Guide to the 2013 Dialysis Facility Reports:

Overview, Methodology, and Interpretation

August 2013

Guide to the 2013Dialysis Facility Reports for Dialysis Patients: Overview, Methodology, and Interpretation

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I. Purpose of this Guide and the Dialysis Facility Reports

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

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

What's New in the 2013 DFR

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 2013 DFR. The UM-KECC ESRD database now includes the new web-based data collection system, CROWNWeb. It was rolled out nationally in June 2012 and replaces the functionality of SIMS. Authorized users may now securely submit, update, and verify data provided to Medicare about people who have ESRD on a monthly basis. In addition, the Influenza Vaccination table (Table 5) has been amended to include vaccinations administered during the month of August to better coordinate with delivery date of vaccine supply to facilities.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the 2013 Dialysis Facility Reports with funding from the Centers for Medicare & Medicaid Services (CMS). Each facility's report is distributed to the facility on the secure Dialysis Reports Web site (<u>www.dialysisreports.org</u>) each July. Those state agencies responsible for certifying dialysis facilities also receive the reports.

Each report provides summary data on each facility's dialysis patients for the years 2009-2012. These summaries are compiled using the UM-KECC ESRD patient database, which is largely derived from the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN), which includes Renal Management Information System (REMIS), and the Standard Information Management System (SIMS) database (formally maintained by the 18 ESRD Networks and now maintained in CROWNWeb), the National Vascular Access Improvement Initiative's Fistula First project (in CROWNWeb starting May 2012), the CMS Annual Facility Survey (Form CMS-2744), Medicare

dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), 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), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. SIMS/CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients.

This year reports are provided for more than 6,000 Medicare-approved dialysis facilities in the United States. Reports were not created for transplant-only facilities or Veterans Administration-only facilities. In the mortality and transplantation tables, the standardized ratio is only calculated if there are at least 3 expected events for the time period. In addition, the standardized transplantation ratio is only reported for the fouryear period since the expected number of transplants is less than 3 nationally. Similarly, the Standardized Hospitalization Ratios is calculated based on at least 5 patient years at risk. This corresponds to approximately 10 expected hospitalizations. Statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret.

This is the eighteenth in this series of individualized reports. We welcome your participation and feedback concerning the clarity, utility, limitations, and accuracy of this report. You will find information on how to directly provide feedback to us at the UM-KECC in Section XXI.

This guide discusses the meaning of the data summaries each report provides, and describes the methodology used to calculate each summary (Sections III- XIX). Sections III-XIX are organized according to the order of the summaries in the Dialysis Facility Report, 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 III- XIX in order.

The first page provides the purpose and overview of the report, what's new and how to submit comments. The following three pages include text and graphical highlights for the facility, followed by fifteen tables which contain detailed information for the facility. To provide more stable estimates of patient outcomes, we combined overall mortality (first half of Table 1), hospitalization information (Table 2), and transplant information (Table 3) over a four-year period, 2009-2012. Similarly, we combined first year mortality information (second half of Table 1) over a three-year period, 2009-2011. The separate estimates provided for each year account for changes over time in national mortality, hospitalization, and transplantation rates and allow you to evaluate facility time trends different from the average US trend. Note that for the three- and four-year summaries,

individual patients typically contribute data for more than one year. Self-reported vascular access is documented in Table 7 for 2009-2012. Comorbidities from Medicare claims for 2009-2012, as well as regional averages for 2012, are reported in Table 11. Table 13 reports the Annual Facility Survey information for 2009-2012. Table 14 reports information about the last survey at this facility. Table 15 reports general information about the facility as of March 31, 2013. The remaining tables (4, 5, 6, 8, 9, 10 and 12) report patient characteristics and practice patterns for the facility each year from 2009-2012, as well as regional averages for 2012 for comparison.

Each row of a table in the report summarizes an item. The facility has a column for each time period, and in most cases, three columns for the corresponding geographical summaries, including averages for the facility's state, it's ESRD Network, and the entire nation. Whenever the statistic reported was a count (n), we calculated regional and national averages by taking the average count for all facilities in that area. When the statistic reported for a period included more than one year, we annualized regional and national values to make them comparable to a single-year period. When a statistic was a percent, rate, or ratio, we calculated regional and national summaries by pooling together all individual patients in that area to obtain an estimate for that area as if it were one large facility. We do not report state summary data for dialysis facilities in states or U.S. territories with only one or two dialysis units, with the exception of Annual Facility Survey data, which is public information. We do provide summaries for the geographic aggregate of the ESRD Network and the nation for facilities in these states or territories.

III. Assigning Patients to Facilities

This section describes the methods we used to assign patients to a facility in order to calculate the summaries appearing in the first half of Table 1 (for all dialysis patients), Tables 2-3 and 10-12. 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 1. Patient assignment for each of the remaining DFR tables, as well as the second half of Table 1, is described in the section specific to that table.

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 below.

General Inclusion Criteria for Dialysis Patients

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

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

Identifying Patients Treated at Each Facility (see also Section XV)

For each patient, we identified the dialysis provider at each point in time using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from the Standard Information Management System (SIMS). 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 the sequelae of treatment there, even when a patient was transferred to another facility (such as a hospital-based facility) after his or her condition worsened.

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

Using SIMS data and paid dialysis claims to determine whether a patient has transferred to another facility, we attributed patient outcomes to the patient's original facility for 60 days after transfer out. On day 61 after transfer from a facility, we placed the patient in the new facility once the patient had been treated at the new facility for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility.

Patients were removed from facilities upon receiving transplants. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. Additionally, patients for whom the only evidence of dialysis treatment is the existence of Medicare claims were considered lost to follow-up and removed from a facility's analysis one year following the last claim, if there was no earlier evidence of transfer, recovery, or death. In other words, if a period of one year passed with neither paid Medicare dialysis claims nor SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up, and did not continue to include that patient in the analysis. If evidence of dialysis reappeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility. Finally, all SIMS 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 SIMS only require checking patient data for continued accuracy, but do not have a requirement for updating if there are not any changes. Table 12 reports how we assigned patients to the facility. It also displays their status at year's end (see Section XIII).

IV. Mortality Summary for All Dialysis Patients (2009-2012) and New Dialysis Patients (2009-2011)

This report compares patient outcomes in the facility with national averages. The first half of Table 1 (rows 1a-1k) provides information about patient mortality for all dialysis patients treated at the facility. The second half of Table 1 (rows 1l-1u) provides information about mortality in the first year of dialysis for patients starting dialysis for the first time at the facility. For each section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for patients in the facility. The SMR compares the observed death rate in the facility to the death rate that was expected based on national death rates during that year for patients with the same characteristics as those in the facility (Wolfe, 1992). The SMR uses expected mortality calculated from a Cox model (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994), adjusting for calendar year, patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and population death rates.

The SMR accounts for many patient characteristics known to be associated with mortality, but cannot account for all factors that may explain differences in mortality between facilities. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients at a facility would not elevate the SMR. Other factors, such as nutritional status, factors relating to the process of care, or comorbid conditions that developed after incidence, are not accounted for. **Therefore, if the SMR statistic indicates potential differences in mortality for the facility compared to regional or national averages, please consider the role other important factors play within the facility.** As with the hospitalization and transplantation summaries which are described below in Sections V and VI, you will find the mortality summaries most informative if you use them as part of an integrated quality assurance process.

In the first half of the table, we reported information on the mortality of all prevalent dialysis patients for each year between 2009 and 2012, and also summarized the statistic for the 2009-2012 period. We also reported the averages in the state, ESRD Network, and the nation for this combined four-year period. In the second half of Table 1, we report similar statistics comparing first year mortality for new dialysis patients in the facility with national averages. This section of the table allows the facility to see how all the patients who started at that facility fared in their first year of dialysis even if the facility is no longer treating some of these patients.

Major Differences Between the Prevalent and First Year Mortality Calculations

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

Patient Placement

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

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

Beginning of Follow-up

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

Calendar Year Headings

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

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

Patients (1a)

We based the mortality summaries in the first half of the table (rows 1a-1k) on the dialysis patients who received treatment in the facility according to the conventions described in Section III.

Patient Years at Risk (1b)

For each patient in row 1a, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility.

Deaths (1c)

We reported the number of deaths that occurred among dialysis patients during each year, as well as the total across the years. This count does not include deaths from street drugs

or accidents unrelated to treatment. Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, we excluded them from the calculations.

Expected Deaths (1d)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, years since start of ESRD, nursing home status, patient comorbidities at incidence, and patient BMI at incidence (BMI = weight (kg)/ height² (m²)). In cases where the comorbidities or 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 2008-2010 (National Center for Health Statistics, 2012). As with the deaths in 1c, we then summed these expected deaths in order to obtain the total number of deaths expected for each year at the facility, and we summed the annual values to yield the expected number of deaths over the four-year period for each facility.

Categories of Death (1e-1g)

Row 1e reports the percentage of dialysis patient deaths (row 1c) 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 1f and 1g, we considered all causes of death (primary and secondary) provided on the form. The percentage of deaths in 1c with a primary or secondary cause of death listed as infection and cardiac causes are reported in row 1f.

Row 1g 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 (see 1c). We did not include these dialysis-unrelated deaths in the total death count in row 1c or the SMR; therefore, differences in SMRs between dialysis facilities do not correspond to differences in the number of dialysis-unrelated deaths.

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

Standardized Mortality Ratio (SMR) (1h)

The SMR equals the ratio of the actual number of deaths (1c) divided by the expected number of deaths (1d). The SMR estimates the relative death rate ratio for the facility, as compared to the national death rate in the same year. Qualitatively, the degree to which the facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2009-2012 national death rates for patients with the same characteristics as those in the facility. Similarly, the degree to which the facility's yearly SMR varies from 1.00 is the degree to which it differs from the national death rates that year for patients with the same characteristics as those in the facilities as those in the facility.

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

Detailed statistical methodology for the SMR is included in a separate document titled *Technical Notes on the Standardized Mortality Ratio for the Dialysis Facility Reports*. This document and an accompanying Microsoft Excel spreadsheet are available on the Dialysis Reports website (www.dialysisreports.org) under the Methodology heading. Quantitatively, if the facility's death rates equal the national death rates (in deaths per patient year or per year at risk) times a multiplicative constant, then the SMR estimates that multiplicative constant. If the multiplicative constant varies for different subgroups of patients, then the SMR estimates a weighted average of those constants according to the facility's patient mix. For example, an SMR=1.10 would indicate that the facility's death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to the facility's patient mix). Similarly, an SMR=0.95 would indicate that the facility's death rates are typically 5% below the national death rates (e.g., 19 versus 20 deaths). An SMR=1.00 would indicate that the facility's death rates.

We calculated the regional and national summaries as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region (1c/1d).

Why the national SMR may not be exactly equal to 1.00

The reported 2009-2012 SMR for the U.S. as a whole may not be precisely equal to 1.00. The SMR value for the U.S. given in the Dialysis Facility Reports does not include all

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U.S. dialysis facilities in its calculation. In particular, as discussed in the Overview, transplant-only, Veteran's Administration, and non-Medicare facilities are not included in the geographic summaries.

Random variation

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

P-value (1i)

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

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

Confidence Interval for SMR (1j)

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

Recommended Course of Action if SMR Is Elevated

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

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

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

3) Examine input data. Table 10 gives some details about the patients assigned to the facility. The Network can provide you with a list of patients used in this report, which includes patient identifiers and death dates, if applicable. Consider whether the counts of patients by year are plausible over time, as well as for any one year. If this list contains substantial errors, we would like to know about them.

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

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

SMR Percentiles for This Facility (1k)

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

Patients for First Year Mortality (11)

Row 11 of this table gives the total number of forms for new dialysis patients submitted by the facility for the year. The first year mortality statistics reported in the second half of the table (11-1s) 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, 2009 and December 31, 2011. 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 (1m)

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

Deaths in First Year (1n)

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 1c above for details).

Expected Deaths in First Year (10)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, year, nursing home status, patient comorbidities at incidence, and patient BMI at incidence (BMI = weight (kg)/ height² (m²)). 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 2008-2010 (National Center for Health Statistics, 2012). As with the deaths in 1r, we then summed these expected deaths in order to obtain the total number of deaths expected for each year at the facility, and we summed the annual values to yield the expected number of deaths over the three-year period for each facility.

First Year Standardized Mortality Ratio (SMR) (1p)

The SMR equals the ratio of the actual number of deaths (1n) divided by the expected number of deaths (1o). The SMR estimates the relative death rate ratio for the facility, as compared to the national death rate in the same year. Qualitatively, the degree to which the facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2009-2011 national death rates for new dialysis patients with the same characteristics as those in the facility. Similarly, the degree to which the facility's yearly SMR varies from 1.00 is the degree to which it differs from the national death rates for patients with the same characteristics as those in the facility as those in the facility that year.

We used similar methods to calculate SMR for new dialysis patients and for all dialysis patients. We adjusted the SMR for age, race, ethnicity, sex, diabetes, nursing home

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

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

We calculated the regional and national summaries as the ratio of the total number of observed deaths among patients from each region to the number of expected deaths among patients from each region (1n/10).

P-value (1q)

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

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

Produced by The University of Michigan Kidney Epidemiology and Cost Center

Confidence Interval for First Year SMR (1r)

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

First Year SMR Percentiles for This Facility (1s)

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

V. Hospitalization Summary for Medicare Dialysis Patients, 2009-2012

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 12 days in the hospital per year (USRDS, 2012). 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 2.

This report includes summaries of the hospitalization rates among dialysis patients in the facility, along with comparative regional and national data. However, the reasons for differences in hospitalization rates by facility are complex. In some cases, a hospitalization may result from deteriorated patient health caused, for example, by inadequate dialysis. In other cases, a hospitalization to treat a pre-existing comorbid condition may effectively prevent additional or more serious hospitalizations. *Thus, we provide hospitalization summaries in this report as indicators of the process of care, rather than as measures of patient outcomes in a facility.*

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-paid 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-paid

inpatient claim. In setting this criterion, our aim is to achieve completeness of information on hospitalizations for all patients included in the years at risk.

Summaries of days hospitalized are reported in rows 2c through 2h, summaries of hospital admissions are reported in Rows 2i through 2s, and summaries of ED visits are reported in Rows 2t through 2bb. These statistics include multiple admissions or ED visits per patient. For each facility, a *Standardized Hospitalization Ratio (Days)*, a *Standardized Hospitalization Ratio (Admissions)*, and a *Standardized Hospitalization Ratio (ED)* were calculated. Like the SMR, these statistics are intended to compare the facility's observed number of events (be it admissions, days hospitalized, or ED visits) to the number that would be expected if patients at the facility were instead subject to the 2009-2012 national average admission, days, and ED visit rates. The expected national rates 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, and calendar year.

We report the hospitalization summaries for each year from 2009-2012 and for the entire four-year period. We also report the results for the average facility over the combined 2009-2012 period for hospitalization summaries at the regional and national levels.

Medicare Dialysis Patients (2a)

The number of Medicare dialysis patients included in the hospitalization summaries (2a) is generally smaller than the number of patients included in the mortality summaries (1a). We calculated hospitalization rates based only on periods in which dialysis patients had satisfied the Medicare payment criterion (described above).

Patient Years at Risk (2b)

The number of patient years at risk indicates the total amount of time we followed patients in this table's analyses. We used the number of patient years at risk reported in 2b as the denominator in the calculation of the total days hospitalized statistics. Patients were at risk for spending another day in the hospital whether or not they were hospitalized at the time. For all patients, time at risk began at the start of the facility treatment period (see Section III) and continued until the earliest occurrence of the following: three days prior to a transplant; date of death; end of facility treatment; or December 31 of the year. Since a facility may have treated a patient for multiple periods during the same year, patient years at risk includes time at risk for all periods of treatment at the facility.

Days Hospitalized Statistics

Total Days Hospitalized (2c)

This represents the total number of days that Medicare dialysis patients assigned to this facility spent as inpatients in the hospital. The total number of days includes multiple admissions (i.e., second, third, etc. hospitalizations for the same patient). If a patient was

admitted near the end of one year and was not discharged until the following calendar year (e.g., admitted on 12/28/2011 and discharged on 1/6/2012), the number of days hospitalized are assigned appropriately to the two years (four days in 2011 and six days in 2012).

Expected Total Days Hospitalized (2d)

We calculated the expected number of hospitalized days among Medicare dialysis patients in a facility based on national rates for days hospitalized in the same year. The expected hospitalization frequency is calculated from a Cox model, adjusting for patient age, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, body mass index (BMI) at incidence, and calendar year of treatment. In cases where the comorbidities or BMI were 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 2d.

Standardized Hospitalization Ratio (SHR) for Days (2e)

The SHR (Days) is calculated by dividing the observed total days hospitalized in 2c by the expected total days hospitalized in 2d. As with the SMR, it enables a comparison of the facility's experience to the national average for the same year(s). A value of less than 1.0 indicates that the total number of days hospitalized in the facility was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the total number of days hospitalized in the facility was higher than the (adjusted) national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI in the facility. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that hospitalization at the facility has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization at the facility decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for the facility would be the same for each year.

P-value (2f)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of hospitalization rates for the facility versus the nation is different (higher or lower) from 1.00. The p-value is the probability that the SHR would, just by chance, deviate from 1.00 as much as does the observed SHR, and is sometimes

naively interpreted as the probability that the true SHR equals 1.00. A smaller p-value tends to occur when the ratio differs more greatly from 1.00 and when one uses more patient data to calculate the SHR value. A p-value of less than 0.05 is usually taken as evidence that the ratio of hospitalization rates truly does differ from 1.00. For instance, a p-value of less than 0.05 would indicate that the difference between the facility's hospitalization rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value, the more *statistically significant* the difference between national and individual facility hospitalization rates is. A small p-value helps rule out the possibility that an SHR's variance from 1.00 could have arisen by chance. However, a small p-value does not indicate the degree of importance of the difference between the facility's hospitalization rates and the nation's.

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

Confidence Interval for SHR (Days) (2g)

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

SHR (Days) Percentiles for This Facility (2h)

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

Admission Statistics

Total Admissions (2i)

This is the total number of inpatient hospital admissions among the Medicare dialysis patients assigned to this facility. The total number of admissions includes multiple admissions (i.e., second, third, etc. hospitalizations for the same patient). If a patient was admitted near the end of one year and not discharged until the following calendar year (e.g., admitted on 12/28/2011 and discharged on 1/6/2012), the admission would count only in the second year (zero admissions in 2011 and one admission in 2012).

Expected Total Admissions (2j)

We calculated the expected number of hospital admissions among Medicare dialysis patients in a facility based on national rates for hospital admissions in the same year. The expected number of admissions is calculated from a Cox model, adjusting for patient age, sex, diabetes, 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 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 2j.

Standardized Hospitalization Ratio (SHR) for Admissions (2k)

The SHR (Admissions) is calculated by dividing the observed total admissions in 2i by the expected total admissions in 2j. As with the SMR, it enables a comparison of the facility's experience to the national average. A value of less than 1.0 indicates that the facility's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the facility had a rate of total admissions higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI in the facility. Additionally, each year's estimate is compared to the US hospitalization rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time at the facility beyond the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that hospitalization at the facility has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization at the facility decreased over the four year period at the same rate that overall US hospitalization decreased over this time period, the SHR for the facility would be the same for each year.

P-value (21)

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

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

Produced by The University of Michigan Kidney Epidemiology and Cost Center

Confidence Interval for SHR (Admissions) (2m)

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

SHR (Admissions) Percentiles for This Facility (2n)

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

Diagnoses Associated with Hospitalization (20)

Row 20 reports the percentage of patients in 2a who had septicemia, acute myocardial infarction, congestive heart failure, cardiac arrhythmia, and cardiac arrest reported as one of the diagnoses on a hospital bill with a start date during a period of treatment at the facility. We first identified ICD-9 diagnosis codes associated with these diagnoses and then looked for these codes on the hospital bills (in any position on the list of diagnoses). Row 20 includes all bills, even if the patient did not leave the hospital in between bills. Note that a patient may appear in more than one of the categories.

One Day Admissions (2p)

We reported the percentage of total inpatient hospital admissions in 2i 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 (2q)

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

Readmissions within 30 Days (2r)

Row 2r reports the number of inpatient hospitalizations for Medicare dialysis patients that were followed by a readmission within 30 days of discharge. The value for 2012 (and the combined period) may be an underestimate as readmissions discharged after December 31, 2012 are not included in the measure.

Admissions that Result in Readmission within 30 Days (2s)

Row 2s reports the percentage of inpatient admissions in 2i that resulted in readmission within 30 days of discharge. The value for 2012 (and the combined period) may be an

underestimate as readmissions discharged after December 31, 2012 are not included in the measure.

Emergency Department (ED) Statistics

Total ED Visits (2t)

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

Expected Total ED Visits (2u)

We calculated the expected number of ED visits among Medicare dialysis patients in a facility based on national rates for ED visits in the same year. The expected number of ED visits is calculated from a Cox model, adjusting for patient age, sex, diabetes, 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 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 2u.

Standardized Hospitalization Ratio (SHR) for ED (2v)

The SHR (ED) is calculated by dividing the observed total ED visits in 2t by the expected total ED visits in 2u. As with the SMR, it enables a comparison of the facility's experience to the national average. A value of less than 1.0 indicates that the facility's total number of ED visits was less than expected, based on national rates; whereas a value of greater than 1.0 indicates that the facility had a rate of ED visits higher than the national average. Note that this measure is adjusted for the actual patient characteristics of age, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI in the facility. Additionally, each year's estimate is compared to the US rates for the same year. Because a different reference year is used for each year's estimate, the SHRs will allow you to identify trends over time in the facility <u>beyond</u> the overall US trend over time. In other words, if the SHR for the facility decreases over the time period, this means that ED visits decreased. If ED visits in the facility decreased over the four year period at the same rate that overall US ED visits decreased over this time period, the SHR for the facility would be the same for each year.

P-value (2w)

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

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

Confidence Interval for SHR (ED) (2x)

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

SHR (ED) Percentiles for This Facility (2y)

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

Patients with ED visit (2z)

Row 2z reports the percentage of Medicare dialysis patients assigned to this facility over the four-year period from 2009-2012 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 (2aa)

Row 2aa reports the percentage of ED visits in 2t that resulted in an inpatient admission.

Admissions that Originated in the ED (2bb)

Row 2bb reports the percentage of inpatient admissions that originated in the Emergency Department. This percentage may exceed 100% because adjacent inpatient admissions for the same patient are combined in the four-year summary. In particular, if a patient is discharged from the hospital but is readmitted within 1 day of discharge, we combine the two inpatient admissions and thus these admissions will only be counted once. However, if both of the inpatient admissions originated in the Emergency Department, then 2 ED visits will be included in the numerator. For this reason, for a very small number of facilities, row 2bb will exceed 100%.

VI. Transplantation Summary for Dialysis Patients under Age 70, 2009-2012

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 Rates (STRs) for dialysis patients. We calculated the STR using the same methods as the SMR, described in more detail in Section IV. Adjustments for the STR differed from those for the SMR because the STR was adjusted for age only. Since we included patients in this table only once they reached day 91 of ESRD, we excluded patients who received a pre-emptive transplant or a transplant within the first three months of treatment. You will find these statistics useful in that they allow a facility to compare the rate of transplantation for the dialysis patients. The percentage of transplants in the U.S. that were not included because the transplant occurred less than 90 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 (3a)

Row 3a reports the number of dialysis patients under age 70. 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 (3b)

Row 3b reports the number of dialysis patients under the age of 70 in each facility who received a transplant.

Donor Type (3c)

Row 3c reports by year the number of patients who received transplants from a living and from a deceased donor. The sum is the number of transplants in row 3b, although it may be lower due to unknown donor type.

Eligible Patients (3d)

Row 3d reports the number of dialysis patients under age 70 from row 3a 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 (3d) was typically much smaller than the number of patients included in the mortality summaries (1a) 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 (3e)

We limited our calculations for 3e 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 facility treatment period (see Section III) and continued until the earliest of the following occurrences: transplant, date of death, end of the facility treatment period, or December 31. A patient may have been treated at one facility for multiple periods during the same year; in such a case, the number of patient years at risk included time at risk for all periods of treatment at that facility.

Actual First Transplants (3f)

Row 3f reports the number of dialysis patients under the age of 70 in each facility who received a first transplant.

Expected First Transplants (3g)

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 3 sums and reports the total number of patients expected to receive a first transplant from the facility, with corresponding regional and national averages.

Standardized Transplantation Ratio (3h)

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

Interpret the STR as you would the SMR. An STR of 1.00 indicates that the observed number of transplants in the facility equals the estimated national rate, adjusted for age.

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

Because a different reference year is used for each year's estimate, the STRs will allow you to identify trends over time at the facility <u>beyond</u> the overall US trend over time. In other words, if the STR for the facility decreases over the time period, this means that transplantation at the facility has decreased more over that time period than the overall US average transplantation decreased. If transplantation at the facility decreased over the four year period at the same rate that overall US transplantation decreased over this time period, the STR for the facility would be the same for each year.

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

Random Variation

The STR tends to show more random variation than the SMR because numbers of transplants are much smaller than numbers of deaths. Small numbers of events contribute to instability, increasing the chances that an observed result owes to chance rather than to the true ratio of observed-to-expected transplants. This makes p-values and confidence intervals instrumental in interpreting the facility's STR. We calculated these statistics based on an assumed Poisson distribution of the observed number of patients transplanted.

P-value (3i)

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

Confidence Intervals for STR (3j)

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

STR Percentile for This Facility (3k)

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

VII. Waitlist Summary for Dialysis Patients under Age 70 Treated as of December 31 of Each Year, 2009-2012

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.

Eligible Patients on 12/31 (4a)

This table reports waitlist summary statistics for all dialysis patients under age 70 that were being treated on December 31 of each year in the facility. Row 4a 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 Tables 1, 2, and 3. For this table, we included patients at the facility they were in on December 31 of each year according to claims data or SIMS. 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 (4b)

Row 4b reports the percentage of patients in 4a who were on the kidney or kidneypancreas transplant waitlist as of December 31, with the corresponding national percentage for 2012 reported for comparison. This information was obtained from Organ Procurement and Transplantation Network (OPTN) / Scientific Registry of Transplant Recipients (SRTR) data.

P-value (4c)

We used a one-sided p-value to test the hypothesis that the true percentage of patients on the waitlist reported in row 4b is higher (or lower) than the U.S. value for that year. The footnote for row 4c 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 the facility and in the U.S. occurred due to chance. A low p-value means that the chances are low that the facility percentage was higher or lower than the national average merely because of random variation. A p-value of less than 0.05 usually indicates a result's statistical significance. You should also use the absolute magnitude of the difference between the facility and national percentage of patients on the waitlist to determine its clinical importance.

Patient Characteristics (4d)

Row 4d reports the percentage of patients in row 4b by age, sex, race and ethnicity, cause of ESRD, previous transplant, and years of ESRD treatment. State, Network, and U.S. averages for 2012 are given for comparison.

VIII. Influenza Vaccination Summary for Medicare Dialysis Patients Treated on December 31st of Each Year, Flu Seasons 2009/2010-2011/2012

This table reports influenza vaccination summary statistics identified on Medicare claims for Medicare dialysis patients treated on December 31st of each year in the facility. Average values for 2011/2012 are also reported among patients in the state, Network, and the U.S. In an effort to emphasize the use of vaccine prior to the peak of flu season, we provide vaccination summaries from August 1st through December 31st each year as well as the overall vaccination summary for the full influenza vaccination season (August 1st through March 31st of the following year).

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 V 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 at the facility at the end of each year. The 60-day 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 counted whether these occurred at the facility or outside of the facility. Vaccinations not billed to Medicare are not captured.

Eligible Patients on 12/31 (5a)

Row 5a reports the number of Medicare dialysis patients included in the influenza vaccination summaries.

Patients Vaccinated between Aug. 1 and Dec. 31 (5b)

Row 5b reports the percentage of patients in 5a who had a Medicare claim for vaccination performed between August 1^{st} and December 31^{st} , with the corresponding national percentage for 2011/2012 reported for comparison.

P-value for Patients Vaccinated between Aug. 1 and Dec. 31 (5c)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 5b, is higher (or lower) than the U.S. value for that year. The footnote for row 5c shows the percentage of patients vaccinated in the U.S. for each year used in this comparison. The p-value indicates the probability that the difference between the percentages of patients vaccinated in the facility and in the U.S. occurred due to

chance. A low p-value means that the chances are low that the facility percentage was higher or lower than the national average merely because of random variation. A p-value of less than 0.05 usually indicates a statistically significant result. You should also use the absolute magnitude of the difference between the facility and national percentage of patients vaccinated to determine its clinical importance.

Patients Vaccinated between Aug. 1 and Mar. 31 (5d)

Row 5d reports the percentage of patients in 5a who had a Medicare claim for vaccination performed between August 1^{st} and March 31^{st} of the following year, with the corresponding national percentage for 2011/2012 reported for comparison.

P-value for Patients Vaccinated between Aug. 1 and Mar. 31 (5e)

We used a one-sided p-value to test the hypothesis that the true percentage of patients vaccinated, reported in row 5d, is higher (or lower) than the U.S. value for that year. The footnote for row 5e shows the percentage of patients vaccinated in the U.S. for each year used in this comparison.

Patient Characteristics (5f)

Row 5f reports the percentage of patients in row 5b by age, sex, race and ethnicity, and years of ESRD treatment. State, Network, and U.S. averages for 2011/2012 are given for comparison.

IX. Facility Modality, Hemoglobin, and Dialysis Adequacy, 2009-2012

Table 6 reports information on facility practice patterns. Each section of the table includes a slightly different group of patients. We restricted dialytic modality and hemoglobin, and Kt/V information to patients who have had ESRD for at least 90 days. Information on urea reduction ratio is restricted to patients who have had ESRD for at least 183 days. For the definition of the value code, occurrence code and V modifier codes, please see the list of diagnostic codes included in a separate document available at <u>www.DialysisReports.org</u> under the Methodology heading. The weekly Kt/V information reported in rows 6p-6y is based on the value code D5: Result of last Kt/V (K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water). The inclusion criteria are described in more detail below. Table 6 includes state, Network, and U.S. summaries for 2011 only. Note that State and U.S. averages may differ from values in the DFC report due to the difference in number of facilities receiving a report.

Modality (6a-6c)

We based the reported dialytic modality information on all Medicare dialysis claims submitted by the facility, excluding patient claims that started before day 90 of ESRD. Each patient treated during January 2009 through December 2012 at the facility was classified each month as receiving hemodialysis (including home hemodialysis), CAPD/CCPD, or other dialysis. Patients were categorized as receiving 'other dialysis' if they had claims for both hemodialysis and peritoneal dialysis in the same month. Rows 6a and 6b report the number of patients, and patient months, treated during the year. Row 6c reports the percentage of patient months covered by each of these therapeutic modalities.

Prescribed Medication (6d)

We based the information reported in row 6d on all Medicare dialysis claims submitted by the facility for patients in 6a. Row 6d reports the percent of patient-months during which the use of iron was prescribed. This measure is reported separately for hemodialysis and CAPD/CCPD patients. We calculated this as a percent of the number of patient-months represented by the corresponding modality percent in 6c.

Hemoglobin (6e-6k)

We based the hemoglobin information reported in rows 6e to 6k on all Medicare dialysis claims submitted by the facility that indicated the use of an erythropoiesis stimulating agent (ESA), specifically, the use of epoetin alfa or 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 90 of ESRD nor claims with hemoglobin values less than 5 or greater than 20. Row 6e reports the number of patients for whom at least four claims fulfilling these criteria were submitted by the facility for each year. A patient treated at more than one facility during the year was included in the report for each facility (as long as the patient had at least 4 claims from the facility). For each patient in row 6e, we calculated the average hemoglobin reported on claims submitted by the facility.

We summed the average hemoglobin values for the patients in 6e and then divided by the number of patients in 6e in order to obtain the facility average reported in 6f. Row 6g presents the percentage of patients from 6e in each of four hemoglobin categories: less than 10g/dl, between 10-<11 g/dl, between 11-12 g/dl, and greater than 12 g/dl.

In rows 6h to 6k, 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. For these statistics, claims from the facility for each patient were further divided by the treatment modality for the claim. This means that patients who received both HD and PD treatment at the facility appear in both the HD (6h-6i) and PD (6j-6k) statistics. Patients who had at least 4 total claims from the facility appear in these rows, even when there were fewer than 4 claims for the particular modality.

Urea Reduction Ratio (61-60)

We base the urea reduction ratio (URR) information reported in rows 6l-60 on all Medicare dialysis claims submitted by the facility, with the following four exclusions: (1) claims which started before day 183 of ESRD for a patient; (2) claims with missing URR category; (3) claims listing a patient's modality as peritoneal dialysis (PD); and (4) claims indicating the occurrence of frequent dialysis, defined as four or more sessions per week. A claim is determined to indicate frequent dialysis if the claim covered seven or fewer days and had four or more sessions, if the claim covered more than seven days and had a rate of four or more sessions per week, or if the patient was identified in the Standard Information Management System (SIMS) as having dialyzed five or more times per week during the month of the claim start date.

Row 6l reports the number of patients for whom at least four claims fulfilling the above criteria had been submitted for the facility for each year. A patient who had been treated at more than one facility during the year was included at both facilities in row 6l when the patient had at least four claims with URR at each facility. We assigned each patient in 6l to the median URR. For patients treated at more than one facility during the year, we calculated separately the URR category for them for each facility based on the claims from each facility only.

Row 6m reports the percentage of patients in the facility in each category. The KDOQI guidelines recommend that all patients with treatment times less than 5 hours have a URR of 65% or more (NKF-KDOQI, 2006). Row 6n reports the percentage of patients in row 6l with URR that meets KDOQI guidelines (i.e., 65% or more). In calculating the percent of patients that have a URR of 65% or more we use a slightly different group of patients than the corresponding measure in the QIP. The QIP calculations are restricted to adult patients obtaining in-center hemodialysis.

Row 60 reports the percentile rank of the facility's URR (percentage of patients who met KDOQI guides for URR) for each year, relative to all other facilities in the state, Network, and nation.

Kt/V (K-dialyzer clearance of urea; t-dialysis time; V-patient's total body water) (6p-6y) This section of the table includes summaries of dialysis adequacy as reported in Medicare claims using value codes and occurrence codes collected beginning July 2010. The statistics are reported for July-December 2010, and January-December 2011 along with comparative regional and national data.

The number of adult patients who had at least one valid Medicare hemodialysis claim submitted by the facility that month is reported in row 6p. The number of adult patient-months with a valid claim is reported in row 6q. Patients may account for up to 12 patient-months per year. A claim was defined as valid if it was from a hemodialysis patient who received dialysis greater than two and less than four times a week, had been on dialysis for at least 90 days, and was at least 18 years old. A patient who had been treated at more than one facility during the month was included at both facilities in rows 6p and 6q when the patient had a claim at each facility. A patient who had switched modalities during the month was included in both the HD and PD eligible patient, and patient-month counts.

The Kt/V value for a patient-month is characterized into five mutually exclusive categories: missing (no Kt/V reported); not performed (Kt/V reported as 9.99); 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); in range (Kt/V value between 0.5 and 2.5 and not

expired); and out of range (Kt/V value less than 0.5 or greater than 2.5, and not missing or 9.99).

The average Kt/V for HD patients at the facility is reported in row 6r and is based only on patient-months with Kt/V values in range. The percentages of all patient-months with in range claims stratified by Kt/V categories, and other non-valid categories, for each month for the facility are shown in 6s. The percentage of all patient-months with in range claims greater than or equal to 1.2, for hemodialysis patients, is reported in 6t.

The number of adult patients who had at least one valid Medicare peritoneal dialysis claim submitted by the facility that month is reported in row 6u. The number of adult patient-months with a valid claim is reported in row 6v. Patients may account for up to 12 patient-months per year. A claim was defined as valid if it came from a peritoneal dialysis patient who had been on dialysis for at least 90 days and was at least 18 years old. A patient who had been treated at more than one facility during the month was included at both facilities in rows 6u and 6v when the patient had a claim at each facility. A patient who had switched modalities during the month was included in both the HD and PD eligible patient, and patient-month counts.

The Kt/V value for a patient-month is characterized into five mutually exclusive categories; missing (no Kt/V reported); not performed (Kt/V reported as 9.99); expired (Kt/V reported from more than four months prior); in range (Kt/V value between 0.5 and 5.0 and not expired); and out of range (Kt/V value less than 0.5 or greater than 5.0, but not missing or 9.99).

The average Kt/V for PD patients at the facility is reported in row 6w and is based only on patient-months with Kt/V values in range. The percentages of all patient-months with in range claims stratified by Kt/V categories, and other non-valid categories, for each month for the facility are shown in 6x. The percentage of all patient-months with in range claims greater than or equal to 1.7, for peritoneal dialysis patients, is reported in 6y.

X. Vascular Access Information, CMS Fistula First (January 2009 – April 2012) and CROWNWeb (May – December 2012)

Table 7 reports vascular access data from the National Vascular Access Improvement Initiative's Fistula First project, which collects monthly data on vascular access from dialysis facilities. We summarized these data, from January 2009 – April 2012, reporting yearly averages for each facility. Starting in May 2012, the Fistula First data are supplemented by patient-level vascular access data collected in CROWNWeb and are likewise summarized as annual measures. We also report comparison values for 2012 for the state, network and U.S. Both the Fistula First and CROWNWeb data are self-reported by dialysis facilities.

Prevalent Hemodialysis Patient Months (7a)

The monthly prevalent hemodialysis patient count at a facility includes all non-transient patients (home and in-center) who receive hemodialysis as of the last day of that calendar month. Incident patients (those who received ESRD treatment for the first time ever) are included in this count. Row 7a reports the number of prevalent hemodialysis patient months reported at the facility each year. The number of patient months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient months per year.

Vascular Access Type in Use (7b)

Row 7b reports the type of vascular access in use during the last hemodialysis treatment of the calendar month, summarized for each year. This row reports the percentage of patient months in 7a in which the patient received dialysis through arteriovenous (AV) fistulae, grafts, catheters or other access types for the last treatment of the month. 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 missing from the record.

Arteriovenous (AV) Fistulae Placed (7c)

Row 7c reports the average percentage of patient months in 7a in which an AV fistula was in place at the time of the last treatment of the month, regardless of whether the patient received hemodialysis treatment using this AV fistula.

Catheter Only \geq 90 Days (7d)

Row 7d reports the average percentage of patient months in 7a in which a catheter was in use at the last treatment of the month; 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 at least 90 days prior to treatment. Again, port access devices are included in the catheter category.

Incident Hemodialysis Patients (7e)

Row 7e reports the total number of incident hemodialysis patients at the facility each year. The average number of incident patients during 2012 is reported for comparison for the state, network and U.S. Incident hemodialysis patients are non-transient hemodialysis patients (home and in-center) who received their first-ever ESRD treatment during the month for which the data was reported. These patients are a subset of prevalent patients.

Vascular Access Type in Use (7f)

Row 7f reports the type of vascular access in use during the last hemodialysis treatment of the calendar month in which the patient was incident, summarized for each year. This row reports the percentage of incident hemodialysis patients in 7e who received dialysis through AV fistulae, 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 missing from the record.

Arteriovenous (AV) Fistulae Placed (7g)

Row 7g reports the percentage of incident patients in 7e 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.

XI. Dialysis Access Type and Access-Related Infection Summary for Medicare Dialysis Patients, 2009-2012

This table includes summaries of the vascular access types reported by V modifiers and dialysis access-related infection rates reported by ICD-9 codes among patients in the facility, along with comparative regional and national data.

Vascular Access

This section of the table includes summaries of facility vascular access type for adult patients as reported in Medicare claims using V modifiers collected beginning July 2010. The statistics are reported for July-December 2010, 2011 and 2012. Modality and vascular access type are determined based on the last claim of the month from the facility for the patient reported. A patient-month is counted in the denominator for a facility if the patient's modality was listed as hemodialysis on the last claim of the month. If dialysis claims are submitted from more than one facility in a month for a patient, the patient is counted in each facility's denominator. For the regional calculations, the month will be included only once for that patient. Please note that the number of eligible patient-months for the statistics calculated in rows 8b-c are not necessarily the same as the numbers shown in row 8e because they are based on different criteria. Pediatric patient statistics for fistula and catheter use can be found in the pediatric table. In addition, State and U.S. averages may differ from values in the DFC report due to the difference in number of facilities receiving a report.

Eligible hemodialysis patient-months (8a)

The total number of months during which each adult patient is treated with hemodialysis at the facility as described above are summed and reported in row 8a.

Hemodialysis Vascular Access Type (8b-c)

Row 8b shows the percentage of adult HD patients at each facility with vascular catheter, arteriovenous (AV) graft, AV fistula, or other access type. These data are reported using V modifiers V5-V7 in Medicare claims. Row 8c reports the percent of HD patients at the facility with a vascular catheter reported as access type in use for all claims for at least three consecutive months. The vascular catheter measure cannot be calculated for July, August, or September of 2010 because catheter use for the previous three months is not available until October of 2010. Medicare claims listing multiple access types prior to

2012 are not included in the numerators of the vascular access type summaries. Starting in January 2012, claims listing a catheter and either a fistula or graft are reported in the fistula or graft summaries respectfully. This is due to changes in vascular access reporting instructions on Medicare claims. Claims listing both graft and fistula are not reported as either access type.

Assignment of Patients to Facilities (Access-Related Infection section only)

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

Any patient treated with dialysis at a facility during a particular month is included in that facility's statistics so long as they also meet the Medicare criteria described above for that month. There is no exclusion of the first 90 days of treatment and patients treated at more than one facility in a particular month are included at both facilities that month. A patient can be included in both the hemodialysis and peritoneal dialysis sections of the table for a particular month if they received both types of treatment 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-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), transplant registration data from the OPTN, and data from the Standard Information Management System (SIMS). 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, SIMS is given precedence.

The ICD-9 codes for dialysis-access related infection reported on this table are 996.62 and 996.68 and are collected from inpatient, outpatient and physician supplier Medicare claims. For a definition of ICD-9 codes, please see the list of diagnostic codes included in a separate document available at <u>www.DialysisReports.org</u> under the Methodology heading.

Hemodialysis (HD): Eligible HD patients and Eligible HD patient-months (8d-e)

The number of Medicare hemodialysis patients treated at the facility during at least one month during the year or four-year period is reported in row 8d. The total number of months during which each patient is treated with hemodialysis at the facility are summed and reported in row 8e. Please refer to section III above for additional detail regarding patient assignment.

HD infection rate per 100 patient-months (8f)

This statistic shows the rate of dialysis access-related infection in HD patients during each year. For each month included in row 8e, the patient is considered to have had an access-related infection during the month if there was a Medicare claim with ICD-9 code

996.62 during that month. The rate is calculated by summing the patient-months with an access-related infection and dividing by the number of eligible HD patient-months in row 8e. The number is then converted to a rate per 100 HD patient-months. Patients can only contribute one dialysis access-related infection to a facility during a month. If the patient is treated at two facilities with HD in a month with an infection, the infection is counted at both facilities. For the regional summaries, the infection will only be counted once in the region.

P-value (compared to U.S. value) (8g)

A one-sided p-value is used to test the hypothesis that the rate of HD patients with dialysis access-related infection per 100 HD patient-months, reported in row 8f, is higher (or lower) than the U.S. value for that year. A low p-value means that the chances are low that the facility rate was higher or lower than the national rate merely because of random variation. A p-value of less than 0.05 usually indicates a statistically significant result. You should also use the absolute magnitude of the difference between the facility and national rate of hemodialysis patients with dialysis access-related infection to determine its clinical importance.

Peritoneal Dialysis (PD): Eligible PD patients and Eligible PD patient-months (8h-i)

The number of Medicare PD patients treated at the facility during at least one month during the year or four-year period is reported in row 8h. The total number of months during which each patient is treated with PD at the facility are summed and reported in row 8i. The *Assignment of Patients to Facilities* section above provides additional detail.

PD catheter infection rate per 100 PD patient-months (8j)

This statistic shows the rate of PD catheter infection in peritoneal dialysis patients during each year. For each month included in row 8i, the patient is considered to have had a PD catheter infection if there was a Medicare claim with ICD-9 code 996.68 during that month. The rate is calculated by summing the patient-months with a peritonitis infection and dividing by the number of eligible PD patient-months in row 8i. The number is then converted to a rate per 100 PD patient-months. Patients can only contribute one dialysis access-related infection to a facility during a month. If the patient is treated at two facilities with PD in a month with an infection, the infection is counted at both facilities. For the regional summaries, the infection will only be counted once in the region.

P-value (compared to U.S. value) (8k)

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 8kl, is higher (or lower) than the U.S. value for that year.

XII. Characteristics of New Dialysis Patients, 2009-2012 (Form CMS-2728)

Table 9 presents detailed data from the ESRD Medical Evidence Form (Form CMS-2728) on the characteristics of new patients in the facility by year. State, Network and national averages for 2011 are also shown for comparison. The patients represented in this table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2008 and December 31, 2011. Please note that we placed the patients included here *not* according to the conventions described in Section III, but rather according to the CMS certification number that appeared on their Medical Evidence Forms.

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

Patient Characteristics (9a-9m)

Row 9a of this table gives the total number of forms submitted by the facility for the year. Rows 9b-9m 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 (9n-9q)

Rows 9n through 9q report lab values prior to the start of ESRD. We estimated the glomerular filtration rate (GFR) reported in row 9q using a formula developed by the Modification of Diet in Renal Disease (MDRD) Study (Levey et al, 1999) — a formula based on serum creatinine before first dialysis, age, race, and gender.

Nephrologist Care Prior to Start of ESRD Therapy (9r, 9s)

Row 9r reports the percentage of incident patients in 9a who have received an ESA prior to ESRD. Row 9s gives the percentage of patients in 9a 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, unknown).

Kidney Transplant Options (9t-9v)

Row 9t reports the percentage of patients in 9a who had been informed of transplant options. Row 9u gives the count of patients who were not informed of their transplant options. The reasons for not informing the patients reported in 9u 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 9v.

Comorbid Conditions (9w, 9x)

Row 9w reports the percentage of patients in the facility 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 9x gives the average number of comorbid conditions reported per new patient in the facility, the state, the Network, and the nation.

XIII. Summaries for All Dialysis Patients Treated as of December 31 of Each Year, 2009-2012

Table 10 summarizes the characteristics of dialysis patients treated on December 31, 2009-2012 in the facility, with corresponding average values for 2011 among patients in the state, ESRD Network, and the U.S.

Patients Treated on 12/31 of Year (10a)

Row 10a reports the total number of dialysis patients treated in the facility on December 31 of each year according to the conventions described in Section III. We based the summaries of the patient characteristics in Table 10 on the patient population count in this row.

Age (10b, 10c)

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 (10d)

Row 10d reports the percentage of female patients.

Race (10e)

We established each patient's race using two sources of information: the Medical Evidence Form and Standard Information Management System (SIMS). 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 (10f)

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 and Non-Hispanic categories.

Cause of ESRD (10g)

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

Duration of ESRD (10h, 10i)

We calculated the number of years since first renal replacement therapy for each patient treated in the facility on December 31 of each year. Row 10h reports the average number

of years of prior ESRD therapy. Row 10i displays ranges of years since start of ESRD and the corresponding percentages of patients per range.

Nursing Facility Patients (10j)

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 (10k)

Row 10k reports the percent of patients on chronic dialysis treatment at the facility (%10a) 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.)

XIV. Comorbidities Reported on Medicare Claims for Medicare Dialysis Patients Treated as of December 31 of Each Year, 2009– 2012

Table 11 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31 of each year(2009-2012) in the facility, with corresponding average values for 2012 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 diagnostic codes and HCPCS CPT codes used to identify comorbidities is included in a separate document available at www.DialysisReports.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 V for the hospitalization statistics. Patient periods are included if each month in the period is within two months after the end of a month having either a) at least \$900 of Medicare-paid dialysis claims or b) at least one Medicare-paid inpatient claim. This table is then further restricted to patients treated at the facility at the end of the year.

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

Row 11a reports the total number of Medicare dialysis patients treated in the facility on December 31 of each year, according to the conventions described in Section III, who also satisfy the criterion described above for assuring that Medicare claims data are complete for the patient. We based the summaries of the patient characteristics in Table 11 on the patient population count in this row.

Comorbid Conditions (11b)

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

Average Number of Comorbid Conditions (11c)

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

XV. How Patients Were Assigned to This Facility and End of Year Patient Status, 2009-2012

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.

Number of Patients Placed in Facility (12a)

Row 12a gives the total number of patients who have been placed in the facility for the mortality summary according to the conventions described in Section III. This number is identical to 1a — the number of patients included in the mortality summaries.

Initial Patient Placement for the Year in This Facility (12b)

Patients entered the facility in one of three ways: as a continuing patient from the previous year; as new to dialysis this year at the facility; as a transfer into the facility during the year. Item 12b reports the percentage of patients who entered the facility each way. We considered a patient who initiated dialysis treatment at one facility and then transferred to another later that year as both new to dialysis at the first facility and transferred into the facility for the second. We considered patients returning to dialysis after transplant as a transfer into the facility.

Patient Status at End of Year (12c)

Row 12c reports the status at year's end for each patient who was placed in the facility. The categories include patients who were alive and receiving treatment in the facility, who were alive and receiving treatment in another facility, who received a transplant, who died and whose death was attributed to the facility, and who died and whose death was attributed to the facility, and who died and whose death was attributed to the facility, and who died and whose death was attributed to another facility, as well as all other patients. 'Other patients' includes those who recovered renal function, who discontinued dialysis, or who were lost to follow-up. It also includes dialysis-unrelated deaths. For the purposes of this report's mortality calculations, we did not attribute dialysis-unrelated deaths to any facility.

XVI. Patient and Staff Counts from Annual Facility Survey (Form CMS 2744), 2009–2012

Table 13 reports patient counts according to the Annual Facility Survey (Form CMS-2744) as of June24, 2013. Facilities self-report this information and submit the data to their respective Network. The table reports the number of patients who were treated in the facility from 2009–2012, and regional averages for 2012 are shown for comparison.

Patients Treated during the Year (13a–13d)

Row 13a reports the number of patients who were treated during each year. Rows 13b– 13d report the percentage of these patients who were incident, transferred into the facility or transferred out of the facility during each year. These numbers include both outpatient and home dialysis patients.

Patients Treated as of 12/31 (13e–13h)

Row 13e reports the number of patients who were treated as of December 31 of each year. Row 13f reports patient modality counts. The percentage of patients aged 18-54 who are employed and/or are attending school (full or part-time) are reported in row 13g. Row 13h reports the percentage of patients who had Medicare coverage, had a Medicare application pending or were non-Medicare patients.

Staffing (13i, 13j)

Row 13i reports the total number of full- and part-time staff positions at the facility as of December 31 of the year. This includes positions that were opened but not filled on this date. Row 13j reports the number of positions in row 13i broken down by type of position. For the purposes of the Annual Facility Survey, a full-time position is defined as a position with at least 32 hours of employment a week, and a part-time position is defined as a full the staff holding a registered nurse, licensed practical nurse, vocational nurse or an advanced practice nurse degree.

XVII. Survey and Certification Activity

Table 14 reports this facility's latest survey and certification information under the updated ESRD Condition for Coverage (CfC) regulations. If this facility has not been surveyed since January 2009—if its last survey was conducted using the old ESRD regulations—this table contains no facility-level information. We obtain these data from the CMS Computing System as of June 2013.

Date and Type of Last Survey (14a, 14b)

Row 14a reports the date of the most recent survey, and row 14b reports the type of survey (initial, recertification or termination).

Compliance Condition after Last Survey (14c)

Row 14c reports the facility's compliance condition after the last survey. The facility either met requirements, did not meet requirements but had an acceptable plan of correction, or did not meet requirements.

Deficiencies Cited at Last Survey (14d, 14e)

Row 14d reports the total number of CfC deficiencies and the number of standard deficiencies cited during the last survey. Row 14d also includes state, network and national summaries of these deficiency counts.

Row 14e reports whether the facility was cited for a particular CfC and includes state, network and national percentages of surveys that included the particular CfC citation.

XVIII. Facility Information, 2013

Table 15 reports the ownership type, organization name, initial Medicare certification date, number of stations, types of services provided by the facility, the CMS certification number included in this report and the National Provider Identifier (NPI). The NPI is not being used for patient placement and if missing, data was not available at the time of the reports. We obtained SIMS data (ownership type, organization name, initial Medicare certification date) as of March 31, 2013; DFC data (modality and number of stations) as of May, 2013; and CROWNWeb data (NPI) as of December 2012. Other CMS certification numbers from which data have been included in this report are also listed in this table.

XIX. Selected Measures for Dialysis Patients under Age 18 (2009 - 2012)

Table 16 reports selected measures from the Dialysis Facility Report tables restricted to the pediatric population. This table compares the characteristics of the facility's pediatric patients, their patterns of treatment, and patterns in transplantation, hospitalization, and mortality to local and national averages. This table is created only for those facilities that treated at least five pediatric patients over the four year period. All pediatric patients, even those at facilities treating very few pediatric patients are include in the regional averages.

Since item numbers in this pediatric table correspond with the same item number in the parent table, please refer to parent section of this *DFR Guide* for more information on the pediatric measures described below. For example, 16.1a is the same measure as item 1a of Table 1 of the DFR, but restricted to pediatric patients only.

The pediatric mortality, hospitalization, and transplantation measures for the facility are shown for each year and as well as for the four-year period combined. Regional summaries for these patient outcomes are shown for the three- or four-year period in order to provide more stable estimates, The remaining sections report patient characteristics and practice patterns for the facility each year from 2009-2012, as well as regional averages for 2012for comparison.

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

Note that for the HD Kt/V section (16.6p-16.6t), a claim was defined as valid if it was from a hemodialysis patient who received dialysis greater than two and less than five times a week, as opposed to less than four times for adults.

XXI. Please Give Us Your Comments

We welcome questions or comments about this report's content, or any suggestions you might have for future reports of this type. Improvements in the content of future reports will depend on feedback from the nephrology community. Facility-specific comments may be submitted on the secure portion of <u>www.DialysisReports.org</u> by authorized users only. General methodological questions may be submitted by anyone using the form available on the "Contact Us" tab on <u>www.DialysisReports.org</u>. Please note "2013 Dialysis Facility Reports" as the topic of your correspondence, and include your contact information.

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