# **2024 MIPS Peer-Reviewed Journal Article Requirement Template**

Section 101(c)(1) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) requires submission of new measures for publication in applicable specialty-appropriate, peer-reviewed journals prior to implementing in the Merit-based Incentive Payment System (MIPS). These measures will be submitted by the Centers for Medicare & Medicaid Services (CMS), to a journal(s), before including any new measure in the MIPS Quality Measures List under MIPS. The measure submitter shall provide the required information for article submission under the MACRA per the CMS Call for MIPS Quality Measures submission process.

Stakeholders submitting measures to the MIPS Call for Quality Measures must complete the required information by the Annual Call for Measures deadline. Some of the information requested below may be listed in specific fields in the Measures Under Consideration (MUC) Entry/Review Information Tool (MERIT); however, to ensure that CMS has all of the necessary information and to avoid delays in the evaluation of your submission, please fully complete this form as an attached Word document. The information in MERIT must be consistent with the information below, which includes the following, but is not limited to:

* **Prevalent Standardized Waitlist Ratio (PSWR)**
* **Person Centered Care**
* **Chronic Conditions**

**Measure Steward:** The Centers for Medicare & Medicaid Services (CMS)

**Measure Developer:** University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)

**Description:** The PSWR measure tracks the number of prevalent dialysis patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. For each practitioner group, the Prevalent Standardized Waitlist Ratio (PSWR) is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The PSWR uses the expected waitlist events calculated from a Cox model, adjusted for patient age, incident and prevalent comorbidities, previous waitlisting and transplant, dual eligibility, Area Deprivation Index (ADI), and transplant center characteristics.

1. **Statement**

* Background (Why is this measure important?).

The PSWR measure tracks the number of prevalent dialysis patients in a practitioner (inclusive of physicians and advanced practice providers) group who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant. For each practitioner group, the Prevalent Standardized Waitlist Ratio (PSWR) is calculated to compare the observed number of waitlist events in a practitioner group to its expected number of waitlist events. The PSWR uses the expected waitlist events calculated from a Cox model, adjusted for patient age, incident and prevalent comorbidities, previous waitlisting and transplant, dual eligibility, Area Deprivation Index (ADI), and transplant center characteristics.

This measure tracks the outcomes of new placement on the kidney or kidney-pancreas transplantation waitlist or receipt of a living donor transplant following dialysis initiation, with the intended objective of improving the overall health of patients on dialysis. Being waitlisted or receiving a living donor kidney transplant are outcomes as they represent a desirable change in health status for patients on dialysis, indicating achievement of a health condition conducive to kidney transplantation. These outcomes result from specific activities directed by dialysis practitioners with the particular goal of achieving suitability for kidney transplantation by addressing the specific healthcare needs of patients on dialysis. These activities can include, but are not limited to, ensuring an ideal dialysis prescription and care, correction and optimization of common underlying chronic health conditions such as heart failure, coronary artery disease, diabetes mellitus, hyperparathyroidism, and obesity, and as needed, optimizing mental health and social support systems. In addition, dialysis practitioners support the path for patients towards waitlisting or living donor transplantation through proper education about the transplantation option, referral to a transplant center and assistance with completion of the transplant evaluation process. The logic model for the steps involved is diagrammed below (with the outcome measure in bold):

Patients with ESRD on maintenance dialysis -> Patients not already on the wait list are educated about the option of kidney transplantation and assessed for eligibility for transplant referral by a dialysis practitioner -> Patients are referred to a transplant center for evaluation of candidacy for kidney or kidney-pancreas transplantation -> Dialysis practitioners assist patient with completion of the transplant evaluation process and optimizing their health and functional status -> Patients deemed to be candidates for transplantation who have compatible living donors receive living donor transplant; otherwise they are placed on the wait list with the potential to receive a deceased donor transplant.

A measure focusing on the outcome of waitlisting is appropriate for several reasons. First, in preparing patients for suitability for waitlisting, dialysis practitioners optimize their health and functional status, improving their overall health state. Second, waitlisting is a necessary step prior to potential receipt of a deceased donor kidney transplant (receipt of a living donor kidney is also accounted for in the measure), which is known to be beneficial for survival and quality of life [1]. Third, dialysis practitioners exert substantial control over the processes that result in waitlisting. This includes proper education of dialysis patients on the option for transplant, referral of appropriate patients to a transplant center for evaluation, and assisting patients with completion of the transplant evaluation process, in order to increase their candidacy for transplant waitlisting. These types of activities are included as part of the conditions for coverage for Medicare certification of ESRD dialysis facilities. Finally, wide regional and facility variations in waitlisting rates highlight substantial room for improvement for this measure [2-5].

Additionally, this measure focuses specifically on the population of prevalent patients on dialysis, examining for the occurrence of new waitlisting or living donor transplant events. This will evaluate and encourage rapid attention from dialysis practitioner groups to the optimization of health of patients to ensure early access to the waitlist, which has been demonstrated to be particularly beneficial [6-9]. Given that many patients may not be ready for transplant candidacy immediately following initiation of dialysis, this measure encourages ongoing attention to transplant candidacy throughout the period following dialysis initiation.

*1. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011;11:2093-2109.*

*2. Ashby VB, Kalbfleisch JD, Wolfe RA, et al. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. American Journal of Transplantation 2007; 7 (5 Part 2):1412-1423.*

*3. Satayathum S, Pisoni RL, McCullough KP, et al. Kidney transplantation and wait-listing rates from the international Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Intl 2005 Jul; 68 (1):330-337.*

*4. Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014 Jul; 14(7):1562-72.*

*5. Melanson TA, Gander JC, Rossi A, et al. Variation in Waitlisting Rates at the Dialysis Facility Level in the Context of Goals for Improving Kidney Health in the United States. Kidney International Reports 2021;6:1965-1968.*

*6. Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. "Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis." Transplantation 74.10 (2002): 1377-1381.*

*7. Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., ... & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311-1317.*

*8. Schold JD, Huml AM, Poggio ED et al. Patients with High Priority for Kidney Transplant Who Are Not Given Expedited Placement on the Transplant Waiting List Represent Lost Opportunities. J Am Soc Nephrol 2021;32:1733-1746.*

*9. Schold J and Meier-Kreische HU. Which Renal Transplant Candidates Should Accept Marginal Kidneys in Exchange for a Shorter Waiting Time on Dialysis? Clin J Am Soc Nephrol 2006;1:532-538.*

* Environmental scan (Are there existing measures in this area?)

There are no existing measures in this area.

1. **Gap Analysis**

* Provide evidence for the measure (What are the gaps and opportunities to improve care?).

Two previous Technical Expert Panels (TEP) have been convened to discuss potential measures directed at improving access to kidney transplantation, in 2015 and most recently, in 2021 (2015 TEP Report: https://dialysisdata.org/sites/default/files/content/ESRD\_Measures/Access\_To\_Kidney\_Transplantation\_TEP\_Summary\_Report.pdf; 2021 TEP Report: https://dialysisdata.org/content/esrd-measures, please see Practitioner Level Measurement of Effective Access to Kidney Transplantation under Ongoing Technical Expert Panels section). Both were comprised of relevant stakeholders, including dialysis nephrologists, transplant nephrologists, transplant surgeons, social workers, researchers, and notably, patient representatives with a history of end-stage kidney disease. Discussions during both TEPs revealed broad support for the importance of waitlisting, and formal voting demonstrated a majority of TEP members were in favor of the development of quality measures targeting waitlisting (at the dialysis facility level for the 2015 TEP, and the practitioner level for the 2021 TEP).

In addition to the above, empirical support for the value of waitlisting to patients comes from a published study reporting on a large survey of 409 patients or family members who agreed to receiving emails from the National Kidney Foundation (Husain S.A. et al, Am. J. Transplant 2018;18(11):2781-2790). Participants included both patients with advanced chronic kidney disease prior to transplant, and recipients of transplants, who were asked about their priorities in choice of a transplant center. Notably, participants were most likely (a plurality of participants) to rank waitlisting characteristics (such as ease of getting on the waitlist) as the most important feature, in contrast to other transplant center characteristics such as post-transplant outcomes and practical considerations (e.g. distance to center).

National or large regional studies provide strong empirical support for the association between processes under dialysis practitioner control and subsequent waitlisting. In one large regional study conducted on facilities in the state of Georgia, a standardized dialysis facility referral ratio was developed, adjusted for age, demographics and comorbidities (Paul S. et al, Clin J Am Soc Nephrol 2018;13:282-289). There was substantial variability across dialysis facilities in referral rates, and a Spearman correlation performed between ranking on the referral ratio and dialysis facility waitlist rates was highly significant (r=0.35, p<0.001). A national study using registry data (United States Renal Data System) from 2005-2007 examined the association between whether patients were informed about kidney transplantation (based on reporting on the Medical Evidence Form 2728) and subsequent access to kidney transplantation (waitlisting or receipt of a live donor transplant) (Kucirka LM et al. Am J Transplant 2012;12:351-357). Approximately 30% of patients were uninformed about kidney transplantation, and this was associated with half the rate of access to transplantation compared to patients who were informed. In a related survey study of 388 hemodialysis patients, whether provision of information about transplantation by nephrologists or dialysis staff occurred was directly confirmed with patients (Salter ML et al, J Am Soc Nephrol 2014;25:2871-2877). Patient report of provision of such information was associated with a three-fold increase in likelihood of waitlisting. Finally, a large survey study of 170 dialysis facilities in the Heartland Kidney Network (Iowa, Kansas, Missouri and Nebraska) was conducted to examine transplant education practices (Waterman AD et al, Clin J Am Soc Nephrol 2015;10:1617-1625). Facilities employing multiple (>3) transplant education strategies (e.g. provision of brochures, referral to formal transplant education program, distribution of transplant center contact information) had 36% higher waitlist rates compared to facilities employing fewer strategies.

*1. Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011;11:2093-2109.*

*2. Ashby VB, Kalbfleisch JD, Wolfe RA, et al. Geographic variability in access to primary kidney transplantation in the United States, 1996-2005. American Journal of Transplantation 2007; 7 (5 Part 2):1412-1423.*

*3. Satayathum S, Pisoni RL, McCullough KP, et al. Kidney transplantation and wait-listing rates from the international Dialysis Outcomes and Practice Patterns Study (DOPPS). Kidney Intl 2005 Jul; 68 (1):330-337.*

*4. Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014 Jul; 14(7):1562-72.*

*5. Melanson TA, Gander JC, Rossi A, et al. Variation in Waitlisting Rates at the Dialysis Facility Level in the Context of Goals for Improving Kidney Health in the United States. Kidney International Reports 2021;6:1965-1968.*

*6. Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. "Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis." Transplantation 74.10 (2002): 1377-1381.*

*7. Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., ... & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311-1317.*

*8. Schold JD, Huml AM, Poggio ED et al. Patients with High Priority for Kidney Transplant Who Are Not Given Expedited Placement on the Transplant Waiting List Represent Lost Opportunities. J Am Soc Nephrol 2021;32:1733-1746.*

*9. Schold J and Meier-Kreische HU. Which Renal Transplant Candidates Should Accept Marginal Kidneys in Exchange for a Shorter Waiting Time on Dialysis? Clin J Am Soc Nephrol 2006;1:532-538.*

* Expected outcome (patient care/patient health improvements, cost savings).

The measure is not yet implemented in a public reporting program, so improvement could not be evaluated. CMS currently anticipates implementation of this measure. Once implemented practitioner performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in waitlisting rates among the target population.

* Recommendation for the measure (Is it based on a study, consensus opinion, USPSTF recommendation etc.?).

This measure was developed based on the evidence described above.

1. **Reliability/Validity**

* What testing has been performed at the level of implementation? (MIPS requires full measure testing at the individual clinician level (and may also need to be tested at the group level) for MIPS Clinical Quality Measures (CQMs) and Electronic Clinical Quality Measures (eCQMs) collection types. Administrative claims measures tested at the group level require a reliability threshold to be implemented at the group level.)

Please provide testing results including the N value, Bonnie test case results, correlation coefficient and any other pertinent information or values to be considered.

* + Reliability Testing Results at the accountable entity level

The IUR is 0.56. The value of IUR indicates that about 56% of the variation in the PSWR measure can be attributed to the between-dialysis practitioner group practice differences (signal) and about 44% of variation to within-dialysis practitioner group practice variation (noise). The value of IUR implies a moderate degree of reliability.

* + Empiric Validity Testing Results at the accountable entity level

The tertile groups based on the performance scores were defined as:

 (best performance): 1.16 - 6.84

 0.77 - 1.16

 (worst performance): 0 - 0.77

The dialysis practitioner group average mortality is 17.7, 17.5, 18.1 deaths per 100 patient-years for  groups, respectively (trend test p=0.255). The Spearman correlation coefficient is: -0.02 (p=0.264).

The dialysis practitioner group average transplant rate is 4.7, 3.8, 2.6 transplants per 100 patient-years for the  groups, respectively (trend test p<.001). The Spearman correlation coefficient is: 0.41 (p<.001).

As expected, better PSWR performance correlated with higher transplant rate, with clear separation of transplant rates across practitioner group tertiles of performance. The direction of the relationship with mortality was as expected (modest negative correlation with better PSWR performance), with the numerically highest mortality in the lowest performance tertile of the PSWR measure, though results did not achieve statistical significance.

* + Exclusion Frequency

**Table 5:** Overall number and percentage of patients excluded

| **\*** | **Before age, nursing home, and hospice exclusion** | **After age, nursing home, and hospice exclusion** | **Percentage excluded** |
| --- | --- | --- | --- |
| Number of patients | 494,134 | 362,093 | 26.7% |

\*Cell intentionally left blank.

**Table 6:** Frequency distribution of patient-months excluded based on each exclusion criteria

| **Variable excluded** | **Frequency (%)** |
| --- | --- |
| Age >=75 | 118,703 (24.0%) |
| Nursing home from Nursing home history file | 42,684 (8.6%) |
| Hospice | 3,310 (0.7%) |
| Dementia | 19,369 (3.9%) |

* + What were the minimum sample sizes used for reliability results?

Over the reporting period from 2017 through 2019, there were 2,202 practitioner groups included in these analyses, after restricting to practitioner group practices that had at least 11 eligible patients and at least 2 expected events.

* + Other Information
* Is it risk adjusted? If so, how?

Variables chosen for inclusion in the model were based on a conceptual rationale that included theoretical/clinical considerations (discussed for each set of factors below) and existing literature (see brief list of references including large national or regional datasets, and clinical practice guidelines for kidney transplant candidate evaluation), for factors affecting kidney transplant waitlisting. We considered variables in three categories: social risk, functional risk, and medical/clinical risk. Choices were also discussed with a Technical Expert Panel held in 2021.

Social Risk Factors:

Under conceptual considerations, and as supported by the TEP, it was deemed important to adjust for social risk on the basis that it could affect suitability for transplant waitlisting. This could occur, for example, through difficulty with ability to pay for transplant immunosuppression medications, or lacking the resources to travel to a transplant center for care, which are considerations taken into account for suitability for transplant waitlisting (the Kidney Disease Improving Global Outcomes [KDIGO] Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation recommends psychosocial assessment and evaluation of adherence). For this purpose, dual Medicare-Medicaid eligibility (at the patient level, representing socioeconomic disadvantage) and Area Deprivation Index (ADI) were investigated and included in our model. Dual eligibility was obtained from Medicare claims and could also be obtained from the CMS-2728 form for incident patients within the first year of ESRD. ADI was obtained based on patient zip code of residence and used as a proxy to adjust for potential differences in waitlisting for neighborhoods of different ranking of socioeconomic disadvantage (see Patzer et al reference below).

Functional Risk Factors:

Given that poor functional status and frailty are associated with worse outcomes following kidney transplantation (see McAdams-Demarco et al, below), patients with low functional status may be less appropriate for waitlisting. We therefore included items available on the CMS Form 2728, indicating whether Assistance with Daily Activities is needed, Inability to transfer, and Inability to ambulate.

Clinical/Medical Risk Factors:

Age adjustment was deemed necessary on clinical grounds and supported by the Technical Expert Panel (TEP) held in 2021. Although age alone is not a contraindication to transplantation, older patients are likely to have more comorbidities and be generally more frail thus making them potentially less suitable candidates for transplantation. This may affect waitlisting rates for dialysis provider group practices with a substantially older age composition than the average.

In addition, incident and prevalent comorbidities were selected for adjustment into the PSWR model based on demonstration of a higher associated mortality (hazard ratio above 1.0) and statistical significance (p-value <0.01) in a first year mortality model, thus reflecting patients at higher risk of early mortality and therefore potentially unsuitable for transplant waitlisting. For prevalent comorbidities, we used the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) diagnosis categories using Medicare claims. First, we selected comorbidity groupers that were positively and statistically significantly associated with one- year mortality, to again identify conditions associated with early mortality, and therefore potential unsuitability for transplant waitlisting. Then, we included potential candidate conditions that had a prevalence greater or equal to 0.1% in our population to identify a final set of 64 prevalent comorbidities.

Finally, the TEP deemed it important to adjust for elements affecting waitlisting that may be partially outside control of dialysis practitioners, such as transplant center behavior. Two transplant center characteristics were chosen for adjustment in the model, including transplant center waitlist mortality rate, and transplant center transplant rate. The former is a reflection in part of transplant center criteria for waitlisting, as centers with more liberal criteria (i.e. less selective) will tend to accept sicker patients and therefore have higher waitlist mortality, whereas centers with more restrictive criteria will tend to have lower waitlist mortality rates. The transplant center transplant rate reflects both local organ availability and center behavior with regards to how quickly they are able to transplant waitlisted patients (e.g. by aggressively pursuing living donation). For adjustment in the model, weighted transplant center waitlist mortality ratio and transplant ratio were calculated on each zip code level. Weight of a transplant center was determined by the likelihood of transplant from neighborhood waitlising patients. patients Patients were then assigned with to transplant center waitlist mortality ratio and transplant ratio based on historical waitlisting patterns in their zip code of residence matched with the corresponding transplant centers.

References:

*1. Jesse D. Schold, Sumit Mohan, Anne Huml, Laura D. Buccini, John R. Sedor, Joshua J. Augustine and Emilio D. Poggio. Failure to Advance Access to Kidney Transplantation over Two Decades in the United States. JASN 2021;32:913*

*2. Jesse D. Schold, Jon A. Gregg, Jeffrey S. Harman, Allyson G. Hall, Pamela R. Patton, and Herwig-Ulf Meier-Kriesche. Barriers to Evaluation and Wait Listing for Kidney Transplantation. CJASN 2011;6:1760.*

*3. Rachel E. Patzer, Sandra Amaral, Haimanot Wasse, Nataliya Volkova, David Kleinbaum, and William M. McClellan. Neighborhood Poverty and Racial Disparities in Kidney Transplant Waitlisting. JASN 2009;20:1333.*

*4. Mara A. McAdams-DeMarco, Andrew Law, Megan L. Salter, Eric Chow, Morgan Grams, Jeremy Walston, and Dorry L. Segev. Frailty and Early Hospital Readmission after Kidney Transplantation. American Journal of Transplantation 2013;13:2089.*

*5. Kidney Disease: Improving Global Outcomes (KDIGO) Kidney Transplant Candidate Work Group. KDIGO Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. Transplantation. 2020;104: S1 – S103.*

* What benchmarking information is available?

N/A

* Collection Type: Specify the data collection type.

N/A

* Specify measure stage of development.

Fully developed

1. **Endorsement**
   * Provide the Consensus-Based Entity (CBE) (i.e., Partnership for Quality Measures (PQM)) endorsement status (and CBE ID) and/or other endorsing body. If the measure is only endorsed for paper records, please note endorsement for only the data source being submitted.

Not recommended for endorsement (3719).

1. **Summary**

* Alignment with CMS Meaningful Measures Initiative or MACRA (if applicable).

Chronic Conditions

* Relevance to MIPS or other CMS programs.

Improving transplant waitlisting is an identified priority at CMS

* Rationale: Use of measure for inclusion in program (specialty society, regional collaborative, other).

N/A

* Public reporting (if applicable).

N/A

* Preferable relevant peer-reviewed journal for publication.

N/A

* Rationale as to how the measure correlates to existing cost measures and improvement activities, as applicable and feasible.

Once implemented dialysis practitioner performance on the measure can be evaluated to determine if the measure has supported and detected quality improvement in waitlisting rates among the target population.