Guide to the New Measures Table for the Quarterly Dialysis Facility Compare Report:

Overview, Methodology, and Interpretation

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Table of Contents

I. Purpose of this Guide and the Quarterly Dialysis Facility Compare Reports

This guide explains in detail the contents of the Quarterly Dialysis Facility Compare (QDFC) reports that were prepared for each dialysis facility under contract to the Centers for Medicare & Medicaid Services (CMS). Included here are the reports' objectives, discussions of methodological issues relevant to particular sections of each report, and descriptions of each data summary.

These reports include information about directly actionable practice patterns such as dose of dialysis, vascular access, mineral metabolism, and anemia management, as well as patient outcomes (such as mortality, hospitalization, hospital readmission and transfusions) that can be used to inform and motivate reviews of practices. The information in the report facilitates comparisons of facility patient characteristics, treatment patterns, and outcomes to local and national averages. Such comparisons help evaluate patient outcomes and account for important differences in the patient mix - including age, sex, and patients' diabetic status - which in turn enhances each facility's understanding of the clinical experience relative to other facilities in the state and nation.

The QDFC report provides facilities with advance notice of their new and updated quality measures that will be reported on the Dialysis Facility Compare (DFC) website, allowing dialysis patients to review and compare characteristics and quality information on dialysis facilities in the United States.

We welcome your participation and feedback concerning the clarity, utility, limitations, and accuracy of this report. You will find information on how to directly provide feedback to us at the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) in Section XI.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center has produced the QDFC reports with funding from CMS. Each facility's report is available to the facility on the secure Dialysis Reports website (www.DialysisData.org).

Each report provides summary data on each facility's maintenance dialysis patients for the years 2014-2017. These summaries are compiled using the UM-KECC ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN/CROWNWeb), which includes Renal Management Information System (REMIS), the CMS Annual Facility Survey (Form CMS-2744), the CMS Medical Evidence Form (Form CMS-2728), and the Death Notification Form (Form CMS-2746). The UM-KECC ESRD patient database also includes data from Medicare

dialysis and hospital payment records; clinical data from the CROWNWeb system, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset; the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER); the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. The CROWNWeb system provides tracking by dialysis provider and treatment modality for non-Medicare patients.

The report includes, starting on page 5, the DFC New Measures table which contain detailed information for your facility as along with regional averages for comparison for measures that will be displayed on DFC in the future. The new measures contained in this table are discussed in more detail below.
Each row of the table in summarizes a data element. Your facility has a column for each time period, and in most cases, two columns for the corresponding geographical summaries, including averages for your facility's state, and the entire nation. In general, unless stated differently for a specific measure, whenever the statistic reported is a count (n), we calculated regional and national averages by taking the average count for all facilities in that area. When the statistic reported for a period included more than one year, we annualized regional and national values to make them comparable to a single-year period. When a statistic is a percent, rate, or ratio, we calculated state and national summaries by pooling together all individual patients in that area to obtain an estimate for that area as if it were one large facility. We do not report state summary data for dialysis facilities in states or U.S. territories with only one or two dialysis units. We do provide summaries for the nation for facilities in these states or territories.

III. New Measures

The table "Upcoming New Measures" provides information about Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) and Percentage of Prevalent Patients Waitlisted (PPPW). The variables in this table will not be released publicly on the DFC website or included in the star rating at this time.

Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) (1.1-1.7)

The SWR measure tracks the number of incident patients at a dialysis facility who are under the age of 75 and were listed on the kidney or kidney-pancreas transplant waitlist or received a living donor transplant within the first year of initiating dialysis. For each facility, the Standardized Waitlist Ratio (SWR) is calculated to compare the observed number of waitlist events in a facility to its expected number of waitlist events. The SWR

uses the expected waitlist events calculated from a Cox model (SAS Institute Inc., 2004; Andersen, 1993; Collett, 1994), adjusted for age and patient comorbidities at incidence. For this measure, patients are assigned to the facility based on the facility information entered on the Medical Evidence 2728 form.

Eligible patients (1.1)
The SWR includes ESRD patients, under the age of 75, who have initiated dialysis during the reporting period. The exclusion criteria applied in the calculation of the SWR are as follows: i) patients who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis; ii) patients who were admitted to a skilled nursing facility (SNF) at incidence or previously, according to Question 17u and 22 on the CMS Medical Evidence Form and the CMS Long Term Care Minimum Data Set (MDS); iii) active hospice patients at time of dialysis initiation, based on Medicare final action claims data.

Patient-years at risk (1.2)
For patients in the SWR analysis, time at risk began at the incidence of dialysis and continued until the earliest occurrence of the following: date of listing on the kidney or kidney-pancreas transplant waitlist; date of receiving a living donor transplant; date of death; or one year after the start of treatment, whichever comes first. In addition, all patients' time at risk are included under the calendar year heading corresponding to the year in which chronic dialysis was initiated on the Medical Evidence Form, even if a portion of the follow-up time occurs in the following year.

Transplant waitlist event or receipt of a living-donor transplant (1.3)
This is the total number of patients on the transplant waitlist or in receipt of a living-donor transplant among new dialysis patients during their first year of dialysis. It is also the numerator of the SWR.

Expected number of transplant waitlist or living-donor transplant events (1.4)
The expected number of waitlist or living donor transplant events was calculated using a Cox model, adjusted for patients' age and comorbidities at incidence (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). All expected events at the same facility are summed up to obtain the total number of expected events in the reporting period.

Standardized Waitlist Ratio (1.5)
The SWR equals the ratio of the observed number of transplant waitlist events or receipt of a living-donor transplant (1.3) divided by the expected number of transplant waitlist events or living donor transplant events (1.4). For regional and national summaries, we calculated the SWR as the ratio of the total number of observed events among patients from each region (or the U.S.) to the number of expected events among patients from each region (or the U.S.). Please note that facilities with less than 11 patients or less than 2 expected

events for the reporting period are included in the State and US summaries. However, their SWR values, p-values and 95% confidence intervals are suppressed at facility level for the relevant years.

Confidence interval for SWR (1.5)
Similar to the Standardized Mortality Ratio (SMR), the 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national waitlist event rates, in light of the calculated SWR. The upper and lower confidence limits enclose the true ratio approximately 95% of the time if this procedure were to be repeated on multiple samples. Statistically significant confidence intervals do not contain the ratio value 1.00, which denotes that the observed event rate was equal to the expected event rate.

P-value for SWR (1.6)
The p-value measures the statistical significance (or evidence) of the hypothesis that the true transplant waitlist rate for a given facility is different from what would be predicted from the overall national rate. The p-value is the probability that the calculated SWR would deviate from 1.00 as much as it does, under the null hypothesis that this ratio is truly equal to 1.00. A smaller p-value tends to occur when the ratio differs greatly from 1.00 and/or when one uses more patient data to calculate the SWR value. A p-value less than 0.05 suggests that the ratio between the observed and expected waitlist event rates differs significantly from 1.00. The smaller the p-value, the lower the probability that a facility's waitlist event rate is equal to the national waitlist event rate. A small p-value helps rule out the possibility that an SWR's deviance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the facility waitlist event rate and the national rate.

Classification Category (1.7)
When a facility's SWR is greater than 1.00 and statistically significant (p-value < 0.05), it is classified as "Better than expected". When a facility's SWR is less than 1.00 and statistically significant (p-value < 0.05), it is classified as "Worse than expected". When a facility's SWR is not significantly different from 1.00, it is classified as "As expected". Please note that the classification of SWR is reported as "Not available" on DFC for facilities with less than 11 patients or less than 2 expected events for the relative reporting year.

Percentage of Prevalent Patients Waitlisted (PPPW) (2.1-2.6)

The PPPW measure tracks the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. It is an adjusted percentage of waitlist events among dialysis patients. Results are averaged across patients who were assigned to

the dialysis facility as of the last day of each month during the reporting year, adjusted for age.

Eligible patients and Patient-months at risk (2.1-2.2)
The total number of dialysis patients included in the PPPW calculation is reported in row 2.1. The total number of patient-months at risk is the sum of patient-months belonging to patients who are under the age of 75 on the last day of each month and who are assigned to the dialysis facility according to each patient's treatment history as of the last day of each month during the reporting year. A patient could be counted up to 12 times per year. The following patients or patient-months were excluded from the analysis: i) patient months that the patients were admitted to a skilled nursing facility (SNF) during the month of evaluation according to CMS Long Term Care Minimum Data Set (MDS) file; ii) patients who were admitted to a SNF previously, according to Question 17u and 22 on the CMS Medical Evidence Form; iii) active hospice patients during the month of evaluation, based on Medicare final action claims data.

Total waitlisted months (2.3)
This is the count of patient-months in which the patient at the dialysis facility is on the kidney or kidney-pancreas transplant waiting list as of the last day of each month during the reporting period.

Percentage of Prevalent Patients Waitlisted (2.4)
The Percentage of Prevalent Patients Waitlisted (PPPW) measure is a directly standardized percentage, in the sense that each facility's percentage waitlisted is adjusted to the national age distribution (with 'national' here referring to all-facilities-combined). The PPPW for each facility is an estimate of what the facility's percentage of prevalent patients would equal if the facility's patient mix was equal to that of the nation as a whole. The model is fitted using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the within-patient correlation across months. Please note that the PPPW calculation is restricted to facilities with 11 or more eligible patients during the reporting time period.

Confidence interval for PPPW (2.4)
The 95% confidence interval gives a range of plausible values for the true waitlist percentage. The upper and lower limits of the confidence interval enclose the true percentage approximately 95% of the time if this procedure were to be repeated on multiple samples.

P-value (2.5)
We use a two-sided Wald test (0.05 significance level) to measure the statistical significance of (or evidence against) the hypothesis that the PPPW for a facility is the same

as (neither higher nor lower than) that from the national average percentage waitlisted. Note that the Wald test is based on the logit of PPPW, which is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version. A p-value of less than 0.05 is usually taken as evidence that the facility PPPW differs from the national PPPW.

Classification Category (2.6)
Facilities were classified as "Better than expected", "As expected" or "Worse than expected" based on their Z score of the logit of PPPW. The Z score value is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version.