

Guide to the Dialysis Facility Reports for Fiscal Year 2021:

Overview, Methodology, and Interpretation

July 2020

**Guide to the Dialysis Facility Reports for FY 2021 for Dialysis Patients:
Overview, Methodology, and Interpretation**

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I. Purpose of this Guide and the Dialysis Facility Reports

This guide explains in detail the contents of the FY 2021 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 (e.g., mortality, hospitalization, and transplantation) and descriptions of each data summary.

In the interest of stimulating quality improvement efforts and facilitating the quality improvement process, the Dialysis Facility Reports make information available to those of you involved in dialysis care and the assurance of its quality. This report allows you to compare the characteristics of a facility's patients, patterns of treatment, and patterns in transplantation, hospitalization, and mortality to local and national averages. Such comparisons help you to evaluate patient outcomes and to account for important differences in the patient mix — including age, sex, race, and patients' diabetic status — which in turn enhances each facility's understanding of the clinical experience relative to other facilities in the state, Network, and nation.

What's New in the DFR for FY 2021

As part of a continuing effort to improve the quality and relevance of this report for your facility, the following changes have been incorporated into the DFR for FY 2021: Medicare Advantage patients are now excluded from the following measures:

- Standardized Hospitalization Ratio (SHR) for emergency department visits (Table 4)
- Influenza summaries (Table 7)
- Transfusion summaries (Table 8)
- Access-related infection summaries (Table 11)

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the Dialysis Facility Reports for FY 2021 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) each July. Those state agencies responsible for certifying dialysis facilities also receive the reports.

Each report provides summary data on each facility's chronic dialysis patients for the years 2016-2019. 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 year reports are provided for more than 7,000 Medicare-approved dialysis facilities in the United States. Reports were not created for transplant-only facilities or U.S. Department of Veterans Affairs (VA)-only facilities. In the mortality and transplantation tables, the standardized ratio is only calculated if there are at least 3 expected events for the time period. In addition, the standardized transplantation ratio is only reported for the four-year period since the expected number of transplants is fewer than 3 nationally. Similarly, the Standardized Hospitalization Ratios are not calculated if based on fewer than 5 patient-years at risk. This corresponds to approximately 10 expected hospitalizations. The Standardized Readmission Ratio (SRR) is not shown if fewer than 11 index discharges occur in the year. The Standardized Transfusion Ratio (STrR) is not calculated if there are fewer than 11 patient-years at risk. For the Standardized Waitlist Ratio, the summary is only reported for a three-year period, and it is not shown for a facility or a state with fewer than 11 patients at risk or fewer than 2 expected events during the reporting period. The age-adjusted waitlist percentage is not reported if there are fewer than 11 eligible patients during the reporting period. Standardized Fistula Rate (SFR) and Long-term Catheter Rate (LTCR) are not calculated if there are fewer than 11 eligible adult patients in the year. Statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret.

This is the twenty-fifth 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 XVIII.

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-XVII are organized according to the order of the summaries in the Dialysis Facility Report, and may serve as references for their interpretation.

The first page provides the purpose and overview of the report, what's new and how to submit comments. The following four pages include highlights for the facility, followed by fourteen tables which contain detailed information for the facility. Patient characteristics for the facility are reported in Tables 1 (all patients) and 2 (new patients) each year from 2016-2019, as well as regional averages for 2019 for comparison. To provide more stable estimates of patient outcomes, we combined overall mortality (first half of Table 3), hospitalization information (Table 4), and transplant information (Table 5) over a four-year period, 2016-2019. Similarly, we combined first year mortality information (second half of Table 3) and the standardized waitlist ratio (second half of Table 6) over a three-year

period, 2016-2018. The separate estimates provided for each year account for changes over time in national mortality, hospitalization, and incident waitlist rates and allow you to evaluate facility time trends different from the average US trend. Note that for the three- and four-year summaries, individual patients typically contribute data for more than one year. The remaining tables report information for the facility each year from 2016-2019, as well as regional averages for 2019 for comparison. Table 6 provides summaries for both prevalent and incident patients on the transplant waitlist and Table 7 reports influenza vaccination statistics. Tables 8-10 report anemia management, dialysis adequacy, and mineral metabolism summaries, respectively. Vascular access type and access-related infection information are reported in Table 11. Comorbidities from Medicare claims are reported in Table 12. Table 13 reports general information about the facility; patient placement and Medicare eligibility summaries from the Annual Facility Survey; and basic information about the last survey at this facility. Selected measures for dialysis patients under 18 are provided in Table 14 for facilities treating at least 5 such patients over the four-year reporting period.

Each row of a table in the report summarizes an item. The facility has a column for each time period, and in most cases, 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 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 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, with the exception of Annual Facility Survey data, which is public information. We do provide summaries for the geographic aggregate of the ESRD Network and the nation for facilities in these states or territories.

III. Assigning Patients to Facilities

The section describes the methods we used to assign patients to a facility in order to calculate the summaries appearing in the Tables 1, 3-5, and 12, followed by the methods used to assign patients to calculate the CROWNWeb measures reported in Tables 8-11. Patient assignment for each of the remaining DFR tables, as well as the second half of Table 3, are described in the section specific to that table.

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. The 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.

Because some patients receive dialysis treatment at more than one facility in a given year, we use standard methods based on assigning person-years to a facility, rather than on assigning a patient's entire follow-up to a facility. We developed conventions which define the group of patients assigned to a facility at any time during the particular year. This method is described in detail below. Additional details regarding patient eligibility for each table may be found in the section specific to that table. It is important to note that these patient assignment methods **do not** apply to the first year mortality statistics appearing in the second half of Table 3.

TABLE 1: Summaries for All Dialysis Patients

TABLE 3: Mortality Summary for All Dialysis Patients (first half of Table)

TABLE 4: Hospitalization Summary for Medicare Dialysis Patients

TABLE 5: Transplantation Summary for Dialysis Patients under Age 75

TABLE 12: Comorbidities Reported on Medicare Claims for Medicare Dialysis Patients

General Inclusion Criteria for Dialysis Patients

We only entered a patient's follow-up into the tabulations after that patient had ESRD for more than 90 days. This minimum 90-day period assures that most patients are eligible for Medicare insurance either as their primary or secondary insurer. It also excludes from analysis patients who died during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a facility only after they had been on dialysis there for at least 60 days. This 60-day period is used both for patients starting renal replacement therapy for the first time and for those who returned to dialysis after a transplant. That is, deaths and survival during the first 60 days do not impact the SMR of that facility.

Identifying Patients Treated at Each Facility

For each patient, we identified the dialysis provider at each point in time using a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. Starting with day 91 of ESRD, we determined facility treatment histories for each patient, and then listed each patient with a facility only once the patient had been treated there for 60 days. When a patient transferred from a facility, the patient remained assigned to it in the database for 60 days. This continued tabulation of the time at risk for 60 days after transfer from a facility attributes to a facility the sequelae of treatment there, even when a patient was transferred to another facility (such as a hospital-based facility) after his or her condition worsened.

In particular, we placed patients in their initial facility on day 91 of ESRD once that facility had treated them for at least 60 days. If on day 91 a facility had treated a patient for fewer than 60 days, we waited until the patient reached day 60 of treatment at that facility before placing him or her there. State and Network summaries do not include patients who were not assigned to a facility; these patients are, however, included in the U.S. summaries.

Using CROWNWeb data and dialysis claims to determine whether a patient has transferred to another facility, we attributed patient outcomes to the patient's original facility for 60

days after transfer out. On day 61 after transfer from a facility, we placed the patient in the new facility once the patient had been treated at the new facility for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility.

Patients were removed from facilities upon receiving transplants. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. 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 continue to include that patient in the analysis. If evidence of dialysis re-appeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility. Finally, all CROWNWeb records noting continuing dialysis were extended until the appearance of any evidence of recovery, transfer, or death. Periods of lost to follow-up were not created in these cases since the instructions for CROWNWeb only require checking patient data for continued accuracy, but do not have a requirement for updating if there are not any changes.

Patient Assignment Methods for CROWNWeb Measures

The methods below describe patient-facility assignment for the summaries of CROWNWeb data in the following tables:

TABLE 8: Anemia Management Summaries for Adult Dialysis Patients

TABLE 9: Dialysis Adequacy Summaries for All Dialysis Patients

TABLE 10: Mineral Metabolism Summaries for Adult Dialysis Patients

TABLE 11: Vascular Access Information for all Dialysis Patients

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. 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. Summaries for All Dialysis Patients Treated as of December 31 of Each Year, 2016-2019

Table 1 summarizes the characteristics of dialysis patients treated on December 31, 2016-2019 in the facility, with corresponding average values for 2019 among patients in the state, ESRD Network, and the U.S.

Patients Treated on 12/31 of Year (1a)

Row 1a reports the total number of dialysis patients treated in the facility on December 31 of each year according to the conventions described in **Section III**. We based the summaries of the patient characteristics in Table 1 on the patient population count in this row.

Age (1b, 1c)

We determined age as of December 31 for each patient for each year. We reported the average age and the percentage of patients in each of several age ranges.

Female (1d)

Row 1d reports the percentage of female patients.

Race (1e)

We established each patient's race using two sources of information: the Medical Evidence Form and CROWNWeb. We reported the percentage of patients in each of five race categories: Asian/Pacific Islander (includes Indian sub-continent), African American, Native American (includes Alaskan Native), White (includes Middle Eastern and Arab), and a combined group for other/unknown/missing race. The 'other/unknown/missing race' category includes patients for whom none of the other race categories was indicated on any of the above sources.

Ethnicity (1f)

We obtained the ethnicity of patients from the CMS Medical Evidence Form, and supplemented it with the ESRD Clinical Performance Measures data sample when available. We reported the percentage of patients in the Hispanic, Non-Hispanic, and unknown categories.

Primary Cause of ESRD (1g)

We ascertained each patient's cause of ESRD using two sources of information: the Medical Evidence Form and CROWNWeb. We reported the percentage of patients in each of five major cause groups: diabetes; hypertension; glomerulonephritis; other/unknown; and missing cause.

Duration of ESRD (1h, 1i)

We calculated the number of years since first renal replacement therapy for each patient treated in the facility on December 31 of each year. Row 1h reports the average number of years of prior ESRD therapy. Row 1i displays ranges of years since start of ESRD and the corresponding percentages of patients per range.

Nursing home patients (1j)

We obtained the nursing facility history of patients from the Nursing Home Minimum Dataset. We reported the percentage of patients treated on December 31 of each year that were also treated at a nursing facility at any time during the year.

Modality (1k)

Row 1k reports the percent of patients on chronic dialysis treatment at the facility (% of 1a) receiving dialysis through the following modalities: In-center hemodialysis, Home hemodialysis, Continuous ambulatory peritoneal dialysis, Continuous cycling peritoneal dialysis and other. The 'Other' modality category includes other dialysis, uncertain modality, and patients not on dialysis but still temporarily assigned to the facility (discontinued dialysis, recovered renal function, and lost to follow-up.)

V. Characteristics of New Dialysis Patients, 2016-2019 (Form CMS-2728)

Table 2 presents detailed data from the ESRD Medical Evidence Form (Form CMS-2728) on the characteristics of new patients in the facility by year. The patients represented in this table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2016 and December 31, 2019. Please note that we placed the patients included here *not* according to the conventions described in Section III, but rather according to the CMS certification number that appeared on their Medical Evidence Forms.

For each patient characteristic, we present the average value for the facility as well as state, Network, and U.S. averages. We excluded from the calculations values for individual patients which fell outside the ranges shown in brackets [] on this table because we considered them to be clinically implausible.

Patient Characteristics (2a-2m)

Row 2a of this table gives the total number of forms submitted by the facility for the year. Rows 2b-2m deal with the patients' demographic characteristics, including their age, sex, race, ethnicity, primary cause of ESRD, medical coverage, body mass index, employment, primary modality, and access type.

Average Lab Values Prior to Dialysis (2n-2q)

Rows 2n-2q report lab values prior to the start of ESRD. We estimated the glomerular filtration rate (GFR) reported in row 2q using a formula developed by the Modification of Diet in Renal Disease (MDRD) Study (Levey et al, 1999) — a formula based on serum creatinine before first dialysis, age, race, and gender.

Care Prior to Start of ESRD Therapy (2r, 2s)

Row 2r reports the percentage of patients in 2a who had received ESA treatment prior to the start of ESRD treatment. Row 2s reports the percentage of patients in 2a who had been under the care of a nephrologist prior to the start of ESRD therapy by categories of time (never, <6 months, 6-12 months, >12 months) and of patients with missing or unknown information about nephrologist care prior to the start of ESRD therapy.

Kidney Transplant Options (2t-2v)

Row 2t reports the percentage of patients in 2a who had been informed of transplant options. Row 2u gives the count of patients who were not informed of their transplant options. The reasons for not informing the patients reported in 2u of their transplant options (due to being medically unfit, unsuitable due to age, psychologically unfit, declining the information, or not yet being assessed) are reported in row 2v. The categories in row 2v may not sum to 100% due to patients for whom multiple reasons are selected, or for whom 'Other' or no reason is selected.

Comorbid Conditions (2w, 2x)

Row 2w reports the percentage of patients in the facility with each of the comorbid conditions (measured before the start of dialysis) listed. Row 2x gives the average number of comorbid conditions reported per new patient in the facility, the state, the Network, and the nation.

VI. Mortality Summary for All Dialysis Patients (2016-2019) and New Dialysis Patients (2016-2018)

The first half of Table 3 (rows 3a-3k) provides information about patient mortality for all dialysis patients treated at the facility. The second half of Table 3 (rows 3l-3u) provides information about mortality in the first year of dialysis for patients starting dialysis for the first time at the facility. For each section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for patients in the facility. The SMR compares the observed death rate in the facility to the death rate that was expected based on national death rates during that year for patients with the same characteristics as those in the facility (Wolfe, 1992). The SMR uses expected mortality calculated from a Cox model (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994), adjusting for calendar year, patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates.

The SMR accounts for many patient characteristics known to be associated with mortality, but cannot account for all factors that may explain differences in mortality between facilities. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients at a facility would not elevate the SMR. Other factors, such as nutritional status, factors relating to the process of care, or comorbid conditions that developed after incidence, are not accounted for. **Therefore, if the SMR statistic indicates potential differences in mortality for the facility compared to**

regional or national averages, please consider the role other important factors play within the facility. As with the hospitalization and transplantation summaries which are described below in Sections VII and VIII, you will find the mortality summaries most informative if you use them as part of an integrated quality assurance process.

In the first half of the table, we reported information on the mortality of all prevalent dialysis patients for each year between 2016 and 2019, and also summarized the statistic for the four-year period. Averages in the state, ESRD Network, and the nation for this combined four-year period were also reported. In the second half of Table 3, we report similar statistics comparing first-year mortality for new dialysis patients in the facility with national averages. This section of the table allows the facility to see how all the patients who started at that facility fared in their first year of dialysis even if the facility is no longer treating some of these patients.

Major Differences between the Prevalent and First-Year Mortality Calculations

The statistics reported in these two sections of the mortality table are very similar, but there are several notable differences.

Patient Placement

The prevalent mortality section includes patients based on the conventions described in Section III. Patients are included in the report for a particular facility while they are treated at that facility, entering the analysis for a facility only after having been treated there for 60 days and leaving the analysis for a facility 60 days after transfer out of the facility.

In contrast, the first-year mortality section places patients based on the facility that submitted the Medical Evidence Form (CMS-2728) for the patient. Patients are included in the analysis for a facility for the entire year of follow-up regardless of whether the patient is treated at that facility.

Beginning of Follow-up

In the prevalent mortality calculation, patients enter the analysis no earlier than day 90 of ESRD. In the first-year mortality calculation, patients enter the analysis on the first day of ESRD.

Calendar Year Headings

In the prevalent mortality section, the calendar years correspond to the patient follow-up time. In other words, time at risk and deaths that occur during a particular year are included in the column for that year.

In the first year mortality section, the calendar years correspond to the year of the first treatment for that patient. Here, time at risk and deaths are included in the column corresponding to when that patient started dialysis rather than when the time at risk or death took place. Because we do not have a full year of follow-up for patients who started dialysis in the fourth year, only three years are included in the first-year mortality section.

Mortality Summaries for All Dialysis Patients (3a-3k)

Patients (3a)

We based the mortality summaries in the first half of the table (rows 3a-3k) on the dialysis patients who received treatment in the facility according to the conventions described in Section III.

Patient Years at Risk (3b)

For each patient in row 3a, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may have been treated at one facility for multiple periods during the same year; patient-years at risk include time at risk for all periods of treatment at a facility.

Deaths (3c)

We reported the number of deaths that occurred among dialysis patients during each year, as well as the total across the years. This count does not include deaths from street drugs or accidents unrelated to treatment. Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, we excluded them from the calculations.

Expected Deaths (3d)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, years since start of ESRD, nursing home status, patient comorbidities at incidence, and patient BMI at incidence ($BMI = \text{weight (kg)} / \text{height}^2 (\text{m}^2)$). We also controlled for age-adjusted population death rates by state and race, based on the U.S. population in 2014-2016 (National Center for Health Statistics Report, 2017). [JS1] As with the deaths in 3c, we then summed these expected deaths in order to obtain the total number of deaths expected for each year at the facility, and we summed the annual values to yield the expected number of deaths over the four year period for each facility.

Categories of Death (3e-3g)

Row 3e reports the percentage of dialysis patient deaths (row 3c) for which the CMS ESRD Death Notification Form (Form-2746) indicated that the patient voluntarily discontinued renal replacement therapy prior to death. For the causes of death calculations in rows 3f and 3g, we considered all causes of death (primary and secondary) provided on the form. The percentage of deaths in 3c with a primary or secondary cause of death listed as infection, cardiac causes and liver disease are reported in row 3f.

Row 3g reports the number of patients who, according to any of the primary or secondary causes of death listed on the Death Notification Form, died from accidents unrelated to

dialysis treatment, or died from street drugs. We did not include these dialysis-unrelated deaths in the total death count in row 3c or the SMR; therefore, differences in SMRs between dialysis facilities do not correspond to differences in the number of dialysis-unrelated deaths.

Information on category of death may help you interpret the SMR value for the facility. For example, a high rate of withdrawal will not increase the SMR substantially if the patients who withdraw have a short expected lifetime, though it will cause an increase if patients have a long expected remaining life. However, we would advise using caution when interpreting these percentages by category of death, since we did not adjust them for patient characteristics. Expressing this information as a simple percentage of the total number of deaths does not indicate whether the percentage of deaths in any particular category differs from the national average for similar patients.

Standardized Mortality Ratio (SMR) (3h)

The SMR equals the ratio of the actual number of deaths (3c) divided by the expected number of deaths (3d). The SMR estimates the relative death rate ratio for the facility, as compared to the national death rate in the same year. Qualitatively, the degree to which the facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2015-2018 national death rates for patients with the same characteristics as those in the facility. Similarly, the degree to which the facility's yearly SMR varies from 1.00 is the degree to which it differs from the national death rates that year for patients with the same characteristics as those in the facility.

As stated previously, we adjusted the SMR for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and state and population death rates. Additionally, each year's estimate is compared to the US mortality rates for the same year. The SMR indicates whether patients treated in the facility had higher or lower mortality given the characteristics of patients treated at the facility. Because a different reference year is used for each year's estimate, the SMR will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SMR for the facility decreases over the time period, this means that mortality at the facility has decreased more over that time period than the overall US average mortality decreased. If mortality at the facility decreased over the four-year period at the same rate that overall US mortality decreased over this time period, the SMR for the facility would be the same for each year.

Detailed statistical methodology for the SMR is included in a separate document titled *Technical Notes on the Standardized Mortality Ratio for the Dialysis Facility Reports*. This document and an accompanying Microsoft Excel spreadsheet are available on the Dialysis Reports website (www.dialysisdata.org) under the Methodology heading.

Quantitatively, if the facility's death rates equal the national death rates (in deaths per patient-year or per year at risk) times a multiplicative constant, then the SMR estimates that multiplicative constant. If the multiplicative constant varies for different subgroups of patients, then the SMR estimates a weighted average of those constants according to the

facility's patient mix. For example, an SMR=1.10 would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an SMR=0.95 would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 versus 20 deaths). An SMR=1.00 would indicate that the facility's death rates equal the national death rates.

We calculated the regional and national summaries as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region (3c/3d).

Why the national SMR may not be exactly equal to 1.00

The reported 2016-2019 SMR for the U.S. as a whole may not be precisely equal to 1.00. The SMR value for the U.S. given in the Dialysis Facility Reports does not include all U.S. dialysis facilities in its calculation. In particular, as discussed in the Overview, transplant-only, VA-only, and non-Medicare facilities are not included in the geographic summaries.

Random variation

The SMR estimates the true ratio of death rates at the facility relative to the national death rates. An SMR value that differs from 1.00 indicates that the facility's death rates differ from the national death rates. ***However, the SMR's value varies from year to year above and below the true ratio, due to random variation.*** Thus, the facility's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between the facility's death rates and the nation's. Both the p-value and the confidence interval, discussed below, will help you interpret the facility's SMR in the face of such random fluctuations. We based our calculations of both items on an assumed Poisson distribution for the number of deaths at the facility.

P-value (3i)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of death rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SMR would, just by chance, deviate from 1.00 as much as does the observed SMR, and is sometimes naively interpreted as the probability that the true SMR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SMR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of death rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's death rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility death rates is. A small p-value helps rule out the possibility that an SMR's variance 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's death rates and the nation's.

The SMR's actual quantitative value reflects the clinical importance of the difference between the facility's and the nation's death rates. An SMR that differs greatly from 1.00 is more important than an SMR in the range of 0.95 to 1.05.

Confidence Interval for SMR (3j)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national death rates, in light of the observed SMR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

Recommended Course of Action if SMR Is Elevated

In past years, Medical Directors have asked the UM-KECC what they should do if their SMR is elevated. Our general guidelines, which are not intended to be exhaustive, follow.

1) Does the SMR deviate from 1.00 by chance? If the facility has few patients, then random variation may explain the deviation. Evaluate the confidence interval and the p-value. Most likely, the true SMR lies between the confidence limits. If the p-value exceeds 0.05, or if the confidence interval includes 1.00, the SMR is not statistically significant at the 0.05 level, and random variation could plausibly explain its elevation. Please note that the p-value is based on an exact calculation, while the confidence interval is an approximation, accurate in most cases. In rare cases, these measures of statistical significance may differ, with one indicating a statistically significant result and the other an insignificant one. Should this occur, use the p-value rather than the confidence interval.

2) Is the result consistent across the years? See if the values are consistent from year to year or if there is a consistent trend towards higher or lower values. If not, then the results may be less reliable than if the individual year estimates follow a pattern.

3) Examine input data. Table 1 gives some details about the patients assigned to the facility. An authorized user may request a list of patients used in this report from DialysisData.org, which includes patient identifiers and death dates, if applicable. Consider whether the counts of patients by year are plausible over time, as well as for any one year. If this list contains substantial errors, we would like to know about them.

4) Consider other characteristics of the facility not adjusted for in the SMR. The SMR adjusts for calendar year, age, race, ethnicity, sex, diabetes, years of ESRD, nursing home status, comorbidities, BMI, and population death rates. The SMR could differ from 1.00 because patients differ with respect to other important factors not adjusted for (e.g., poor nutritional status).

5) A statistically significant SMR greater than 1.10 likely reflects truly elevated mortality. Therefore, you may best address such a finding by evaluating various treatment factors in the unit, as well as other patient characteristics.

SMR Percentiles for This Facility (3k)

This section reports the percentile rank of the facility's SMR relative to all other facilities in the state, Network, and nation. This percentile — reported for each year's SMR and for the four year combined SMR — is the percentage of facilities with an SMR **lower** than the facility's. In other words, a high or low percentile indicates that the facility has a high or low SMR relative to other facilities in the state, Network, or nation.

Mortality Summaries for New Dialysis Patients (3l-3u)

Patients for First Year Mortality (3l)

Row 3l of this table gives the total number of forms for new dialysis patients submitted by the facility for the year. The first-year mortality statistics reported in the second half of the table (3l-3u) are based on these patients. As described above, the patients represented in this part of the table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2016 and December 31, 2018. Please note that we placed the patients included here **not** according to the conventions described in Section III, but rather according to the provider that submitted their Medical Evidence Forms.

Patient-Years at Risk for First-Year Mortality (3m)

For new dialysis patients, time at risk began at first dialysis treatment and continued until the earliest occurrence of the following: transplant; date of death, or one year after the start of treatment. This is in contrast to the time at risk for the first half of the table which begins no earlier than day 90 of ESRD and ends if a patient transfers out of the facility. For the first-year mortality statistics, all of a particular patient's time at risk is included in the report for their initial facility regardless of whether the patient was treated at that facility for the entire year. In addition, all of a patient's time at risk is included under the calendar year heading corresponding to the Medical Evidence Form even if some of that follow-up time occurs in the following year. In other words, the calendar year headings refer to the year the patients initiated treatment.

Deaths in First Year (3n)

We reported the number of deaths that occurred among new dialysis patients during their first year of dialysis, as well as the total across the years. As in the overall mortality section, this count does not include deaths from street drugs or deaths from accidents unrelated to treatment (see row 3c above for details).

Expected Deaths in First Year (3o)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient-years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, year, nursing home status, patient comorbidities at incidence, and patient BMI at incidence ($BMI = \text{weight (kg)} / \text{height}^2 \text{ (m}^2\text{)}$). We also controlled for age-adjusted population death rates by state and race, based on the U.S. population in 2014-2016 (National Center for Health Statistics, 2017). [JS2] We then summed these expected deaths in order to obtain the total number of deaths expected for each year at the facility, and we summed the annual values to yield the expected number of deaths over the three year period for each facility.

New Patients: Categories of Death (3p, 3q)

Row 3p reports the percentage of dialysis patient deaths (row 3n) for which the CMS ESRD Death Notification Form (Form-2746) indicated that the patient voluntarily discontinued renal replacement therapy prior to death. For the causes of death calculations in rows 3q, we considered all causes of death (primary and secondary) provided on the form. The percentage of deaths in 3n with a primary or secondary cause of death listed as infection, cardiac causes and liver disease are reported in row 3q.

First Year Standardized Mortality Ratio (SMR) (3r)

The SMR equals the ratio of the actual number of deaths (3n) divided by the expected number of deaths (3o). The SMR estimates the relative death rate ratio for the facility, as compared to the national death rate in the same year. Qualitatively, the degree to which the facility's three-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2014-2016 national death rates for new dialysis patients with the same characteristics as those in the facility. Similarly, the degree to which the facility's yearly SMR varies from 1.00 is the degree to which it differs from the national death rates for patients with the same characteristics as those in the facility that year.

We used similar methods to calculate SMR for new dialysis patients and for all dialysis patients. We adjusted the SMR for age, race, ethnicity, sex, diabetes, nursing home status, comorbidities at incidence, BMI at incidence, and state and population death rates. Additionally, each year's estimate is compared to the US mortality rates for the same year. The SMR indicates whether patients treated in the facility had higher or lower mortality than expected given the characteristics of patients treated at the facility. Because a different reference year is used for each year's estimate, the SMRs will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SMR for the facility decreases over the time period, this means that mortality at the facility has decreased more over that time period than the overall US average mortality decreased. If mortality at the facility decreased over the three year period at the same rate that overall US mortality decreased over this time period, the SMR for the facility would be the same for each year.

Quantitatively, if the facility's death rates equal the national death rates (in deaths per patient year or per year at risk) times a multiplicative constant, then the SMR estimates that multiplicative constant. If the multiplicative constant varies for different subgroups of patients, then the SMR estimates a weighted average of those constants according to the facility's patient mix. For example, an $SMR=1.10$ would indicate that the facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an $SMR=0.95$ would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 versus 20 deaths). An $SMR=1.00$ would indicate that the facility's death rates equal the national death rates.

We calculated the regional and national summaries as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region (3n/3o).

P-value (3s)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of death rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SMR would, just by chance, deviate from 1.00 as much as does the observed SMR, and is sometimes naively interpreted as the probability that the true SMR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SMR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of death rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's death rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility death rates is. A small p-value helps rule out the possibility that an SMR's variance 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's death rates and the nation's.

The SMR's actual quantitative value reflects the clinical importance of the difference between the facility's and the nation's death rates. An SMR that differs greatly from 1.00 is more important than an SMR in the range of 0.95 to 1.05.

Confidence Interval for First Year SMR (3t)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national first year death rates, in light of the observed SMR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

First Year SMR Percentiles for This Facility (3u)

This section reports the percentile rank of the facility's first year SMR relative to all other facilities in the state, Network, and nation. This percentile — reported for each year's SMR and for the three year combined SMR — is the percentage of facilities with an SMR **lower** than the facility's. In other words, a high or low percentile indicates that the facility has a high or low SMR relative to other facilities in the state, Network, or nation.

VII. Hospitalization Summary for Medicare Dialysis Patients, 2016-2019

Overview: Hospitalization Summaries for Dialysis Patients

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital approximately twice a year and spend an average of 11 days in the hospital per year (USRDS, 2017). Measures of the frequency of hospitalization and diagnoses associated with hospitalization help efforts to control escalating medical costs, and play an important role in providing cost-effective health care. Hospitalization summaries for Medicare dialysis patients are reported in Table 4.

This report includes summaries of hospitalization rates among dialysis patients in the facility, along with regional and national hospitalization rates for comparison. However, the reasons for differences in hospitalization rates by facility are complex. The clinical decision associated with individual hospitalization events is not possible to ascertain with the available administrative data. Therefore, these facility data may be best characterized as an assessment of hospital resource utilization across facilities.

Hospitalization rates are more difficult to summarize than are mortality rates. For example, a patient can be hospitalized more than once during a year. Further, hospitalization data are not always as complete as mortality data. Ideally, this table includes only patients whose Medicare billing records include all hospitalizations for the period. To achieve this goal, we require that patients reach a certain level of Medicare-paid dialysis bills to be included in hospitalization statistics, or that patients have Medicare inpatient claims during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period is considered 'eligible'. A month is deemed eligible for days hospitalized and admissions calculations if it is within two months following a month having at least \$900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim, and a month is deemed eligible for ED calculations if it is within two months following a month having at least \$1,200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. Additionally, months identified as having Medicare Advantage according to the Medicare Enrollment Database (EDB) coverage were excluded for ED calculations. In setting this criterion, our aim is to achieve completeness of information on hospitalizations for all patients included in the years at risk. Note that these criteria do not apply to the readmission statistics reported in this table.

Summaries of days hospitalized are reported in rows 4c through 4h, summaries of hospital admissions are reported in Rows 4i through 4q, and summaries of ED visits are reported in Rows 4r through 4z. These statistics include multiple admissions or ED visits per patient. For each facility, a *Standardized Hospitalization Ratio (Days)*, a *Standardized Hospitalization Ratio (Admissions)*, a *Standardized Hospitalization Ratio (ED)* were calculated. Like the SMR, these statistics are intended to compare the facility's observed number of events (be it admissions, days hospitalized, or ED visits) to the number that would be expected if patients at the facility were instead subject to the 2016-2019 national average admission, days, and ED visit rates. The expected national rates for days hospitalized and admissions are calculated from Cox models (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994) which make adjustments for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, calendar year, and prevalent comorbidities. The expected national rates for ED visits are calculated from Cox models which make adjustments for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and calendar year.

Hospitalization summaries are reported for each year from 2016-2019 and for the entire four-year period. We also report the results for the average facility over the combined 2016-2019 period for hospitalization summaries at the regional and national levels. Because

statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret, the Standardized Hospitalization Ratios are calculated based on at least 5 patient-years at risk. This corresponds to approximately 10 expected hospitalizations.

Overview: Hospital Readmission Summary for Dialysis Patients

Hospital readmission rates are an important indicator of patient morbidity and quality of life. Relative to the general population, dialysis patients experience much higher levels of mortality (de Jager et al., 2009) and morbidity (e.g., hospital readmission; MedPAC, 2007). Both hospitalization and readmission rates reflect morbidity and quality of life of dialysis patients as well as medical costs. For example, during the calendar year 2012 dialysis patients were admitted to the hospital twice on average and spent an average of 11 days in the hospital. This is indicative of a poorer quality of life for dialysis patients and also accounts for approximately 37% of Medicare expenditures for ESRD patients (USRDS, 2014). Furthermore, 35% of hemodialysis patients discharged from the hospital had a readmission within 30 days (USRDS, 2014). In other settings (e.g., cardiovascular disease, cancer), studies show that about 25% of unplanned readmissions are preventable, that preventability varies widely across diagnoses, and that readmissions were more likely to be preventable for patients with more severe conditions (van Walraven et al., 2011).

Readmission summaries for dialysis patients are reported in rows 4aa through 4af of Table 4. Because statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret, the Standardized Readmission Ratio (SRR) is not shown for a particular year if there are fewer than 11 index discharges in that year.

This report includes summaries of unplanned readmission rates among all dialysis patients in your facility, along with regional and national hospitalization rates for comparison. These summaries are based on administrative data obtained primarily from Medicare claims and are risk adjusted for the discharging hospital and for patient-level factors. This readmission rate, as well as the SHR, can be viewed as giving a partial assessment of hospital resource utilization across facilities.

Like the SMR and SHR, the Standardized Readmission Ratio (SRR) compares a facility's observed number of unplanned readmissions with the number that would be expected if patients at the facility were instead subject to the national average readmission rate. The expected number is computed given the number and characteristics of the hospital discharges during the year. The probability that a given discharge results in a readmission is based on a hierarchical logistic model that makes adjustments for the discharging hospital of the index hospitalization and for the patient characteristics of age, sex, diabetes, duration of ESRD at index hospital discharge, comorbidities in the year preceding the index hospital discharge, the presence of a high-risk diagnosis at index hospital discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD.

Identifying Patients Treated at Each Facility

The readmission summaries are not based on similar conventions described in Section III but differ as described below. Each patient's dialysis provider over time was identified using a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728) and data from CROWNWeb. We determined these facility treatment histories as of day 1 of ESRD and used them to identify a patient's dialysis treatment facility at the time of each index discharge.

We remove a patient from a facility upon receiving a transplant, withdrawing from dialysis or recovering renal function. Additionally, we considered a patient lost to follow-up for whom the only evidence of dialysis treatment is the existence of Medicare claims, and we removed them 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 continue to include that patient in the analysis. If evidence of dialysis re-appeared, the patient re-entered the analysis. Finally, we extended all CROWNWeb records noting continuing dialysis until the appearance of any evidence of recovery, transfer or death. We did not create periods of lost to follow-up in these cases since the instructions for CROWNWeb only require checking patient data for continued accuracy and do not require updating if there are no changes.

Differences in Inclusion Criteria for SRR Measure

The inclusion criteria and facility assignment methods for the SRR described above are somewhat different than those for the SMR, SHR and the Standardized Transfusion Ratio (STrR). First, patients are included in the SRR as of the first day of ESRD treatment. Second, patients are included in the SRR for a facility as soon as the patient begins treatment at the facility. This is in contrast to the other standardized measures, which require a patient to have ESRD for more than 90 days and be in a facility for at least 60 days before he or she is included in the measure. The last difference is that patients are removed from the SRR analysis at withdrawal or lost to follow-up rather than 60 days later as is done for the other standardized measures.

Medicare Dialysis Patients (4a)

The number of Medicare dialysis patients included in the hospitalization summaries (4a) is generally smaller than the number of patients included in the mortality summaries (3a). We based the hospitalization summaries (rows 4a-4z) on the dialysis patients who received treatment in the facility according to the conventions described in Section III. In addition, we calculated hospitalization rates based only on periods in which dialysis patients had satisfied the Medicare payment criterion (described above).

Patient Years at Risk (4b)

The number of patient years at risk indicates the total amount of time we followed patients in this table's analyses. We used the number of patient years at risk reported in 4b as the denominator in the calculation of the total days hospitalized statistics. Patients were at risk for spending another day in the hospital whether or not they were hospitalized at the time.

For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: three days prior to a transplant; date of death; end of facility treatment; or December 31 of the year. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at the facility.

Days Hospitalized Statistics (4c-4h)

Total Days Hospitalized (4c)

This represents the total number of days that Medicare dialysis patients assigned to this facility spent as inpatients in the hospital. The total number of days includes multiple admissions (i.e., second, third, etc. hospitalizations for the same patient). If a patient was admitted near the end of one year and was not discharged until the following calendar year (e.g., admitted on 12/28/2017 and discharged on 1/6/2018), the number of days hospitalized are assigned appropriately to the two years (four days in 2017 and six days in 2018).

Expected Total Days Hospitalized (4d)

We calculated the expected number of hospitalized days among Medicare dialysis patients in a facility based on national rates for days hospitalized in the same year. The expected hospitalization frequency is calculated from a Cox model, adjusting for patient age, sex, diabetes at incidence, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, calendar year of treatment, and prevalent comorbidities. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each interval is multiplied by the (adjusted) national hospitalization rate for that interval, and a sum over the intervals gives the expected number of days hospitalized for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 4d.

Standardized Hospitalization Ratio (SHR) for Days (4e)

The SHR (Days) is calculated by dividing the observed total days hospitalized in 4c by the expected total days hospitalized in 4d. As with the SMR, it enables a comparison of the facility's experience to the national average for the same year(s). A value of less than 1.0 indicates that the total number of days hospitalized in the facility was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the total number of days hospitalized in the facility was higher than the (adjusted) national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes at incidence, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and prevalent comorbidities. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that hospitalization at the facility has decreased more over

that time period than the overall US average hospitalization decreased. If hospitalization at the facility decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for the facility would be the same for each year.

P-value (4f)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of hospitalization rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SHR would, just by chance, deviate from 1.00 as much as does the observed SHR, and is sometimes naively interpreted as the probability that the true SHR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SHR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of hospitalization rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's hospitalization rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility hospitalization rates is. A small p-value helps rule out the possibility that an SHR's variance 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's hospitalization rates and the nation's.

The SHR's actual quantitative value reflects the clinical importance of the difference between the facility's and the nation's hospitalization rates. An SHR that differs greatly from 1.00 is more important than an SHR in the range of 0.95 to 1.05.

Confidence Interval for SHR (Days) (4g)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national hospitalization rates, in light of the observed SHR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

SHR (Days) Percentiles for This Facility (4h)

This section reports the percentile rank of the facility's SHR (Days) relative to all other facilities in the state, Network, and nation. This percentile — reported for each year's SHR and for the four year combined SHR — is the percentage of facilities with an SHR **lower** than the facility's. In other words, a high or low percentile indicates that the facility has a high or low SHR relative to other facilities in the state, Network, or nation.

Hospital Admission Statistics (4i-4q)

Total Admissions (4i)

This is the total number of inpatient hospital admissions among the Medicare dialysis patients assigned to this facility. The total number of admissions includes multiple admissions (i.e., second, third, etc. hospitalizations for the same patient). If a patient was

admitted near the end of one year and not discharged until the following calendar year (e.g., admitted on 12/28/2017 and discharged on 1/6/2018), the admission would count only in the second year (zero admissions in 2017 and one admission in 2018).

Expected Total Admissions (4j)

We calculated the expected number of hospital admissions among Medicare dialysis patients in a facility based on national rates for hospital admissions in the same year. The expected number of admissions is calculated from a Cox model, adjusting for patient age, sex, diabetes at incidence, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, calendar year, and prevalent comorbidities. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the (adjusted) national admissions rate for that interval, and a sum over the intervals gives the expected number of admissions for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 4j.

Standardized Hospitalization Ratio (SHR) for Admissions (4k)

The SHR (Admissions) is calculated by dividing the observed total admissions in 4i by the expected total admissions in 4j. As with the SMR, it enables a comparison of the facility's experience to the national average. A value of less than 1.0 indicates that the facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the facility had a rate of total admissions higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes at incidence, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and prevalent comorbidities. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that hospitalization at the facility has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization at the facility decreased over the four -year period at the same rate that overall US hospitalization decreased over this time period, the SHR for the facility would be the same for each year.

P-value (4l)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of hospitalization rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SHR would, just by chance, deviate from 1.00 as much as does the observed SHR, and is sometimes naively interpreted as the probability that the true SHR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SHR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of hospitalization rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's hospitalization rates and

the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility hospitalization rates is. A small p-value helps rule out the possibility that an SHR's variance 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's hospitalization rates and the nation's.

The SHR's actual quantitative value reflects the clinical importance of the difference between the facility's and the nation's hospitalization rates. An SHR that differs greatly from 1.00 is more important than an SHR in the range of 0.95 to 1.05.

Confidence Interval for SHR (Admissions) (4m)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national hospitalization rates, in light of the observed SHR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

SHR (Admissions) Percentiles for This Facility (4n)

This section reports the percentile rank of the facility's SHR (Admissions) relative to all other facilities in the state, Network, and nation. This percentile — reported for each year's SHR and for the four year combined SHR — is the percentage of facilities with an SHR **lower** than the facility's. In other words, a high or low percentile indicates that the facility has a high or low SHR relative to other facilities in the state, Network, or nation.

Diagnoses Associated with Hospitalization (4o)

Row 4o reports the percentage of patients in 4a who had septicemia, acute myocardial infarction, congestive heart failure, cardiac arrhythmia, and cardiac arrest reported as any one of the diagnoses on a hospital bill with a start date during a period of treatment at the facility. We first identified ICD-9 and ICD-10 (beginning on 10/01/2015) diagnosis codes associated with these diagnoses and then looked for these codes on the hospital bills (in any position on the list of diagnoses). Row 4o includes all bills, even if the patient did not leave the hospital in between bills. Note that a patient may appear in more than one of the categories.

One Day Admissions (4p)

We reported the percentage of total inpatient hospital admissions in 4i that lasted one day or less. One-day admissions included hospitalizations in which the patient was discharged either the same or the following day. We did not adjust this statistic for patient characteristics.

Average Length of Stay (4q)

As a measure of severity of hospitalizations, we reported the average duration (in days) of hospital admissions among Medicare dialysis patients assigned to this facility. We calculated this duration from Medicare payment records, which listed an admission and discharge date for each hospitalization. The average length of stay is not adjusted for patient characteristics.

Emergency Department (ED) Statistics (4r-4z)

Total ED Visits (4r)

This is the total number of emergency department (ED) visits among the Medicare dialysis patients assigned to this facility. This includes both ED visits that result in inpatient admission and those that do not result in admission. The total number of ED visits includes multiple visits (i.e., second, third, etc. visits for the same patient). However, multiple visits within a single day are counted as a single visit, where ED visits resulting in an inpatient admission are included over visits that do not result in an inpatient admission.

Expected Total ED Visits (4s)

We calculated the expected number of ED visits among Medicare dialysis patients in a facility based on national rates for ED visits in the same year. The expected number of ED visits is calculated from a Cox model, adjusting for patient age, sex, diabetes at incidence, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and calendar year. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years and ED visit rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the (adjusted) national ED visit rate for that interval, and a sum over the intervals gives the expected number of ED visits for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 4s.

Standardized Hospitalization Ratio (SHR) for ED (4t)

The SHR (ED) is calculated by dividing the observed total ED visits in 4r by the expected total ED visits in 4s. As with the SMR, it enables a comparison of the facility's experience to the national average. A value of less than 1.0 indicates that the facility's total number of ED visits was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the facility had a rate of ED visits higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI at incidence. Additionally, each year's estimate is compared to the US rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time in the facility beyond the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that ED visits in the facility has decreased more over that time period than the overall US average ED visits decreased. If ED visits in the facility decreased over the four year period at the same rate that overall US ED visits decreased over this time period, the SHR for the facility would be the same for each year.

P-value (4u)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of ED visit rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SHR would, just by

chance, deviate from 1.00 as much as does the observed SHR, and is sometimes naively interpreted as the probability that the true SHR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SHR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of ED visit rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's ED visit rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility ED visit rates is. A small p-value helps rule out the possibility that an SHR's variance 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's ED visit rates and the nation's.

The SHR's actual quantitative value reflects the clinical importance of the difference between the facility's and the nation's ED visit rates. An SHR that differs greatly from 1.00 is more important than an SHR in the range of 0.95 to 1.05.

Confidence Interval for SHR (ED) (4v)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national ED visit rates, in light of the observed SHR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

SHR (ED) Percentiles for This Facility (4w)

This section reports the percentile rank of the facility's SHR (ED) relative to all other facilities in the state, Network, and nation. This percentile — reported for each year's SHR and for the four year combined SHR — is the percentage of facilities with an SHR **lower** than the facility's. In other words, a high or low percentile indicates that the facility has a high or low SHR relative to other facilities in the state, Network, or nation.

Patients with ED visit (4x)

Row 4x reports the percentage of Medicare dialysis patients assigned to this facility over the four year period that had at least one ED visit. If a patient had more than one ED visit during the year, they were counted only once in the numerator of this statistic.

ED Visits that Result in Hospitalization (4y)

Row 4y reports the percentage of ED visits in 4r that resulted in an inpatient admission.

Admissions that Originated in the ED (4z)

Row 4z reports the percentage of inpatient admissions that originated in the Emergency Department. If a patient had more than one ED visit resulting in an admission during an inpatient admission, we only counted one ED visit in the numerator of this statistic. For example, if a patient is discharged from the hospital but is readmitted within 1 day of discharge, we combine the two inpatient admissions and thus, only count the admissions as one hospitalization. Furthermore, if both of the inpatient admissions originated in the Emergency Department, we will count the admissions as one ED visit for this statistic (in all other ED visit statistics they are counted as two ED visits).

Readmission Statistics (4aa-4af)

Index discharges (4aa)

Index discharges are those hospitalizations that serve as starting points for identifying readmissions. This is the number of Medicare-covered hospital discharges occurring at acute-care hospitals in the calendar year for dialysis patients treated at your facility. Note that this does not include discharges from long-term care hospitals (LTCHs) or skilled nursing facilities (SNFs). An index discharge is attributed to the dialysis facility to which the patient is assigned as of his/her discharge date.

Total readmissions (4ab)

The number of readmissions for the facility is defined as the number of index discharges followed by an unplanned readmission within 4-30 days of discharge—in other words, the number of index discharges for which the next admission was unplanned and occurred within 4-30 days of the index discharge. Like index discharges, those hospitalizations considered as potential readmissions are restricted to hospitalizations for inpatient care at acute care hospitals. Note that a hospitalization identified as a readmission may also be an index discharge.

Hospital admissions were classified as being planned or unplanned according to the algorithm developed for CMS' hospital-wide readmission measure (Horwitz et. al., 2012). A detailed description of this algorithm is available at www.dialysisdata.org.

The readmission is assigned to the index discharge dialysis facility regardless of the treatment facility at the time of readmission. In other words, if a patient is discharged from a hospital while assigned to Facility A, transfers to Facility B on her 15th day after hospital discharge, then is readmitted to the hospital on the 20th day after discharge while in Facility B, that readmission will be attributed to Facility A, not to Facility B.

Expected total readmissions (4ac)

We calculated the number of hospital readmissions that would be expected given the set of index discharges of dialysis patients in your facility based on national rates for hospital readmissions in the same year. The expected number of readmissions is calculated from a hierarchical logistic model, adjusted for the discharging hospital of the index hospitalization and for the patient characteristics of age, sex, diabetes, duration of ESRD at index hospital discharge, comorbidities in the year preceding the index hospital discharge, the presence of a high-risk diagnosis at index hospital discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD. For each patient, the expected number is adjusted for the characteristics of that patient.

Standardized Readmission Ratio (SRR) (4ad)

We calculated the SRR by dividing the observed total readmissions in 4ab by the expected total readmissions in 4ac. As with the SMR and SHR, the SRR compares your facility's experience to what should be expected on the basis of the national norm. A value of less

than 1.0 indicates that your facility's total number of readmissions is less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total readmissions higher than would be expected given national rates. Note that this measure is adjusted for the discharging hospital of the index hospitalization and for the patient characteristics described above in section 4ac. In addition, the estimate is compared with the US readmission rates for the same year.

P-value for SRR (4ae)

The p-value measures the statistical significance of (or evidence regarding) the hypothesis that the true ratio of the readmission rates for your facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SRR would differ from 1.00 as much as does the observed SRR and is often used to assess evidence. A small p-value indicates that the observed SRR is not likely due to chance and occurs when the observed SRR differs markedly from 1.00. A p-value of less than 0.05 is often taken as evidence that the ratio of readmission rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between your facility's readmission rate and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more statistically significant is the difference between national and individual facility readmission rates. A small p-value helps rule out the possibility that an SRR's variance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between your facility's readmission rate and the nation's.

The SRR's actual quantitative value reflects the clinical importance of the difference between your facility's and the nation's readmission rates. An SRR of 1.25, for example, indicates that your facility's readmission rate is 25% higher than the national average, which may well be judged to be clinically important. On the other hand, SRR values in the range of 0.95 to 1.05 would generally not be considered to be of clinical interest. With very large facilities, even relatively small differences in the SRR can lead to significant results, so both aspects (the actual value of the SRR and the p-value) are important.

Confidence Interval (Range of Uncertainty) for SRR (4af)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national readmission rates, in light of the observed SRR. The upper and lower limits enclose the true ratio between them approximately 95% of the time if this procedure is repeated on multiple samples. Statistically significant confidence intervals do not contain 1.00.

VIII. Transplantation Summary for Dialysis Patients under Age 75, 2016-2019

The results of numerous studies have indicated that the recipients of renal transplants have better survival than comparable dialysis patients (Wolfe, 1999). Although the number of renal transplants has increased, it has not kept pace with the rising number of patients on transplant waiting lists. This report includes Standardized Transplantation Ratios (STRs) for dialysis patients who never received a transplant. The STR is only calculated if there

are at least 3 expected events for the time period. In addition, the STR is only reported for the four-year period since the expected number of transplants is less than 3 nationally.

We calculated the STR using the same methods as the Standardized Mortality Ratio (SMR), described in more detail in Section VI. Adjustments for the STR differed from those for the SMR because the STR was adjusted for age only. Since we included patients in this table only once they reached day 91 of ESRD, we excluded patients who received a pre-emptive transplant or a transplant within the first three months of treatment. You will find these statistics useful in that they allow a facility to compare the rate of transplantation for the dialysis patients they treat, though these statistics should not be interpreted as including all transplants. The percentage of transplants in the U.S. that were not included because the transplant occurred less than 91 days after the start of ESRD, as well as those that were not included because the patients were not assigned to facilities at times of transplant are indicated in a footnote to the table.

Eligible Patients (5a)

Row 5a reports the number of dialysis patients under age 75. The transplantation summaries were assigned to the facility according to the conventions described in Section III. In addition, all transplantation statistics in this report refer only to those patients less than 75 years of age because transplants in people aged 75 or greater occurred much less frequently than did transplants in younger patients.

Transplants (5b)

Row 5b reports the number of dialysis patients under the age of 75 in each facility who received a transplant.

Donor Type (5c)

Row 5c reports by year the number of patients who received transplants from a living and from a deceased donor. The sum is the number of transplants in row 5b, although it may be lower due to unknown donor type.

Eligible Patients (5d)

Row 5d reports the number of dialysis patients under age 75 from row 5a who had never received a kidney transplant before. The first transplant rates in the rest of the table are restricted to these patients. The number of dialysis patients included in this report's transplantation summaries (5d) was typically much smaller than the number of patients included in the mortality summaries (3a) for two reasons. First, all transplantation statistics in this report refer only to those patients less than 75 years of age. Second, we computed transplantation statistics only for patients who had never received a kidney transplant before.

Patient Years at Risk (5e)

We limited our calculations for 5e to patients under the age of 75 who had not previously received a transplant. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest of the following occurrences: transplant, date of death, end of the facility treatment period, or December 31. A patient

may have been treated at one facility for multiple periods during the same year; in such a case, the number of patient years at risk included time at risk for all periods of treatment at that facility.

Actual First Transplants (5f)

Row 5f reports the number of dialysis patients under the age of 75 in each facility who received a first transplant.

Expected First Transplants (5g)

We calculated the expected number of patients who had received transplants during the year in a manner similar to calculating the expected number of deaths, but with one important difference: we adjusted transplantation statistics for age only. We did not adjust transplantation statistics for sex, race, or diabetes because, generally speaking, these are inappropriate adjustments for access to transplantation. We used a Cox model to calculate the expected number of first transplants during the year for each patient based on the age of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 1999; Andersen, 1993; Collett, 1994). Table 5 sums and reports the total number of patients expected to receive a first transplant from the facility, with corresponding regional and national averages.

Standardized Transplantation Ratio (5h)

The Standardized Transplantation Ratio (STR) is the ratio of the actual number (5f) of first transplants to the expected number (5g) of first transplants for the facility, given the age composition of the facility's patients. The STR is adjusted for patient age and calendar year only. In order to provide stable estimates, the STR is only reported for the combined four year period when there are 3 or more expected transplants (note: the number of expected transplants annually in the Nation is less than 3).

The interpretation of STR is similar to SMR. An STR of 1.00 indicates that the observed number of transplants in the facility equals the estimated national rate, adjusted for age. An STR of less than 1.00 indicates that the facility's transplant rate is lower than the national average. An STR greater than 1.00 indicates that the facility's transplant rate exceeds the national average. The amount by which an STR lies above or below 1.00 corresponds to the percentage the facility's transplant rate is above or below the national average, respectively. For example, an STR of 0.90 would mean that the facility's rate of transplantation is 10% less than the estimated national rate (e.g., nine transplants where ten are expected). An STR exceeding 1.00 is desirable.

We calculated the STRs for the regional and national summaries as the ratio of the total observed number of first transplant summed across facilities to the total expected number of first transplants summed across facilities.

Random Variation

The STR tends to show more random variation than the SMR because numbers of transplants are much smaller than numbers of deaths. Small numbers of events contribute to instability, increasing the chances that an observed result owes to chance rather than to

the true ratio of observed-to-expected transplants. This makes p-values and confidence intervals instrumental in interpreting the facility's STR. We calculated these statistics based on an assumed Poisson distribution of the observed number of patients transplanted.

P-value (5i)

We used the p-value to determine the statistical significance of the STR. The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of transplantation rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value indicates the probability that the result obtained owed to chance alone, with smaller values meaning chances are low that the STR differs from the national average merely because of random variation. Although a p-value of less than 0.05 usually indicates a result's statistical significance, you should also use the absolute magnitude of the STR's deviation from 1.00 to determine its clinical importance.

Confidence Intervals for STR (5j)

The 95% confidence interval gives a range of plausible values for the true ratio of facility-to-national first transplant rates, in light of the observed STR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

STR Percentile for This Facility (5k)

This section reports the percentile rank of the facility's STR relative to all other facilities in the state, Network, and nation. We report these percentiles for each year's STR and for the four year combined STR. The percentile indicates the percentage of facilities with an STR **lower** than the facility's STR. In other words, a high or low percentile number indicates that the facility has a high or low STR relative to other facilities in the state, Network, or nation. All facilities are included in the ranking, regardless of the number of expected transplants.

IX. Waitlist Summary for All Dialysis Patients (2016-2019) and New Patients (2016-20178) under Age 75

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.

The first half of Table 6 (rows 6a-6g) provides a snapshot of transplant waitlist for prevalent patients at the end of each month. For this section, both unadjusted (6c) and age-adjusted percentage (6e) of patient-months waitlisted from the facility for each year from 2016-2019. State, Network, and U.S. averages for 2019 are reported for comparison.

The second half of Table 6 (rows 6h-6n) provides information about transplant waitlist in the first year of dialysis for patients starting dialysis for the first time at the facility. For this section, we have calculated the Standardized First Kidney Transplant Waitlist Ratio

(SWR) for each year from 2016-2018 to compare the observed event rate in the facility to the expected event rate for incident dialysis patients. State, Network, and U.S. averages for 2016-2018 are reported for comparison.

Calendar Year Headings

In the prevalent waitlist section, the calendar years are the reporting period. However, in the new patients section, the calendar years correspond to the year of the first treatment for that patient. Here, time at risk and deaths are included in the column corresponding to when that patient started dialysis rather than when the time at risk or the event took place. Because we do not have a full year of follow-up for patients who started dialysis in the fourth year, only three years are included in the incident waitlist section. Additionally, due to the low expected number of events in each year, the SWR, p-value and confidence interval are only reported for the three-year period.

Percent Waitlisted among Prevalent Dialysis Patients (6a-6g)

The measures reported in this section track the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist.

Eligible Patients and Patient-Months at Risk (6a-6b)

The number of eligible dialysis patients who were under age 75 and assigned to the facility for at least one month during the year are reported in row 6a. 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 for CROWNWeb measures. 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. Row 6b reports the total number of eligible patient-months. Patients may be counted up to 12 times per year.

Percentage of Patient-months on the Waitlist (6c)

Row 6c reports the percentage of patient-months among eligible patient-months reported in 6b on the kidney or kidney-pancreas transplant waiting list as of the last day of each calendar month during the year. Patients may be counted up to 12 times per year.

Patient Characteristics (6d)

Row 6d reports the percentage of patient-months among eligible patients from row 6b on the kidney or kidney-pancreas transplant waiting list as of the last day of each calendar month during the year by categories of age, sex, race and ethnicity, cause of ESRD, previous transplant, and years of ESRD treatment. Similar to 6b, patients may be counted up to 12 times per year.

Age-Adjusted Percentage of Patient-Months Waitlisted (6e)

Row 6e reports the percentage of patient-months among eligible patient-months reported in 6b on the kidney or kidney-pancreas transplant waiting list as of the last day of each calendar month during the year, adjusted for age. This measure is a directly standardized percentage, in the sense that each facility's percent waitlisted is adjusted to the national age distribution (with 'national' here referring to all-facilities-combined). The outcome 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. Results reported in row 6e are averaged across eligible patient-months (6b). The age-adjusted percentage waitlisted is restricted to facilities with 11 or more eligible patients (6a) during the reporting period.

P-Value for Age-Adjusted Percent Waitlisted (6f)

We use a two-sided Wald test (0.05 significance level) to measure the statistical significance of (or evidence against) the hypothesis that the age-adjusted percentage of patient-months waitlisted for a facility is the same as (neither higher nor lower than) that from the national average percent waitlisted. Note that the Wald test is based on the logit of the age-adjusted percent waitlisted, which is much more likely to follow a normal distribution, 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's age-adjusted percent waitlisted differs from the national percentage.

Confidence Interval for Age-Adjusted Percent Waitlisted (6g)

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.

Standardized First Kidney Transplant Waitlist Ratio (SWR; 6h-6n)

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 this measure, patients are assigned to the facility based on the facility information entered on the Medical Evidence 2728 form.

Eligible patients (6h)

The incident waitlist section includes ESRD patients, under the age of 75, who have initiated dialysis during the reporting period. The exclusion criteria applied in this section 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 (6i)

For patients in the Standardized First Kidney Transplant Waitlist Ratio (SWR) analysis, time at risk began at incidence of dialysis and continued until the earliest occurrence of one of the following events: (i) listed on the kidney or kidney-pancreas transplant waitlist; (ii) receipt of a living donor transplant; (iii) death; or (iv) one year after the start of treatment. 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. Row 6i reports the total patient years at risk for the SWR.

First Waitlist Events (6j)

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 (6l).

Expected 1st Waitlist Events (6k)

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). Row 6k reports the total number of patients expected to be either waitlisted or recipients of living donor transplants from the facility.

Standardized Waitlist Ratio (SWR) (6l)

For each facility, the SWR is calculated to compare the observed number of waitlist events in a facility to its expected number of waitlist events. It 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. The SWR equals the ratio of the observed number of transplant waitlist events or receipt of a living-donor transplant (6j) divided by the expected number of transplant waitlist events or living donor transplant events (6k).

We calculated the SWRs for the regional and national summaries as the ratio of the total number of observed events to the number of expected events in the region or nation, respectively. Facilities with less than 11 patients or less than 2 expected events for the reporting period are not reported but are included in the state, Network, and US summaries.

The interpretation of SWR is similar to STR. An SWR of 1.00 indicates that the observed number of waitlist events in the facility equals the estimated national rate, adjusted for age and incident comorbidities. An SWR of less than 1.00 indicates that the facility's waitlist rate is lower than the national average. An SWR greater than 1.00 indicates that the facility's waitlist rate exceeds the national average. The amount by which an SWR lies above or below 1.00 corresponds to the percentage the facility's waitlist rate is above or below the national average, respectively. For example, an SWR of 0.90 would mean that

the facility's rate of waitlistings or living-donor transplants is 10% less than the estimated national rate (e.g., nine transplants where ten are expected). An SWR exceeding 1.00 is desirable.

Random Variation

The SWR tends to show more random variation than the SMR because numbers of transplant waitlists are much smaller than numbers of deaths. Small numbers of events contribute to instability, increasing the chances that an observed result owes to chance rather than to the true ratio of observed-to-expected waitlists.

P-value for SWR (6m)

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.

Confidence Interval for SWR (6n)

Similar to other standardized ratio measures, 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.

X. Influenza Vaccination Summary for Medicare Dialysis Patients Treated on December 31st of Each Year, Flu Seasons August 2016-December 2019

This table reports influenza vaccination summary statistics identified on Medicare claims for Medicare dialysis patients treated on December 31st of each year in the facility. Average values for the most current year are also reported among patients in the state, Network, and the U.S. In an effort to emphasize the use of vaccine prior to the peak of flu season, we provide vaccination summaries from August 1st through December 31st each year as well as the overall vaccination summary for the full influenza vaccination season (August 1st through March 31st of the following year).

Eligible Patients on 12/31 (7a)

Like the hospitalization and comorbidity tables, this table is limited to patients who are covered by Medicare. To achieve this goal, we use the Medicare criterion described above in Section VII for the hospitalization statistics. Since it takes a month to accrue > \$1,200 in claims, we have excluded patients who have had ESRD less than 30 days. This table is then further restricted to patients being treated at the facility at the end of each year. The 60-day transfer rule does not apply, and we include incident patients who have had ESRD for at least 30 days. Additionally, months identified as having Medicare Advantage according to the Medicare Enrollment Database (EDB) coverage were excluded. In setting this criterion, our aim is to achieve completeness of information on vaccinations for all patients included in the years at risk.

Vaccinations that are billed to Medicare are counted whether these occurred at the facility or outside of the facility. Since vaccinations not billed to Medicare are not captured, vaccinations for non-Medicare patients or patients that receive a vaccine for which no Medicare claims are filed are excluded from the vaccination summaries. Please note a claim with only ICD-10 code "Z23" is not sufficient to identify influenza vaccinations. For a vaccination to be included in these percentages, the claim must include one of the CPT or HCPCS codes to specify that the vaccination was for influenza. A complete list of the ICD codes included in these statistics are available on DialysisData.org beginning on page 8: <https://dialysisdata.org/sites/default/files/content/Codes.pdf>.

Row 7a reports the number of Medicare dialysis patients included in the influenza vaccination summaries.

Patients Vaccinated between Aug. 1 and Dec. 31 (7b)

Row 7b reports the percentage of patients in 7a who had a Medicare claim for vaccination performed between August 1st and December 31st, with the corresponding national percentage for 2019 reported for comparison.

P-value for Patients Vaccinated between Aug. 1 and Dec. 31 (7c)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 7b, is higher (or lower) than the U.S. value for that year. The footnote for row 7c shows the percentage of patients vaccinated in the U.S. for each year used in this comparison. The p-value indicates the probability that the difference between the percentages of patients vaccinated in the facility and in the U.S. occurred due to chance. A low p-value means that the chances are low that the facility percentage was higher or lower than the national average merely because of random variation. A p-value of less than 0.05 usually indicates a statistically significant result. You should also use the absolute magnitude of the difference between the facility and national percentage of patients vaccinated to determine its clinical importance.

Patients Vaccinated between Aug. 1 and Mar. 31 of the following year (7d)

Row 7d reports the percentage of patients in 7a who had a Medicare claim for vaccination performed between August 1st and March 31st of the following year, with the corresponding

national percentage for 2018 reported for comparison. A statistic does not exist for the most recent flu season (2019) because data is not yet available for January through March 2020.

P-value for Patients Vaccinated between Aug. 1 and Mar. 31 of the following year (7e)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 7d, is higher (or lower) than the U.S. value for that year. The footnote for row 7e shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patient Characteristics (7f)

Row 7f reports the percentage of patients in row 7b by age, sex, race and ethnicity, and years of ESRD treatment. State, Network, and U.S. averages for 2019 are given for comparison.

XI. Anemia Management Summaries for Adult Dialysis Patients, 2016-2019

Table 8 reports anemia management measures such as hemoglobin, ESA usage, and a standardized transfusion ratio for each year of the reporting period. Average values for the most current year are also reported among patients in the state, Network, and U.S. The inclusion criteria are described in more detail below.

Hemoglobin and ESA Information (8a-8i)

Eligible hemodialysis patients and patient-months (8a-8b)

The number of adult hemodialysis (HD) patients who had ESRD for more than 90 days and were assigned to the facility for a whole calendar month according to the methods described in Section III for CROWNWeb measures are reported in row 8a. Patients who switch between HD and PD during the month and patients for whom modality is unknown are excluded. The number of eligible patient-months for all adult HD patients is reported in row 8b. Patients may be counted up to 12 times per year.

Hemoglobin (HD; 8c-8d)

The average hemoglobin for adult HD patients at the facility is reported in row 8c and is based only on patient-months in row 8b with values in range (between 5 g/dL and 20 g/dL). The percentages of all patient-months with in-range values, stratified by hemoglobin categories, and other non-valid categories, for each month for the facility are shown in 8d.

ESA prescribed (HD; 8e)

The percentage of patient-months from row 8b for which a HD patient was prescribed an ESA is reported in 8e.

Eligible peritoneal dialysis patients and patient-months (8f-8g)

The number of adult peritoneal dialysis (PD) patients who had ESRD for more than 90 days and were assigned to the facility for a whole calendar month according to the methods described in Section III for CROWNWeb measures are reported in row 8a. Patients who

switch between HD and PD during the month and patients for whom modality is unknown are excluded. The number of eligible patient-months for all adult PD patients is reported in row 8g. Patients may be counted up to 12 times per year.

Hemoglobin (PD; 8h-8i)

The average hemoglobin for adult PD patients at the facility is reported in row 8h and is based only on patient-months in row 8g with values in range (between 5 g/dL and 20 g/dL). The percentages of all patient-months with in-range values, stratified by hemoglobin categories, and other non-valid categories, for each month for the facility are shown in 8i.

ESA prescribed (PD; 8j)

The percentage of patient-months from row 8g for which a PD patient was prescribed an ESA is reported in 8j.

Transfusion Summary for Adult Medicare Dialysis Patients-Overview (8k-8p)

Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g. erythropoiesis-stimulating agents (ESAs), iron). In addition, dialysis patients who are eligible for kidney transplant are at some risk of becoming sensitized to the donor pool through exposure to tissue antigens in blood products, thereby making transplant more difficult to accomplish. Blood transfusions also carry a small risk of transmitting blood borne infections and the development of a reaction to the transfusion. Using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of differences in dialysis facility anemia treatment patterns. This is of particular importance due to recent FDA guidance regarding the use of ESAs and new economic incentives to minimize ESA use introduced by Medicare bundling payment for ESAs. In early 2012, a highly publicized United States Renal Data System (USRDS) study presented at the National Kidney Foundation (NKF) clinical meeting reported increased dialysis patient transfusion rates in 2011 compared to 2010. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for an over-use of blood transfusions to treat ESRD-related anemia. Transfusion summaries for Medicare dialysis patients are reported in the second section of Table 8. Because statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret, the Standardized Transfusion Ratio (STrR) is not calculated if there are fewer than 11 patient-years at risk.

This report includes summaries of the transfusion rates among adult Medicare dialysis patients in your facility, along with comparative state and national data. Because the intention behind the measure is to detect the possibility of underutilization of alternatives to transfusion, patients' time at risk and transfusion events are not included if they occur within one year of diagnoses contraindicating the use of ESAs. In particular, patients' time at risk is excluded beginning with a Medicare claim for hemolytic or aplastic anemia, solid

organ cancer, lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissues, skin, and others), metastatic cancer, and sickle cell anemia. Once a patient is diagnosed with one of these comorbidities, a patient's time at risk is included only after a full year free of claims that list any diagnosis on the exclusions list.

Transfusion rates are similar to hospitalization rates in that patients can be transfused more than once during a year and transfusion data are not always as complete as mortality data. As with the hospitalization statistics, this section of the table should ideally include only patients whose Medicare billing records include all transfusions for the period. To achieve this goal, we apply the same rules as for hospitalization and require that patients reach a certain level of Medicare-paid dialysis bills to be included in transfusion statistics, or that patients have Medicare inpatient claims during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period is considered 'eligible'; a month is deemed eligible if it is within two months of a month having at least \$1,200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. Additionally, months identified as having Medicare Advantage according to the Medicare Enrollment Database (EDB) coverage were excluded. In setting this criterion, our aim is to achieve completeness of information on transfusions for all patients included in the years at risk.

The expected national rates are calculated from Cox models (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994) which make adjustments for patient age, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, BMI at incidence, and calendar year. Like the SMR, SHR, and SRR, the STrR is intended to compare your facility's observed number of transfusions to the number that would be expected if patients at your facility were instead subject to the national average transfusion rates, adjusted for the patient characteristics described above.

Adult Medicare Dialysis Patients (8k)

The number of adult Medicare dialysis patients included in the transfusion summaries (8k) is generally smaller than the number of patients included in the mortality and hospitalization summaries (Tables 3 and 4) because of the exclusion criteria.

Patient Years at Risk (8l)

The number of patient years at risk indicates the total amount of time patients were followed in this table's analyses. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: a Medicare claim indicating a diagnosis on the exclusions list, three days prior to a kidney transplant, death, end of facility treatment, or December 31 of the year. Patients whose time at risk was terminated due to a comorbidity on the exclusions list will have future time at risk included beginning after a full year free of claims with diagnoses on the exclusions list. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at your facility.

Total Transfusion Events (8m)

This is the total number of transfusion events during eligible time-at-risk among the adult Medicare dialysis patients assigned to this facility. The total number of transfusion events includes multiple transfusions (i.e., second, third, etc. transfusions for the same patient). If there was more than one transfusion event identified from inpatient or outpatient claims on the same day, only one transfusion event was counted per day.

Our method for counting transfusion events relies on a conservative counting algorithm and, because of the way transfusion information is reported in Medicare claims, we use different rules for counting transfusion events, depending on whether or not the event occurs in the inpatient setting, or an outpatient setting. The most common way that events are reported on claims is by reporting a revenue center, procedure, or value code (inpatient claims) or for outpatient claims, reporting Healthcare Common Procedure Coding System (HCPCS) codes with at least one revenue center codes.

One “transfusion event” is counted per inpatient claim if one or more transfusion-related revenue center, procedure or value codes are present. We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center, procedure and value codes reported so that the number of discrete events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood. This results in a very conservative estimate of blood transfusions from inpatient claims.

Transfusion events are not common in outpatient settings, but similar rules apply. One or more transfusion-related HCPCS codes with at least one transfusion-related revenue center codes, or one or more transfusion-related value codes listed on an outpatient claim are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, 3 units of blood would be counted as a single transfusion event.

A detailed list of procedure codes, value codes, and HCPCS codes used to identify transfusion events is included in a separate document available at www.Dialysisdata.org under the DFR Methods heading.

Expected Total Transfusion Events (8n)

We calculated the expected number of transfusion events among Medicare dialysis patients in a facility based on national rates for transfusion events in the same year. The expected number of transfusion events is calculated from a Cox model, adjusting for patient age, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, BMI at incidence, and calendar year. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years, and 5 years and transfusion rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the adjusted national transfusion rate for that interval, and a sum over the intervals gives the expected number of transfusions for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 8n.

Standardized Transfusion Ratio (STrR) (8o)

The STrR is calculated by dividing the observed total transfusions in 8m by the expected total transfusions in 8n. As with the SMR and SHR, the STrR enables a comparison of your facility's experience to the national average. A value of less than 1.0 indicates that your facility's total number of transfusion events was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your facility had a rate of total transfusion events higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI in your facility. Additionally, the estimate is compared to the US transfusion rates for the same year.

Confidence Interval (Range of Uncertainty) for STrR (8o)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true ratio of facility-to-national transfusion rates, in light of the observed STrR. The upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

P-value for STrR (8p)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of transfusion rates for your facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the STrR would, just by chance, deviate from 1.00 as much as does the observed STrR, and is sometimes naively interpreted as the probability that the true STrR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the STrR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of transfusion rates truly differs from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between your facility's transfusion rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more statistically significant the difference between national and individual facility transfusion rates is. A small p-value helps rule out the possibility that an STrR's variance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between your facility's transfusion rates and the nation's.

The STrR's actual quantitative value reflects the clinical importance of the difference between your facility's and the nation's transfusion rates. An STrR that differs greatly from 1.00 is more important than an STrR in the range of 0.95 to 1.05.

XII. Dialysis Adequacy Summaries for All Dialysis Patients, 2016-2019

Table 9 report measures of dialysis adequacy separately for hemodialysis (HD) and peritoneal dialysis (PD) patients. If a patient switched modality during the year, that patient would be counted as both an HD and a PD patient.

Hemodialysis (HD) Adequacy (9a-9k)

Eligible Adult HD Patients (9a-9b)

This section of the table is based on information collected in CROWNWeb. Measures reported in 9a include 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 for CROWNWeb measures. The number of eligible patient-months for adult hemodialysis patients is reported in row 9b. 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 12 times per year.

Serum albumin for adult HD patients (9c-9e)

Serum albumin was assessed among all eligible HD patient-months reported in 9b and was characterized into five mutually exclusive categories. Average serum albumin is reported in 9c and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 9d. The percentage of all patient-months with serum albumin less than 4.0 g/dL is reported in 9e. 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.

Ultrafiltration rate for adult HD patients (UFR; 9f-9g)

The ultrafiltration rate (UFR) was assessed among all eligible HD patients in 9a 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 average UFR for HD adult patients is reported in 9f and is based only on eligible patient-months in 9b with in-range values. The percentages of all patient-months with in-range values stratified by UFR categories, and missing/out-of-range values, for each month for the facility are shown in 9g. When multiple values were submitted for the patient (by any facility) during the month, the last value reported was selected.

Kt/V for adult HD patients (9h-9k)

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

This section of the table is primarily based on information collected in CROWNWeb. If Kt/V was missing or out of range in CROWNWeb during the reporting month, the last valid Kt/V value collected for the patient during the reporting month according to paid, type-72 Medicare dialysis claims was selected (if available). Additional details are provided below.

Eligible patients were 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 (9h). Patient-months

were excluded from the denominator if there was evidence the patient was not dialyzing thrice weekly anytime during the month. 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 for CROWNWeb measures. A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 9h. Patients may be counted up to 12 times per year.

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 (or pediatric in-center HD for pediatric HD measure) 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: $7 * (\# \text{ of HD sessions} / \# \text{ of days})$. 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.

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 ($Kt/V > 5.0$) 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 reported in row 9i 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 average Kt/V for HD adult patients at the facility is reported in row 9j and is based only on patient-months in 9h with Kt/V values in range. The percentages of all patient-months with in range values stratified by Kt/V categories, and missing/out of range values, for each month for the facility are shown in 9k. Patients with missing or out of range Kt/V ($Kt/V > 5.0$) values from either data source (CROWNWeb or Medicare claims) (9k) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected.

Peritoneal Dialysis (PD) Adequacy (9l-9r)

Eligible Adult PD Patients (9l-9m)

This section of the table is based on information collected in CROWNWeb. Measures reported in 9l include 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 for CROWNWeb measures. The number of eligible patient-months for adult hemodialysis patients is reported in row 9m. Patients may be counted up to 12 times per year.

Kt/V for adult PD patients (9n-9o)

(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 ($Kt/V > 8.5$) 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 reported in row 9m 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 average Kt/V for PD adult patients at the facility is reported in row 9n and is based only on patient-months in 9m with Kt/V values in range. The percentages of all patient-months with in-range values stratified by Kt/V categories, and missing/out-of-range values, for each month for the facility are shown in 9o. Patients with missing or out of range Kt/V ($Kt/V > 8.5$) values from either data source (CROWNWeb or Medicare claims) (9o) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected.

Serum albumin for adult PD patients (9p-9r)

Serum albumin value was assessed among all eligible PD patient-months reported in 9m and was characterized into five mutually exclusive categories. Average serum albumin is reported in 9p and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 9q. The percentage of all patient-months with serum albumin less than 4.0 g/dL is reported in 9r. 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.

XIII. Mineral Metabolism for All Adult Dialysis Patients, 2016-2019

Table 10 reports measures of mineral metabolism for adult dialysis patients. The statistics in this table are based on information collected in CROWNWeb. Statistics reported for each year, 2016-2019, along with regional and National averages for the most current year.

Eligible patients and patient-months (10a-10b)

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 year is reported in row 10a. 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 for CROWNWeb measures. Patients who switch between HD and PD during the month are included. Patients for whom modality is unknown are excluded from calculations. The

number of patient-months for all adult patients is reported in row 10b. Patients may be counted up to 12 times per year.

Phosphorus (10c-10d)

The average phosphorous for HD and PD adult patients at the facility is reported in row 10c and is based only on patient-months with values in range (0.1 mg/dL to 20 mg/dL); The patient counts differ from those reported in row 10b since phosphorus summaries include patient-months within the first 90 days of ESRD and exclude patients receiving home hemodialysis anytime during the month. Values outside of this range are considered missing. The percentages of all patient-months with in-range values stratified by phosphorus categories, and other non-valid categories, for each month for the facility are shown in 10d. 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.

Calcium uncorrected (10e-10f)

The average uncorrected calcium value for HD and PD adult patients at the facility is reported in row 10e and is based only on patient-months in row 10b with values in range (0.1 mg/dL to 20 mg/dL). Values outside of this range are considered missing. The percentages of all patient-months with in range values stratified by uncorrected calcium categories, and other non-valid categories, for each month for the facility are shown in 10f. 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.

Average uncorrected serum or plasma calcium > 10.2 mg/dL (10g)

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 10g. This value is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period among eligible patients reported in 10b who are 18 years or older two months prior to the reporting month. In other words, the denominator for this measure is a subset of the patient-months in 10b.

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.

XIV. Vascular Access Information for All Dialysis Patients and Access-Related Infection for All Medicare Dialysis Patients, 2016–2019

Table 11 reports vascular access information and access-related infection summaries. The statistics in this table are reported for each year, 2016-2019, along with regional and National averages for the most current year.

Vascular Access Information (11a-11j)

The statistics in this section of the table are based on information collected in CROWNWeb. The Standardized Fistula Rate (SFR) is an adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous (AV) fistula as the sole means of vascular access. SFR 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. The fistula measure adjusts for patient factors where fistula placement may be either more difficult or not appropriate and acknowledges that in certain circumstances an AV graft may be the best access option. This paired incentive structure that relies on both measures (SFR, 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.

Prevalent Adult Hemodialysis Patients (11a)

The prevalent hemodialysis patient count (11a) at a facility includes each unique adult patient (home and 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 under *Patient Assignment Methods for CROWNWeb Measures*.

Prevalent Adult Hemodialysis Patient Months (11b)

The monthly prevalent hemodialysis patient count (11b) at a facility includes all adult patients (home and in-center) who have received hemodialysis at the facility for the entire reporting month according to the methods described above in Section III under *Patient Assignment Methods for CROWNWeb Measures* and was at least 18 years old as of the first day of that month. An individual patient may contribute up to 12 patient months per year. Patient months with a catheter that have 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.

Vascular Access Type in Use (11c)

Row 11c reports the type of vascular access reported by the facility in CROWNWeb during the calendar month. If multiple access types were reported for a month, the most recent non-missing access type was selected. This row reports the percentage of patient months

in 11b in which the patient received dialysis through arteriovenous (AV) fistulae (one or two needles), grafts, catheters or other access types. 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. A patient's vascular access is classified as *Other* if it was different from the above categories (e.g., lifeline). Patients are classified as having missing access types if the vascular access data were not available.

Standardized Fistula Rate (SFR) (11d)

The SFR measure is a standardized rate, in that each facility's percentage of AV fistula in use (11c) is adjusted to the national distribution of covariates (risk factors), with 'national' referring to all-facilities-combined. An AV fistula is considered in use if the CROWNWeb "Access Type IDs" of 14 or 22 has been recorded for a given month, where "14" represents AV fistula only (with 2 needles) and "22" represents AV fistula only with an approved single-needle device. The SFR for a facility is an estimate of what the facility's percentage of AVF would equal if the facility's patient mix was equal to that of the nation as a whole. Risk adjustment is based on a multivariate logistic regression model. The adjustment is made for age, BMI at incidence, nursing home status, nephrologist's care prior to ESRD, duration of ESRD, diabetes as primary cause of ESRD and a set of combined incident and prevalent comorbidities, and an indicator for Medicare coverage for at least 6 months during the past 12 months. This model includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. Common risk effects are assumed in order to improve computational stability in estimating facility-specific effects. SFR is not reported if there are fewer than 11 eligible adult patients in the facility during the year.

P-value for SFR (11e)

The p-value measures the statistical significance of (or evidence against) the hypothesis that the true fistula rate for a facility is the same as (neither higher nor lower than) that of the overall national fistula rate. The p-value is the probability that the observed SFR would deviate from the national rate as much as it does, under the null hypothesis that the two rates are equal. A small p-value (often taken as <0.05) indicates that the observed rate would be highly unlikely under the null hypothesis. The smaller the p-value, the lower the probability that a facility's SFR is equal to the national rate. Note that the p-value is less than 0.05 whenever the confidence interval does not include the national rate. Because the p-value depends on the facility size, a small p-value in a large facility does not necessarily indicate that the difference between one facility's SFR and the national rate is of clinically meaningful difference.

If one facility's SFR is greater than the national rate and statistically significant ($p < 0.05$), its SFR is better than overall national fistula rate. If one facility's SFR is less than the national rate and statistically significant ($p < 0.05$), then is worse than overall national fistula rate. Otherwise, it is the same as overall national fistula rate.

Confidence Interval (Range of Uncertainty) for SFR (11f)

The 95% confidence interval (or range of uncertainty) gives a range of plausible values for the true standardized fistula rate. The upper and lower confidence limits enclose the true rate approximately 95% of the time if this procedure were to be repeated on multiple samples.

Long-Term Catheter Rate (11g)

This row reports the percentage of patient-months in 11b 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 place. 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 place 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.

Incident Hemodialysis Patients (11h)

Row 11h reports the total number of incident hemodialysis patients (adults and pediatrics) at the facility each year. Incident hemodialysis patients are hemodialysis patients (home and in-center) who received their first-ever ESRD treatment during the month for which the data was reported.

Vascular Access Type in Use (11i)

Row 11i reports the first vascular access type recorded in CROWNWeb after first-ever ESRD treatment for the incident patients. This row reports the percentage of incident hemodialysis patients in 11h who received dialysis through AV fistulae (one or two needles), AV grafts, catheters, or other access types. 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. Port access devices are included in the catheter category. A patient’s vascular access is classified as *Other* if it was different from the above categories (e.g., lifeline). Patients are classified as having missing access types if the vascular access data were not available.

Arteriovenous (AV) Fistulae in Place (11j)

Row 11j reports the percentage of incident patients in 11h with an AV fistula in place at the last treatment. Patients with an AV fistula in place are included in this row regardless of whether they received their hemodialysis treatments using the fistula.

Access-Related Infection Summary (11k-11n)

This section of the table includes summaries of dialysis access-related infection rates reported by ICD-9 codes and, beginning on 10/01/2015, ICD-10 codes reported on Medicare dialysis claims for patients with Medicare as their primary insurance.

Similar to the hospitalization and comorbidity tables, the determination of periods of Medicare coverage is based on periods in which the dialysis patient had satisfied the Medicare payment criterion. For each patient, a month is considered ‘eligible’ if it is within two months following a month having at least \$1,200 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. For more information on the Medicare payment criterion, please see Section VII. Additionally, months identified as having Medicare Advantage according to the Medicare Enrollment Database (EDB) coverage were excluded. In setting this criterion, our aim is to achieve completeness of information on access-related infection for all patients included in the years at risk.

Any patient treated with dialysis at a facility during a particular month is included in that facility’s statistics so long as they also meet the Medicare criteria described above for that month. There is no exclusion of the first 90 days of treatment and patients treated at more than one facility in a particular month are included at both facilities that month. For the regional calculations, the month will be included only once for that patient. Treatment modality is identified using a combination of Medicare dialysis claims, the Medical Evidence Form (Form CMS-2728), transplant registration data from the OPTN, and data from the CROWNWeb. Starting with the first date of ESRD service, we determined treatment histories for each patient. Using the above data sources to determine whether a patient has transferred to another treatment modality, CROWNWeb is given precedence.

Dialysis-access related infections are identified by ICD-9 code 996.68 and, beginning on 10/1/2015, by ICD-10 code T8571XA and collected from inpatient, outpatient and physician supplier Medicare claims. For a definition of the ICD-9 and ICD-10 codes, please see the list of diagnostic codes included in a separate document available at www.Dialysisdata.org under the DFR Methods heading.

Infection: Peritoneal Dialysis (PD) (11k-11l)

The number of Medicare PD patients meeting the Medicare payment criterion described above and treated at the facility during at least one month during the year or four year period is reported in row 11k. The total number of months during which each patient is treated with PD at the facility are summed and reported in row 11l.

PD catheter infection rate per 100 PD patient-months (11m)

This statistic shows the rate of PD catheter infection in peritoneal dialysis patients during each year. For each month included in row 11l, the patient is considered to have had a PD catheter infection as defined above during that month. The rate is calculated by summing the patient-months with a PD catheter infection and dividing by the number of eligible PD patient-months in row 11l. The number is then converted to a rate per 100 PD patient-months (11m). Patients can only contribute one dialysis access-related infection to a facility

during a month. If the patient is treated at two facilities with PD in a month with an infection, the infection is counted at both facilities. For the regional summaries, the infection will only be counted once in the region.

P-value (compared to U.S. value) (11n)

We used a one-sided p-value to test the hypothesis that the rate of PD patients with peritoneal dialysis catheter infection per 100 PD patient-months, reported in row 11m, is higher (or lower) than the U.S. value for that year.

XV. Comorbidities Reported on Medicare Claims for Medicare Dialysis Patients Treated as of December 31st of Each Year, 2016–2019

Table 12 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31 of each year (2016-2019) in the facility, with corresponding average values for 2019 among patients in the state, network and U.S. Comorbidities are determined on the basis of each patient's Medicare claims for the period, including inpatient stays, outpatient visits and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9 and ICD-10 diagnostic codes and HCPCS CPT codes used to identify comorbidities is included in a separate document available at www.Dialysisdata.org under the DFR Methods heading.

Like the hospitalization table, this table includes only patients who are covered by Medicare (so that Medicare billing records have complete information about the patient). To achieve this goal, we use the criterion described in Section V for the hospitalization statistics. Patient periods are included if each month in the period is within two months after the end of a month having either a) at least \$900 of Medicare-paid dialysis claims or b) at least one Medicare inpatient claim. This table is then further restricted to patients treated at the facility at the end of the year.

Patients Treated on 12/31 of Year (12a)

Row 12a reports the total number of Medicare dialysis patients treated in the facility on December 31 of each year, according to the conventions described in Section III, who also satisfy the criterion described above for assuring that Medicare claims data are complete for the patient. We based the summaries of the patient characteristics in Table 12 on the patient population count in this row.

Comorbid Conditions (12b)

Row 12b reports the percentage of patients in the facility with each of the comorbid conditions listed.

Average Number of Comorbid Conditions (12c)

Row 12c reports the average number of the comorbid conditions listed in 12b on Medicare claims for patients in the facility.

XVI. Facility Information, 2019

Facility Information (13a-13i)

The first section of Table 13 reports the following information on the facility: ownership type, organization name, initial Medicare certification date, number of stations, types of services provided by the facility, whether the facility provides shifts after 5pm and/or practices dialyzer reuse, the CMS certification number and the National Provider Identifier (NPI) associated with the facility. Information in this table is based on information reported in CROWNWeb as of March 31, 2020 and is not being used for patient placement.. Other CMS certification numbers from which data have been included in this report are also listed in this table.

Long-Term Care (13j-13k)

Information in this section was obtained from questions 18 and 20 on the facility's most recent submission of the CMS Form-3427: ESRD Application and Survey and Certification Report regarding dialysis offered in a long-term care setting.

Patient Placement (13l-13p)

This section of the table reports patient counts according to the Annual Facility Survey (Form CMS-2744) as of May 31, 2020. The table reports the number of patients who were treated in the facility in 2019, and regional averages provided for comparison.

Row 13l reports the number of patients who were treated at the facility during the year. Rows 13m–13n report the percentage of these patients who transferred into the facility or transferred out of the facility during the year. These numbers include both outpatient and home dialysis patients. Row 13o reports the number of patients who were treated as of December 31st. Row 13p reports the percentage of patients who had Medicare coverage, had a Medicare application pending or were non-Medicare patients.

Survey and Certification (13q-13u)

This section of the table reports this facility's latest survey and certification information under the updated ESRD Condition for Coverage (CfC) regulations. If this facility has not been surveyed since January 2009—if its last survey was conducted using the old ESRD regulations—this table contains no facility-level information. We obtain these data from the Quality Improvement and Evaluation System (QIES) Business Intelligence Center (QBIC) as of June 2020.

Row 13q reports the date of the most recent survey, and row 13r reports the type of survey (initial, recertification or termination). Row 13s reports the facility's compliance condition after the last survey (met requirements, did not meet requirements but had an acceptable plan of correction, did not meet requirements, or unknown). The total number of CfC deficiencies and standard deficiencies cited during the last survey are reported in rows 13t and 13u, respectively. State, network and national summaries of these deficiency counts are also reported (13t-13u).

XVII. Selected Measures for Dialysis Patients under Age 18 (2016 - 2019)

Table 14 reports selected measures from the Dialysis Facility Report tables restricted to the pediatric population. This table compares the characteristics of the facility's pediatric patients, their patterns of treatment, and patterns in transplantation, hospitalization, and mortality to local and national averages. This table is created only for those facilities that treated at least five pediatric patients over the four year period. All pediatric patients, even those at facilities treating very few pediatric patients are included in the regional averages.

Since item numbers in this pediatric table correspond with the same item number in the parent table, please refer to parent section of this *DFR Guide* for more information on the pediatric measures described below. For example, 14.1a is the same measure as item 1a of Table 1 of the DFR, but restricted to pediatric patients only.

All summaries are reported for the facility each year from 2016-2019, as well as regional averages for 2019 for comparison.

Because pediatric patients make up a very small proportion of dialysis patients nationally, the average number of pediatric patients per facility is extremely low. These average counts are not useful for comparison with counts from facilities treating more pediatric patients, so the state, Network, and U.S. average counts have been suppressed from the table. The regional percentages shown for comparison are calculated based on all pediatric patients in the state, Network or U.S.

Note that for the HD Kt/V section (14.9j), patients must also be receiving treatment at the facility (i.e., Kt/V home HD patients are excluded). For the PD Kt/V section (14.9n), if Kt/V was missing for the reporting month, the most recent available value collected up to 5 months prior was selected when available (as opposed to 3 months' prior for the adult measure).

XVIII. 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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