

Guide to the 2009 Region Profiles for Dialysis Patients and Facilities:

Overview, Methodology, and Interpretation

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315 West Huron Street, Suite 240
Ann Arbor, MI 48103
(p) 734.998.9823 (f) 734.998.6620
kecc@umich.edu
www.sph.umich.edu/kecc

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I. Purpose of this Guide and the Region Profile

This guide explains in detail the contents of the 2009 Region Profiles that were individually prepared for each of the CMS Regional Offices under contract to the Centers for Medicare & Medicaid Services (CMS). Included here are the profiles' objectives, discussions of methodological issues relevant to particular sections of each profile (e.g., mortality, hospitalization, and transplantation) and descriptions of each data summary.

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

What's New in the 2009 Region Profile

Table 1 of the Region Profile now reports the percent of deaths related to cardiac causes. In addition, first year mortality measures for new dialysis patients are now included in Table 1. We reported information on the mortality for new dialysis patients for each year between 2005 and 2007, and also summarized the statistic for the 2005-2007 period. We also reported the averages in the nation for this combined three-year period. New dialysis patients are those who started dialysis between January 1, 2005 and December 31, 2007. Please note that we placed the patients included here *not* according to the conventions described in Section III, but according to the provider that submitted their Medical Evidence Forms. Comorbidity data on Medicare dialysis patients treated each year from 2005-2007 have been added in Table 9.

II. Overview

Each profile provides summary data from the Medicare certified dialysis facilities in the region for the years 2005 through 2008. Patients treated at transplant-only facilities or Veterans Administration facilities are not included in these profiles. We compiled these summaries using the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) ESRD patient database, which is largely derived from the CMS Program Medical Management and Information System (PMMIS/REBUS), the SIMS database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, 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, 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 is the ninth in this series of individualized reports. We welcome your participation and feedback concerning the clarity, utility, limitations, and accuracy of this profile. You will find information on how to directly provide feedback to us at the UM-KECC in Section XIV.

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

The profile starts with three pages of text highlights for your region, followed by eleven tables—each with detailed information for your region. Mortality statistics for all dialysis patients are reported in the first half of Table 1 annually from 2005-2008 with national statistics for 2008 reported for comparison. Mortality statistics for new dialysis patients are reported in the second half of Table 1 annually from 2005-2007 with national statistics for 2007 reported for comparison. Hospitalization statistics (Table 2) are reported in a similar format but include only 2005-2007. Transplantation statistics (Table 3), waitlist statistics (Table 4), and practice patterns (Table 5) are reported for each year 2005-2008 with national statistics reported for 2008. Vascular access statistics are reported for 2005-2008 (Table 6) with national statistics reported for 2008. Incident patient characteristics are reported for 2006-2008 (Table 7) with national statistics reported for 2008. Facility and patient characteristics are reported for all treated dialysis patients for each year 2005-2008 (Table 8) with national statistics reported for 2008. Comorbidities as they are reported on Medicare claims for 2005-2007, as well as national averages for 2007, are reported in Table 9. Descriptive and clinical data for a random sample of adult hemodialysis and peritoneal patients (Tables 10-11) are reported for 2005-2007.

Each row of a table in the Region Profile summarizes an item. Your region has a column for each time period. There is also a column for the corresponding national summary. When the statistic reported was a count (n), the national value was usually not printed (n/a). Some exceptions are lines 8a, 10a, and 11a which report the total number of facilities or patients in the U.S. Whenever the statistic was a percent, a rate, or a ratio, the national summary was calculated by pooling together all individual patients in the nation to obtain the estimate.

III. Assigning Patients to Facilities

This section describes the methods we used to assign patients to a facility in order to calculate the summaries appearing in the 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

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

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

Identifying Patients Treated at Each Facility

For each patient, we identified the dialysis provider at each point in time using 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 ensures that we attributed to a facility the sequelae of treatment there, even when a patient was transferred to another facility (such as a hospital-based 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. Region 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 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 there for 60 days. When a patient was not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we did not attribute that patient to any facility.

Patients were removed from facilities upon receiving transplants. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery.

We removed any patient from a facility's analysis whose last evidence of dialysis treatment was one year old, considering them lost to follow-up. In other words, if a

period of one year passed with neither paid 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 use him or her in the analysis. When dialysis claims or other evidence of dialysis reappeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility.

IV. Mortality Summary for All Dialysis Patients, (2005-2008) and New Dialysis Patients (2005-2007)

This report compares patient outcomes in your region with national averages. The first half of Table 1 (lines 1a-1j) provides information about patient mortality for all dialysis patients treated in your region. The second half of Table 1 (line 1k-1s) provides information about mortality in the first year of dialysis for patients starting dialysis for the first time in your region. For each section of the table, we have calculated a relative mortality rate, or Standardized Mortality Ratio (SMR), for patients in your region. The SMR compares the observed death rate in your region to the death rate that was expected based on national death rates for patients with the same characteristics as those in your region (Wolfe, 1992). The SMR uses expected mortality calculated from a Cox model (SAS Institute Inc., 2008; Andersen, 1993; Collett, 1994), adjusting for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, patient body mass index (BMI), 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 regions. For example, since the SMR accounts for age and diabetes, an older average age or large percentage of diabetic patients in a region would not elevate the SMR. Other factors, such as nutritional status, factors relating to the process of care, or comorbid conditions that developed after incidence, are not accounted for. **Therefore, if the SMR statistic indicates potential differences in mortality for your region compared to national averages, please consider the role other important factors play within your region.** As with the hospitalization and transplantation summaries which are described below in Sections 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, 2005-2008. U.S. averages are also reported for 2008—the most recent full year. In the second half of Table 1, we reported similar statistics comparing first year mortality for new dialysis patients in your region with national averages. This section of the table allows the region to see how all of the patients who started dialysis in the region fared in their first year of dialysis even if the region is no longer treating some of these patients.

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-1j) on the dialysis patients who received treatment in your region according to the conventions described in Section III. Patients who died of AIDS are no longer excluded from this count. This change was necessary because AIDS is no longer listed as a cause of death on the ESRD Death Notification Form (Form-2746) and we therefore can no longer identify patients who died of AIDS.

Patient Years at Risk (1b)

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: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may have been treated in facilities in one region for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at facilities in the region.

Deaths (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. This count also does not include deaths related to Hurricanes Katrina and Rita. These are identified as deaths occurring between August 27, 2005 and October 31, 2005 that are noted in the Death Notification Form or in SIMS as being related to Hurricane Katrina or Hurricane Rita.

Expected Deaths (1d)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient and the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2008; Andersen, 1993; Collett, 1994). We adjusted the Cox model for age, race, ethnicity, sex, diabetes, years since start of ESRD, nursing home status, patient comorbidities at incidence, and BMI at incidence ($\text{BMI} = \text{weight (kg)} / \text{height}^2 \text{ (m}^2\text{)}$). 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 2003-2005 (National Center for Health Statistics, 2007). 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 in your region.

Categories of Death (1e-1h)

Row 1e reports the percentage of dialysis patient deaths (row 1c) for which the CMS ESRD Death Notification Form (Form-2746) indicated that the patient voluntarily discontinued renal replacement therapy prior to death. For the causes of death calculations in rows 1f and 1g, we considered all causes of death (primary and secondary) provided on the form. Row 1f reports the percentage of deaths in 1c listed as due to infection for either the primary or one of the secondary causes of death.

Line 1h 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, died from street drugs, or those whose deaths were determined to be related to Hurricanes Katrina or Rita (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 different regions do not correspond to differences in the number of dialysis-unrelated deaths.

Information on category of death may help you interpret the SMR value for your region. For example, a high rate of withdrawal will not increase the SMR substantially if the patients who withdraw have a short expected lifetime, though it will cause an increase if patients have a long expected remaining life. However, we would advise using caution

when interpreting these percentages by category of death, since we did not adjust them for patient characteristics. Expressing this information as a simple percentage of the total number of deaths does not indicate whether the percentage of deaths in any particular category differs from the national average for similar patients.

Standardized Mortality Ratio (SMR) (1i)

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 region, as compared to the national death rate. Qualitatively, the degree to which your region's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2005-2008 national death rates for patients with the same characteristics as those in your region.

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

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

We calculated the national summary SMR as the ratio of the total number of observed deaths among patients in the nation to the number of expected deaths among patients in the nation (1c/1d).

Random variation

The SMR estimates the true ratio of death rates in your region relative to the national death rates. An SMR value that differs from 1.00 indicates that your region's death rates differ from the national death rates. ***However, the SMR's value varies from year to year above and below the true ratio, due to random variation.*** Thus, your region's SMR could differ from 1.00 due to random variation rather than to a fundamental difference between your region's death rates and the nation's. Both the p-value and the confidence interval, discussed below, will help you interpret your region'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 in your region.

P-value (1j)

The p-value measures the statistical significance (or evidence) for testing the two-sided hypothesis that the true ratio of death rates for your region 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 greatly from 1.00. P-values also tend to be smaller when more patient data is used 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 region's death rates and the nation's is unlikely to have arisen from random fluctuations alone. The smaller the p-value is, the more *statistically significant* the difference between national and individual region death rates becomes. 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 region's death rates and the nation's.

The SMR's actual quantitative value reflects the clinical importance of the difference between your region'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.

Patients for First Year Mortality (1k)

Line 1k of this table gives the total number of forms for new dialysis patients submitted by your region for the year. The first year mortality statistics reported in the second half of the table (1k-1s) are based on these patients. As described above, the patients represented in this part of the table were hemodialysis and peritoneal dialysis patients who **started dialysis** between January 1, 2005 and December 31, 2007. 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 (1l)

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 region regardless of whether the patient was treated at a facility in that region for the entire year. In addition, all of a patient's time at risk is included under the calendar year heading corresponding to the Medical Evidence Form even if some of that follow-up time occurs in the following year. In other words, the calendar year headings refer to the year the patients initiated treatment.

Deaths in First Year (1m)

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, deaths from accidents unrelated to treatment, or deaths related to Hurricanes Katrina and Rita (see line 1c above for details).

Expected Deaths in First Year (1n)

We used a Cox model to calculate the expected deaths for each patient based on the characteristics of that patient and the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2008; Andersen, 1993; Collett, 1994). We adjusted the Cox model for age, race, ethnicity, sex, diabetes, nursing home status, patient comorbidities at incidence, and patient BMI at incidence ($BMI = \text{weight (kg)} / \text{height}^2 (\text{m}^2)$). 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 region and race based on the U.S. population in 2003-2005 (National Center for Health Statistics, 2007).

Categories of Death (1o-1q)

Row 1o reports the percentage of new dialysis patient deaths (row 1m) 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 1p and 1q, we considered all causes of death (primary and secondary) provided on the form. Rows 1p and 1q report the percentage of deaths in 1m 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 region. For example, a high rate of withdrawal will not increase the SMR substantially if the patients who withdraw have a short expected lifetime, though it will cause an increase if patients have a long expected remaining life. However, we would advise using caution when interpreting these percentages by category of death, since we did not adjust them for patient characteristics. Expressing this information as a simple percentage of the total number of deaths does not indicate whether the percentage of deaths in any particular category differs from the national average for similar patients.

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

The SMR equals the ratio of the actual number of deaths (1m) divided by the expected number of deaths (1n). The SMR estimates the relative death rate ratio for your region, as compared to the national death rate. Qualitatively, the degree to which your region's SMR varies from 1.00 is the degree to which it exceeds (>1.00) or is under (<1.00) the 2005-2007 national death rates for new dialysis patients with the same characteristics as those in your region.

We used similar methods to calculate SMR for new dialysis patients and for all dialysis patients. We adjusted the SMR for age, race, ethnicity, sex, diabetes, nursing home status, comorbidities at incidence, BMI at incidence, and population death rates. The

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

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

We calculated the national summaries as the ratio of the total number of observed deaths among patients in the nation to the number of expected deaths among patients in the nation ($1m/1n$).

P-value (Is)

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

The SMR's actual quantitative value reflects the clinical importance of the difference between your region'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.

V. Hospitalization Summary for Medicare Dialysis Patients, 2005-2007

Hospitalization rates strongly indicate patient morbidity and quality of life. The typical dialysis patient is admitted to the hospital once or twice a year. Hospitalizations—also very costly—represent approximately 36 percent of total Medicare expenditures for

dialysis patients (U.S. Renal Data System, 2007). Measures of the frequency of hospitalization and diagnoses present at 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 on Table 2.

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

Hospitalization rates are more difficult to summarize than are mortality rates. First, 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 during 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 patients from that facility are not included in the region or US hospitalization statistics. The rationale for excluding patients in 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 *Standardized Hospitalization Ratio (SHR) for Days* reports the total number of days patients assigned to facilities in the region spent in the hospital. The *Standardized Hospitalization Ratio (SHR) for Admissions* reports the total number of hospital admissions per year, including multiple admissions per patient. We are unable to distinguish a hospital admission as an independent event from a re-admission that occurs largely as the consequence of a previous hospitalization. However, the frequency of all hospital admissions among patients in a region may usefully measure the morbidity of dialysis patients in there.

Summaries of the total number of hospitalized days are reported on rows 2c through 2e and summaries of the total number of hospital admissions are reported on rows 2f through 2h. We calculated for each region a Standardized Hospitalization Ratio for Days and a Standardized Hospitalization Ratio for Admissions. Like the SMR, these statistics

are based on comparing your region's observed rate to the expected, national rates for 2005-2007 for patients with the same characteristics as those in your region. The expected national rates are calculated from logistic models (SAS Institute Inc., Agresti, 2002; Hosmer and Lemeshow, 2000) which make adjustments for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status and BMI.

We reported the hospitalization summaries for each year from 2005-2007. National summaries are shown for the year 2007 for comparison.

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 hospitalization rates for days and admissions.

Total Days Hospitalized Rate (2c)

We calculated the hospitalized day rate by dividing the total number of days hospitalized by the total number of patient years at risk in 2b. This yielded a measure of the hospitalized day rate in your region during the period. We expressed the number of hospitalized days 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.

The total number of days hospitalized in this statistic was calculated for the Medicare dialysis patients eligible for the hospitalization summaries. The total number of days includes multiple admissions (i.e., second hospitalization for the same patient, third, etc.).

The summary includes days until discharge for all admissions that start during the year. If a patient who was admitted during one year was not discharged until the following year, the number of hospital days for the year of the admission includes the days spent in the hospital for this admission during the subsequent year.

Expected Days Hospitalized Rate (2d)

We calculated the expected days hospitalized rate reported in row 2d by dividing the number of expected hospitalized days by the number of patient years at risk. 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 did not receive treatment for a full calendar year.

The expected number of days hospitalized in this statistic was calculated for Medicare dialysis patients in a region for 2005-2007 based on national hospitalization rates (days per year). The expected hospitalization frequency is calculated from a logistic model,

adjusting for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status and BMI. 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 expected number of days for patients in this region.

Standardized Hospitalization Ratio for Days (2e)

We calculated the Standardized Hospitalization Ratio for Days by dividing the observed total hospitalized days by the expected total hospitalized days. As with the SMR, it enables a comparison of your region's experience to the national average. A value of less than 1.00 indicates that your region's total number of hospitalized days was less than expected, based on national rates; whereas a value of greater than 1.00 indicates that your region had a rate of total hospitalized days higher than the national average. We adjusted this measure for your region's patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, and BMI characteristics.

Admission Rate (2f)

We calculated the admission rate by dividing the number of hospital admissions by the total number of patient years at risk in 2b. This yielded a measure of your region's admission rate during the period. We expressed the number of admissions 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.

The total number of hospital admissions in this calculation includes multiple admissions (i.e., second hospitalization for the same patient, third, etc.). The number of admissions in a particular calendar year includes a hospital admission in which a patient was admitted during the year but was discharged the following year (e.g., a stay from December 31-January 1). Such admissions are not counted again for the following year.

Expected Admission Rate (2g)

We obtained the expected admission fraction by dividing the number of expected admissions 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 did not receive treatment for a full calendar year.

The expected number of hospital admissions in this statistic was calculated for Medicare dialysis patients in a region for 2005-2007 based on national hospitalization rates (admissions per year). The expected number of admissions is calculated from a logistic model, adjusting for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, and BMI. 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 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 expected number of hospital admissions in this region.

Standardized Hospitalization Ratio for Admissions (2h)

We calculated the Standardized Hospitalization Ratio for Admissions by dividing the observed total admissions by the expected total admissions. As with the SMR, it enables a comparison of your region's experience to the national average. A value of less than 1.00 indicates that your region's total number of admissions was less than expected, based on national rates; whereas a value of greater than 1.00 indicates that your region had a rate of total admissions higher than the national average. We adjusted this measure for your region's patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, and BMI characteristics.

Patients with Septicemia (2i)

Row 2i 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 a facility in this region. 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). All bills are included, even if the patient did not leave the hospital in between bills.

One Day Admissions (2j)

We reported the percentage of total hospital admissions lasting 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 (2k)

We reported, as a measure of the severity of hospitalizations, the average duration (in days) of hospital admissions among Medicare dialysis patients eligible for the hospitalization summaries. We calculated this duration from Medicare payment records, which listed an admission and discharge date for each hospitalization. We calculated the average duration per admission, with no adjustment for patient characteristics.

VI. Transplantation Summary for Dialysis Patients under Age 70, 2005-2008

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 who have not previously received a kidney transplant. These statistics do not include patients who have returned to dialysis after a kidney transplant has failed. 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, these statistics do not include 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 region to compare the rate of transplantation for the dialysis patients they treat, though these statistics should not be interpreted as including all transplants. Footnote 2 gives 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.

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 the region who received a transplant.

Eligible Patients (3c)

Row 3c 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 profile's transplantation summaries (3c) was typically much smaller than the number of patients included in the mortality summaries (1a) for two reasons. First, all transplantation statistics in this profile 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 (3d)

We limited our calculations for 3d 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 in facilities in one region for multiple periods during the same year; in such a case, the number of patient years at risk included time at risk for all periods of treatment in that region.

Actual First Transplants (3e)

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

Expected First Transplants (3f)

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 characteristics of that patient and the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2008; Andersen, 1993; Collett, 1994). Table 3 sums and reports the total number of patients expected to receive a first transplant in your region, with corresponding national averages.

Standardized Transplantation Ratio (STR) (3g)

The STR is the ratio of the actual number of first transplants (3e) to the expected number of first transplants (3f) for your region, given the age composition of your region's patients. Note that we adjusted the STR for patient age only. Interpret the STR as you would the SMR. An STR of 1.00 indicates that the observed number of transplants in your region equals the estimated national rate, adjusted for age. An STR of less than 1.00 indicates that your region's transplant rate is lower than the national average. An STR greater than 1.00 indicates that your region's transplant rate exceeds the national average. The amount by which an STR lies above or below 1.00 corresponds to the percentage your region's transplant rate is above or below the national average for 2005-2008, respectively. For example, an STR of 0.90 would mean that your region's rate of transplantation is 10% less than the national rate (e.g., nine transplants where ten are expected). An STR exceeding 1.00 is desirable.

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

Random Variation

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

P-value (3h)

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 region 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 (3i)

We also present 95% confidence intervals as a further check of statistical significance. These upper and lower limits enclose the true ratio between them approximately 95% of the time. Statistically significant confidence intervals do not contain 1.00.

VII. Waitlist Summary for Dialysis Patients under Age 70 Treated as of December 31st of Each Year, 2005-2008

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 31st of each year in your region. 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 in the region where they were 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 on December 31, with the corresponding national percentage for 2008 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 region and in the U.S. occurred due to chance. A low p-value means that the chances are low that the region 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 region and national percentage of patients on the waitlist to determine its clinical importance.

Patients on the Waitlist by Subgroup (4d)

Line 4d breaks down the information in lines 4b by various patient characteristics. Patient counts are reported by age, sex, race/ethnicity, diabetes, previous transplant, and years of ESRD treatment.

VIII. Region Modality, Hemoglobin, and Urea Reduction Ratio, 2005-2008

Table 5 reports information on region practice patterns and each section 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.

Modality (5a, 5b)

We based the reported dialytic modality information on all Medicare dialysis claims submitted by facilities in your region, excluding patient claims that started before day 90 of ESRD. Each patient treated during January 2005 through December 2008 in your region was classified as receiving hemodialysis (including home hemodialysis), CAPD/CCPD, or other dialysis. Patients were said to be 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-5f)

We based the hemoglobin information reported in lines 5c to 5f on all Medicare dialysis claims submitted in your region 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 facilities in your region for each year. A patient treated in more than one region during the year was included in the report for each region (as long as the patient had at least 4 claims from the region). For each patient in line 5c, we calculated the average hemoglobin reported on claims submitted by facilities in your region.

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 region 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 facilities in your region for each patient were further divided by the treatment modality for the claim. This means that patients who received both HD and PD treatment in the region appear in line 5f in both the HD and PD statistics. Patients who had at least 4 total claims from the region appear in this line, even when there were fewer than 4 claims for the particular modality.

Urea Reduction Ratio (5g-5i)

We base the urea reduction ratio (URR) information reported in lines 5g-5i on all Medicare dialysis claims submitted by facilities in your region, with the following three exclusions: (1) patients identified in the Standard Information Management System (SIMS) as having dialyzed five or more times per weeks; (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 5g reports the number of patients for whom at least four claims fulfilling these criteria had been submitted by facilities in your region for each year. A patient who had been treated in more than one region during the year was included in both regions in line 5g when the patient had at least four claims with URR in each region. We assigned each patient in 5g to the median URR. For patients treated by more than one region during the year, we calculated separately the URR category for them for each region based on the claims from each region only.

Row 5h reports the percentage of patients in your region 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 5i reports the percentage of patients with URR that meets KDOQI guidelines (i.e., 65% or more).

IX. Vascular Access Information (CMS Fistula First), 2005-2008

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 2005-2008, reporting yearly averages for each region. We also report comparison values as well for U.S. in 2008.

Vascular Access Type in Use (6a)

Line 6a 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 (AV) Fistulae Placed (6b)

Line 6b reports the average percentage of patient months during 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 > 90 Days (6c)

Line 6c reports the average percentage of patient months 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.

Vascular Access Type in Use at First Treatment (6d)

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.

Line 6d 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 who received dialysis through arteriovenous (AV) fistulae, AV grafts, catheters, or other access types.

Patients 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 type if the vascular access data were missing from the record.

Arteriovenous (AV) Fistulae Placed (6e)

Line 6e reports the percentage of incident patients 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 (Form CMS-2728), 2006-2008

Table 7 presents detailed data from the ESRD Medical Evidence Form (Form CMS-2728) on the characteristics of new patients in your region by year. National averages are also shown for comparison. The patients represented in this table were hemodialysis and peritoneal dialysis patients who started dialysis in 2006-2008. Please note that we placed

the patients included here *not* according to the conventions described in Section III, but rather according to the provider number that appeared on their Medical Evidence Forms (Box 21).

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

Patient Characteristics (7a-7m)

Line 7a of this table gives the total number of forms submitted by facilities in your region for the year. Lines 7b-7m show the patient demographic characteristics, including their age, sex, ethnicity, race, primary cause of ESRD, medical coverage, BMI, 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 shows the percentage of patients in 7a who had been informed of transplant options. Line 7u shows the count of patients in 7a who were not informed of their transplant options. Line 7v shows the reasons these patients 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 region 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 patients in your region and the nation.

XI. Summaries for All Dialysis Patients Treated as of December 31 of Each Year, 2005-2008

Table 8 summarizes the characteristics of dialysis patients treated on December 31 of each year, 2005-2008 in your region, with corresponding U.S. average values reported for 2008.

Facilities (8a)

Line 8a reports the total number of facilities with patients on December 31 each year.

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

Row 8b reports the total number of dialysis patients treated at facilities in your region on December 31st of each year, according to the conventions described in Section III. We based the summaries of the patient characteristics in this table on the patient population count in this row.

Age (8c, 8d)

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 (8e)

Line 8e reports the percentage of female patients.

Race (8f)

We established each patient's race using two sources of information: the Medical Evidence Form and Standard Information Management System (SIMS). We report 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 (8g)

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 (8h)

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 (8i, 8j)

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

Nursing Facility Patients (8k)

We obtained the nursing facility history of patients in your region from the Nursing Home Minimum Dataset. We report the percentage of patients treated on December 31 of each year who were treated at a nursing facility at any time during the year.

Modality (8l)

Line 8l reports the percentage of patients in the region receiving dialysis through the following modalities: In-center hemodialysis, In-center self-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 a facility in your region (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, 2005-2007

Table 9 reports comorbid conditions identified on Medicare claims for Medicare dialysis patients treated on December 31, 2005-2007 in your region, with corresponding average values for 2007 among patients in the U.S. 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 facilities in your region 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, patients from the facility are not included in the region or US hospitalization statistics. Patients from such facilities are also excluded from the comorbidity statistics. In addition, if fewer than 30% of the patients being treated on December 31 at a facility (8a) meet the inclusion criteria for any year, patients from the facility are not included in the region or US comorbidity statistics.

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

Row 9a reports the total number of Medicare dialysis patients treated in your region on December 31 of each year, according to the conventions described in Section III who also satisfy the criterion described above for assuring that Medicare claims data are complete for the patient. We based the summaries of the patient characteristics in Table 9 on the patient population count in this row.

Comorbid Conditions (9b)

Line 9b reports the percentage of patients in your region 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 region.

XIII. Descriptive and Clinical Data for Adult Hemodialysis Patients, 2005-2007

Table 10 summarizes the clinical data collected for a sample of adult in-center hemodialysis patients from October-December 2005, 2006 and 2007 in the region and in the entire U.S. These data come from the CMS ESRD Clinical Performance Measures (CPM) Project. These data were for a Network-stratified random sample of adult (age ≥ 18 years as of September 30, 2005, 2006 or 2007) in-center hemodialysis patients alive and dialyzing on December 31, 2005, 2006 or 2007 (CMS 2006, CMS 2007).

Although the sample was stratified by Network, unweighted values are reported here. Since some Networks are over-represented in the sample, their results will also be over-emphasized in these summaries. Thus, the national summaries should not be interpreted as representative of the entire population. Since California is included in two Networks with different rates, summaries for it may not be representative of the entire region population for the same reason. For all other regions, the region summaries do represent the entire region population of adult hemodialysis patients.

Patients in the Sample (10a)

Line 10a reports the number of patients in the region for whom data were collected for the ESRD CPM Project. The total number of patients in the U.S. is also reported on this line.

Age (10b)

The percent of patients in 10a who were in each of five age categories is reported in line 10b. These percentages sum to 100% for each year.

Female (10c)

The percent of patients in 10a who were female is reported in line 10c.

Race (10d)

The percent of patients in 10a in each of five race categories is reported in line 10d. Indian sub-continent is included in 'Asian', Alaskan Native is included in 'Native American', and Middle Eastern and Arabian are included in 'White'. These percentages sum to 100% for each year.

Hispanic (10e)

The percent of patients in 10a who were Hispanic is reported in line 10e.

Cause of ESRD (10f)

The percent of patients in 10a in each of four diagnosis categories is reported in line 10f. These percentages sum to 100% for each year.

Starting Treatment during Year (10g)

The percent of patients in 10a who started treatment for ESRD during the year is reported in line 10g.

Average Years since Start of ESRD (10h)

The average number of years since start of ESRD for patients in the region and nation is reported in line 10h. Patients who had missing data were excluded from the calculation.

Hemoglobin (10i)

The first hemoglobin for each month October, November, and December was collected for the CPM Project; the average was calculated for each patient in 10a. The average of these values and the percent of patients who were in each of five hemoglobin categories are reported in line 10i. Patients whose data were missing for all three months were excluded from the calculations.

Erythropoiesis-stimulating agent (ESA) Prescription (10j)

The CPM Project collected information on the epoetin and darbepoetin prescription during the seven days immediately before the hemoglobin was collected. Line 10j reports the percent of patients in 10a who had an ESA prescription immediately before the hemoglobin was collected in any of the three months (October-December).

Serum Ferritin (10k)

The first serum ferritin for each month October, November, and December was collected for the CPM Project and the average was calculated for each patient in 10a. The average of these values and the percent of patients who had an average serum ferritin of 100 or more, 200 or more, and 500 or more are reported in line 10k. Patients whose data were missing for all three months were excluded from the calculations.

Transferrin Saturation (10l)

The first transferrin saturation for each month October, November, and December was collected for the CPM Project. The average of these values and the percent of patients

who had an average transferrin saturation of 20 or more are reported in line 10l. Patients whose data were missing for all three months were excluded from the calculations.

Iron Prescription (10m)

The percent of patients in 10a who had an iron prescription at any time during any of the three months October-December is reported in line 10m.

Dose of Dialysis (10n)

The first recorded Kt/V and URR for each month October, November, and December were collected for the CPM Project; the average of each was calculated for each patient in 10a. The average of these values is reported in line 10n. This line also reports the percent of patients whose average URR was in each of six URR categories. The percent of patients who had an average URR of 65 or more is reported in line 10n. Patients whose data were missing for all three months were excluded from the calculations. Note that for some patients both Kt/V and URR were available, while others had only one or the other.

Average Length of Dialysis Session (10o)

The time of dialysis at the first session at which BUNs were drawn during each month October-December was collected by the CPM Project. The average length of dialysis was calculated for each patient in 10a. The average of these values is reported in line 10o. Patients whose data were missing for all three months were excluded from the calculations.

Serum Albumin (10p)

The first serum albumin for each month October, November, and December was collected for the CPM Project, and the average was calculated for each patient in 10a. Before this average was calculated, 0.3 was added to any serum albumin values measured using the bromcresol purple method to make them comparable to those measured using the bromcresol green method. The average of these values is reported in line 10p. The percent of patients who had an average Serum Albumin of 3.5 or more is reported in line 10p. Note that as mentioned previously, this threshold value was 3.5 for values measured using the bromcresol green method, or 3.2 for those using the bromcresol purple method. Patients whose data were missing for all three months were excluded from the calculations.

Vascular Access Type (10q-10s)

For each patient in 10a, the type of vascular access used on the last hemodialysis session during each month of the year at the patient's primary in-center facility is reported. The percent of patients in 10a using each type of vascular access is shown in line 10q. These percentages sum to 100% for each year. The number of patients with catheter placement and the reason for catheter placement are reported in line 10r. The number of patients with an AV fistula or graft and the type of surveillance used for presence of stenosis if AV fistula or graft is present are reported in line 10s.

Mineral Metabolism (10t, 10u)

The first serum calcium for each month was collected for the CPM Project, and the average was calculated for each patient. The average serum calcium and the percent of patients with average serum calcium between 8.4 and 10.2 are reported in line 10t. Patients whose data were missing for all three months were excluded from the calculations.

The first serum phosphorus for each month was collected for the CPM Project, and the average was calculated for each patient. The average serum phosphorus and the percent of patients with average serum phosphorus between 3.5 and 5.5 are reported in line 10u. Patients whose data were missing for all three months were excluded from the calculations.

Clinical Performance Measures (10v- 10x)

The percent of patients in 10a who met each of the In-center Hemodialysis Adequacy CPMs is reported in line 10v. The CPMs for Adequacy are: Patient had at least monthly measurement of delivered dose; Method of measurement was UKM or Daugirdas method; and Mean delivered dose Kt/V 1.2+.

The percent of patients in 10a who met each of the HD Anemia CPMs is reported in line 10w. The CPMs for Anemia Management are: Mean Hgb 11-12; At least one transferrin saturation and one serum ferritin values during study period; Iron stores maintained at KDOQI thresholds: at least one transferrin saturation $\geq 20\%$ and one serum ferritin ≥ 100 ng/ml; and Administration of IV iron to anemic patients.

The percent of patients in 10a who met each of the Vascular Access CPMs is reported in line 10x. The CPMs for Vascular Access are: Incident patients with AV fistula; Prevalent patients with AV fistula; Patients dialyzed with a chronic catheter; and AV fistula or graft was monitored for stenosis.

XIV. Descriptive and Clinical Data for Adult Peritoneal Dialysis Patients, 2005-2007

Table 11 summarizes the clinical data collected for a sample of adult peritoneal dialysis patients from 2005-2007 in this region, as well as in the U.S. These data came from the CMS ESRD Clinical Performance Measures Project. These data were collected for a random sample of adult (age ≥ 18 years as of September 30, 2005, 2006, or 2007) peritoneal dialysis patients who were alive and dialyzing on December 31, 2005, 2006, or 2007 (CMS 2006, CMS 2007).

The year indicated on the table refers to the year in which the period started, e.g. 2005 refers to October 2005-March 2006.

Patients in the Sample (11a)

The number of adult patients in the region for whom data were collected for the ESRD CPM Project is reported in line 11a. The average number of adult patients for the U.S. is also reported on this line.

Age (11b)

The percent of patients in 11a who were in each of five age categories is reported in line 11b. These percentages sum to 100% for each year.

Female (11c)

The percent of patients in 10a who were female is reported in line 11c.

Race (11d)

The percent of patients in 11a who were in each of five race categories is reported in line 11d. These percentages sum to 100% for each year.

Hispanic (11e)

The percent of patients in 10a who were Hispanic is reported in line 10e.

Cause of ESRD (11f)

The percent of patients in 11a who were in each of four diagnosis categories is reported in line 11f. These percentages sum to 100% for each year.

Starting Treatment during Year (11g)

The percent of patients in 11a who started treatment for ESRD during the year is reported in line 11g.

Average Years since Start of ESRD (11h)

The average number of years since start of ESRD for patients in the region and nation is reported in line 11h. Patients who had missing data were excluded from the calculation.

Peritoneal Dialysis Modality (11i)

The peritoneal dialysis modality for each patient at the time of the first and second adequacy measures during the time period October-March was collected by the CPM Project. Patients who were on CAPD (Cycler) at both times or whose modality information was not available for one of the measurements are classified as CAPD (Cycler). Patients who were on CAPD at one time and Cycler at the other are classified as *Both CAPD and Cycler*. Those whose modality information was missing both times are classified as Unknown. The percentage of patients in line 11a in each of these categories is reported in line 11i.

Hemoglobin (11j)

The first hemoglobin for each two-month time period October-November, December-January, and February-March was collected by the CPM Project. The average was calculated for each patient in 11a. The average of these values and the percent of patients

in each of five hemoglobin categories is reported in line 11j. Patients whose data were missing for all three periods were excluded from the calculations.

Erythropoiesis-stimulating agent (ESA) Prescription (11k)

The CPM Project collected information on the ESA prescription immediately before the hemoglobin was collected. The percent of patients in 11a who had an ESA prescription immediately before the hemoglobin was collected in any of the three two-month time periods October-March is reported in line 11k.

Serum Ferritin (11l)

The first serum ferritin for each two-month time period October-November, December-January, and February-March was collected by the CPM Project. The average was calculated for each patient in 11a. The average of these values and the percent of patients who had an average serum ferritin of 100 or more is also reported in line 11l. Patients whose data were missing for all three periods were excluded from the calculations.

Transferrin Saturation (11m)

The first transferrin saturation for each two-month time period October-November, December-January, and February-March was collected by the CPM Project. The average was calculated for each patient in 11a. The average of these values and the percent of patients who had an average transferrin saturation of 20 or more is also reported in line 11m. Patients whose data were missing for all three periods were excluded from the calculations.

Iron Prescription (11n)

The percent of patients in 11a who had an iron prescription at any time during the three two-month time periods October-March is reported in line 11n.

Dose of Dialysis (11o)

The average weekly Kt/V for the first two times adequacy was measured during October through March was calculated for each patient in 11a (these two measures were required to be in two different months). The average of these values and the percent of patients whose average Kt/V was at least 2.0 is reported in line 11o. Patients whose data were missing for all three periods were excluded from the calculations.

The first recorded Kt/V and URR for each month October, November, and December were collected by the CPM Project; the average of each was calculated for each patient in 11a.

Creatinine Clearance (11p)

The average weekly creatinine clearance for the first two times adequacy was measured during October through March was calculated for each patient in 11a (these two measures were required to be in two different months). Creatinine clearance values that were not corrected for body surface area were excluded from the calculations. The average of these values and the percent of patients whose average creatinine clearance was at least 60 L/week/1.73 m² is also reported in line 11p. Patients who were missing

both the first and second weekly creatinine clearance measures were excluded from the calculations.

Serum Albumin (11q)

The first serum albumin for each two-month time period October-November, December-January, and February-March was collected by the CPM Project. The average was calculated for each patient in 11a. Before this average was calculated, 0.3 was added to any serum albumin values measured using the bromcresol purple method to make them comparable to those measured using the bromcresol green method. The average of these values and the percent of patients who had an average serum albumin of 3.5 or more is also reported in line 11q. Note that as mentioned previously, this threshold value was 3.5 for values measured using the bromcresol green method or 3.2 for those using the bromcresol purple method. Patients whose data were missing for all three periods were excluded from the calculations.

Serum Calcium (11r)

The first serum calcium for each two-month time period October-November, December-January, and February-March was collected by the CPM Project, and the average was calculated for each patient in 11a. The average serum calcium and the percent of patients with average serum calcium between 8.4 and 10.2 are reported in line 11r. Patients whose data were missing for all three periods were excluded from the calculations. Data began to be collected in 2006.

Serum Phosphorus (11s)

The first serum phosphorus for each two-month time period October-November, December-January, and February-March was collected by the CPM Project, and the average was calculated for each patient in 11a. The average serum phosphorus and the percent of patients with average serum phosphorus between 3.5 and 5.5 are reported in line 11s. Patients whose data were missing for all three periods were excluded from the calculations. Data began to be collected in 2006.

Clinical Performance Measures (11t, 11u)

The percent of patients in 11a who met each of the Peritoneal Dialysis Adequacy CPMs is reported in line 11t. The CPMs for Peritoneal Dialysis Adequacy are: Patient had at least one measured total solute clearance for urea and creatinine; Patient had total solute clearance for urea and creatinine measured in a standard way; and Delivered dose meets KDOQI thresholds (CAPD: $Kt/V_{\text{urea}} \geq 2.0$ and mean weekly creatinine clearance $\geq 60\text{L/week}/1.73\text{m}^2$; CCPD: $Kt/V_{\text{urea}} \geq 2.1$ and mean weekly creatinine clearance $\geq 63\text{L/week}/1.73\text{m}^2$).

The percent of patients in 11a who met each of the PDAnemia CPMs is reported in line 11u. The CPMs for Anemia Management are: Mean Hgb 11-12; At least two transferrin saturation and two serum ferritin values during study period; Iron stores maintained at KDOQI thresholds: at least one transferrin saturation $\geq 20\%$ and one serum ferritin ≥ 100 ng/ml; and Administration of IV iron to anemic patients.

XIV. Please Give Us Your Comments

We welcome questions or comments about this report's content, or any suggestions you might have for future reports of this type. Improvements in the content of future reports will depend on feedback from the nephrology community.

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

UM-KECC

315 West Huron, Suite 240

Ann Arbor, MI 48103

(734) 998-9823 (phone)

(734) 998-6620 (fax)

kecc@umich.edu

www.sph.umich.edu/kecc

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