

**Guide to the Fiscal Year 2022
Region Profiles for
Dialysis Patients and Facilities:**
Overview, Methodology, and Interpretation

September 2021

Guide to the FY 2022 Region Profiles: Overview, Methodology, and Interpretation

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I. Purpose of this Guide and the Region Profile

This guide explains in detail the contents of the FY 2022 Region Profiles that were individually prepared for each of the CMS Regional Offices under contract to the Centers for Medicare & Medicaid Services (CMS). Included here are the profiles' objectives, discussions of methodological issues relevant to particular sections of each profile (e.g., mortality, hospitalization, and transplantation) and descriptions of each data summary.

In the interests of stimulating quality improvement efforts and facilitating the quality improvement process, the Region Profiles make information available to those of you involved in dialysis care and the assurance of its quality. This profile allows you to compare the characteristics of your region's patients, patterns of treatment, and patterns in transplantation, hospitalization, and mortality, relative to national averages. Such comparisons help you to evaluate patient outcomes and account for important differences in the patient mix—including age, sex, race, and patient diabetic status—which in turn enhances each region's understanding of the clinical experience relative to the nation.

What's New in the FY 2022 Region Profile

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 Region Profile for FY 2022:

- COVID-19 patient counts, deaths, and hospitalizations among Medicare dialysis patients are reported in the new Table C1, and among Medicare nursing home (NH) dialysis patients in the new Table C2 (see section XIX. COVID Tables). These summaries are presented for each quarter of 2020, with national averages presented for Quarter 4 (October 2020 – December 2020).
- COVID adjustments are included in the models for Standardized Mortality Ratio (Table 3), Standardized Hospitalization Ratio – Admissions (Table 4), and Standardized Readmission Ratio (Table 4).
- Influenza vaccinations reported in CROWNWeb are now included in Table 6.
- Medicare Advantage patients are now included in the Standardized Hospitalization Ratio (Admissions and Days) in Table 4 and Prevalent Comorbidities in Table 11. As a result, prevalent comorbidity summaries are restricted to inpatient claims.

Data Limitations in FY 2022 Profiles

Due to incomplete CROWNWeb data for 2020 and the COVID Extraordinary Circumstances Exception (ECE) data policy from CMS, the measures reported in the FY 2022 Region Profiles based on calendar year 2020 have been modified to optimize the available information. Here we provide a brief overview of the impact of data incompleteness and exclusions in the FY 2022 Region Profiles.

The CMS ECE policy restricts the use and availability of claims data from March-June 2020 and CROWNWeb clinical data from January-June 2020. In addition, CROWNWeb data incompleteness for the end of 2020 results in:

- Unavailable clinical data for the last four months of the calendar year;
- Unavailable incident dialysis patient data during the last three months of the calendar year;

- An inability to place patients in dialysis facilities for the last two months of the calendar year.

Although this affects all measures, several measures in the Region Profiles do not need incident patients or patient assignment through the end of 2020 because of the 90-day new patient rule and 60-day transfer rules. (Please see the section entitled “General Inclusion Criteria for Dialysis Patients” for details on the 90-day and 60-day rules.) Information on hospitalizations, transplants, wait listing, nursing home, and deaths are available through the end of 2020. CROWNWeb clinical data are only available for July and August 2020 (due to both ECE and data incompleteness). A summary of data available for 2020 measures reported in the FY 2022 Region Profiles is provided in the table below. Table footnotes provide additional information for specific measures impacted by the data limitations.

Incorporating COVID-19 Data Exclusions

Data from January 2020 – June 2020 CROWNWeb clinical data will be excluded from all calculations. This affects summaries for measures as applicable: Influenza Vaccination reported in CROWNWeb (Table 6); Anemia Management - Hemoglobin (Table 7); Dialysis Adequacy (Table 8); Mineral Metabolism (Table 9); and Vascular Access (Table 10). PD Kt/V, long-term catheter rates, and influenza vaccination rates for all dialysis patients in 2020 are not available due to insufficient data. Outcomes during the period March 2020 – June 2020 for remaining measures will not be reported. This includes summaries for both adult and pediatric measures as applicable: Mortality (Table 3); Hospitalization including Emergency Department and Readmission statistics (Table 4); Transplantation (Table 5); Waitlist (Table 5); Influenza Vaccination (Table 6); Anemia Management - STRR (Table 7); and Vascular Access – PD Infection (Table 10).

In addition to the March through June 2020 data exclusions, further limitations in data availability result in data being complete only through October 2020 for Transplantation summaries, SRR, and deaths due to infection. The following CROWNWeb clinical measures have data availability limited to July and August 2020: Eligible Patient counts; Arteriovenous Fistula, Ultrafiltration Rate; Hemoglobin; Dialysis Adequacy; Nutrition; and Mineral Metabolism. Two measures, namely, Infection/Dialysis Access: Long-Term Catheter Rate and Dialysis Adequacy: Kt/V (PD) are not reported due to insufficient data availability. The table below summarizes the 2020 data availability for all measures in the FY 2022 DFR Pre-Survey Extract report.

Table of Data Availability for 2020 Summaries in the FY 2022 Region Profiles

Profile Table	2020 Data Availability
Table C1: COVID-19 in Medicare Dialysis Patients, 2020 Table C2: COVID-19 in Medicare Dialysis Patients Treated in Nursing Home Facilities, 2020	January-December (12 months)
Table 1: Summaries for All Dialysis Patients Treated as of December 31	
Table 11: Comorbidities Reported on Inpatient Medicare Claims for Medicare Dialysis Patients	

Profile Table	2020 Data Availability
Table 2: Characteristics of New Dialysis Patients (Form CMS-2728)	January-September (9 months)
Table 3: Mortality Summaries: All Dialysis Patients (SMR) and New Patients (FY 2019 SMR)	January-February, July-December (8 months)
Table 4: Hospitalization Summary: Standardized Hospitalization Ratios (SHRs)	
Table 5: Transplantation Summary for Dialysis Patients (STR)	
Table 5: Summary for New Dialysis Patients (2019 SWR)	
Table 7: Anemia Management: Transfusion (STrR)	
Table 4: Readmission Summaries (SRR)	January 1-30, July-October (5 months)
Table 3: Categories of death (3e-3i, 3p-3s)	January-February, July-October (6 months)
Table 5: Waitlist Summary for All Dialysis Patients (Patients Waitlisted)	
Table 10: Access-Related Infection Summaries for All Medicare Patients	
Table 6: Influenza Vaccination Summary for Medicare Dialysis Patients for August 2019 - March 2020 flu season	January-February (2 out of 3 months)
Table 7: Anemia Management: Hemoglobin	July-August (2 months)
Table 8: Dialysis Adequacy Summaries: HD Kt/V, UFR, and Albumin (HD and PD)	
Table 9: Mineral Metabolism Summaries: Calcium, Phosphorous, Hypercalcemia	
Table 10: Vascular Access Information for All Dialysis Patients and at Incidence (VA types and SFR)	

Claims data from March 2020 – June 2020 will be used for the determination of comorbidities, hospice status and Medicare eligibility. This affects SHR, SRR, STrR, SFR, and Prevalent Comorbidities.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the FY 2022 Region Profiles with funding from the Centers for Medicare & Medicaid Services (CMS).

Each report provides summary data from all Medicare certified dialysis facilities in the region for the years 2017-2020. Patients treated at transplant-only facilities or U.S. Department of Veterans Affairs (VA)-only facilities are not included in these profiles. These summaries are compiled using the the University of Michigan Kidney Epidemiology and Cost Center (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 is the twenty-sixth in this series of individualized reports. We welcome your participation and feedback concerning the clarity, utility, limitations, and accuracy of this profile. 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 that each profile provides, and describes the methodology used to calculate each summary. Sections IV-XVII are organized according to the order of the summaries in the profiles, and may serve as references for their interpretation. Section XVII summarizes the new COVID Tables C1 and C2. This is the only section whereby the table order found in the profiles does not correspond with the section order. These tables are presented after the introductory pages and are found prior to Table 1.

The profile starts with two pages of text highlights for your region, followed by fourteen tables—each with detailed information for your region. Patient counts, deaths, and hospitalizations among Medicare dialysis patients and among Medicare nursing home (NH) dialysis patients are reported in Tables C1 and C2 respectively. These summaries are presented for each quarter of 2020, with national averages presented for Quarter 4 (October 2020 – December 2020). A summary for all dialysis patients as of December 31 is reported in Table 1. Characteristics of new dialysis patients are reported in Table 2. Mortality statistics for all dialysis patients are reported in the first half of Table 3 annually from 2017-2020 with national statistics for 2020 reported for comparison and for new dialysis patients from 2017-2019 with national statistics for 2019 reported for comparison. Tables 4-11 (hospitalization, transplantation, waitlist, influenza vaccination, anemia management, dialysis adequacy, mineral metabolism, vascular access, and comorbidities as they are reported on Medicare claims) are reported for each year 2017-2020 with national statistics reported for 2020. Table 12 reports selected measures restricted to the nursing home population.

Each row of a table in the Region Profile summarizes an item. Your region has a column for each time period. There is also a column for the corresponding national summary. When the statistic reported was a count (n), the national value was usually not printed (n/a). Whenever the statistic was a percent, a rate, or a ratio, the national summary was calculated by pooling together all individual patients in the nation to obtain the estimate.

III. Assigning Patients to Facilities

This section describes the methods we used to assign patients to a facility in order to calculate the summaries appearing in the tables listed below. 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. Patient assignment for each of the remaining Profile tables, as well as the second half of Table 3, is described in the section specific to that table.

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 7: Anemia Management Summaries for Adult Dialysis Patients - Standardized Transfusion Ratio (STrR)

TABLE 11: Comorbidities Reported on Medicare Claims for Medicare Dialysis Patients

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.

General Inclusion Criteria for Dialysis Patients

A patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy. For the purposes of this report, we only entered a patient into the tabulations after that patient had received chronic renal replacement therapy 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, since such patients have incomplete data.

In order to exclude patients who only received temporary dialysis therapy, we assigned patients to a region only if they had been on dialysis there for at least 60 days. This 60 day period was required both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. The Region Profile includes all patients placed in facilities in the region.

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 ensures that we attributed to a facility the sequelae of treatment there, even when a patient

was transferred to another facility (such as a hospital-based region) 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. Region 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 region once the patient had been treated there 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 use him or her in the analysis. When dialysis claims or other evidence of dialysis reappeared, 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 6: Influenza Vaccination Summary for Medicare Dialysis Patients and All Dialysis Patients (the second section)

TABLE 7: Anemia Management Summaries for Adult Dialysis Patients

TABLE 8: Dialysis Adequacy Summaries for All Dialysis Patients

TABLE 9: Mineral Metabolism Summaries for Adult Dialysis Patients

TABLE 10: 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-paid 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 paid 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, 2017-2020

Table 1 summarizes the characteristics of dialysis patients treated on December 31, 2017-2020 in your region with national averages for 2020.

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

Row 1a reports the total number of dialysis patients treated in your 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 your region 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 region (% 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.) For 2020, modality is reported as of October 31, 2020.

V. Characteristics of New Dialysis Patients, 2017-2020 (Form CMS-2728)

Table 2 presents detailed data from the ESRD Medical Evidence Form (Form CMS-2728) on the characteristics of new patients in your region by year. The patients represented in this table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2017 and September 30, 2020. Because of CROWNWeb data incompleteness, incident dialysis patient data for 2020 is available from January through September 2020. 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 your region 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.

COVID-19 Data Exclusions

Table 2 summaries on the characteristics of new patients includes January through September for 2020. The months of October through December 2020 are excluded due to CROWNWeb data incompleteness.

Patient Characteristics (2a-2m)

Row 2a of this table gives the total number of forms submitted by your region 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 through 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 your region 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 your region and the nation.

VI. Mortality Summary for All Dialysis Patients (2017-2020) and New Dialysis Patients (2017-2019)

The first half of Table 3 (rows 3a-3k) provides information about patient mortality for all dialysis patients treated in your region. 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 in your region. For each section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for patients in your region. The SMR compares the observed death rate in the region 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 region (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.

Starting in Fiscal Year 2022, due to the ECE and the COVID-19 pandemic, the expected deaths in 2020 are calculated in a separate Cox model from the expected deaths of 2017 through 2019. Then, the expected deaths for your region are summed across all 4 years before calculating the SMR.

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 regions. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients in a region 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 your region compared to national averages, please consider the role other important factors play within your region.** 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, 2017-2020. U.S. averages are also reported for 2020—the most recent full year. In the second half of Table 3, we reported similar statistics comparing first year mortality for new dialysis patients in your region with national averages. This section of the table allows the region to see how all of the patients who started dialysis in the region fared in their first year of dialysis even if the region is no longer treating some of these patients.

COVID-19 Data Exclusions

The CMS ECE policy restricts the use and availability of claims data from March 2020 through June 2020. Therefore, outcome data from March 2020 through June 2020 are excluded from all calculations due to data exceptions, including time at risk and events. For 2020, Table 3 mortality summaries are based on 8 months which include January, February, and July through December. In Table 3, the measures under Categories of Death (3e-3i and 3p-3s) from the CMS ESRD Death Notification Form (Form-2746) have an additional exclusion of November and December 2020 due to data availability.

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 region while they are treated at that region, entering the analysis for a region only after having been treated there for 60 days and leaving the analysis for a region 60 days after transfer out of the region.

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

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 your region 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 region treatment period (see Section III) and continued until the earliest occurrence of the following: transplant; date of death; end of region treatment period; or December 31 of the year. A patient may have been treated in facilities in one region for multiple periods during the same year; patient-years at risk include time at risk for all periods of treatment at facilities in the region.

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 region, 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 region 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., 2008; 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 BMI at incidence (BMI = weight (kg)/ height² (m²)). We also controlled for age-adjusted population death rates by region and race based on the U.S. population in 2014-2016 (National Center for Health Statistics, 2017) and the monthly county level COVID-19 case rate (<https://coronavirus.1point3acres.com>) in 2020. 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 in your region.

Categories of Death (3e-3i)

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, 3g, and 3h, we considered all causes of death (primary and secondary) provided on the form. Row 3f-3h report the percentages of deaths in 3c listed as due to infection, cardiac causes, and liver disease. Row 3i 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 different regions 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 your region. 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) (3j)

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 your region, as compared to the national death rate in the same year. Qualitatively, the degree to which the region's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2017-2020 national death rates for patients with the same characteristics as those in your region. Similarly, the degree to which the region'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 your region.

As regiond previously, we adjusted the SMR for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and population death rates. The SMR indicates whether patients treated in your region had higher or lower mortality than expected when adjusted for these factors.

Detailed statistical methodology for the SMR is included in a separate document titled *Technical Notes on the Standardized Mortality Ratio for the Dialysis Region Reports*. This document and

an accompanying Microsoft Excel spreadsheet are available on the Dialysis Reports Web site at www.dialysisdata.org under the DFR Methodology heading.

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

We calculated the national summary SMR as the ratio of the total number of observed deaths among patients in the nation to the number of expected deaths among patients in the nation (3c/3d).

Random variation

The SMR estimates the true ratio of death rates in your region relative to the national death rates. An SMR value that differs from 1.00 indicates that your region'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, your region's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between your region's death rates and the nation's.

P-value (3k)

The Region Profile uses more conservative criterion for identifying exceptional SMR values in comparison to the criterion used for the DFR. The DFR identifies SMR values significantly different (higher or lower) than 1.00, while the Region Profile identifies SMR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SMR that is statistically significant ($p < 0.05$) and regions with an SMR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of death rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SMR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SMR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 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 is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SMR of 1.06 would indicate that the region's high death rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SMR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's death rates and 0.95 or 1.05.

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

Patients for First Year Mortality (3l)

Row 3k of this table gives the total number of forms for new dialysis patients submitted by your region 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, 2017 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 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 region. For the first year mortality statistics, all of a particular patient's time at risk is included in the report for their initial region regardless of whether the patient was treated in that region 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 and the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2008; Andersen, 1993; Collett, 1994). We adjusted the Cox model for age, race, ethnicity, sex, diabetes, 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 region and race based on the U.S. population in 2014-2016 (National Center for Health Statistics, 2017).

Categories of Death (3p-3s)

Row 3p reports the percentage of new 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. Rows 3q-3s report the percentage of deaths in 3n listed as due to infection, due to cardiac causes or due to liver disease for either the primary or one of the secondary causes of death.

Information on category of death may help you interpret the SMR value for new dialysis patients for your region. 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.

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

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 your region, as compared to the national death rate. Qualitatively, the degree to which your region's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the national death rates for new dialysis patients with the same characteristics as those in your region.

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 population death rates. The SMR indicates whether patients treated in your region had higher or lower mortality than expected when adjusted for age, race, ethnicity, sex, diabetes, years of ESRD, nursing home status, comorbidities, BMI, and population death rates.

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

We calculated the national summaries as the ratio of the total number of observed deaths among patients in the nation to the number of expected deaths among patients in the nation ($3m/3n$).

P-value (3u)

The Region Profiles use a more conservative criterion for identifying exceptional SMR values in comparison to the criterion used for the DFR. The DFR identifies SMR values significantly different (higher or lower) than 1.00, while the Region Profile identifies SMR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SMR that is statistically significant ($p<0.05$) and regions with an SMR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of death rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SMR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SMR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 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 is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SMR of 1.06 would indicate that the region's high death rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SMR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's death rates and 0.95 or 1.05.

VII. Hospitalization Summary for Medicare Dialysis Patients, 2017-2020

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 9 days in the hospital per year (USRDS, 2020). 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 the hospitalization rates among dialysis patients in your region, along with comparative national data.

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 are either enrolled in Medicare Advantage, or reach a certain threshold of Medicare dialysis and inpatient claims. 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 the patient is enrolled in Medicare Advantage for that month, or 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. 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 4f, summaries of hospital admissions are reported in Rows 4g through 4m, and summaries of ED visits are reported in Rows 4n through 4t. These statistics include multiple admissions or ED visits per patient. For each region, 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 region's observed number of events (be it admissions, days

hospitalized, or ED visits) to the number that would be expected if patients at the region were instead subject to the 2017-2020 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, prevalent comorbidities, and Medicare Advantage status. 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.

We report the hospitalization and ED visit summaries for each year from 2017-2020. We also report 2020 U.S. averages for the hospitalization and ED visit summaries for comparison.

Detailed statistical methodology for the SHR is included in a separate document titled *Technical Notes on the Standardized Hospitalization 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.

COVID-19 Data Exclusions

For the hospitalization summaries (including days hospitalized, admission, and emergency department statistics), outcome data from March 2020 through June 2020 are excluded from all calculations due to CMS ECE policy for data exceptions. This includes all time at risk and events. Determination of past year comorbidities, and Medicare eligibility adjustments includes March through June 2020 claims data.

For readmission statistics in 2020 (including SRR), all index discharges between January 31st through February 29th were also excluded since the 30-day follow-up period from those discharges would have occurred during the CMS ECE data exception period. Furthermore, readmission statistics exclude indexed discharges from November through December 2020 because during these months, patients are unable to be properly assigned to facilities due to CROWNWeb data incompleteness. In total, the readmissions statistics for 2020 include 5 months of data: January 1st through January 30th, and July through October.

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-4x) on the dialysis patients who received treatment in the region 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.

Days Hospitalized Statistics (4c-4f)

Total Days Hospitalized (4c)

This represents the total number of days that Medicare dialysis patients in the region 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 region 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, prevalent comorbidities, and Medicare Advantage status. 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. The prevalent comorbidities are based on inpatient claims only. Medicare Advantage status is determined on a patient-month level, and is based on the Medicare Enrollment Database (EDB). 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 for Days (4e)

The SHR (Days) is calculated by dividing the observed total days hospitalized by the expected total days hospitalized. As with the SMR, it enables a comparison of your region'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 your region 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 your region 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, prevalent comorbidities, and Medicare Advantage status. 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 in your region beyond the overall US trend over time. In other words, if the SHR for your region decreases over the time period, this means that hospitalization in your region has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization in your region decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for your region would be the same for each year.

P-value (4f)

The Region Profiles use a more conservative criterion for identifying exceptional SHR values in comparison to the criterion used for the DFR. The DFR identifies SHR values significantly

different (higher or lower) than 1.00, while the Region Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SHR that is statistically significant ($p < 0.05$) and regions with an SHR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of hospitalization rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SHR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SHR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 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 is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SHR of 1.06 would indicate that the region's high hospitalization rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SHR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's hospitalization rates and 0.95 or 1.05.

Hospitalization Admissions Statistics (4g-4m)

Total Admissions (4g)

This is the total number of inpatient hospital admissions among the Medicare dialysis patients in this region. 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 (4h)

We calculated the expected number of hospital admissions among Medicare dialysis patients in the region 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, prevalent comorbidities, and Medicare Advantage status and COVID-19 status. 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. The prevalent comorbidities are based on inpatient claims only. Medicare Advantage status is determined on a patient-month level, and is based on the Medicare Enrollment Database (EDB). 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 4h.

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

The SHR (Admissions) is calculated by dividing the observed total admissions by the expected total admissions. As with the SMR, it enables a comparison of your region's experience to the national average. A value of less than 1.0 indicates that your region's total number of admissions

was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your region 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, prevalent comorbidities, and Medicare Advantage status and COVID-19 status. 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 in your region beyond the overall US trend over time. In other words, if the SHR for your region decreases over the time period, this means that hospitalization in your region has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization in your region decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for your region would be the same for each year.

P-value (4j)

The Region Profiles uses more conservative criterion for identifying exceptional SHR values in comparison to the criterion used for the DFR. The DFR identifies SHR values significantly different (higher or lower) than 1.00, while the Region Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SHR that is statistically significant ($p < 0.05$) and regions with an SHR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of hospitalization rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SHR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SHR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 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 is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SHR of 1.06 would indicate that the region's high hospitalization rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SHR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's hospitalization rates and 0.95 or 1.05.

Patients with Septicemia (4k)

Row 4k reports the percentage of patients in 4a who had septicemia reported as one of the diagnoses on a hospital bill with a start date during a period of treatment at a region in your region. We first identified diagnosis codes ICD-9 and ICD-10 (beginning on 10/01/2015) associated with this diagnosis and then looked for these codes on the hospital bills (in any position on the list of diagnoses). Row 4k includes all bills, even if the patient did not leave the hospital in between bills.

One Day Admissions (4l)

We reported the percentage of total inpatient hospital admissions 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 (days per admission) (4m)

As a measure of severity of hospitalizations, we reported the average duration (in days) of hospital admissions among Medicare dialysis patients assigned to facilities in the region. 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.

Admissions that Originated in the ED (4n)

Row 4n 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).

Emergency Department (ED) Statistics (4o-4t)***Total ED Visits (4o)***

This is the total number of emergency department (ED) visits among the Medicare dialysis patients in the region. 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 (4p)

We calculated the expected number of ED visits among Medicare dialysis patients in the region 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 4p.

Standardized Hospitalization Ratio for ED (4q)

The SHR (ED) is calculated by dividing the observed total ED visits in 4o by the expected total ED visits in 4p. As with the SMR, it enables a comparison of your region's experience to the national average. A value of less than 1.0 indicates that your region's total number of ED visits was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your region 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 at incidence, 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 your region beyond the overall US trend over time. In other words, if the SHR for your region decreases over the time period, this means that ED visits in your region has decreased more over that time period than the overall US average ED visits decreased. If ED visits in your region decreased over the four-year period at the same rate that overall US ED visits decreased over this time period, the SHR for the region would be the same for each year.

P-value (4r)

The Region Profiles uses more conservative criterion for identifying exceptional SHR values in comparison to the criterion used for the DFR. The DFR identifies SHR values significantly different (higher or lower) than 1.00, while the Region Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SHR that is statistically significant ($p < 0.05$) and regions with an SHR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of ED visit rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SHR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SHR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 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 is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SHR of 1.06 would indicate that the region's high ED visit rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SHR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's ED visit rates and 0.95 or 1.05.

Medicare Dialysis Patients with ED Visit (4s)

Row 4s reports the percentage of Medicare dialysis patients in row 4a 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. Medicare Advantage patients are excluded from this summary.

ED visits that result in hospitalization (4t)

Row 4t reports the percentage of ED visits in row 4n that resulted in an inpatient admission.

Readmission Statistics (4u-4x)

Index discharges (4u)

Index discharges are those hospitalizations that serve as starting points for identifying readmissions. This is the number of Medicare-covered hospital discharges (including Medicare Advantage) occurring at acute-care hospitals in the calendar year for dialysis patients in the region. 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 (4v)

The number of readmissions for the region 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 (4w)

We calculated the number of hospital readmissions that would be expected given the set of index discharges of dialysis patients in the region 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 as cause of ESRD, 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, and COVID-19 diagnosis. For each patient, the expected number is adjusted for the characteristics of that patient.

Standardized Readmission Ratio (SRR) (4x)

We calculated the SRR by dividing the observed total readmissions in 4v by the expected total readmissions in 4w. As with the SMR and SHR, the SRR compares the region's experience to what should be expected on the basis of the national norm. A value of less than 1.0 indicates that the region's total number of readmissions is less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the region 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 4w. In addition, the estimate is compared with the US readmission rates for the same year.

VIII. Transplantation and Waitlist Summaries for All Dialysis Patients (2017-2020) and New Dialysis Patients (2017-2019) 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). 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. We report the transplant summaries for each year from 2017-2020. We also report 2020 U.S. averages for the transplant summaries for comparison. The STR is only calculated if there are at least 3 expected events for the time period.

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 preemptive transplant or a transplant within the first three months of treatment. You will find these statistics useful in that they allow a region 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.

COVID-19 Data Exclusions

Outcome data from March 2020 through June 2020 are excluded from all calculations due to CMS ECE policy for data exceptions. This includes all time at risk and events. Summaries for Waitlist: All Dialysis Patients (5i-5m) also exclude data between November and December 2020 due to data exceptions.

Transplantation Statistics (5a-5h)

Eligible Patients (5a)

Row 5a reports the number of dialysis patients under age 75. The transplantation summaries were assigned to the region 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 the region who received a transplant.

Eligible Patients (5c)

Row 5c 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 (5c) 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 (5d)

We limited our calculations for 5d 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 region treatment period

(see Section III) and continued until the earliest of the following occurrences: transplant; date of death; end of the region treatment period; or December 31. A patient may have been treated in facilities in one region 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 in that region.

Actual First Transplants (5e)

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

Expected First Transplants (5f)

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 in your region, with corresponding regional and national averages.

Standardized Transplantation Ratio (5g)

The Standardized Transplantation Ratio (STR) is the ratio of the actual number of first transplants (5e) to the expected number (5f) of first transplants for the region, given the age composition of the region's patients. The STR is adjusted for patient age and calendar year only.

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

The national STR is calculated as the ratio of the total number of first transplants in the nation to the total expected number of first transplants in the nation.

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.

P-value (5h)

The Region Profiles uses more conservative criterion for identifying exceptional STR values in comparison to the criterion used for the DFR. The DFR identifies STR values significantly

different (higher or lower) than 1.00, while the Region Profile identifies STR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an STR that is statistically significant ($p < 0.05$) and regions with an STR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of transplantation rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the STR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed STR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 and when one uses more patient data to calculate the STR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of transplantation rates is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a STR of 1.06 would indicate that the region's high transplantation rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an STR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's transplantation rates and 0.95 or 1.05.

Waitlist Statistics (5i-5s)

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.

Rows 5i-5m provide a snapshot of transplant waitlist for prevalent patients at the end of each month. For this section, both unadjusted (5k) and age-adjusted (5m) percentage of patient-months waitlisted from the region are shown for each year from 2017-2020. U.S. averages for 2020 are reported for comparison.

Rows 5n-5s provide information about transplant waitlist in the first year of dialysis for patients from the region starting dialysis for the first time. For this section, we have calculated the Standardized First Kidney Transplant Waitlist Ratio (SWR) for each year from 2017-2019 to compare the observed event rate to the expected event rate for incident dialysis patients in your region. U.S. averages for 2019 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.

Percent Waitlisted Among Prevalent Dialysis Patients (5i-5m)

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 (5i-5j)

The number of eligible dialysis patients in the region who were under age 75 assigned to facilities in this region for at least one month during the year are reported in row 5i. For each month, a patient is included in the prevalent waitlist summary if they were indicated as receiving treatment at a facility in this region 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 16u and 21), and/or active hospice patients reported on Medicare final action claims data were excluded. Row 5j 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 (5k)

Row 5k reports the percentage of patient-months among eligible patient-months reported in 5j 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 (5l)

Row 5l reports the percentage of patient-months among eligible patients from row 5j 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 5k, patients may be counted up to 12 times per year.

Age-adjusted percentage of patient-months waitlisted (5m)

Row 5m reports the percentage of patient-months among eligible patient-months reported in 5j 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 model is fit using Generalized Estimating Equations (GEE; Liang and Zeger, 1986) in order to account for the within-patient correlation across months. Results are averaged across eligible patient-months (5j). The age-adjusted percentage waitlisted is restricted to regions with 11 or more eligible patients (5i) during the reporting time period.

Standardized First Kidney Transplant Waitlist Ratio (SWR; 5n-5s)

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 region based on the facility information entered on the Medical Evidence 2728 form.

Eligible patients (5n)

The incident waitlist section includes ESRD patients, under the age of 75, who have initiated dialysis during the reporting period. Patients meeting any of the following criteria were excluded: i) patients on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis; ii) patients admitted to a skilled nursing facility (SNF) at incidence on the CMS Medical Evidence Form 2728 (questions 16u and 21) or previously according to the CMS long term care minimum data set ; and/or iii) active hospice patients at time of dialysis initiation based on Medicare final action claims data.

Patient-years at risk (5o)

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 5o reports the total patient years at risk for the SWR.

First Waitlist Events (5p)

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 in the region. It is also the numerator of the SWR.

Expected 1st Waitlist Events (5q)

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 5q reports the total number of patients expected to be either waitlisted or recipients of living donor transplants from the region.

Standardized Waitlist Ratio (SWR) (5r)

For each region, the SWR is calculated to compare the observed number of waitlist events in a region 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 (5p) divided by the expected number of transplant waitlist events or living donor transplant events (5q) in the region.

For national summaries, we calculated the SWR as the ratio of the total number of observed events to the number of expected events in the nation.

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 (5s)

The Region Profiles uses more conservative criterion for identifying exceptional SWR values in comparison to the criterion used for the DFR. The DFR identifies SWR values significantly different (higher or lower) than 1.00, while the Region Profile identifies SWR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an SWR that is statistically significant ($p < 0.05$) and regions with an SWR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of transplantation waitlist rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the SWR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed SWR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 and when one uses more patient data to calculate the SWR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of transplantation waitlist rates is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a SWR of 1.06 would indicate that the region's high transplantation waitlist rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an SWR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's transplantation waitlist rates and 0.95 or 1.05.

X. Influenza Vaccination Summary for Medicare Dialysis Patients and All Dialysis Patients, Flu Seasons August 2017-December 2020

The first section of this table reports influenza vaccination summary statistics identified on Medicare claims for Medicare dialysis (excluding Medicare Advantage) patients treated on December 31st of each year in your region. The second section separately reports summaries for all dialysis patients, regardless of Medicare status, based on vaccinations reported in CROWNWeb. These include all HD, PD, and uncertain dialysis patients greater than six months of age treated at a facility for at least one full reporting month during the corresponding flu season.

For the 'Medicare Dialysis Patients' section of the table, average values for the most current year are also reported among patients in 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).

Medicare Dialysis Patients (6a-6f)

COVID-19 Data Exclusions

Medicare claims from March 2020 through June 2020 are excluded from all calculations due to data exceptions.

Eligible Patients on Dec. 31 (6a)

Row 6a reports the number of patients who are covered by Medicare on December 31st. 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 more than \$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 Medicare 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 first section. 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 6a reports the number of Medicare dialysis patients included in the first section of influenza vaccination summaries.

Patients Vaccinated between Aug. 1 and Dec. 31 (6b)

Row 6b reports the percentage of patients in 6a who had a Medicare claim for vaccination performed between August 1st and December 31st, with the corresponding national percentage for 2020 reported for comparison.

P-value for Patients Vaccinated between Aug. 1 and Dec. 31 (6c)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 6b, is higher (or lower) than the U.S. value for that year. The footnote for row 6c 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 (6d)

Row 6d reports the percentage of patients in 6a who had a Medicare claim for vaccination performed between August 1st and March 31st of the following year, with the corresponding national percentage for 2019 reported for comparison. A statistic does not exist for the most recent flu season (2020) because data is not yet available for January through March 2021.

P-value for Patients Vaccinated between Aug. 1 and Mar. 31 of the following year (6e)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 6d, is higher (or lower) than the U.S. value for that year. The footnote for row 6e shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patient Characteristics (6f)

Row 6f reports the percentage of patients in row 6b by age, sex, race and ethnicity, and years of ESRD treatment. The national average for 2020 is given for comparison.

All Dialysis Patients (6g-6p)***COVID-19 Data Exclusions***

CROWNWeb clinical data from January 2020 through March 2020 and September 2020 through December 2020 are excluded from applicable calculations below due to data exceptions. Therefore, summaries for the 2020 Half Flu Season in row 6h and the 2019 Full Flu Season in row 6m are not reported.

Eligible patients between Aug. 1 and Dec. 31 (6g)

Row 6g reports the number of patients greater than six months of age at the beginning of the flu season and treated for at least one full reporting month during the flu season between August 1st and December 31st according to the methods described in Section III for CROWNWeb measures. Patients with a medical contraindication to flu vaccination are excluded in 6g and reported in 6k.

Patients vaccinated between Aug. 1 and Dec. 31 (6h)

Row 6h reports the percentage of patients in 6g who had a vaccination reported in CROWNWeb that was performed between August 1st and December 31st.

P-value for patients vaccinated between Aug. 1 and Dec. 31 (6i)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 6h, is higher (or lower) than the U.S. value for that year. The footnote for row 6i shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patients that declined vaccination between Aug. 1 and Dec. 31 (6j)

Row 6j reports the percentage of patients in 6g that declined vaccination between August 1st and December 31st.

Patients excluded due to medical contraindication between Aug. 1 and Dec. 31 (6k)

Row 6k reports the number of patients that were excluded from row 6g due to a medical contraindication.

Eligible patients between Aug. 1 and Mar. 31 of the following year (6l)

Row 6l reports the number of patients greater than six months of age at the beginning of the flu season and treated for at least one full reporting month during the flu season between August 1st and March 31st of the following year according to the methods described in Section III for CROWNWeb measures. Patients with a medical contraindication to flu vaccination are excluded in 6l and reported in 6p.

Patients vaccinated between Aug. 1 and Mar. 31 of following year (6m)

Row 6m reports the percentage of patients in 6l who had a vaccination reported in CROWNWeb that was performed between August 1st and March 31st of the following year, with the corresponding national percentage for 2019 reported for comparison.

P-value for patients vaccinated between Aug. 1 and Mar. 31 of following year (6n)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 6m, is higher (or lower) than the U.S. value for that year. The footnote for row 6n shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patients that declined vaccination between Aug. 1 and Mar. 31 of the following year (6o)

Row 6o reports the percentage of patients in 7l that declined vaccination between August 1st and March 31st of the following year.

Patients excluded due to medical contraindication between Aug. 1 and Mar. 31 of the following year (6p)

Row 6p reports the number of patients that were excluded entirely from row 6l due to a medical contraindication between August 1st and March 31st of the following year.

XI. Anemia Management Summaries for Adult Dialysis Patients, 2017-2020

Table 7 reports anemia management measures such as hemoglobin, ESA usage, and a standardized transfusion ratio for each year of the reporting period. National average values for the most current year is also reported. The inclusion criteria are described in more detail below.

Hemoglobin and ESA Information (7a-7j)***COVID-19 Data Exclusions***

CROWNWeb clinical data from January 2020 through June 2020 and from September through December 2020 are excluded from all calculations due to data exceptions.

Eligible hemodialysis patients and patient-months (7a-7b)

The number of adult hemodialysis (HD) patients who had ESRD for more than 90 days in your region for a whole calendar month according to the methods described in Section III for CROWNWeb measures are reported in row 7a. Only patients who were on HD for the entire month are included. The number of eligible patient-months for all adult patients is reported in rows 7b. Patients may be counted up to 12 times per year.

Hemoglobin (HD; 7c-7d)

The average hemoglobin for HD adult patients in your region is reported in row 7c and is based only on patient-months in row 7b 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 your region are shown in 7d.

ESA prescribed (HD; 7e)

The percentage of patient-months from row 7b for which an HD patient was prescribed an ESA is reported in 7e.

Eligible peritoneal dialysis patients and patient-months (7f-7g)

The number of adult peritoneal dialysis (PD) patients who had ESRD for more than 90 days in your region for a whole calendar month according to the methods described in Section III for CROWNWeb measures are reported in row 7a. Only patients who were on PD for the entire month are included. The number of eligible patient-months for all adult patients is reported in rows 7b. Patients may be counted up to 12 times per year.

Hemoglobin (PD; 7h-7i)

The average hemoglobin for PD adult patients in your region is reported in row 7h and is based only on patient-months in row 7g 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 your region are shown in 7i.

ESA prescribed (PD; 7j)

The percentage of patient-months from row 7b for which a PD patient was prescribed an ESA is reported in 7j.

Transfusion Summary for Adult Medicare Dialysis Patients-Overview (7k-7p)

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 region level, relative to a national standard, allows for detection of differences in dialysis region 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 Regions 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 Table 7.

This report includes summaries of the transfusion rates among adult Medicare dialysis patients in your region, along with comparative region 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 STTrR 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, as described above.

Detailed statistical methodology for the STTrR is included in a separate document titled *Technical Notes on the Standardized Transfusion 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.

COVID-19 Data Exclusions

Outcome data from March 2020 through June 2020 are excluded from all calculations due to CMS ECE policy for data exceptions. This includes all time at risk and events. Determination of

past year comorbidities, and Medicare eligibility adjustments will include March-June 2020 claims data.

Adult Medicare Dialysis Patients (7k)

We based the transfusion summaries (rows 7k-7p) on the dialysis patients who received treatment in the facility according to the conventions described in Section III and only on periods in which dialysis patients had satisfied the Medicare payment criterion. A month is deemed 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. Additionally, months identified as having Medicare Advantage according to the Medicare Enrollment Database (EDB) coverage were excluded for transfusion calculations. The number of adult Medicare dialysis patients included in the transfusion summaries (7k) is generally smaller than the number of patients included in hospitalization summaries (Table 4) because of the Medicare Advantage and prevalent comorbidities exclusion criteria (described above).

Patient Years at Risk (7l)

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 region 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 region 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 region 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 in the region.

Total Transfusion Events (7m)

This is the total number of transfusion events during eligible time-at-risk among the adult Medicare dialysis patients assigned to this region. 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, 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.

If there are more than one transfusion events identified from inpatient or outpatient claims in the same day, we only count one transfusion event per day.

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 (7n)

We calculated the expected number of transfusion events among Medicare dialysis patients in a region 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 7n.

Standardized Transfusion Ratio (STrR) (7o)

The STrR is calculated by dividing the observed total admissions in 7m by the expected total admissions in 7n. As with the SMR and SHR, the STrR enables a comparison of your region's experience to the national average. A value of less than 1.0 indicates that your region'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 region 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 region. Additionally, the estimate is compared to the US transfusion rates for the same year.

P-value for STrR (7p)

The Region Profiles uses more conservative criterion for identifying exceptional STrR values in comparison to the criterion used for the DFR. The DFR identifies STrR values significantly different (higher or lower) than 1.00, while the Region Profile identifies STrR values significantly less than 0.95 or greater than 1.05. This means that few regions will have an STrR that is statistically significant ($p < 0.05$) and regions with an STrR between 0.95 and 1.05 will not have a p-value.

The p-value measures the statistical significance (or evidence) for testing the hypothesis that the true ratio of transfusion rates for the region is lower than 0.95 or higher than 1.05. The p-value is the probability that the STTrR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed STTrR. A smaller p-value tends to occur when the ratio differs more greatly from 0.95 or 1.05 and when one uses more patient data to calculate the STTrR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of transfusion rates is truly less than 0.95 or greater than 1.05. For instance, a p-value of less than 0.05 for a STTrR of 1.06 would indicate that the region's high transfusion rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an STTrR's variance from 0.95 or 1.05 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the region's transfusion rates and 0.95 or 1.05.

XII. Dialysis Adequacy Summaries for All Dialysis Patients, 2017-2020

Table 8 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.

COVID-19 Data Exclusions

CROWNWeb clinical data from January 2020 through March 2020 and September 2020 through December 2020 are excluded from all calculations due to data exceptions. For 2020, dialysis adequacy measures include data from July and August.

Hemodialysis (HD) Adequacy (8a-8j)

Eligible Adult HD Patients (8a-8b)

This section of the table is based on information collected in CROWNWeb Measures reported in this section include adult hemodialysis patients who had ESRD for more than 90 days and in the region for at least one whole calendar month during the year (8a). Patients are assigned to a facility for the reporting month only if they were assigned to the facility in the region 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 8b. 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 (8c-8d)

Serum albumin was assessed among all eligible HD patient-months reported in 8b and was characterized into five mutually exclusive categories. Average serum albumin is reported in 8c and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 8d.

Ultrafiltration rate for adult HD patients (UFR; 8e-8f)

The ultrafiltration rate (UFR) was assessed among all eligible HD patients in 8a 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 8e and is based only on eligible patient-months in 8b 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 region are shown in 8f.

Kt/V for adult HD patients(8g-8j)

(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 in the region for at least one whole calendar month during the reporting period (i.e., 'assigned' facility), and dialyzed thrice weekly (8g). 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 8h. 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: $7 \times (\text{\# of HD sessions} / \text{\# of days})$. 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 ($\text{Kt/V} > 5.0$) 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 8h 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 in your region is reported in row 8i and is based only on patient-months in 8h 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 8j. Patients with missing or out of range Kt/V ($\text{Kt/V} > 5.0$) values from either data source (CROWNWeb or Medicare claims) (8j) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected.

Peritoneal Dialysis (PD) Adequacy (8k-8p)

This section of the table is based on information collected in CROWNWeb. Measures reported in this section include adult peritoneal patients who had ESRD for more than 90 days and were in the facility in the region for at least one whole calendar month during the year (8k). The number of eligible patient-months for adult hemodialysis patients is reported in row 8l. Patients may be counted up to 12 times per year.

Kt/V for adult Peritoneal Dialysis (PD) (8m-8n)

(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 8l 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 in your region is reported in row 8m and is based only on patient-months in 8l 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 your region are shown in 8n. Patients with missing or out of range Kt/V ($Kt/V > 8.5$) values from either data source (CROWNWeb or Medicare claims) (8n) are included in the denominator but not the numerator and therefore may result in a lower percentage than expected.

Serum albumin for adult Peritoneal Dialysis (PD) (8o-8p)

Serum albumin value was assessed among all eligible PD patient-months reported in 8l and was characterized into five mutually exclusive categories. Average serum albumin is reported in 8o and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 8p

Kt/V for All Pediatric Dialysis Patients (8q-8x)

This section of the table provides the same summaries as described in the adult HD and PD Kt/V sections above, but restricted to patients less than 18 years of age. The only difference is the HD summaries are restricted to patients receiving dialysis at the facility (i.e., excludes home HD patients).

XIII. Mineral Metabolism for All Adult Dialysis Patients, 2017-2020

Table 9 report measures of mineral metabolism for adult dialysis patients. The statistics in this table are based on information collected in CROWNWebStatistics reported for each year, 2017-2020, along with regional and National averages for the most current year.

COVID-19 Data Exclusions

CROWNWeb clinical data from January 2020 through June 2020 and September 2020 through December 2020 are excluded from all calculations due to data exceptions. For 2020, mineral metabolism measures include data from July and August.

Eligible patients and patient-months (9a-9b)

The number of adult dialysis patients in your region who had ESRD for more than 90 days and were in a facility for at least one whole calendar month during the year is reported in row 9a. 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 rows 9b. Patients may be counted up to 12 times per year.

Phosphorous (9c-9d)

The average phosphorous for HD and PD adult patients in your region is reported in row 9c 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 9b since phosphorus summaries include patient-months within the first 90 days of ESRD and excludes 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 region are shown in 9d.

Calcium uncorrected (9e-9f)

The average uncorrected calcium value for HD and PD adult patients in your region is reported in row 9e and is based only on patient-months in row 9b 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 region are shown in 9f.

Average uncorrected serum or plasma calcium > 10.2 mg/dL (9g)

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 9g. This value is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period among eligible patients reported in 9b 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 reported in 9b.

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, 2017–2020

Table 10 reports vascular access information and access-related infection summaries. The statistics in this table are reported for each year, 2017-2020, along with regional and National averages for the most current year.

Vascular Access Information (10a-10h)

COVID-19 Data Exclusions

CROWNWeb clinical data from January 2020 through June 2020 and September through December 2020 are excluded from vascular access summaries due to data exceptions. For 2020, vascular access measures include data from July and August. All claims data in 2020 is used for the determination of comorbidities, Medicare eligibility, and hospice status for exclusion and model adjustment.

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 (10a)

The prevalent hemodialysis patient count (10a) in your region includes each unique adult patient (home and in-center) who have received hemodialysis at a 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 (10b)

The monthly prevalent hemodialysis patient count (10b) in your region includes all adult patients (home and in-center) who have received hemodialysis at a facility for the entire reporting month according to the methods described above in Section III under *Patient Assignment Methods for CROWNWeb Measures*. 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 (10c)

Row 10c reports the type of vascular access 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 10b 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). The most recent non-missing vascular access type, regardless of facility, was selected if the access type was missing from a reporting facility. Patients were classified as having missing access types if no previous vascular access data were available.

Standardized Fistula Rate (SFR) (10d)

For each region, the SFR is the average of facility level results in the same region. The SFR measure is a standardized rate, in that each facility's percentage of AV fistula in use 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 , a set of combined incident and prevalent comorbidities, an indicator for having at least one comorbidity, an indicator for Medicare coverage for at least 6 months during the past 12 months or at least 1 month with Medicare Advantage, and an indicator for missing Form CMS-2728. 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.

Long-Term Catheter Rate (10e)

This row reports the percentage of patient-months in 10b in which a patient received dialysis through a catheter for at least three consecutive months (the reporting month and preceding two months) in the same facility. The last vascular access type listed in CROWNWeb during each of these three complete months for the patient was selected to determine whether a catheter was in use. Before indicating that a catheter was present for three consecutive months, we checked that the access type reported on the last day of the month that was three months before the reporting month was also a catheter. A catheter was considered in use if the CROWNWeb "Access Type IDs" of 16, 18, 19, 20, and 21 had been recorded for a given month, where "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown. If there was no CROWNWeb vascular access type entry for a given month, we counted the vascular

access type for that month as a catheter. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

Incident Hemodialysis Patients (10f)

Row 10f reports the total number of incident hemodialysis patients (adults and pediatrics) in the region 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 (10g)

Row 10g 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 10f 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 Placed (10h)

Row 10h reports the percentage of incident patients in 10f 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 (10i-10l)

COVID-19 Data Exclusions

Outcome data from March through June 2020 and from November through December 2020 are excluded in the 2020 infection summaries due to CMS ECE policy for data exceptions and CROWNWeb data limitations. This includes all time at risk and events.

This section of the table includes summaries of dialysis access-related infection rates reported by ICD-9 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 in your region during a particular month is included in that region'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 Methodology heading.

Infection: Peritoneal Dialysis (PD) (10i-10l)

The number of Medicare PD patients meeting the Medicare payment criterion described above and treated in the region during at least one month during the year or four year period is reported in row 10i. The total number of months during which each patient is treated with PD in the region are summed and reported in row 10j.

PD catheter infection rate per 100 PD patient-months (10k)

This statistic shows the rate of PD catheter infection in peritoneal dialysis patients during each year. For each month included in row 10j, 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 10j. The number is then converted to a rate per 100 PD patient-months in row 10k. Patients can only contribute one dialysis access-related infection to a region during a month. If the patient is treated in two regions with PD in a month with an infection, the infection is counted in both regions. For the national summary, the infection will only be counted once.

P-value (compared to U.S. value) (10l)

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 10k, 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, 2017–2020

Table 11 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31 of each year (2017-2020) in the region, with corresponding average values for 2020 among patients in 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 VII 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 \$1,200 of Medicare-paid dialysis claims or b) at least one Medicare inpatient claim. This table is then further restricted to patients treated at the region at the end of the year.

COVID-19 Data Exclusions

There are no data exclusions or limitations in 2020 for Table 11.

Patients Treated on 12/31 of Year (11a)

Row 11a reports the total number of Medicare dialysis patients treated in the region 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 11 on the patient population count in this row.

Comorbid Conditions (11b)

Row 11b reports the percentage of patients in the region with each of the comorbid conditions listed.

Average Number of Comorbid Conditions (11c)

Row 11c reports the average number of the comorbid conditions listed in 11b on Medicare claims for patients in the region.

XVI. Selected Summaries for Nursing Home (NH) Patients, 2017–2020

Table 12 reports selected measures from the Dialysis Facility Report restricted to the nursing home population. Nursing home patients are defined as the patients in CMS Long Term Care Minimum Data Set (MDS) at any time during the reporting period. This table compares the characteristics of the region's nursing home patients, their patterns of treatment, and patterns in comorbidities, hospitalization, and mortality to national averages. All summaries are reported for the region each year from 2017-2020, as well as national averages for 2020 for comparison.

Since item numbers in this nursing home table correspond with the same item number in the parent table, please refer to each parent section of this *Region Profile Guide* for more information on the measures described below. For example, 12.3a is the same measure as item 3a of Table 3 of the Region Profiles, but restricted to nursing home patients only.

XVII. COVID in Medicare Dialysis Patients (C1) and Medicare Dialysis Patients Treated at Nursing Home Facilities ((C2)

The COVID-19 pandemic continues to have a profound impact on the US healthcare system including ESRD providers and the high-risk dialysis population. To assist dialysis surveyors and other stakeholders in investigating the impact of COVID-19, we have developed tables to report on COVID-19 patient counts, deaths, and hospitalizations among Medicare dialysis patients (Table C1) and Medicare nursing home (NH) dialysis patients (Table C2) in 2020 Q1-Q4. National averages for 2020 Q4 are included for comparison.

Population

Since the main source for COVID-19 diagnosis is Medicare Claims, we calculate the COVID-19 patient counts among all Medicare dialysis patients (any modality), including those within the first 90 days of ESRD. For each patient, a month is deemed Medicare eligible if the patient is enrolled in Medicare Advantage for that month, or 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. Patients with at least one Medicare eligible month during the quarter are reported in item 1 in Table C1. Medicare dialysis patients who were treated at a nursing home facility according to the CMS Long Term Care Minimum Data Set (MDS) for at least one day are reported in item 1 in Table C2.

Identifying COVID-19 patients

Throughout the COVID-19 pandemic, UM-KECC has been actively monitoring data indicators related to diagnosis and treatment of COVID-19 across all available and relevant data sources. Patients ever identified with COVID are defined as those patients who were diagnosed with COVID by the end of each quarter or quarters, regardless of whether the diagnosis occurred prior to or during the reporting period (**Item 2**). Patients first identified with COVID are defined as those patients who were newly diagnosed with COVID within the quarter (**Item 3**). The percentages of patients first or ever identified with COVID among Medicare dialysis patients are also reported.

Mortality and hospitalization counts

Death (**Items 4 and 5**) and hospitalization (**Items 6 and 7**) counts are calculated among all patients in Item 1 and patients ever identified with COVID in Item 2 during the reporting period. Deaths are obtained from multiple data sources including the Death Notification Form (CMS Form 2746), the Enrollment Database (EDB), and Medicare claims. Hospitalization is defined as having at least one day in a hospital from Medicare inpatient claims during the reporting period. A death or a hospitalization in this category does not mean a patient died or hospitalized from COVID. The percentages of deaths or hospitalizations of patients ever identified with COVID out of all deaths or hospitalizations are also reported.

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. If you have questions or comments, please directly contact the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) by

phone, email, or post. Region-specific comments may be submitted on the secure portion of www.Dialysisdata.org by authorized users only. General methodological questions may be submitted by anyone using the form available on the “Contact Us” tab on www.Dialysisdata.org.

References

- Andersen PK, Borgun O, Gill RD, Keiding N. *Statistical Models Based on Counting Processes*. New York: Springer-Verlag; 1993. p. 334, 406-407.
- Agresti, A. *Categorical Data Analysis*, Second Edition, New York: John Wiley & Sons, Inc.; 2002
- Collett D. *Modeling Survival Data in Medical Research*. London, England: Chapman and Hall; 1994. p. 153, equation 5.6 and p. 151, equation 5.1.
- Hosmer, DW, Jr. and Lemeshow, S. *Applied Logistic Regression*, Second Edition, New York: John Wiley & Sons, Inc.; 2000
- Levey AS, Bosch JP, Lewis JB, Greene T, Rogers N, Roth D. A more accurate method to estimate glomerular filtration rate from serum creatinine: a new prediction equation. Modification of Diet in Renal Disease Study Group. *Ann Intern Med* 1999;130(6):461-470.
- Health, United States, 2015 With Special Feature on Racial and Ethnic Health Disparities. Centers for Disease Control and Prevention, Health and Human Services Dept., 99-102.
<http://www.cdc.gov/nchs/hus/contentns2015.htm#017>
- NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy. National Kidney Foundation. *Am J Kidney Dis*. 1997 Sep; 30(3 Suppl 2): S15-66.
- NKF-DOQI Clinical Practice Guidelines for the Treatment of Anemia of Chronic Renal Failure. National Kidney Foundation-Dialysis Outcomes Quality Initiative. *Am J Kidney Dis*. 1997 Oct; 30(4 Suppl 3): S192-240.
- NKF-KDOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2000. *Am J Kidney Dis*. 2001 Jan; 37(1 Suppl 1): S7-S64.
- NKF-KDOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2000. *Am J Kidney Dis*. 2001 Jan; 37(1 Suppl 1): S182-238.
- NKF-DOQI Clinical Practice Guidelines for Hemodialysis Adequacy: Update 2006. *Am J Kidney Dis*. 2006 July; 48(Suppl 1): S2-S90.
- NKF-DOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: Update 2006. *Am J Kidney Dis*. 2006 May; 47(Suppl 3): S146.
- SAS Institute Inc. 2008. *SAS/STAT 9.2 User's Guide*. Cary, NC: SAS Institute Inc.
- Turenne MN, Loos ME, Port FK, Emmert G, Hulbert-Shearon TE, Wolfe RA, Levine GN, Daugirdas JT, Agodoa LYC, Held PJ. The impact of deaths due to AIDS, accidents, and street drugs on standardized mortality ratios (SMRs) by state. U.S. Renal Data System and University of Michigan, Ann Arbor. Poster presented at the American Society of Nephrology, New Orleans, LA, November 1996. Abstracts – *J Am. Soc Nephrol* 1996;7:1467.
- U.S. Renal Data System, *USRDS 2007 Annual Data Report: Atlas of End-Stage Renal Disease in the United States*, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2007.

Wolfe RA, Gaylin DS, Port FK, Held PJ, Wood CL. Using USRDS generated mortality tables to compare local ESRD mortality rates to national rates. *Kidney Int* 1992;42:991-96.

Wolfe RA, Ashby VB, Milford EL, Ojo AO, Ettenger RE, Agodoa LYC, Held PJ, Port FK: Comparison of mortality in all patient on dialysis, patients awaiting transplantation, and recipients of a first cadaveric transplant. *N Engl J Med* 1999;341:1725-1730.

Liang, K., & Zeger, S. (1986). Longitudinal Data Analysis Using Generalized Linear Models. *Biometrika*, 73(1), 13-22. doi:10.2307/2336267

Zeger, S., Liang, K., & Albert, P. (1988). Models for Longitudinal Data: A Generalized Estimating Equation Approach. *Biometrics*, 44(4), 1049-1060. doi:10.2307/2531734