Guide to the Fiscal Year 2019 State Profiles for Dialysis Patients and Facilities:

Overview, Methodology, and Interpretation

August 2018

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I. Purpose of this Guide and the State Profile

This guide explains in detail the contents of the FY 2019 State 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 State 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 state'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 state's understanding of the clinical experience relative to the nation.

What's New in the FY 2019 State 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 State Profile for FY 2019: The Standardized Hospitalization Ratio (SHR) measures for days hospitalized and admissions were replaced by the new NQF-endorsed measures, which adjust for several prevalent comorbidities identified through Medicare claims. Hypercalcemia now includes patients with a missing three-month calcium average in both the numerator and denominator.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the FY 2019 State Profiles with funding from the Centers for Medicare & Medicaid Services (CMS).

Each report provides summary data from all Medicare certified dialysis facilities in the state for the years 2014-2017. 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) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER); and data from the Dialysis Facility Compare (DFC). The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records.

CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients.

This is the twenty-third 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 XVI.

This guide discusses the meaning of the data summaries that each profile provides, and describes the methodology used to calculate each summary (Sections IV-XV). Sections IV-XV are organized according to the order of the summaries in the Profile, and may serve as references for their interpretation. Since in many cases, understanding a particular section's contents requires you to understand the issues presented in the previous section, we recommend that you review Sections IV-XV in order.

The profile starts with two pages of text highlights for your state, followed by twelve tables—each with detailed information for your state. 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 2014-2017 with national statistics for 2017 reported for comparison and for new dialysis patients from 2014-2016 with national statistics for 2016 reported for comparison. Tables 4-12 (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 2014-2017 with national statistics reported for 2017.

Each row of a table in the State Profile summarizes an item. Your state 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 DFR 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 70
TABLE 12: 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 state 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 State Profile includes all patients placed in facilities in the state.

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 state) after his or her condition worsened.

In particular, we placed patients in their initial facility on day 91 of ESRD once that facility had treated them for at least 60 days. If on day 91 a facility had treated a patient for fewer than 60 days, we waited until the patient reached day 60 of treatment at that facility before placing him or her there. State 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 state 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 8: Anemia Management Summaries for Adult Dialysis Patients
TABLE 9: Dialysis Adequacy Summaries for All Dialysis Patients
TABLE 10: Mineral Metabolism Summaries for Adult Dialysis Patients
TABLE 11: Vascular Access Information for all Dialysis Patients

For each patient, we identified the dialysis provider at each point in time primarily using data from CROWNWeb, the Medical Evidence Form (Form CMS-2728) and Medicare-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. If a patient transferred in or out of the facility, discontinued dialysis, recovered renal function or died anytime during the month, the entire patient-month is excluded. Please note that the number of sessions are not considered and the patient may not have received treatment at the facility for the entire month to be included. For example, if a patient is hospitalized or travels during the month, the patient may still be included in the facility's measure if they are indicated as the facility's patient that month according to the data as described above. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither 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, 2014-2017

Table 1 summarizes the characteristics of dialysis patients treated on December 31, 2014-2017 in your state with national averages for 2017.

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

V. Characteristics of New Dialysis Patients, 2014-2017 (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 state by year. The patients represented in this table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2014 and December 31, 2017. 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 state and U.S. averages. We excluded from the calculations values for individual patients which fell outside the ranges shown in brackets [] on this table because we considered them to be clinically implausible.

Patient Characteristics (2a-2m)
Row 2a of this table gives the total number of forms submitted by your state for the year. Rows 2b-2m deal with the patients' demographic characteristics, including their age, sex, ethnicity, race, medical coverage, body mass index, primary cause of ESRD, 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, 1222) — a formula based on serum creatinine before first dialysis, age, race, and gender.

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

Comorbid Conditions (2w, 2x)

Row 2w reports the percentage of patients in your state with each of the comorbid conditions (measured before the start of dialysis) listed. The 2005 changes in Form CMS-2728 have affected the cardiac and diabetes listings; note that 'Ischemic Heart Disease' and 'Myocardial Infarction' are included in *Atherosclerotic Heart Disease (ASHD)*, and 'Cardiac Arrest', 'Cardiac Dysrhythmia', and 'Pericarditis' are included in *Other Cardiac Disease*. Row 2x gives the average number of comorbid conditions reported per new patient in your state and the nation.

VI. Mortality Summary for All Dialysis Patients (2014-2017) and New Dialysis Patients (2014-2016)

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

The SMR accounts for many patient characteristics known to be associated with mortality, but cannot account for all factors that may explain differences in mortality between states. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients in a state 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 state compared to national averages, please consider the role other important factors play within your state.** 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, 2014-2017. U.S. averages are also reported for 2017—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 state with national averages. This section of the table allows the state to see how all of the patients who started dialysis in the state fared in their first year of dialysis even if the state is no longer treating some of these patients.

Major Differences between the Prevalent and First Year Mortality Calculations

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

Patient Placement

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

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

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.

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

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 state, 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 state 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)/ height^2 (m^2)). In cases where the BMI was missing for a patient, we used the average values of the group of patients with similar characteristics (age, race, ethnicity, sex, diabetes). We also controlled for age-adjusted population death rates by state and race based on the U.S. population in 2013-2015 (National Center for Health Statistics, 2017). 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 state.

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 states 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 state. 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 state, as compared to the national death rate in the same year. Qualitatively, the degree to which the state's four year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2014-2017 national death rates for patients with the same characteristics as those in your state. Similarly, the

degree to which the state'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 state.

As stated previously, we adjusted the SMR for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and population death rates. The SMR indicates whether patients treated in your state 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 State Reports*. This document and an accompanying Microsoft Excel spreadsheet are available on the Dialysis Reports Web site at www.dialysisdata.org under the methodology heading.

Quantitatively, if your state'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 state's patient mix. For example, an SMR=1.10 would indicate that your state's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to your state's patient mix). Similarly, an SMR=0.95 would indicate that your state'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 state'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 state relative to the national death rates. An SMR value that differs from 1.00 indicates that your state'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 state's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between your state's death rates and the nation's.

P-value (3k)

The State 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 State Profile identifies SMR values significantly less than 0.95 or greater than 1.05. This means that few states will have an SMR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state's death rates and 0.95 or 1.05.

Patients for First Year Mortality (3l)

Row 3k of this table gives the total number of forms for new dialysis patients submitted by your state 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, 2014 and December 31, 2016. 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 state. For the first year mortality statistics, all of a particular patient's time at risk is included in the report for their initial state regardless of whether the patient was treated at a state in that state 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 = weight (kg)/ height^2 (m^2)). In cases where BMI were missing for a patient, we used the average values of the group of patients with similar

characteristics (age, race, ethnicity, sex, diabetes). We also controlled for age-adjusted population death rates by state and race based on the U.S. population in 2013-2015 (National Center for Health Statistics, 2018).

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 state. 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 state, as compared to the national death rate. Qualitatively, the degree to which your state'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 state.

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 state 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 state'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 state's patient mix. For example, an SMR=1.10 would indicate that your state's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to your state's patient mix). Similarly, an SMR=0.95 would indicate that your state'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 state'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 State Profiles 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 State Profile identifies SMR values significantly less than 0.95 or greater than 1.05. This means that few states will have an SMR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state's death rates and 0.95 or 1.05

VII. Hospitalization Summary for Medicare Dialysis Patients, 2014-2017

Overview: Hospitalization Summaries for Dialysis Patients

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital approximately twice a year and spend an average of 11 days in the hospital per year (USRDS, 2017). Measures of the frequency of hospitalization and diagnoses associated with hospitalization help efforts to control escalating medical costs, and play an important role in providing cost-effective health care. Hospitalization summaries for Medicare dialysis patients are reported in Table 4. This report includes summaries of the hospitalization rates among dialysis patients in your state, 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 reach a certain level of Medicare-paid dialysis bills to be included in hospitalization statistics, or that patients have Medicare inpatient claims during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period

is considered 'eligible'. Having at least $900 of Medicare-paid claims or at least one Medicare inpatient claim is sufficient for that month and the following two months to be eligible.
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 state, 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 state's observed number of events (be it admissions, days hospitalized, or ED visits) to the number that would be expected if patients at the state were instead subject to the 2014-2017 national average admission, days, and ED visit rates. The expected national rates for days hospitalized and admissions are calculated from Cox models (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994) which make adjustments for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, calendar year, and prevalent comorbidities. The expected national rates for ED visits are calculated from Cox models which make adjustments for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and calendar year.

We report the hospitalization and ED visit summaries for each year from 2014-2017. We also report 2017 U.S. averages for the hospitalization and ED visit summaries for comparison

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 state 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.

<u>Days Hospitalized Statistics (4c-4f)</u>

Total Days Hospitalized (4c)
This represents the total number of days that Medicare dialysis patients in the state 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 12/28/2014 and

discharged on 1/6/2015), the number of days hospitalized are assigned appropriately to the two years (four days in 2014 and six days in 2015).

Expected Total Days Hospitalized (4d)

We calculated the expected number of hospitalized days among Medicare dialysis patients in a state 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, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence,calendar year of treatment, and prevalent comorbidities. In cases where BMI was missing for a patient, we used the average values of the group of patients with similar characteristics (age, sex, diabetes). Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each interval is multiplied by the (adjusted) national hospitalization rate for that interval, and a sum over the intervals gives the expected number of days hospitalized for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 4d.

Standardized Hospitalization Ratio 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 state'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 state 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 state was higher than the (adjusted) national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, BMI, and prevalent comorbidities. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time in your state beyond the overall US trend over time. In other words, if the SHR for your state decreases over the time period, this means that hospitalization in your state has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization in your state decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for your state would be the same for each year.

P-value (4f)

The State 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 State Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few states will have an SHR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state's hospitalization rates and 0.95 or 1.05.

Hospitalization Admissions Statistics

Total Admissions (4g)

This is the total number of inpatient hospital admissions among the Medicare dialysis patients in this state. 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 12/28/2014 and discharged on 1/6/2015), the admission would count only in the second year (zero admissions in 2014 and one admission in 2015).

Expected Total Admissions (4h)

We calculated the expected number of hospital admissions among Medicare dialysis patients in the state 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, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence,calendar year, and prevalent comorbidities. Duration of ESRD is divided into six intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years and hospitalization rates are estimated separately within each interval. For each patient, the time at risk in each ESRD interval is multiplied by the (adjusted) national admissions rate for that interval, and a sum over the intervals gives the expected number of admissions for each patient. For each patient, the expected number is adjusted for the characteristics of that patient and summing over all patients gives the result reported in 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 state's experience to the national average. A value of less than 1.0 indicates that your state's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that your state 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, duration of ESRD, nursing home status, comorbidities at incidence, BMI, and prevalent comorbidities. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time in your state beyond the overall US trend over time. In other words, if the SHR for your state decreases over the time period, this means that hospitalization in your state has decreased

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

P-value (4j)

The State 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 State Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few states will have an SHR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state'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 state in your state. 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 state. We calculated this duration from Medicare payment records, which listed an admission and discharge date for each hospitalization. The average length of stay is not adjusted for patient characteristics.

Emergency Department (ED) Statistics

Total ED Visits (4n)

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

We calculated the expected number of ED visits among Medicare dialysis patients in the state 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, 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 4o.

Standardized Hospitalization Ratio for ED (4p)

The SHR (ED) is calculated by dividing the observed total ED visits by the expected total ED visits. As with the SMR, it enables a comparison of your state's experience to the national average. A value of less than 1.0 indicates that your state'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 state had a rate of ED visits higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI. 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 state beyond the overall US trend over time. In other words, if the SHR for your state decreases over the time period, this means that ED visits in your state has decreased more over that time period than the overall US average ED visits decreased. If ED visits in your state decreased over the four-year period at the same rate that overall US ED visits decreased over this time period, the SHR for the state would be the same for each year.

P-value (4q)

The State 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 State Profile identifies SHR values significantly less than 0.95 or greater than 1.05. This means that few states will have an SHR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state's ED visit rates and 0.95 or 1.05.

Patients with ED Visit (4r)
Row 4r reports the percentage of 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.

ED visits that result in hospitalization (4s)
Row 4s reports the percentage of ED visits in row 4n that resulted in an inpatient admission.

Admissions that originated in the ED (4t)
Row 4t reports the percentage of inpatient admissions (4g) 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). Therefore, it is possible for row 4t to exceed 100%.

Readmission Statistics

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 occurring at acute-care hospitals in the calendar year for dialysis patients in the state. 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 state 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 state based on national rates for hospital readmissions in the same year. The expected number of readmissions is calculated from a hierarchical logistic model, adjusted for the discharging hospital of the index hospitalization and for the patient characteristics of age, sex, diabetes, duration of ESRD at index hospital discharge, comorbidities in the year preceding the index hospital discharge, the presence of a high-risk diagnosis at index hospital discharge, length of stay of the index hospital discharge, and BMI at onset of ESRD. For each patient, the expected number is adjusted for the characteristics of that patient.

Standardized Readmission Ratio (SRR) (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 state's experience to what should be expected on the basis of the national norm. A value of less than 1.0 indicates that the state's total number of readmissions is less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the state 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 Summary for Dialysis Patients under Age 70, 2014-2017

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 whom never received a transplant. 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 pre-emptive transplant or a transplant within the first three months of treatment. You will find these statistics useful in that they allow a state to compare the rate of transplantation for the dialysis patients they treat, though these statistics should not be interpreted as including all transplants. The percentage of transplants in the U.S. that were not included because the transplant occurred less than 91 days after the start of ESRD, as well as those that were not included because the patients were not assigned to facilities at times of transplant are indicated in a footnote to the table.

Eligible Patients (5a)
Row 5a reports the number of dialysis patients under age 70. The transplantation summaries were assigned to the state according to the conventions described in Section III. In addition, all transplantation statistics in this report refer only to those patients less than 70 years of age because transplants in people aged 70 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 70 in the state who received a transplant.

Eligible Patients (5c)
Row 5c reports the number of dialysis patients under age 70 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 70 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 70 who had not previously received a transplant. For all patients, time at risk began at the start of the state treatment period (see Section III) and continued until the earliest of the following occurrences: transplant; date of death; end of the state treatment period; or December 31. A patient may have been treated in facilities in one state 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 state.

Actual First Transplants (5e)
Row 5e reports the number of dialysis patients under the age of 70 in each state 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 state, 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 state, given the age composition of the state'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 state equals the estimated national rate, adjusted for age. An STR of less than 1.00 indicates that your state's transplant rate is lower than the national average. An STR greater than 1.00 indicates that your state's transplant rate exceeds the national average. The amount by which an STR lies above or below 1.00 corresponds to the percentage your state's transplant rate is above or below the national average, respectively. For example, an STR of 0.90 would mean that your state'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 State 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 State Profile identifies STR values significantly less than 0.95 or greater than 1.05. This means that few states will have an STR that is statistically significant ($p<0.05$) and states 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 state 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 state'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 state's transplantation rates and 0.95 or 1.05.

IX. Waitlist Summary for Dialysis Patients under Age 70 Treated on December 31 of Each Year, 2014-2017

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.

Eligible Patients on 12/31 (6a)

This table reports waitlist summary statistics for all dialysis patients under age 70 that were being treated on December 31 of each year in your state. Row 6a reports the number of dialysis patients included in the waitlist summaries. All waitlist statistics in this profile refer only to those patients less than 70 years of age because transplants in people aged 70 or greater occur with much less frequency than do transplants in younger patients. This table gives a snapshot of the waitlist at four dates. The criteria for including patients in this table are different than those described in Section III. For this table, we included patients in the state where they were treated on December 31 of each year according to claims data or CROWNWeb. The 60-day transfer rule did not apply, and we included patients new to dialysis (the 90 day rule did not apply).

Patients on the Waitlist (6b)

Row 6b reports the percentage of patients in 6a who were on the kidney or kidney-pancreas transplant waitlist as of December 31, with the corresponding national percentage for 2017 reported for comparison.

P-value (6c)

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

A footnote to the table shows the percentage of patients on the waitlist in the U.S. for each year used in this comparison. The p-value indicates the probability that the difference between the percentage of patients on the waitlist in your state and in the U.S. occurred due to chance. A low p-value means that the chances are low that the state 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 result's statistical significance. You should also use the absolute magnitude of the difference between your state and national percentage of patients on the waitlist to determine its clinical importance.

Patient Characteristics (6d)

Row 6d reports the percentage of patients in row 6b by age, sex, race and ethnicity, cause of ESRD, previous transplant, and years of ESRD treatment. State, Network, and U.S. averages for 2017 are given for comparison.

X. Influenza Vaccination Summary for Medicare Dialysis Patients Treated on December 31st of Each Year, Flu Seasons August 2014-December 2017

This table reports influenza vaccination summary statistics identified on Medicare claims for Medicare dialysis patients treated on December 31st of each year in your state. The national average for 2016 or 2017 is also given for comparison. 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).

Like hospitalization and comorbidity, this table is limited to patients who are covered by Medicare. To achieve this goal, we use the Medicare criterion described above in Section VII for the hospitalization statistics. Since it takes a month to accrue > $900 in claims, we have excluded patients who have been on dialysis less than 30 days. This table is then further restricted to patients being treated in your state at the end of each year. The 60-day facility transfer rule does not apply, and we include incident patients who have been on dialysis for at least 30 days. Vaccinations that are billed to Medicare are attributed to the state whether these occurred within the patients' dialysis state or outside of the state. Vaccinations not billed to Medicare are not captured.

Eligible Patients on 12/31 (7a)

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

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

Row 7b reports the percentage of patients in 7a who had a Medicare claim for vaccination performed between August 1st and December 31st, with the corresponding national percentage for 2017 reported for comparison.

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

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 7b, is higher (or lower) than the U.S. value for that year. A footnote to the table 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 your state and in the U.S. occurred due to chance. A low p-value means that the chances are low that the state 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 your state and national percentage of patients vaccinated to determine its clinical importance.

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

Row 7d reports the percentage of patients in 7a who had a Medicare claim for vaccination performed between August 1st and March 31st of the following year, with the corresponding national percentage for 2016 reported for comparison. A statistic does not exist for the most recent flu season (2017) because data is not yet available for January through March 2018.

P-value for Patients Vaccinated between Aug. 1 and Mar. 31 of the following year (7e)
We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 7d, is higher (or lower) than the U.S. value for that year. A footnote to the table shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patient Characteristics (7f)
Row 7f breaks down the information in row 7b by various patient characteristics. Row 7f reports the percentage of patients in each category who were vaccinated between August 1st and December 31st. The national average for 2017 is given for comparison.

XI. Anemia Management Summaries for Adult Dialysis Patients, 2014-2017

Table 8 report 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-CROWNWeb (8a-8e)

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

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

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

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

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 state level, relative to a national standard, allows for detection of differences in dialysis state anemia treatment patterns. This is of particular importance due to recent FDA guidance regarding the use of ESAs and new economic incentives to minimize ESA use introduced by Medicare bundling payment for ESAs. In early 2012, a highly publicized United States Renal Data System (USRDS) study presented at the National Kidney Foundation (NKF) clinical meeting reported increased dialysis patient transfusion rates in 2011 compared to 2010. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for an over-use of blood transfusions to treat ESRD-related anemia. Transfusion summaries for Medicare dialysis patients are reported in Table 8.

This report includes summaries of the transfusion rates among adult Medicare dialysis patients in your state, along with comparative state and national data. Because the intention behind the measure is to detect the possibility of underutilization of alternatives to transfusion, patients' time at risk and transfusion events are not included if they occur within one year of diagnoses contraindicating the use of ESAs. In particular, patients' time at risk is excluded beginning with a Medicare claim for hemolytic or aplastic anemia, solid organ cancer, lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissues, skin, and others), metastatic cancer, and sickle cell anemia. Once a patient is diagnosed with one of these comorbidities, a patient's time at risk is included only after a full year free of claims that list any diagnosis on the exclusions list.

Transfusion rates are similar to hospitalization rates in that patients can be transfused more than once during a year and transfusion data are not always as complete as mortality data. As with the hospitalization statistics, this section of the table should ideally include only patients whose Medicare billing records include all transfusions for the period. To achieve this goal, we apply the same rules as for hospitalization and require that patients reach a certain level of Medicare-paid dialysis bills to be included in transfusion statistics, or that patients have Medicare inpatient claims during the period. For the purpose of analysis, each patient's follow-up time is broken into periods defined by time since dialysis initiation. For each patient, months within a given period are included if that month in the period is considered 'eligible'; a month is deemed eligible if it is within two months of a month having at least $900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. In setting this criterion, our aim is to achieve completeness of information on transfusions for all patients included in the years at risk.

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

subject to the national average transfusion rates, adjusted for the patient characteristics, as described above.

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

Patient Years at Risk (8g)
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 state 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 state 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 state 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 state.

Total Transfusion Events (8h)
This is the total number of transfusion events during eligible time-at-risk among the adult Medicare dialysis patients assigned to this state. 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.

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 Methodology heading.

Expected Total Transfusion Events (8i)

We calculated the expected number of transfusion events among Medicare dialysis patients in a state 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 8i.

Standardized Transfusion Ratio (STrR) (8j)

The STrR is calculated by dividing the observed total admissions in 6n by the expected total admissions in 8i. As with the SMR and SHR, the STrR enables a comparison of your state's experience to the national average. A value of less than 1.0 indicates that your state'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 state 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 state. Additionally, the estimate is compared to the US transfusion rates for the same year.

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

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

P-value for STrR (8k)

The State 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 State Profile identifies STrR values significantly less than 0.95 or greater than 1.05. This means that few states will have an STrR that is statistically significant ($p<0.05$) and states 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 state is lower than 0.95 or higher than 1.05. The p-value is the probability that the STrR would, just by chance, deviate from 0.95 or 1.05 as much as does the observed STrR. 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 STrR 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 STrR of 1.06 would indicate that the state's high transfusion rate is unlikely to have arisen from random fluctuations alone. A small p-value helps rule out the possibility that an STrR'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 state's transfusion rates and 0.95 or 1.05.

Hemoglobin—Medicare Claims (8l-8o)

We based the hemoglobin information reported in rows 8l to 8o on all Medicare dialysis claims submitted in your state that indicated the use of an erythropoiesis stimulating agent (ESA), specifically, the use of epoetin alfa, epoetin betaor darbepoetin alfa. We calculated hemoglobin as hematocrit divided by three (and rounded to the tenth of a g/dL) for claims that report hematocrit but not hemoglobin. We included neither patient claims starting before day 91 of ESRD nor claims with hemoglobin values less than 5 or greater than 20.

For each year, patients were included in this section if there were at least four claims fulfilling the criteria described above submitted by facilities in your state for each year. A patient treated in more than one state during the year was included in the report for each state (as long as the patient had at least 4 claims from the state). Patients who received both HD and PD appear in both the HD (8l) and PD (8n) eligble patient counts. Patients who had at least 4 total claims submitted by facilities in your state appear in these rows, even when there were fewer than 4 claims for the particular modality.

For each patient in row 8l and 8n, we calculated the average hemoglobin reported on claims submitted by facilities in your state. In rows 8l to 8o, the number of hemodialysis (HD) and peritoneal dialysis (PD) patients are given along with the percent whose average hemoglobin was in each of the four categories discussed above.

XII. Dialysis Adequacy Summaries for All Dialysis Patients, 2014-2017

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

<u>Hemodialysis (HD) Adequacy (9a-9j)</u>

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 state for at least one whole calendar month during the year (9a). Patients are assigned to a facility for the reporting month only if they were assigned to the facility for the whole calendar month according to the methods described in Section III for CROWNWeb measures. The number of eligible patient-months for adult hemodialysis patients is reported in row 9b. A patient may only be assigned to one facility each month and may not switch modalities during the month. Patients may be counted up to 12 times per year.

Serum albumin for adult HD patients (9c-9d)
Serum albumin was assessed among all eligible HD patient-months reported in 9b and was characterized into five mutually exclusive categories. Average serum albumin is reported in 9c and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 9d.

Ultrafiltration rate for adult HD patients(UFR; 9e-9f)
The ultrafiltration rate (UFR) was assessed among all eligible HD patients in 9a and was characterized into three mutually exclusive categories: missing (no UFR reported), in range (UFR between 0 and 20 ml/kg/hr), and out of range (UFR greater than 20 ml/kg/hr). The average UFR for HD adult patients is reported in 9e and is based only on eligible patient-months in 9b with in-range values. The percentages of all patient-months with in range values stratified by UFR categories, and missing/out of range values, for each month for the state are shown in 9f.

Kt/V for adult HD patients (K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water) (9g-9j)

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

Eligible patients were adults (18+ years) who had ESRD for more than 90 days, were receiving hemodialysis at the facility for at least one whole calendar month during the reporting period (i.e., 'assigned' facility), and dialyzed thrice weekly (9g). Patient-months were excluded from the denominator if there was evidence the patient was not dialyzing thrice weekly anytime during the month. A patient may only be assigned to one dialysis facility each month and may not switch modalities during the month. The corresponding number of eligible patient-months is reported in row 9h. Patients may be counted up to 12 times per year.

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

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

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

Calculating "frequent" and" infrequent" dialysis in Medicare dialysis claims

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

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

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

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

A claim was considered eligible if it was from a HD patient who had ESRD for more than 90 days, was at least 18 years old, and the claim was neither a "frequent" dialysis claim nor an "infrequent" dialysis claim as described above. The last eligible claim with an in-range (less than or equal to 5.0) and not expired (in-center HD with Kt/V reported from a previous claim, or home HD with Kt/V reported from more than four months' prior) Kt/V value reported was selected when there were multiple claims reported in a month. Patient-months were excluded if any claim submitted during the month for the patient identified the patient as undergoing 'frequent' or 'infrequent' dialysis anytime during the reporting month.

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

<u>Peritoneal Dialysis (PD)Adequacy (9k-9p)</u>

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 for at least one whole calendar month during the year (9k). The number of eligible patient-months for adult hemodialysis patients is reported in row 9l. Patients may be counted up to 12 times per year.

Kt/V for adult Peritoneal Dialysis (PD) (K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water) (9m-9n)

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 9l 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 state is reported in row 9m and is based only on patient-months in 9l 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 state are shown in 9n. Patients with missing or out of range Kt/V (Kt/V > 8.5) values from either data source (CROWNWeb or Medicare claims) (9n) 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) (9o-9p)

Serum albumin value was assessed among all eligible PD patient-months reported in 9l and was characterized into five mutually exclusive categories. Average serum albumin is reported in 9o and the percentage of all patient-months stratified by serum albumin categories, and missing values, for each month for the facility are shown in 9p

<u>Kt/V for All Pediatric Dialysis Patients (9q-9x)</u>

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, 2014-2017

Table 10 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, 2014-2017, along with regional and National averages for the most current year.

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

The number of adult dialysis patients in your state who had ESRD for more than 90 days and were in the facility for at least one whole calendar month during the year is reported in row 10a. Patients who switch between HD and PD during the month and patients for whom modality is unknown are included. The number of patient-months for all adult patients is reported in rows 10b. Patients may be counted up to 12 times per year.

Phosphorous (10c-10d)

The average phosphorous for HD and PD adult patients in your state is reported in row 10c and is based only on patient-months with values in range (0.1 mg/dL to 20 mg/dL); The patient counts differs from those reported in row 10b since phosphorus summaries include patient-monthss 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 state are shown in 10d.

Calcium uncorrected (10e-10f)

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

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

The percentage of all eligible patient-months with a 3-month rolling average uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing is reported in 10g. This value is averaged from uncorrected serum or plasma calcium values over a rolling 3-month period among eligible patients reported in 10b who are 18 years or older two months prior to the reporting month.

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, 2014 – 2017

Table 11 reports vascular access information and access-related infection summaries. The statistics in this table are reported for each year, 2014-2017, along with regional and National averages for the most current year.

Vascular Access Information (11a-11h)

The statistics in this section of the table are based on information collected in CROWNWeb

Prevalent Adult Hemodialysis Patients (11a)
The prevalent hemodialysis patient count (11a) in your state 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 (11b)
The monthly prevalent hemodialysis patient count (11b) in your state 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.

Vascular Access Type in Use (11c)
Row 11c reports the type of vascular access in CROWNWeb during the calendar month. If multiple access types were reported for a month, the most recent was selected. This row reports the percentage of patient months in 11b in which the patient received dialysis through arteriovenous (AV) fistulae (one or two needles), grafts, catheters or other access types. Patients who had an AV graft or a catheter in use with an AV fistula in place for *future* use are included in the AV graft or catheter category, respectively. Port access devices are included in the catheter category. A patient's vascular access is classified as *Other* if it was different from the above categories (e.g., lifeline). Patients are classified as having missing access types if the vascular access data were not available.

Arteriovenous (AV) Fistulae Placed (11d)
Row 11d reports the percentage of patient months in 11b in which an AV fistula was in place, regardless of whether the patient received hemodialysis treatment using this AV fistula.

Catheter Only ≥ 90 Days (11e)
Row 11e reports the percentage of patient months in 11b in which a catheter was in use; a catheter was the *only* means of vascular access (i.e., patient did not have an AV fistula or AV graft in place); and the catheter was in place for more than 90 days of the last day of the reporting month. Again, port access devices are included in the catheter category.

Incident Hemodialysis Patients (11f)
Row 11f reports the total number of incident hemodialysis patients (adults and pediatrics) in the state 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 (11g)
Row 11g 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 11f 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 (11h)
Row 11h reports the percentage of incident patients in 11f 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 (11i-11l)

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 $900 of Medicare-paid dialysis claims or at least one Medicare inpatient claim. For more information on the Medicare payment criterion, please see Section V.

Any patient treated with dialysis in your state during a particular month is included in that state'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) (11i-11l)
The number of Medicare PD patients meeting the Medicare payment criterion described above and treated in the state during at least one month during the year or four year period is reported in row 11i. The total number of months during which each patient is treated with PD in the state are summed and reported in row 11k.

PD catheter infection rate per 100 PD patient-months (11k)
This statistic shows the rate of PD catheter infection in peritoneal dialysis patients during each year. For each month included in row 11j, 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 11j. The number is then converted to a rate per 100 PD patient-months in row 11k. Patients can only contribute one dialysis access-related infection to a state during a month. If the patient is treated in two states with PD in a month with an infection, the infection is counted in both states. For the national summary, the infection will only be counted once.

P-value (compared to U.S. value) (11l)
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 11k, 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, 2014– 2017

Table 12 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31 of each year (2014-2017) in the state, with corresponding average values for 2017 among patients in the state, network and U.S. Comorbidities are determined on the basis of each patient's Medicare claims for the period, including inpatient stays, outpatient visits and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9 and ICD-10 diagnostic codes and HCPCS CPT codes used to identify comorbidities is included in a separate document available at www.Dialysisdata.org under the Methodology 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 $900 of Medicare-paid dialysis claims or b) at least one Medicare inpatient claim. This table is then further restricted to patients treated at the state at the end of the year.

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

Comorbid Conditions (12b)
Row 12b reports the percentage of patients in the state with each of the comorbid conditions listed.

Average Number of Comorbid Conditions (12c)
Row 12c reports the average number of the comorbid conditions listed in 12b on Medicare claims for patients in the state.

XVI. 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. State-specific comments may be submitted on the secure portion of www.Dialysisdata.org by authorized users only. General methodological questions may be submitted by anyone using the form available on the "Contact Us" tab on www.Dialysisdata.org.

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