Guide to the Quarterly Updates of the Fiscal Year (FY) 2019 Dialysis Facility Reports (DFR):

Overview, Methodology, and Interpretation

November 2018

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

Table of Contents

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 2019 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 2019 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 2016 and 2017 from the FY 2019 DFR along with summaries for January-March of 2018. Regional and national averages for 2017 are included to allow for comparisons. Summaries include chronic dialysis patients who were treated in this facility between January 2016 and March 2018. 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) Workbench, 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 quarter reports are provided for more than 7,000 Medicare-approved dialysis facilities in the United States that received a FY 2019 DFR and were indicated as active according to QIES as of 9/05/2018 and/or CROWNweb as of 9/14/18. Reports were not created for transplant-only facilities or U.S. Department of Veterans Affairs (VA)--only facilities.

This is the first Quarterly Update of the Dialysis Facility Report in this series of individualized reports. 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 X.

This guide discusses the meaning of the data summaries each report provides, and describes the methodology used to calculate each summary. Section III describes UM-KECC's patient assignment algorithms used for some of the measures reported throughout the DFR. Sections IV-IX 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 2019 DFR for the following measure areas for the facility: dialysis access, fluid management, anemia, dialysis adequacy, nutrition, and mineral metabolism. Annual summaries for 2016 and 2017, and regional averages for 2017 from the FY 2019 DFR are included for comparison. With the exception of anemia management measures, all clinical data 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. Patient assignment for measures reported for anemia management (rows 1f-1i) are described in the section specific to those rows. 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 Medicare-dialysis 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. Infection/Dialysis Access

Rows 1a through 1c report infection and dialysis access information. The statistics in this section of the table are based on information collected in CROWNWeb.

Eligible Adult Hemodialysis (HD) Patients (1a)
The eligible adult hemodialysis patient count at a facility includes each unique adult patient (home or in-center) who has received hemodialysis at the facility for at least one entire reporting month according to the methods described above in Section III. A patient 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. Summaries for 2014-2017 are reported in Table 11 (row a) of the FY 2019 DFR.

Adult HD Patients with Catheter Only ≥ 90 Days (1b)
Row 1b reports the percentage of patient-months in which a catheter was in use, a catheter was the *only* means of vascular access (i.e., patient did not have an AV fistula or AV graft in place), and the catheter was in place for more than 90 days as of the last day of the reporting month. Port access devices are included in the catheter category. If multiple access types were reported for the patient by the facility for the month, the most recent value was selected. Summaries for 2014-2017 are reported in Table 11 (row e) of the FY 2019 DFR.

Adult HD Patients with Arteriovenous (AV) Fistulae in Place (1c)
Row 1c reports the percentage of patient-months in which an AV fistula was in place, regardless of whether the patient received hemodialysis treatment using this AV fistula. If multiple access types were reported for a month by the facility, the most recent was selected. Summaries for 2014-2017 are reported in Table 11 (row d) of the FY 2019 DFR.

V. Fluid Management

Rows 1d and 1e report measures of fluid management for hemodialysis (HD) patients. This section of the table is based on information collected in CROWNWeb.

Eligible Adult Hemodialysis Patients (1d)
The number of eligible adult hemodialysis patients reported in row 1d includes adult hemodialysis patients who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the quarter. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III. A patient 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. Summaries for 2014-2017 are reported in Table 9 (row a) of the FY 2019 DFR.

Ultrafiltration Rate (UFR) Among Adult HD Patients (1e)
The ultrafiltration rate (UFR) was assessed among all eligible HD patients in 1d 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 row 1e. When multiple values were submitted for the patient (by any facility) during the month, the last value reported was selected. Summaries for 2014-2017 are reported in Table 9 (row f) of the FY 2019 DFR.

VI. Anemia

Rows 1f through 1i report hemoglobin separately for hemodialysis (HD) and peritoneal dialysis (PD) patients. This section of the table is based on information collected in Medicare Dialysis Claims. Due to differences in the methodology between the annual summaries from the FY 2019 DFR and the new quarterly summaries, a larger percentage of patients with hemoglobin < 10 g/dL may be reported for the quarter compared to the annual summaries. Please refer to the section titled, *Difference between hemoglobin in quarterly and yearly DFR*, below for more information. Summaries for 2014-2017 are reported in Table 8 (rows 8l-8o) of the FY 2019 DFR.

Eligible patients (1f, 1h)
The number of eligible adult hemodialysis (HD) and peritoneal (PD) dialysis patients reported in rows 1f and 1h, respectively, include patients with at least one HD or PD Medicare dialysis claim submitted by the facility during the quarter that indicated the use of an erythropoiesis stimulating agent (ESA), specifically, the use of epoetin alfa, epoetin beta or darbepoetin alfa. The annual summaries require at least 4 eligible claims during

the year. We included neither patient claims starting before day 91 of ESRD nor claims with hemoglobin values less than 5 or greater than 20.

A patient treated at more than one facility during the quarter (or year) was included in the report for each facility (as long as the patient had required number of claims from each facility). Patients who received both HD and PD treatment at the facility appear in both the HD (1f) and PD (1h) patient counts as long as they had the minimum number of claims submitted by each facility.

Adult patients with hemoglobin < 10 g/dL (1g, 1i)
We calculated hemoglobin as hematocrit divided by three (and rounded to the tenth of a g/dL) for claims that report hematocrit but not hemoglobin. Hemoglobin values less than 5 or greater than 20 were considered out of range and excluded. If multiple claims were submitted for a patient during the month by the facility, the last in-range claim meeting the criteria described above was selected.

For each patient in row 1f or 1h, we calculated the average hemoglobin reported on the monthly claims submitted in each quarter by the facility. If multiple claims were submitted by the facility for a patient during the month, only the last valid claim meeting the criteria described above was kept to be included in this average. Rows 1g and 1i report the percentage of hemodialysis (HD) and peritoneal dialysis (PD) patients from 1f and 1h, respectively, with an average hemoglobin less than 10g/dl.

Difference between hemoglobin in quarterly and yearly DFR
For a patient to be included in each quarterly summary, only one claim over the quarter is required to be included in the summaries, whereas four claims are required for patients to be included in the annual summaries reported in the FY 2019 DFR hemoglobin calculations. As a result, the average hemoglobin is calculated using between 4 and 12 hemoglobin values for each patient in the annual summary whereas the quarterly summary is based on a maximum of three values. Therefore, due to the inclusion of fewer claims in the averages for the quarterly summaries, the percentage of patients with a hemoglobin < 10 g/dL reported for any quarter may be larger than what was reported for the annual summaries. In other words, the average hemoglobin for annual measures is more stable and is more likely to categorize more patients near the center of the distribution as opposed to the extremes (<10 g/dL or >12g/dL).

VII. Dialysis Adequacy
Rows 1j through 1m report measures of dialysis adequacy separately for hemodialysis (HD) and peritoneal dialysis (PD) patients. If a patient switched modality during the reporting period, the patient may be included in both HD and PD summaries.

Eligible Adult Hemodialysis (HD) Kt/V Patients (1j)
Eligible patients include adults (18+ years) who had ESRD for more than 90 days, were receiving hemodialysis at the facility for at least one whole calendar month during the reporting period (i.e., 'assigned' facility), and dialyzed thrice weekly. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III above. A patient may

only be assigned to one dialysis facility each month, may not switch modalities during the month, and may be counted up to 3 or 12 times per quarter or year, respectively. Patients with missing or out of range Kt/V (Kt/V value greater than 5.0) values are included in the denominator. Additional 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 ($\geq$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 (1k)
(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 in-range (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 row 1k. Summaries for 2014-2017 are reported in Table 9 (rows 9j) of the FY 2019 DFR.

Eligible Adult PD Patients (1l)
Row 1l reports the number of adult peritoneal patients who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the year. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III above. A patient may only be assigned to one dialysis facility each month, may not switch modalities during the month, and may be counted up to 3 or 12 times per quarter or year, respectively. Patients with missing or out of range Kt/V (Kt/V value greater than > 8.5) values are included in the denominator.

Weekly Kt/V Categories for Adult PD Patients (1m)
(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 in row 1m. Summaries for 2014-2017 are reported in Table 9 (rows 9n) of the FY 2019 DFR.

VIII. Nutrition

Rows 1n through 1q report measures of nutrition separately for adult hemodialysis (HD) and peritoneal dialysis (PD) patients. If a patient switched modalities during the reporting period, that patient may be counted in both HD and a PD summaries. This section of the table is based on information collected in CROWNWeb.

Eligible Adult Hemodialysis Patients (1n)
Row 1n reports the number adult hemodialysis patients who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the year. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III. A patient 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.

Serum Albumin Categories Among HD Patients (1o)
Serum albumin was assessed among all eligible HD patient-months during the reporting period and was characterized into five mutually exclusive categories. 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 of all patient-months stratified by serum albumin categories, and missing values are shown in row 1o. Summaries for 2014-2017 are reported in Table 9 (row d) of the FY 2019 DFR.

Eligible Adult Peritoneal Dialysis Patients (1p)
Row 1p reports the number of adult peritoneal patients who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the year. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III.

Serum Albumin Categories Among PD patients (1q)
Serum albumin was assessed among all eligible PD patient-months and was characterized into five mutually exclusive categories. The percentage of all patient-months stratified by serum albumin categories, and missing values are shown in row 1q. Summaries for 2014-2017 are reported in Table 9 (row p) of the FY 2019 DFR.

IX. Mineral Metabolism

Rows 1r through 1u report measures of mineral metabolism for adult dialysis patients. The statistics in these rows are based on information collected in CROWNWeb.

Eligible Adult Patients (1r)
The number of adult dialysis patients who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the quarter is reported in row 1r. Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III. Patients who switch between HD and PD during the month and patients for whom modality is unknown are included. A patient may only be assigned to one facility each month may be counted up to 3 or 12 times per quarter or year, respectively.

Phosphorus summaries include patient-months within the first 90 days of ESRD. Therefore, the patient-count reported in 1r does not include all patients included in the phosphorous summaries.

Phosphorous Categories Among Adult Patients (1s)
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 shown in row 1s. 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 2014-2017 are reported in Table 10 (row d) of the FY 2019 DFR.

Calcium Uncorrected Categories Among Adult Patients (1t)
The percentage of all patient-months 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 shown in row 1t. 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 2014-2017 are reported in Table 10 (row f) of the FY 2019 DFR.

Average Uncorrected Calcium > 10.2 mg/dL (1u)
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 row 1u. This value is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period among eligible patients reported in row 1r 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 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 2014-2017 are reported in Table 10 (row g) of the FY 2019 DFR.

X. 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.

References

Agresti, A. *Categorical Data Analysis*, Second Edition, New York: John Wiley & Sons, Inc.; 2002

Health, United States, 2015 *With Special Feature on Racial and Ethnic Health Disparities.* Centers for Disease Control and Prevention, Health and Human Services Dept., 99-102. http://www.cdc.gov/nchs/hus/contetns2015.htm#017

NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy. National Kidney Foundation. Am J Kidney Dis. 1997 Sep; 30 (3 Suppl 2): S15-66.

NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure. National Kidney Foundation-Dialysis Outcomes Quality Initiative. Am J Kidney Dis. 1997 Oct;30(4 Suppl 3):S192-240.

NKF-KDOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2000. Am J Kidney Dis. 2001 Jan; 37 (1 Suppl 1): S7-S64.

NKF-KDOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000. Am J Kidney Dis. 2001 Jan;37(1 Suppl 1): S182-238.

NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2006. Am J Kidney Dis. Volume 48, Supplement S1 (July 2006) *pages S2-S90*

NKF-DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2006. Am J Kidney Dis. Volume 47, Supplement S3, Pages 146-146 (May 2006):