of comorbidities, and furthermore include adjustment for transplant center characteristics. An example is waitlist mortality, which can be viewed as a proxy for stringency of center waitlisting criteria. Further, the prevalent waitlisting measures include adjustment for transplant center random effects, capturing broad aspects of each transplant center's tendency to waitlist patients.

1.5 Proposals for Alternative Measures

One commenter recommends that referral rates are more appropriate than waitlisting rates as a metric, although they acknowledge the challenges in data acquisition. Several commenters recommend the adoption of measures related to whether patients have received education regarding transplantation as a modality option. Another comment encourages CMS to develop similar waitlisting measures for transplant centers to ensure coordination across the range of stakeholders in the transplant system.

Response: The developer emphasizes that there are already requirements in place for transplant centers per the CMS Conditions of Participation for communication of waitlisting status of patients to the dialysis facility. See Section 482.94(c):

> "Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of: 1) Patient's placement on the center's waitlist; the center's decision not to place the patient on its waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed 2) Removal from waitlist for reasons other than transplantation or death within 10 days." (42, C.F.R. § 482.94).

Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on performance of dialysis practitioner groups. The developer agrees that measures directed at referral and transplant education would be potentially valuable, but limitations in national data availability on referral and appropriate tools to capture quality of transplant education pose practical hurdles to development of such measures.

Measure-Specific Stakeholder Comments:

1.6 First Year Standardized Waitlist Ratio (FYSWR)

One comment requests that the developer provide performance scores from measure testing to stakeholders for review. Additionally, they request that the developer provide stratification of reliability scores by provider size for the measures. Specifically, the commenter is concerned about the FYSWR's IUR of 0.64, which the commenter classifies as moderate reliability. They refer to an unrelated measure with a similar moderate reliability and poor reliability for "small" facilities.

Response: Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a *similar size*. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

One commenter expresses concern that one year is not enough time for patients to be referred to a transplant center and to complete the steps to be placed on the waitlist.

Response: The purpose of the FYSWR measure is to encourage rapid attention to waitlisting of patients as soon as is appropriate after initiation of dialysis, and many patients are in fact waitlisted during the year after initiation of dialysis. The measure is structured to assess relative performance across dialysis practitioners without an expectation that all patients are appropriate or ready for waitlisting in the first year after dialysis initiation.

One commenter references a drop in waitlisting as a result of the 2014 KAS change due to a lack of urgency to get a patient on the waitlist early as the average wait time will be many years. The commenter acknowledges that this results in patients potentially missing out on getting evaluated earlier for living donor transplant or for early offers.

Response: We agree that not waitlisting patients because they have high anticipated waiting times could lead to them missing out on living donor offers as well as early national priority offers.

1.7 Percentage of Prevalent Patients Waitlisted (PPPW)

A commenter noted that another organization, KCQA, has developed a dialysis facility-level Transplant Access Measure Set, which pairs a referral rate metric with a measure assessing the waitlisting rate specifically among those patients who were referred by the facility within the preceding three years; moreover, because the waitlisting measure denominator is limited to those patients who were deliberately referred by the dialysis facility within a defined time period, facilities have considerably more agency over the measure than metrics such as the PPPW; this construct will also provide a counterbalance to the referral measure to prevent unnecessary patient and transplant center burden. The commenter notes that the approach could be applied at the practitioner group level.

> **Response:** Although we agree that information on referral can be valuable for incorporation into access to transplantation measures, there is currently no mechanism to capture data on referral on a national scale. Further, in light of known ongoing disparities in access to transplantation, and in the spirit of ensuring fair access to kidney transplantation, we believe a denominator including all dialysis patients is still appropriate, rather than only those the dialysis facilities chooses to refer.

One comment expresses concern about adopting the PPPW as a clinical measure, rather than a reporting measure. The commenter notes that, under the new kidney allocation system (KAS), waiting time starts at dialysis initiation, which eliminates the benefit of early waitlisting for deceased donor transplantation. The commenter cites that this change caused providers to wait until a patient has spent several years on dialysis prior to making a transplant referral.

> **Response:** As noted in response to a prior comment, even with the changes to the KAS, there are still potential benefits to patients of being waitlisted early. These include an impetus to find living donors, the possibility of early national priority offers, as well as the emotional and psychological benefits of being on the transplant waitlist, as articulated by patient members during the recent access to transplantation TEP (CMS 2021).

Two commenters write that they are concerned about geographic inequity: areas of the country with fewer transplant centers have been shown to have less access to renal transplantation; transplant eligibility varies by transplant center and geographic region, factors outside of the dialysis practitioner's control.

> **Response:** Distance from a patient's residence to a transplant center has not been consistently associated with access to kidney transplantation (see for example, CJASN April 2020, 15 (4) 539-549). However, there are known variations in organ availability regionally – to adjust for this, we have included transplant center effects (both a random effect, and adjustment for transplant center transplant rates) in the model for this measure.

One commenter writes that "many low-income patients with limited family support, with depression, or other barriers to obtaining complex care may struggle with completing the additional visits required for achieving a complete workup to achieve waitlisted status."

Response: We agree that financial and other social issues can pose substantial barriers to waitlisting for patients. However, they do not take away from the fact that many patients with these issues will still stand to benefit substantially from transplantation as compared with remaining on dialysis. As such it is expected that dialysis practitioner groups will work with transplant centers, advocate for patients and assist them in overcoming barriers to waitlisting to the extent possible. We also recognize that even with the best efforts, not all dialysis patients will ultimately be suitable candidates for waitlisting. Thresholds for the measures are assessed at the dialysis practitioner group level. Examination of dialysis practitioner group measures essentially allows comparison of an individual group practice's performance to a consensus standard, empirically set by the achievement of dialysis practitioner groups across the nation. Through comparison with the performance of other practitioner groups these measures may help individual dialysis practitioner groups identify opportunities for improvement in their waitlisting rates.

One commenter expresses concern that the PPPW will exclude patients who received a kidney transplant for the months after they receive the transplant; in other words, practitioners will lose credit for a reduced waitlisting prevalence once the patient has been transplanted. The writer adds that one of the payment incentives for the voluntary Kidney Care Choices models is the Transplant Bonus, which is only paid once the patient receives a transplant as that transplant remains functioning for up to three years. They recommend including patients who receive a kidney transplant during the measurement year in the numerator as equal to being on the waitlist for the 12 months following the kidney transplant.

Response: Relative to prevalent waitlisting rates, transplant events are rare such that how these are handled is unlikely to substantially affect performance on the measure. Nevertheless, we do include an adjustment for transplant center effects (both as a random effect, and a transplant center transplant rate variable) to account for the potentially disadvantaging effect on prevalent waitlisting performance among dialysis practitioners referring to transplant centers that more rapidly transplant patients.

1.8 Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)

A commenter expresses that the actual waitlisting of patients and whether they are active or inactive on the waitlist is beyond the control of dialysis units or individual nephrologists. They detail the information that is needed by referring physicians and dialysis units in order for the measures to be valid assessments of the quality of care, such as waitlisting criteria, relative contraindications, easy and timely access to the status of the patient in the transplant evaluation process, reasons for not listing a patient, and waitlist status; the commenter also references notification of patients who are on "internal hold" instead of being inactivated. The commenter states that the Health Resources and Services Administration and the Organ Procurement and Transplantation Network need to provide access to waitlist data, information on steps to transplantation from centers, and organ offer data in a manner that is timely, easily accessible, and actionable. Another commenter notes concerns that a patient's status on the waitlist can change frequently within the transplant centers and can be difficult to track.

Response: We recognize the significant role of the transplant center in making waitlist decisions. However, inactive status on the waitlist is usually the result of changes in medical condition, pending testing or changes in the social situation of the patient. Dialysis practitioners play a substantial role, even a primary role in many cases, to address the issues that can allow the patient to return to active status. Further, there are already requirements in place for transplant centers per the CMS Conditions of Participation for communication of waitlisting status of patients to dialysis facilities. See Section 482.94(c): "Transplant centers must maintain up-to-date and accurate patient management records for each patient who receives an evaluation for placement on a center's waitlist and who is admitted for organ transplantation. This includes notification to patient (and patient's usual dialysis facility if patient is a kidney patient) of: 1) Patient's placement on the center's waitlist; the center's decision not to place the patient on its waitlist; or the center's inability to make a determination regarding the patient's placement on its waitlist because further clinical testing or documentation is needed 2) Removal from waitlist for reasons other than transplantation or death within 10 days." (42, C.F.R. § 482.94). Although waitlisting measures directed at the transplant center may also be potentially appropriate, the scope of this particular measure development effort was focused on dialysis facilities.

One comment recognizes the importance of patients being actively waitlisted prior to receiving a kidney transplant and that the active listing rate may be a more clinically relevant measure of access to transplant than overall waitlisting, which includes inactively listed patients.

Response: We agree that an active waitlisting measure is particularly meaningful given active status is necessary to receive an organ offer and potentially get transplanted. We nevertheless believe overall waitlisting (as captured in the PPPW) is still important given it can serve as an impetus to take action towards readiness for transplantation (e.g. medical optimization, searching for living donors) as well as may provide emotional and psychological benefits, as articulated by patient members during the recent access to transplantation TEP (CMS 2021).

One commenter prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio for reasons of comprehension, transparency, and utility to all stakeholders.

Response: As noted in the Measure Information Form, the measure is specified as a ratio, but can be expressed as a ratio or a rate. The approach used is based on indirect standardization which also forms the basis of many approved measures and leads naturally to a standardized ratio. This ratio compares the rate for this facility with the national rate, having adjusted for the patient mix and as such is relatively easy to understand. The basis of the statement that rates are more easily understood than ratios is not clear. Stratified rates are not the same as actual rates and are not apparently any easier to interpret. We agree that a conversion to rates would require careful consideration.

One comment is concerned about reliability data for small providers.

Response: As stated previously, given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have

outcomes that are extreme when compared to the variation in outcomes for other facilities of a *similar size*. That is, smaller facilities have to have more extreme outcomes compared to other smaller facilities to be flagged.

Preliminary Recommendations

Based on the comments made, no specific changes to the measure specification will be implemented immediately.

Overall Analysis of the Comments and Recommendations

We appreciate the breadth and thoughtfulness of the comments provided. The major theme was concern over the extent to which the dialysis practitioner group is responsible for waitlisting of patients. As discussed in our responses, dialysis practitioner groups do play a very substantial part in most of the activities that ultimately contribute to the waitlisting of dialysis patients. As such, the proposed measures are a strong reflection of the care provided by dialysis practitioner groups for their patients.

Public Comment Verbatim Report

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
1	March 30, 2022	Timothy Pflederer, MD President, Renal Physicians Association (RPA)	Professional Organization	rpa@renalmd.org	First Year Standard Waitlist Ratio (FYSWR) Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)	See appendix.	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.
2	March 30, 2022	Susan E. Quaggin, MD, FASN President, American Society of Nephrology (ASN)	Professional Organization	ASN Regulatory and Quality Officer David L. White, dwhite@asn-online.org	First Year Standard Waitlist Ratio (FYSWR) Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)	See appendix.	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.
3	March 30, 2022	Kevin Longino, CEO and Transplant Patient	Professional Organization	Morgan Reid, Director of Transplant Policy and Strategy, morgan.reid@kidney.org	First Year Standard Waitlist Ratio (FYSWR)	See appendix.	We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
(cont.)	(cont.)	Paul M. Palevsky, MD, President, National Kidney Foundation	(cont.)	Miriam Godwin, miriam.godwin@kidney.org	Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)	(cont.)	Responses to comment themes are provided above.
4	March 30, 2022	David E. Henner, DO, President, Forum of ESRD Networks Kam Kalantar-Zadeh, MD, MPH, PhD, Chair, Forum Medical Advisory Council Derek Forfang, Co-Chair, Forum Kidney Patient Advisory Council Dawn Edwards, Co-Chair, Forum Kidney Patient Advisory Council Forum of ESRD Networks	Professional Organization	Kelly Brooks, MPA, Coordinator, Forum of ESRD Networks, kbrooks@esrdnetworks.org	First Year Standard Waitlist Ratio (FYSWR) Percentage of Prevalent Patients Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)	See appendix.	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.
							We thank you for your feedback. Stakeholder comments will be reviewed by measure developers and taken under consideration. Responses to comment

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
(cont.)	(cont.)	American Nephrology Nurses Association American Society of Nephrology American Society of Pediatric Nephrology Ardelyx AstraZeneca Atlantic Dialysis Management Services, LLC Baxter International, Inc. Cara Therapeutics, Inc. Centers for Dialysis Care CorMedix Inc. DaVita, Inc. Dialysis Patient Citizens, Inc. Dialysis Vascular Access Coalition DialyzeDirect Fresenius Medical Care North America Greenfield Health Systems Kidney Care Council North American Transplant	(cont.)	(cont.)	Waitlisted (PPPW) Percentage of Prevalent Patients Waitlisted in Active Status (aPPPW)	(cont.)	themes are provided above.

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
(cont.)	(cont.)	Coordinators Organization Nephrology Nursing Certification Commission Otsuka America Pharmaceutical, Inc. Renal Healthcare Association (formerly NRAA) Renal Physicians Association Renal Support Network Rockwell Medical Rogosin Institute Satellite Healthcare, Inc. U.S. Renal Care, Inc. Vertex Pharmaceuticals Vifor Pharma Ltd.	(cont.)	(cont.)	(cont.)	(cont.)	(cont.)

*Optional

REFERENCES

Centers for Medicare & Medicaid Services. *Practitioner Level Measurement of Effective Access to Kidney Transplantation Technical Expert Panel Summary Report*. September 24, 2021, from https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-Practitioner-Level-Measurement-Kidney-Transplantation.pdf.

Department of Health and Human Services; Centers for Medicare & Medicaid Services; Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers to Perform Organ Transplants; Final Rule, 72 Fed. Reg. 42, C.F.R. § 405, 482, 488, and 498. March 30, 2007, from https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Downloads/trancenterreg2007.pdf.