Guide to the December Quarterly Update of the Fiscal Year (FY) 2020 Dialysis Facility Report (DFR):

Overview, Methodology, and Interpretation

Guide to the Quarterly Updates of the FY 2019 Dialysis Facility Reports: Overview, Methodology, and Interpretation

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

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

In the interest of stimulating quality improvement efforts and facilitating the quality improvement process, the Quarterly Updates of the Dialysis Facility Reports make more recent data for select measures reported in the FY 2020 DFR available to those of you involved in dialysis care and the assurance of its quality. This report allows you to compare the patterns in dialysis access, fluid management, anemia, dialysis adequacy, nutrition, and mineral metabolism to local and national averages. Such comparisons help you to evaluate patient outcomes, which in turn enhances each facility's understanding of the clinical experience relative to other facilities in the state, Network, and nation.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the Quarterly Updates of the Dialysis Facility Reports for FY 2020 with funding from the Centers for Medicare & Medicaid Services (CMS). Each facility's report is distributed to the facility on the secure Dialysis Reports Web site (www.Dialysisdata.org). Those state agencies responsible for certifying dialysis facilities utilize the reports as a resource during the survey and certification process.

Each report provides summary data on each facility's chronic dialysis patients for the years 2017 and 2018 from the FY 2020 DFR along with quarterly summaries for January-March of 2019. Regional and national averages for 2018 are included to allow for comparisons. Italicized outcomes are updated annually in September. Please refer to the Guide to the FY 2020 Dialysis Facility Reports for details regarding their calculation. Unless otherwise specified, data refer to combined results for hemodialysis (HD) and peritoneal dialysis (PD) patients.

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), which includes Renal Management Information System (REMIS), the CMS Annual Facility Survey (Form CMS-2744), the CMS Medical Evidence Form (Form CMS-2728), the Medicare Enrollment Database (EDB), and the Death Notification Form (Form CMS-2746); Medicare dialysis and hospital payment records; transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset; the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC), which includes data from the Certification and Survey Provider Enhanced Report System (CASPER); and data from the Dialysis Facility Compare (DFC). The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources

except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients.

This quarterly report is provided for more than 7,000 Medicare-approved dialysis facilities in the United States that received a FY 2020 DFR and were indicated as active according to QIES as of 9/05/2019 and/or CROWNWeb as of 9/19/19. Reports were not created for transplant-only facilities or U.S. Department of Veterans Affairs (VA)--only facilities. 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 UM-KECC in Section XII.

This guide discusses the meaning of the data summaries each report provides, and describes the methodology used to calculate each quarterly summary. For additional information regarding the outcomes updated annually in italic font, please refer to section of the *Guide to the FY 2020 Dialysis Facility Reports* referenced in the footnote for the outcome. Section III describes UM-KECC's patient assignment algorithms used for all (except waitlist) quarterly measures reported. Section IV describes the eligible patient counts from which the eligible patients for the measures in this report are derived. Sections V-XII are organized according to the order of the summaries in the Quarterly Update of the Dialysis Facility Report, and may serve as references for their interpretation.

The first page provides the purpose and overview of the report, and instructions for submitting questions to UM-KECC and comments for your state surveyor(s). The following two pages include a table with quarterly updates from the FY 2020 DFR for the following measure areas for the facility: dialysis access, fluid management, anemia, dialysis adequacy, nutrition, and mineral metabolism. Annual mortality, hospitalization, infection, influenza vaccinations, transplant, and age-adjusted waitlist summaries for 2017 and 2018 from the FY 2020 DFR are also reported. For all summaries, annual summaries for 2017 and 2018, and regional averages for 2018 from the FY 2020 DFR are included for comparison. With the exception of the waitlist measure, all quarterly summaries are from CROWNWeb

Each row of a table in the report summarizes an item. The facility has a column for each time period and three columns for the corresponding geographical summaries, including averages for the facility's state, its ESRD Network, and the entire nation. Whenever the statistic reported was a count (n), we calculated regional and national averages by taking the average count for all facilities in that area. When a statistic was a percent, rate, or ratio, we calculated regional 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.

III. Assigning Patients to Facilities

This section describes the methods we used to assign patients to facilities to calculate all measures based on data from CROWNWeb. Additional details regarding patient eligibility for each summary may be found in the section specific to that measure.

An important purpose of this report is to provide and seek feedback on the quality of these data. Much of this report relies on a reasonably accurate and complete description of the patients being treated in each facility at a particular point in time. We believe the overall results warrant a high level of confidence in the assignment of patients to providers. UM-KECC will continue its efforts to measure and improve the quality of all data presented in this report through comparisons with other available data sources.

For each patient, we identified the dialysis provider at each point in time primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicaredialysis claims. Both patient assignment to the provider and modality (either hemodialysis or peritoneal dialysis) were determined according to the information reported in the above mentioned data sources. For each reporting month, patients were required to have been indicated as treated by the facility for the complete month in order to be included in the denominator for these measures. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither Medicare dialysis claims nor CROWNWeb information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not use him or her in the analysis.

IV. Eligible Patients

This section reports eligible patient counts for the CROWNWeb summaries that are updated quarterly. The counts reported in this section may differ from the eligible patients included in each measure. Any differences from the criteria described below for these counts are noted in the specific section of this Guide related to the measure and is also provided in the footnote for the outcome.

Eligible Adult Patients

The number of adult patients on ESRD more than 90 days who have received dialysis (any modality) at the facility for at least one entire reporting month according to the methods described above in Section III are reported in this row. A patient may only be assigned to one facility each month. Patients may be counted up to 3 or 12 times per quarter or year, respectively. Calcium uncorrected categories reported under the Mineral Metabolism section are based on this count.

Eligible Adult Hemodialysis and Peritoneal Patients

These counts include the number of eligible adult hemodialysis (HD; home or in-center) and peritoneal dialysis (PD) patients on ESRD more than 90 days who have received HD or PD, respectively, at the facility for at least one entire reporting month according to the methods described above in Section III. Patients included in the HD and PD counts may only be assigned to one facility each month and may not switch modalities during the month. Patients may be counted up to 3 or 12 times per quarter or year, respectively.

V. Infection/Dialysis Access

This section of the table reports infection and dialysis access information and is based on information collected in CROWNWeb. Eligible HD patients from Section IV with a limited life expectancy, including under hospice care in the current reporting month, or with metastatic cancer, end stage liver disease, coma or anoxic brain injury in the past 12 months, were excluded.

The percentage of adult hemodialysis patient-months using an autogenous arteriovenous (AV) fistula as the sole means of vascular access is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. These two vascular access quality measures, when used together, consider AV fistula use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome. With the growing recognition that some patients have exhausted options for an AV fistula or have comorbidities that may limit the success of AV fistula creation, joint reporting of the measures accounts for all three vascular access options: fistula, graft, and catheter. This paired incentive structure that relies on both measures (AV fistula and long-term catheter rate) reflects consensus best practice, and supports maintenance of the gains in vascular access success achieved via the Fistula First/Catheter Last Project over the last decade.

Long-Term Catheter Rate

This measure reports the percentage of all eligible adult HD patient-months from Section IV where a long-term catheter was in use, i.e., a catheter was reported for three consecutive months (the reporting month and preceding two months) in the same facility.

This row reports the percentage of patient-months in which the patient received dialysis through a catheter for at least three consecutive months (the reporting month and preceding two months) in the same facility. The last vascular access type listed in CROWNWeb during each of these three complete months for the patient was selected to determine whether a catheter was in use. Before indicating that a catheter was present for three consecutive months, we checked that the access type reported on the last day of the month that was three months before the reporting month was also a catheter. A catheter was considered in use if the CROWNWeb "Access Type IDs" of 16, 18, 19, 20, and 21 had been recorded for a given month, where "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown. If there was no CROWNWeb vascular access type entry for a given month, we counted the vascular access type for that month as a catheter. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility. Summaries for 2015-2018 are reported in Table 11 (row g) of the FY 2020 DFR.

Adult HD Patients with Arteriovenous (AV) Fistulae in Use

The percentage of adult HD patient months from Section IV in which the patient received dialysis through arteriovenous (AV) fistulae (one or two needles). If multiple access types were reported for a month, the most recent non-missing access type was selected. Patients who had an AV graft or a catheter in use with an AV fistula in place for *future* use are included in the AV graft or catheter category, respectively. Port access devices are included in the catheter category. Patients are classified as having missing access types if the vascular access data were not available. Summaries for 2015-2018 are reported in Table 11 (row c) of the FY 2020 DFR.

VI. Fluid Management

This section includes measures of fluid management for hemodialysis (HD) patients and is based on information collected in CROWNWeb.

<u>Ultrafiltration Rate (UFR) Among Adult HD Patients</u>

The ultrafiltration rate (UFR) was assessed among all eligible adult HD patients from Section IV and was characterized into three mutually exclusive categories: missing (no UFR reported), in range (UFR between 0 and 20 ml/kg/hr), and out of range (UFR greater than 20 ml/kg/hr). The percentage of patient-months with in-range values > 13 ml/kg/hr and with missing or out of range values are shown in this row. When multiple values were submitted for the patient (by any facility) during the month, the last value reported was selected. Summaries for 2015-2018 are reported in Table 9 (row f) of the FY 2020 DFR.

VII. Anemia

This section of the table reports hemoglobin separately for hemodialysis (HD) and peritoneal dialysis (PD) patients and is based on information collected in CROWNWeb. Summaries for 2015-2018 are reported in Table 8 (rows 81-80) of the FY 2020 DFR.

Patients with hemoglobin < 10 g/dL

Hemoglobin values less than 5 or greater than 20 were considered out of range and set to missing. The percentages of all HD and PD patient-months with in-range values with hemoglobin less than 10g/dL among patients reported in Section IV are reported in this section, respectively. Summaries for 2015-2018 are reported in Table 8 (row d for HD, row i for PD) of the FY 2020 DFR.

VIII. Dialysis Adequacy

This section of the table reports measures of dialysis adequacy separately for hemodialysis (HD) and peritoneal dialysis (PD) patients for patients reported in Section IV. Additionally, the HD Kt/V summaries require patients dialyzed thrice weekly. Information regarding the determination of thrice-weekly dialysis is provided below.

Determination of thrice weekly dialysis

A patient-month was excluded from the hemodialysis Kt/V patient counts described above if the prescribed number of sessions reported in CROWNWeb by the patient's 'assigned' facility was not equal to 3 and/or the patient was identified in CROWNWeb as undergoing 'frequent' or 'infrequent' dialysis anytime during the reporting month. If information regarding the frequency of dialysis was not available for the reporting month in CROWNWeb by the patient's 'assigned' facility, session information submitted by other dialysis facilities where the patient received treatment was considered.

If the dialysis frequency was not reported in CROWNWeb for the reporting month, eligible hemodialysis Medicare claims submitted by the patient's 'assigned' facility during the reporting month were considered. A claim was considered eligible if it was for an adult (≥18 years old) HD patient with ESRD for more than 90 days as of the start of the claim. Any patient-month in which the patient received "frequent" or "infrequent" dialysis according to claims was excluded entirely (more details provided below).

If the prescribed dialysis information was not available for the patient during the reporting month in either data source (CROWNWeb or Medicare claims), the patient-month was excluded from the denominator.

Calculating "frequent" and "infrequent" dialysis in Medicare dialysis claims
The number of dialysis sessions per week on a claim was calculated as a rate: 7*(# of HD sessions/# of days). This rate was only calculated for claims that covered at least seven days. A claim was identified as indicating "frequent" dialysis if any of the following criteria were met:

- (a) reported a Kt/V value of 8.88,
- (b) covered seven or more days and had a rate of four or more sessions/week, or
- (c) covered fewer than seven days and had four or more total sessions indicated

A claim was identified as indicating "infrequent" dialysis if it covered at least seven days and had a rate of two or fewer sessions/week. No short claims (less than 7 days) were considered as indicating "infrequent" dialysis.

Kt/V Categories for Adult HD Patients

(K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water)

Adult HD Kt/V summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V value greater than 5.0) in CROWNWeb, then the Kt/V (based on value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a HD patient who had ESRD for more than 90 days, was at least 18 years old, and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described above. The last eligible claim with an inrange (less than or equal to 5.0) and not expired (in-center HD with Kt/V reported from a

previous claim, or home HD with Kt/V reported from more than four months' prior) Kt/V value reported was selected when there were multiple claims reported in a month. Patient-months were excluded if any claim submitted during the month for the patient identified the patient as undergoing 'frequent' or 'infrequent' dialysis anytime during the reporting month.

The Kt/V value for each patient-month was characterized into three mutually exclusive categories: missing (no Kt/V reported), in range (Kt/V less than or equal to 5.0), and out of range (Kt/V value greater than 5.0). The percentages of all patient-months with Kt/V values <1.2, and missing/out of range values are shown in for HD adequacy. Summaries for 2015-2018 are reported in Table 9 (rows 9j) of the FY 2020 DFR.

Weekly Kt/V Categories for Adult PD Patients

(K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water)

Adult PD Kt/V values are only required to be reported every four months for adult PD patients. Therefore, if Kt/V was missing for the reporting month, the most recent available value collected up to 3 months prior was selected when available. If all values in a 4-month look-back period were missing, then the PD Kt/V value was considered missing for that reporting month.

Summaries are calculated using CROWNWeb as the primary data source. The last Kt/V collected (from any facility) during the reporting month for the patient was selected. If Kt/V was missing or out of range (Kt/V value greater than 8.5) in CROWNWeb, then the Kt/V (based on value code 'D5: Result of last Kt/V') reported on the last eligible Medicare claim for the patient during the reporting month was selected when available.

A claim was considered eligible if it was from a PD patient who had ESRD for more than 90 days and was at least 18 years old. The last eligible claim with an in-range (less than or equal to 8.5) and not expired (Kt/V reported from more than four months' prior) Kt/V value was selected when there were multiple claims reported in a month.

The Kt/V value for each patient-month was characterized into three mutually exclusive categories: missing (no Kt/V reported), in range (Kt/V value less than or equal to 8.5), and out of range (Kt/V value greater than 8.5). The percentages of all patient-months with Kt/V values <1.7, and missing or out of range values are shown for PD adequacy. Summaries for 2015-2018are reported in Table 9 (rows 9n) of the FY 2020 DFR.

IX. Nutrition

This section reports measures of nutrition separately for adult hemodialysis (HD) and peritoneal dialysis (PD) patients among patients reported in Section IV, respectively. This section of the table is based on information collected in CROWNWeb.

Serum Albumin Categories Among HD Patients

Serum albumin was assessed among all eligible HD patient-months during the reporting period among HD patients reported in Section IV. When multiple values were submitted during the month for the patient (by any facility), the most recent value was selected. The

highest value was selected if multiple values were submitted on the same day. The percentage all patient-months with serum albumin less than 4.0 g/dL is reported. Summaries for 2015-2018 are reported in Table 9 (row d) of the FY 2020 DFR.

Serum Albumin Categories Among PD patients

Serum albumin was assessed among all eligible PD patient-months among PD patients reported in Section IV. The percentage of all patient-months with serum albumin less than 4.0 g/dL is reported. Summaries for 2015-2018 are reported in Table 9 (row p) of the FY 2020 DFR.

X. Mineral Metabolism

This section reports measures of mineral metabolism for adult dialysis patients based on information collected in CROWNWeb.

Phosphorous Categories Among Adult Patients

Phosphorus summaries include all adult patient-months from Section IV (HD and PD) within the first 90 days of ESRD. Therefore, the patient-count reported in Section IV does not include all patients included in the phosphorous summaries. The percentage of all patient-months with in-range (0.1 mg/dL to 20 mg/dL) phosphorous values >7.0 mg/dL, and missing or out of range phosphorous values are reported. When multiple values were submitted during the month for the patient (by any facility), the most recent value was selected. The highest value was selected if multiple values were submitted on the same day. Summaries for 2015-2018 are reported in Table 10 (row d) of the FY 2020 DFR.

Calcium Uncorrected Categories Among Adult Patients

The percentage of all patient-months (HD and PD) for patients reported in Section IV with in-range (0.1 mg to 20 mg/dL) calcium uncorrected value greater than 10.2 mg/dL, and missing or out of range values are reported. When multiple values were submitted during the month for the patient (by any facility), the most recent value was selected. The highest value was selected if multiple values were submitted on the same day. Summaries for 2015-2018 are reported in Table 10 (row f) of the FY 2020DFR.

Average Uncorrected Calcium > 10.2 mg/dL (1y)

The percentage of all eligible patient-months with a 3-month rolling average uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing is reported in this row. This value is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period among eligible patients (HD and PD) reported in Section IV who are 18 years or older two months prior to the reporting month.

The percentage for a given month uses the average of the last reported uncorrected serum or plasma calcium value and the last reported values for the previous 2 months (if available). The acceptable range for calcium is $0.1-20\,\text{mg/dL}$. Values outside of this range are considered missing. For example, the percentage calculated for April would be based on the average of uncorrected serum calcium values submitted in April, March and/or February. Patients with missing values who meet the criteria above are included in the numerator. Summaries for 2015-2018 are reported in Table 10 (row g) of the FY 2020 DFR.

XI. Transplantation

For detailed explanation about the Standardized 1st Transplantation Ratio (row 1x) and the Age-Adjusted percentage of patients waitlisted (row 1z), please refer section VIII and IX on the Guide to the Dialysis Facility Reports for FY 2020, which can be found on the Methodology page of www.DialysisData.org.

The results of numerous studies have indicated that the recipients of renal transplants have better survival than comparable dialysis patients (Wolfe, 1999). The first step in the transplant process is getting placed on the transplant waitlist. This information was obtained from Organ Procurement and Transplantation Network (OPTN) / Scientific Registry of Transplant Recipients (SRTR) data.

Percentage of Patient-months on the Waitlist

This measure tracks the percentage of patients under age 75 at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist. For each month, a patient is included in the prevalent waitlist summary if they were indicated as receiving treatment at the facility on the last day of the calendar month according to the methods described in Section III. In addition, months indicating patients were admitted to a skilled nursing facility (SNF) according to the CMS long-term care minimum data set, patients who were admitted to a SNF previously according to the CMS Medical Evidence Form (questions 17u and 22), and/or active hospice patients reported on Medicare final action claims data were excluded. A patient may only be assigned to one facility each month may contribute up to 3 or 12 times per quarter or year, respectively.

This row reports the percentage of eligible patient-months on the kidney or kidney-pancreas transplant waiting list as of the last day of each calendar month during the reporting period.

XII. Please Give Us Your Comments

We welcome questions or comments about this report's content, or any suggestions you might have for future reports of this type. Improvements in the content of future reports will depend on feedback from the nephrology community. Facility-specific comments may be submitted on the secure portion of www.Dialysisdata.org by authorized users only. General methodological questions may be submitted by anyone using the form available on the "Contact Us" tab on www.Dialysisdata.org.

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