

Guide to the 2010 Dialysis Facility Reports:

Overview, Methodology, and Interpretation

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**Guide to the 2010 Dialysis 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 your 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 2010 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 your 2010 DFR.

An important change to the report this year is that the standardized mortality (SMR), hospitalization (SHR), and transplantation (STR) statistics for a particular calendar year are now compared to the US mortality, hospitalization, and transplantation rates for that same year rather than to the entire 4-year period. The advantage to this is that the reference year for a particular estimate will be the same in each DFR and therefore the SMR, SHR, and STR values will change less between DFRs. In the past, because these statistics were compared to a different reference population in each DFR, the values changed more over time, even for the same year across reports. The use of a different reference year for each year's estimate will allow you to identify trends over time at your facility beyond the overall US trend over time. In other words, if the SMR for your facility decreases over the time period, this means that mortality at your facility has decreased more over that time period than the overall US average mortality decreased. If mortality at your facility decreased over the four year period at the same rate that overall US mortality decreased over this time period, the SMR for your facility would be the same for each year.

Table 9 of the DFR now includes a line for the percentage of patients in your facility with dialysis access-related infection, as identified on Medicare claims.

Table 12 of the DFR has been updated to reflect the new set of ESRD Conditions for Coverage (CfC) mandated in October 2008.

II. Overview

The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) has produced the 2010 Dialysis Facility Reports with funding from the Centers for Medicare & Medicaid Services (CMS). Each facility's report is available to the facility on the secure Dialysis Reports Web site (www.dialysisreports.org). 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 2006-2009. We compiled these summaries using the UM-KECC ESRD patient database, which is largely derived from the CMS Program Medical Management and Information System (PMMIS/REMIS), the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the National Vascular Access Improvement Initiative's Fistula First project, 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 Online Survey Certification and Reporting (OSCAR) system, 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 provides tracking by dialysis provider and treatment modality for non-Medicare patients.

This year we provided reports for more than 5,000 Medicare-approved dialysis facilities in the United States. We did not create reports for transplant-only facilities or Veterans Administration-only facilities. We have suppressed information about the Standardized Mortality Ratio (SMR) and its components for facilities with either less than one expected death for any given year, or fewer than three expected deaths for the three- or four-year period. Statistics produced for such a small group of patients can be unstable and particularly subject to random variation, and thus difficult to interpret. Similarly, we suppressed information about the Standardized Hospitalization Ratios and Standardized Transplantation Ratio and their components, for facilities with either less than one expected event (hospitalization or transplant) for any given year, or fewer than three expected events for the three- or four-year period.

This is the fifteenth 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 XVII.

This guide discusses the meaning of the data summaries each report provides, and describes the methodology used to calculate each summary (Sections III-XVI). Sections III-XVI 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-XVI in order.

The report starts with five pages of text highlights for your facility, followed by thirteen tables which contain detailed information for your facility. To provide more stable estimates of patient outcomes, we combined overall mortality (first half of Table 1) and transplant information (Table 3) over a four-year period, 2006-2009. Similarly, we combined first year mortality information (second half of Table 1) and hospitalization information (Table 2) over a three-year period, 2006-2008. 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. We document self-reported vascular access (Table 6) for 2006-2009. Comorbidities as they are reported on Medicare claims for 2006-2008, as well as regional averages for 2008 are reported in Table 9. Table 11 reports Annual Facility Survey information for 2006-2009. Table 12 reports information about the last survey at this facility as well as information about deficiencies cited at the last state survey. Table 13 reports general information about your facility as of March 31, 2010. The remaining tables (4, 5, 7, 8, and 10) report patient characteristics and practice patterns for your facility each year from 2006-2009, as well as regional averages for 2009 for comparison.

Each row of a table in the report summarizes an item. Your facility has a column for each time period, and in most cases, three columns for the corresponding geographical summaries, including averages for your facility's state, its ESRD Network, and the entire nation. Whenever the statistic reported was a count (*n*), we calculated regional and national averages by taking the average count for all facilities in that area. When the statistic reported for a period included more than one year, we annualized regional and national values to make them comparable to a single-year period. When a statistic was a percent, rate, or ratio, we calculated regional and national summaries by pooling together all individual patients in that area to obtain an estimate for that area as if it were one large

facility. We do not report state summary data for dialysis facilities in states or U.S. territories with only one or two dialysis units, with the exception of Annual Facility Survey data, which is public information. We do provide summaries for the geographic aggregate of the ESRD Network and the nation for facilities in these states or territories.

III. Assigning Patients to Facilities

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 8-10. The sections on the other tables describe the other tables' methods for identifying patients. 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.

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 XIII)

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 attributes to a facility the sequelae of treatment there, even when a

patient was transferred to another facility (such as a hospital-based facility) after his or her condition worsened.

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

Using 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 re-appeared, 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 10 reports how we assigned patients to your facility. It also displays their status at year's end (see Section XIII).

IV. Mortality Summary for All Dialysis Patients (2006-2009) and New Dialysis Patients (2006-2008)

This report compares patient outcomes in your facility with national averages. The first half of Table 1 (lines 1a-1o) provides information about patient mortality for all dialysis patients treated at your facility. The second half of Table 1 (lines 1p-1z) provides

information about mortality in the first year of dialysis for patients starting dialysis for the first time at your facility. For each section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for patients in your facility. The SMR compares the observed death rate in your 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 your 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 your facility compared to regional or national averages, please consider the role other important factors play within your 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 2006 and 2009, and also summarized the statistic for the 2006-2009 period. We also reported the averages in your state, your 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 your 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 (lines 1a-1o) on the dialysis patients who received treatment in your facility according to the conventions described in Section III.

Patient Years at Risk (1b)

For each patient in line 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 ($BMI = \text{weight (kg)} / \text{height}^2 \text{ (m}^2\text{)}$). 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 2004-2006 (National Center for Health Statistics, 2009). 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 your facility, and we summed the annual values to yield the expected number of deaths over the four-year period for each facility.

Death Rate per 100 Patient Years (1e)

We calculated the death rate by dividing the number of deaths by the total number of patient years at risk and then multiplying the result by 100. This yielded a measure of your facility's death rate during the period. We expressed the number of deaths relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Expected Death Rate per 100 Patient Years (1f)

We obtained the expected death fraction by dividing the number of expected deaths by the number of patient years at risk, and then multiplying the result by 100. This measures your facility's expected death rate based on the calendar year, age, race, ethnicity, sex, diabetes, year, years since start of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and population death rates. We expressed the expected number of deaths relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Categories of Death (1g, 1h, 1i)

Row 1g 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 1h and 1i, 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 1h.

Line 1i 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 line 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 your 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) (1j)

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 your facility, as compared to the national death rate [in the same year](#). Qualitatively, the degree to which your facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2006-2009 national death rates for patients with the same characteristics as those in your facility. Similarly, the degree to which your 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 your 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 your facility had higher or lower mortality given the characteristics of patients treated at your facility. Because a different reference year is used for each year's estimate, the SMR will allow you to identify trends over time at your facility beyond the overall US trend over time. In other words, if the SMR for your facility decreases over the time period, this means that mortality at your facility has decreased more over that time period than the overall US average mortality decreased. If mortality at your facility decreased over the four year period at the same rate that overall US mortality decreased over this time period, the SMR for your 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 at www.DialysisReports.org under the Methodology heading. Quantitatively, if your 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 your facility's patient mix. For example, an SMR=1.10 would indicate that your facility's death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to your facility's patient mix). Similarly, an SMR=0.95 would indicate that your 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 your 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 (1c/1d).

Why the national SMR may not be exactly equal to 1.00

The reported 2006-2009 SMR for the U.S. as a whole may not be precisely equal to 1.00. The SMR value for the U.S. given in the Dialysis Facility Reports does not include all U.S. dialysis facilities in its calculation. In particular, as discussed in the Overview, transplant-only, 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 your facility relative to the national death rates. An SMR value that differs from 1.00 indicates that your 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, your facility's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between your facility's death rates and the nation's. Both the p-value and the confidence interval, discussed below, will help you interpret your 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 your facility.

P-value (1k)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of death rates for your 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 your 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 your facility's death rates and the nation's.

The SMR's actual quantitative value reflects the clinical importance of the difference between your 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 (11)

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

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

3) Examine input data. Table 10 gives some details about the patients assigned to your facility. Your 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 your 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 your unit, as well as other patient characteristics.

SMR Percentiles for This Facility (1m, 1n, 1o)

This section reports the percentile rank of your 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 your facility's. In other words, a high or low percentile indicates that your facility has a high or low SMR relative to other facilities in the state, Network, or nation.

Patients for First Year Mortality (1p)

Line 1p of this table gives the total number of forms for new dialysis patients submitted by your facility for the year. The first year mortality statistics reported in the second half of the table (1p-1z) 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, 2006 and December 31, 2008. 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 (1q)

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 (1r)

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 line 1c above for details).

Expected Deaths in First Year (1s)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient, the amount of follow-up time (patient years at risk) for that patient during the year, and the calendar year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). We adjusted the Cox model for calendar year, age, race, ethnicity, sex, diabetes, year, nursing home status, patient comorbidities at incidence, and patient BMI at incidence ($BMI = \text{weight (kg)} / \text{height}^2 \text{ (m}^2\text{)}$). 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 2004-2006 (National Center for Health Statistics, 2009). 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 your facility, and we summed the annual values to yield the expected number of deaths over the three-year period for each facility.

Death Rate per 100 Patient Years in First Year (1t)

We calculated the death rate by dividing the number of deaths by the total number of patient years at risk and then multiplying the result by 100. This yielded a measure of your facility's death rate for new dialysis patients during the period. We expressed the number of deaths relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Expected Death Rate per 100 Patient Years in First Year (1u)

We obtained the expected death fraction by dividing the number of expected deaths by the number of patient years at risk, and then multiplying the result by 100. This measures your facility's expected death rate based on the calendar year, age, race, ethnicity, sex, diabetes, year, nursing home status, comorbidities at incidence, BMI at incidence, and population death rates. We expressed the expected number of deaths relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Categories of Death (1v, 1w)

Row 1v reports the percentage of new dialysis patient deaths (row 1r) 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 row 1w, we considered all causes of death (primary and secondary)

provided on the form. Row 1w reports the percentage of deaths in 1r listed as due to infection or due to cardiac causes for either the primary or one of the secondary causes of death.

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

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

The SMR equals the ratio of the actual number of deaths (1r) divided by the expected number of deaths (1s). The SMR estimates the relative death rate ratio for your facility, as compared to the national death rate [in the same year](#). Qualitatively, the degree to which your facility's four-year SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2006-2008 national death rates for new dialysis patients with the same characteristics as those in your facility. Similarly, the degree to which your 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 your 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 your facility had higher or lower mortality than expected given the characteristics of patients treated at your facility. Because a different reference year is used for each year's estimate, the SMRs will allow you to identify trends over time at your facility beyond the overall US trend over time. In other words, if the SMR for your facility decreases over the time period, this means that mortality at your facility has decreased more over that time period than the overall US average mortality decreased. If mortality at your facility decreased over the three year period at the same rate that overall US mortality decreased over this time period, the SMR for your facility would be the same for each year.

Quantitatively, if your 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 your facility's patient mix. For example, an SMR=1.10 would indicate that your facility's

death rates typically exceed national death rates by 10% (e.g., 22 deaths observed where 20 were expected, according to your facility's patient mix). Similarly, an SMR=0.95 would indicate that your 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 your 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 (1r/1s).

P-value (1y)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of death rates for your 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 your 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 your facility's death rates and the nation's.

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

Confidence Interval for First Year SMR (1z)

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.

V. Hospitalization Summary for Medicare Dialysis Patients, 2006-2008

Hospitalization rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital twice a year and hospitalizations account for approximately 36 percent of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2007). 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 your 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, a given period is included if each 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. Overall, 71% of the total time at risk for the mortality statistics (1b) satisfies this criterion for inclusion in the hospitalization statistics (2b). For a given facility, if (for any year) less than 30% of the original time at risk satisfies the criterion for inclusion in the hospitalization statistics, then no hospitalization statistics are reported for that facility. The rationale for excluding such facilities is that the corresponding hospitalization statistics may not be at all representative of the patients treated at the facility since a large percentage of the data is essentially missing.

We report two standardized statistics for hospitalization rates. The *days hospitalized per patient year* represents the average number of inpatient days that patients assigned to this facility spent in the hospital per year at risk. The *admissions per patient year* reports the total number of hospital admissions per patient year at risk. Both statistics include multiple admissions per patient.

Summaries of the total number of hospitalized days are reported in rows 2c through 2i, and summaries of hospital admissions are reported in Rows 2j through 2p. For each facility, a *Standardized Hospitalization Ratio (Days)* and a *Standardized Hospitalization Ratio (Admissions)* were calculated. Like the SMR, these statistics are intended to compare your facility's observed number of events (be it admissions or days hospitalized) to the number that would be expected if patients at your facility were instead subject to the 2006-2008 national average rates. The expected national rates are calculated from Cox models (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994) which make adjustments for patient age, race, ethnicity, 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 2006-2008 and for the entire three-year period. We also report the results for the average facility over the combined 2006-2008 period for regional and national facilities.

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 your facility.

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 12/28/2006 and discharged on 1/6/2007), the number of days hospitalized are assigned appropriately to the two years (four days in 2006 and six days in 2007).

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, race, ethnicity, 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, race, ethnicity, 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.

Days Hospitalized per Patient Year (2e)

We calculated the days hospitalized per patient year by dividing the total number of days hospitalized in 2c by the total number of patient years at risk in 2b. This value represents the average number of days spent in the hospital per year for patients in your facility. This measure of hospital use reflects both the number and the length of hospital admissions. We expressed the number of days hospitalized relative to the total number of patient years (rather than the number of patients) because many patients do not receive treatment for a full calendar year.

Expected Days Hospitalized per Patient Year (2f)

The expected days hospitalized per patient year is obtained by dividing the expected total days hospitalized in 2d by the number of patient years at risk in 2b. We expressed the expected number of hospitalized days relative to the total number of patient years (rather than the number of patients) because many patients do not receive treatment for a full calendar year.

Standardized Total Days Hospitalized Ratio (2g)

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 your 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 your 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 your facility was higher than the (adjusted) national average. Note that this measure is adjusted for the actual patient characteristics of age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, comorbidities at incidence, and BMI in your 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 your facility beyond the overall US trend over time. In other words, if the SHR for your facility decreases over the time period, this means that hospitalization at your facility has decreased more over that time period than the overall US average hospitalization decreased. If hospitalization at your facility decreased over the three year period at the same rate that overall US hospitalization decreased over this time period, the SHR for your facility would be the same for each year.

Total Admissions (2h)

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 12/28/2006 and discharged on 1/6/2007), the admission would count only in the first year (one admission in 2006 and zero admissions in 2007).

Expected Total Admissions (2i)

The expected number of hospital admissions among Medicare dialysis patients in a facility for is calculated based on national hospital admission rates in the same year (admissions per year). The expected number of admissions is calculated from a Cox model, adjusting for patient age, race, ethnicity, 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 2i.

Admissions per Patient Year (2j)

We calculated the admissions per patient year by dividing the total number of admissions in 2h by the total number of patient years at risk in 2b. This value represents the average number of admissions per year for patients in your facility. We expressed the number of admissions relative to the total number of patient years (rather than the number of patients) because many patients do not receive treatment for a full calendar year.

Expected Admission Rate (2k)

The expected admissions per patient year is obtained by dividing the expected total admissions in 2i by the number of patient years at risk in 2b. We expressed the expected number of admissions relative to the total number of patient years (rather than the number of patients) because many patients do not receive treatment for a full calendar year.

Standardized Hospitalization Ratio for Admissions (2l)

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

Diagnoses Associated with Hospitalization (2m-2q)

Row 2m reports the percentage of patients in 2a who had septicemia reported as one of the diagnoses on a hospital bill with a start date during a period of treatment at your facility. This includes diagnoses present at admission and added during the hospital stay. In order to determine which hospitalizations listed septicemia as a contributing cause, we first identified ICD-9 diagnosis codes associated with septicemia, and then looked for these codes on the hospital bills (in any position on the list of diagnoses). Similarly, rows 2n through 2q give the percentage of patients in 2a who had 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 your facility. We also identified these through their ICD-9 diagnosis codes. Rows 2m through 2q include 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 (2r)

We reported the percentage of total inpatient hospital admissions in 2j 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 (2s)

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.

VI. Transplantation Summary for Dialysis Patients under Age 70, 2006-2009

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 they treat, though these statistics should not be interpreted as including all transplants. The percentage of transplants in the U.S. that were not included because the transplant occurred less than 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.

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 your facility, with corresponding regional and national averages.

First Transplant Rate per 100 Patient Years (3h)

We calculated the first transplantation rate for patients under 70 by dividing the number of patients receiving a kidney transplant for the first time during the period (3f) by the total number of patient years at risk for transplant (3e), and then multiplying the result by 100. We expressed the number of transplants relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Expected First Transplant Rate per 100 Patient Years at Risk (3i)

We calculated the expected first transplantation rate by dividing the expected number of first transplants (3g) by the total number of patient years at risk (3e), and then multiplying the result by 100. We expressed the expected number of transplants as relative to the total number of patient years (rather than the number of patients) because many patients did not receive treatment for a full calendar year.

Donor Type (3j)

Row 3j 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 3f.

Standardized Transplantation Ratio (3k)

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 your facility, given the age composition of your facility's patients. The STR is adjusted for patient age and calendar year only. Each year's estimate gives a comparison to the US transplantation rates for the same year.

Interpret the STR as you would the SMR. An STR of 1.00 indicates that the observed number of transplants in your facility equals the estimated national rate, adjusted for age. An STR of less than 1.00 indicates that your facility's transplant rate is lower than the national average. An STR greater than 1.00 indicates that your facility's transplant rate exceeds the national average. The amount by which an STR lies above or below 1.00 corresponds to the percentage your facility's transplant rate is above or below the national average, respectively. For example, an STR of 0.90 would mean that your 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 your facility beyond the overall US trend over time. In other words, if the STR for your facility decreases over the time period, this means that transplantation at your facility has decreased more over that time period than the overall US average transplantation decreased. If transplantation at your facility decreased over

the four year period at the same rate that overall US transplantation decreased over this time period, the STR for your 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 your facility's STR. We calculated these statistics based on an assumed Poisson distribution of the observed number of patients transplanted.

P-value (3l)

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 your 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 (3m)

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 (3n, 3o, 3p)

This section reports the percentile rank of your 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 your facility's STR. In other words, a high or low percentile number indicates that your facility has a high or low STR relative to other facilities in the state, Network, or nation.

VII. Waitlist Summary for Dialysis Patients under Age 70 Treated as of December 31 of Each Year, 2006-2009

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 your 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 kidney-pancreas transplant waitlist as of December 31, with the corresponding national percentage for 2009 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.

Footnote 3 shows the percentage of patients on the waitlist in the U.S. for each year used in this comparison. The p-value indicates the probability that the difference between the percentage of patients on the waitlist in your 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 your facility and national percentage of patients on the waitlist to determine its clinical importance.

Patient Characteristics (4d-4e)

Lines 4d and 4e break down the information in lines 4a and 4b by various patient characteristics. Line 4e reports the patient counts by age, sex, race and ethnicity, cause of ESRD, previous transplant, and years of ESRD treatment. These counts sum to line 4a for

each set of categories. Line 4d reports the percentage of patients in each category in 4e who were on the kidney or kidney-pancreas transplant waitlist. State, Network, and U.S. averages for 2009 are given for comparison.

VIII. Facility Modality, Hemoglobin, and Urea Reduction Ratio, 2006-2009

Table 5 reports information on facility practice patterns, each section of which includes a slightly different group of patients. We restricted dialytic modality and hemoglobin 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. The inclusion criteria are described in more detail below. Table 5 includes state, Network, and U.S. summaries for 2009 only.

Modality (5a, 5b)

We based the reported dialytic modality information on all Medicare dialysis claims submitted by your facility, excluding patient claims that started before day 90 of ESRD. Each patient treated during January 2006 through December 2009 at your facility was classified 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 year. Rows 5a and 5b report the number and percentage of patients who received each of these therapeutic modalities.

Hemoglobin (5c-5g)

We based the hemoglobin information reported in lines 5c to 5g on all Medicare dialysis claims submitted by your 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 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. Line 5c reports the number of patients for whom at least four claims fulfilling these criteria were submitted by your 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 line 5c, we calculated the average hemoglobin reported on claims submitted by your facility.

We summed the average hemoglobin values for the patients in 5c and then divided by the number of patients in 5c in order to obtain your facility average reported in 5d. Row 5e presents the percentage of patients from 5c in each of three hemoglobin categories: less than 10g/dl, between 10-12 g/dl, and greater than 12 g/dl.

In line 5f, the percent of patients whose average hemoglobin was between 10-12 g/dl is reported separately for hemodialysis (HD) and peritoneal dialysis (PD) patients. For this statistic, 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 line 5f in both the HD and PD statistics. Patients who had at least 4 total claims from the facility appear in this line, even when there were fewer than 4 claims for the particular modality.

Line 5g reports for each year the percentile rank of your facility's hemoglobin relative to all other facilities in the state, Network, and nation.

Urea Reduction Ratio (5h-5k)

We base the urea reduction ratio (URR) information reported in lines 5h-5k on all Medicare dialysis claims submitted by your facility, with the following three exclusions: (1) patients identified in the Standard Information Management System (SIMS) as having dialyzed five or more times per week; (2) claims which started before day 183 of ESRD for a patient; and (3) claims with missing URR category. (Although we did not explicitly exclude peritoneal dialysis (PD) patients, PD patients would not have URR reported.) Line 5h reports the number of patients for whom at least four claims fulfilling these criteria had been submitted for your facility for each year. A patient who had been treated at more than one facility during the year was included at both facilities in line 5h when the patient had at least four claims with URR at each facility. We assigned each patient in 5h 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 5i reports the percentage of patients in your 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). Line 5j reports the percentage of patients in row 5h with URR that meets KDOQI guidelines (i.e., 65% or more).

Line 5k reports the percentile rank of your 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.

IX. Vascular Access Information (CMS Fistula First), 2006-2009

Table 6 reports vascular access data from the National Vascular Access Improvement Initiative's Fistula First project. The Fistula First project collects monthly data on vascular access from dialysis facilities. We summarized these data for each year, from 2006-2009, reporting yearly averages for each facility. We also report comparison values

for 2009 for the state, Network, and U.S. These vascular access data are self-reported at the facility level.

Prevalent hemodialysis patient months (6a)

The Fistula First project defines the monthly prevalent hemodialysis patient count at a facility to include 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) were included in this count. Line 6a reports the number of prevalent hemodialysis patient months reported at your 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 (6b)

Line 6b reports the type of vascular access in use during the last hemodialysis treatment of the calendar month, summarized for each year. This line reports the percentage of patient months in 6a in which the patient received dialysis through arteriovenous (AV) fistulae, AV grafts, catheters, or other access types for the last treatment of the month. Patients who are reported as having 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. For the Fistula First project, port access devices were reported as catheters. A patient's vascular access was classified as *Other* if it was considered to be different from the above categories (e.g., lifeline). Patients were classified as having missing access types if the vascular access data were missing from the record.

Arteriovenous Fistulae placed (AV) (6c)

Line 6c reports the average percentage of patient months in 6a in which an AV fistula was in place at the time of the last treatment of the month, regardless of whether or not the patient received hemodialysis treatment using this AV fistula.

Catheter only \geq 90 days (6d)

Line 6d reports the average percentage of patient months in 6a 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. For the Fistula First project, port access devices were reported as catheters.

Incident hemodialysis patients (6e)

Line 6e reports the total number of incident hemodialysis patients at your facility each year. The average number of incident patients during 2009 is reported for comparison for your state, Network, and the U.S. The Fistula First project defines incident hemodialysis patients to be 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 (6f)

Line 6f 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 line reports the percentage of incident hemodialysis patients in 6e who received dialysis through arteriovenous (AV) fistulae, AV grafts, catheters, or other access types.

Patients who are reported as having 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. For the Fistula First project, port access devices were reported as catheters. A patient's vascular access was classified as *Other* if it was considered to be different from the above categories (e.g., lifeline). Patients were classified as having missing access types if the vascular access data were missing from the record.

Arteriovenous Fistulae placed (AV) (6g)

Line 6g reports the percentage of incident patients in 6e with an AV fistula in place at the last treatment for the month the patient was incident. Patients with an AV fistula in place are included in this line regardless of whether or not they received their hemodialysis treatments using the fistula.

X. Characteristics of New Dialysis Patients, 2006-2009 (Form CMS-2728)

Table 7 presents detailed data from the ESRD Medical Evidence Form (Form CMS-2728) on the characteristics of new patients in your facility by year. State, Network and national averages for 2009 are also shown for comparison. The patients represented in this table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2006 and December 31, 2009. Please note that we placed the patients included here *not* according to the conventions described in Section III, but rather according to the provider number that appeared on their Medical Evidence Forms.

For each patient characteristic, we present the average value for your 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. Lines 7j-7m and 7s-7v were added to the Form CMS-2728 in June 2005; we report data on the DFR from 2006 through 2009.

Patient Characteristics (7a-7m)

Line 7a of this table gives the total number of forms submitted by your facility for the year. Lines 7b-7m deal with your 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 (7n-7q)

Lines 7n through 7q report lab values prior to start of ESRD. We estimated the glomerular filtration rate (GFR) reported in line 7q 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 (7r-7s)

Line 7r reports the percentage of incident patients in 7a who have received an ESA prior to ESRD. Line 7s gives the percentage of patients in 7a 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 (7t-7v)

Line 7t reports the percentage of patients in 7a who had been informed of transplant options. Line 7u gives the count of patients who were not informed of their transplant options. The reasons for not informing the patients reported in 7u 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 line 7v.

Comorbid Conditions (7w-7x)

Line 7w reports the percentage of patients in your 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*. Line 7x gives the average number of comorbid conditions reported per new patient in your facility, your state, your Network, and the nation.

XI. Summaries for All Dialysis Patients Treated as of December 31 of Each Year, 2006-2009

Table 8 summarizes the characteristics of dialysis patients treated on December 31, 2006-2009 in your facility, with corresponding average values for 2009 among patients in your state, ESRD Network, and the U.S.

Patients Treated on 12/31 of Year (8a)

Row 8a reports the total number of dialysis patients treated in your facility on December 31 of each year, according to the conventions described in Section III. We based the

summaries of the patient characteristics in Table 8 on the patient population count in this row.

Age (8b, 8c)

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 (8d)

Line 8d reports the percentage of female patients.

Race (8e)

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 (8f)

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 (8g)

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 (8h, 8i)

We calculated the number of years since first renal replacement therapy for each patient treated in your facility on December 31 of each year. Row 8h reports the average number of years of prior ESRD therapy. Row 8i displays ranges of years since start of ESRD and the corresponding percentages of patients per range.

Nursing facility patients (8j)

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 (8k)

Line 8k reports the percent of patients on chronic dialysis treatment at your facility (%8a) 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.)

XII. Comorbidities Reported on Medicare Claims for Medicare Dialysis Patients Treated as of December 31 of Each Year, 2006 - 2008

Table 9 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31, 2006-2008 in your facility, with corresponding average values for 2008 among patients in your state, Network, and the U.S. Comorbidities reported on Table 9 are determined based on all of the 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 used to identify hospitalizations and comorbidities is included in a separate document available at www.DialysisReports.org under the Methodology heading.

Like the hospitalization table, this table should include 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 meets the criterion of being within two months after the end of a month having at least \$900 of Medicare-paid dialysis claims or at least one Medicare-paid inpatient claim. This table is then further restricted to patients being treated at the facility at the end of the year.

As noted in Section V, if less than 30% of the original time at risk (1b) at a facility satisfies the criterion for inclusion in the hospitalization statistics for any year, no hospitalization statistics are reported for the facility. The comorbidity statistics are also not reported for these facilities. In addition, if fewer than 30% of the patients being treated on December 31 at the facility (8a) meet the inclusion criteria for any year, no comorbidity statistics are reported for the facility. Again, statistics for such facilities would not be representative of the patients treated at the facility.

Patients Treated on 12/31 of Year (9a)

Row 9a reports the total number of Medicare dialysis patients treated in your 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 9 on the patient population count in this row.

Comorbid Conditions (9b)

Line 9b reports the percentage of patients in your facility with each of the comorbid conditions listed.

Average Number of Comorbid Conditions (9c)

Line 9c reports the average number of the comorbid conditions listed in 9b on Medicare claims for patients in your facility.

XIII. How Patients Were Assigned to This Facility and End of Year Patient Status, 2006-2009

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 (10a)

Line 10a gives the total number of patients who have been placed in your 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 (10b)

Patients entered your facility in one of three ways: as a continuing patient from the previous year; as new to dialysis this year at your facility; as a transfer into the facility during the year. Item 10b reports the percentage of patients who entered your 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 (10c)

Item 10c reports the status at year's end for each patient who was placed in your facility. The categories include patients who were alive and receiving treatment in your facility, who were alive and receiving treatment in another facility, who received a transplant, who died and whose death was attributed to your 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.

XIV. Patient and Staff Counts from Annual Facility Survey (Form CMS 2744), 2006-2009

Table 11 reports patient counts according to the Annual Facility Survey (Form CMS-2744) as of March 2010. This information was self-reported by the facilities. We report the number of patients who were treated during each year in your facility from 2006-2009, and we show regional averages for 2009 for comparison.

Patients Treated during the Year (11a-11d)

Line 11a reports the number of patients who were treated during each year. Lines 11b-11d report the percentage of these patients who were incident, transferred into your facility, and transferred out of your facility during each year. These numbers include both outpatient and home dialysis patients.

Patients Treated as of 12/31 (11e-11g)

Line 11e reports the number of patients who were treated as of December 31 of each year. Line 11f reports patient modality counts. Line 11g reports the percentage of these patients who had Medicare coverage, had a Medicare application pending, or were non-Medicare patients.

Staffing (11h-11i)

Line 11h 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. Line 11i reports the number of positions in line 11h 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 position with less than 32 hours of employment a week. In this report, nurses include all staff holding a registered nurse, licensed practical nurse, vocational nurse, or an advanced practical nurse degree.

XV. Survey and Certification Activity, 2010

Table 12 reports the latest survey and certification information for this facility as of June 2010. We obtained this data from the CMS Computing System. If this facility was surveyed after October 2008, the updated ESRD Condition for Coverage (CfC) regulations are reflected in the table. If this facility was surveyed prior October 2008, the old ESRD CfC regulations are used.

Date and type of last survey (12a, 12b)

Line 12a reports the date of the most recent survey, and line 12b reports the type of survey. The type can be an initial survey, a recertification survey, or a termination survey.

Compliance condition after last survey (12c)

Line 12c reports the compliance condition after the last survey. The possible values are: meets requirements, acceptable plan of correction, or does not meet requirements.

Deficiencies cited at last survey (12d, 12e)

Line 12d reports the number of CfC deficiencies cited during the last survey and separately reports the number of standard deficiencies cited during the last survey. If a the survey was done prior October 2008, there is a total of 11 CfC deficiencies, and a total of 16 if the new ESRD CfC regulations were used. Line 12d includes summary of these numbers using surveys from January 2006-June 2010 in this state, ESRD Network, and the nation. Line 12e reports each of the eleven (or sixteen, if the new ESRD CfC regulations are used) CfC deficiencies separately and includes a summary reporting the percent of surveys citing each deficiency between January 2006 and June 2010 in this state, Network, and the nation.

XVI. Facility Information, 2010

Table 13 reports the ownership type, organization name, initial Medicare certification date, number of stations, types of services provided by the facility as of March 31, 2010, the provider number included in this report and, starting this year, we are adding 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. These data were obtained from SIMS as of March 31, 2010 and CROWNWeb as of April 2010. Other provider numbers from which data have been included in this report are also listed in this table.

XVII. 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. Comments can be submitted on www.DialysisReports.org between July 12, 2010 and August 18, 2010. If you have questions after the comment period is over, please contact The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) directly by email, fax, or mail. Please note "2010 Dialysis Facility Reports" as the topic of your correspondence, and include your contact information and facility's Medicare provider number.

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