Some nights stay up till dawn, as the moon sometimes does for the sun. Be a full bucket pulled up the dark way of a well, then lifted out into light.

Rumi, “Some nights stay up...”
In this appendix we present details on the USRDS database, its standardized working datasets and specialized code definitions, and our common data processing practices. We also describe the statistical methods used in this ADR. The Researcher’s Guide to the USRDS Database, available online, provides additional information about the database and Standard Analysis Files.

Data sources
The USRDS maintains a stand-alone database with data on diagnoses and demographic characteristics of ESRD patients, along with biochemical data, dialysis claims, and information on treatment and payer histories, hospitalization events, deaths, physician/supplier services, and providers.

REMIS/REBUS/PMMIS DATABASE
The major source of ESRD patient information for the USRDS is the CMS (formerly HCFA) Renal Beneficiary and Utilization System (REBUS), adopted in 1995 as the On-Line Transaction Processing system from the previous Program Management and Medical Information System (PMMIS) database. The REBUS/PMMIS database contains demographic, diagnosis, and treatment history information for all Medicare beneficiaries with ESRD. The database has also been expanded to include non-Medicare patients, as discussed later in this appendix. Having advanced its database technology, CMS migrated the REBUS database into an Oracle relational database in the fall of 2003, including all patients who were alive and had ESRD as of January 1, 1995, or incident after this date. This database is known as the Renal Management Information System (REMIS).

CMS MEDICARE ENROLLMENT DATABASE
CMS regularly updates the REMIS/REBUS/PMMIS database, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the United Network for Organ Sharing (OPTN) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notification forms (2746) obtained from renal providers, as well as the Standard Information Management System (SIMS) database of the ESRD networks. CMS has also established data integrity rules to ensure accurate identification of patients in the SIMS and CMS databases. Each ESRD patient (old and new) will now be identified with a unique patient identification number common to both databases, ensuring that data on all patients are consistently managed over time.

OPTN TRANSPLANT DATABASE
In the early 1980s CMS began collecting data on all Medicare kidney transplants. In 1988, the United Network of Organ Sharing (now OPTN) was created to provide a national system for allocating donor organs and to maintain a registry on transplantation. OPTN also began collecting data on all transplants. These two efforts were consolidated in 1994, and OPTN became the single source of data on transplant donors and recipients.

The CMS and OPTN transplant data files overlap for 1988–1993, and some patients with Medical Evidence (ME) forms indicating transplant as the initial modality are not included in either file. To resolve conflicts among the three sources, the USRDS has adopted the following procedure:

- OPTN transplants are accepted into the database.
- CMS transplants before 1988 are accepted.
- CMS transplants from 1988 to 1993 are accepted if there is no OPTN transplant record for that patient within 30 days of the CMS transplant.
- Transplants indicated on ME forms are accepted if there is no previously accepted record of a transplant for that patient within 30 days of the date listed on the ME form.
CMS STANDARD ANALYTICAL FILES (SAFS)
These files contain billing data from final action claims, submitted by Medicare beneficiaries, in which all adjustments are resolved. For inpatient/outpatient institutional claims we use the following data: inpatient, 100 percent SAF; outpatient, 100 percent SAF; home health agency (HHA), 100 percent SAF; hospice, 100 percent SAF; and skilled nursing facility (SNF), 100 percent SAF. For physician/supplier claims, we use: physician/supplier, 100 percent SAF; and durable medical equipment (DME), 100 percent SAF.

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2008 ADR includes all claims up to December 31, 2006. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2007.

Inpatient transplant and outpatient dialysis claims records are used to identify new ESRD patients for whom no Medical Evidence form has been filed. These patients, primarily non-Medicare patients, or beneficiaries who develop ESRD while already on Medicare because of age or disability, will eventually be entered into the REMIS/REBUS/PMMIS—and hence the USRDS—database through the claims records. For patients without Medical Evidence forms these claims are the only reliable information from which to determine first ESRD service dates. These paid claims records are, however, only a supplement to, rather than a replacement of, other sources of information on incidence and prevalence.

The problem of timely identification has lessened since the revision of the Medical Evidence form in April 1995, and the amended ESRD entitlement policy that now requires the form to be submitted for all ESRD patients regardless of insurance and eligibility status.

STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS) DATABASE (ESRD NETWORKS)
The USRDS continues to collaborate with CMS and the ESRD networks to address data tracking issues relating to non-Medicare ESRD patients. Past ADRs have documented the lack of consistent Medicare claims data among these patients. Working solely with data from the Medical Evidence form, the USRDS could establish the first ESRD service date for them, but could not generate a more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can now address issues in the non-Medicare ESRD population such as the large and growing number of lost-to-follow-up patients, and look as well at patients for whom there previously were no data on initial modality or death. This data integration is detailed in the section on data management and preparation.

CMS DIALYSIS FACILITY COMPARE DATA
The USRDS uses the CMS Dialysis Facility Compare data to define chain and ownership information for each renal facility. Prior to the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

ESRD CLINICAL PERFORMANCE MEASURES PROJECT
CMS developed its ESRD Clinical Performance Measures Project (CPM, formerly the ESRD Core Indicators Project) to collect information on the quality of care provided to dialysis patients. The data originate from data collection forms completed by staff at primary care facilities, and focus on dialysis adequacy measures, anemia management, and vascular access. Additional clinical parameters such as albumin are available as well. These data have been collected annually since 1994, using a random sample of adult (age 18 and older) patients alive and on dialysis at the end of each calendar year; on average, roughly 8,500 adult in-center hemodialysis patients and 1,500 peritoneal dialysis patients are surveyed each year. Data collection for all hemodialysis patients age 12–17 was begun in 2000. In 2002 it was expanded to all in-center hemodialysis patients younger than 18, and in 2005 to all peritoneal dialysis patients of this age. The USRDS Coordinating Center, in collaboration with CMS, is now making these ESRD CPM data available to the general research community.

MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)
The Medicare Current Beneficiary Survey (MCBS) is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. MCBS contains information on the health status, health care use and expenditures, drug prescriptions, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. The data is made available by CMS in two datasets: Access to Care (1992–2005) and Cost and Use (1992–2004).

MCBS began in fall 1991 to survey three times per calendar year (i.e. Winter, Summer and Fall), and later introduced a sample rotation scheme in the 1994 calendar year. Survey people are kept in the sample for 4 years, with approximately one third of them leaving each year, and new people being added each fall to keep the overall sample size around 12,000 each calendar year.

NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)
NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1960, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2006 were nationally representative cross-sectional surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

ANNUAL FACILITY SURVEY (AFS)
Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS’s Annual Facility Survey (CMS 2744), which all Medicare-certified dialysis units must complete at the end of each year. The AFS reports counts of patients being
| Network 1 | Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
| Network 2 | New York
| Network 3 | New Jersey, Puerto Rico, Virgin Islands
| Network 4 | Delaware, Pennsylvania
| Network 5 | Virginia, West Virginia, Maryland, District of Columbia
| Network 6 | Georgia, North Carolina, South Carolina
| Network 7 | Florida
| Network 8 | Alabama, Mississippi, Tennessee
| Network 9/10 | Illinois, Indiana, Kentucky, Ohio
| Network 11 | Minnesota, Michigan, North Dakota, South Dakota, Wisconsin
| Network 12 | Iowa, Kansas, Missouri, Nebraska
| Network 13 | Arkansas, Louisiana, Oklahoma
| Network 14 | Texas
| Network 15 | Arizona, Colorado, Nevada, New Mexico, Utah, Wyoming
| Network 16 | Alaska, Idaho, Montana, Oregon, Washington
| Network 17 | American Samoa, Guam, Mariana Islands, Hawaii, Northern California
| Network 18 | Southern California

**ESRD networks**
treated at the end of the year, new ESRD patients starting treatment during the year, and patients dying during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they provide independent patient counts used to complement the CMS patient-specific records. Starting with the 2005 AFS, CMS stopped its effort in posting data from these surveys on the web. And beginning with the 2007 ADR, the USRDS has extracted the relevant facility survey data directly from the SIMS database.

**CDC Surveillance**
The CDC used its National Surveillance of Dialysis-Associated Diseases to collect data from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment, therapy, vascular access use, antibiotic use, hepatitis vaccination and conversion rates, and the incidence of HIV, AIDS, and tuberculosis. No data are patient-specific. The CDC did not conduct a survey in 1998, and terminated this program after 2002.

**United States Census**
In rate calculations throughout this year’s ADR we use data from the 2000 U.S. Census, and also incorporate CDC population estimates by race. Our methods are described on later in this appendix.

**Data Management & Preparation**
Our main computer system is based on a VMS cluster running Alpha EV6 processors. We currently maintain three nodes in the cluster: two 4-CPU 16-GB systems, and the other a dual CPU with 4-GB of memory. Through the HP Advanced Server System, we map VMS directories to network shares accessible to Windows clients as mapped network drives. The Alpha EV6s are one-GHz CPUs and are connected to 25 terabytes of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, all managed by five interconnecting high-speed disk controllers.

We use SAS database management system and development tools as our core database technology platform; this differs from the Oracle RDBMS system used by the previous contractor only in physical data allocation and management. All information in the earlier system was integrated into the new database, and its continuity and completeness are maintained.

**Data Loading & Cleaning**
Data files come to the USRDS in IBM 3490 and 3490e cartridges/CD-ROMs with EBCDIC, ASCII, or SAS formats. Due to increased awareness of and concern over data security and patient privacy protection, CMS has instituted data encryption procedures on all out-bound data regardless of their file formats and transportation mediums. Once loaded and decrypted, files are converted into SAS data sets for processing, and a series of data verification steps is completed to ensure data quality and integrity before updating the USRDS database.

**Database Updates**
For this ADR, patient demographic and diagnosis data are updated through October, 2007, and Medicare inpatient/outpatient and physician/supplier claims through December 31, 2006.

**ESRD Patient Determination**
A person is identified as having ESRD when a physician certifies the disease on the CMS Medical Evidence (ME) form, or when there is evidence of chronic dialysis or a kidney transplant. Patients with acute kidney failure who are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database if their Medical Evidence forms have not been submitted. Patients who die soon after kidney failure without receiving dialysis are sometimes missed. The ESRD First Service Date (FSD) is the single most important data element in the USRDS database, and each patient must, at a minimum, have a valid FSD. This date is used to determine the incident year of each new patient and the first year in which the patient is counted as prevalent. The date 90 days after the FSD is used as the starting point for most survival analyses.

The FSD is derived by taking the earliest of the date of start of dialysis for chronic kidney failure, as reported on the ME form; the date of a kidney transplant, as reported on a CMS or OPTN transplant form, an ME form, or a hospital inpatient claim; or the date of the first Medicare dialysis claim. Most FSDs are obtained from the ME form. In the absence of this form, the date of the first Medicare dialysis claim or transplant usually supplies the FSD. In the few cases in which the date of the earliest dialysis claim precedes the first dialysis date reported on the ME form, the earliest claim date is used as the FSD. However, starting with the 2007 ADR, a patient entering into the ESRD program after December 31, 1994 will have his/her FSD defined solely by the regular dialysis start date or the preemptive transplant date, whichever is earliest, on the ME form. This new method of determining the FSD has been introduced in this ADR so as to align more closely to the methods used by CMS. After years of careful monitoring and repeated comparative analyses of the traditional USRDS method to the new ME method, the USRDS believes it is time to begin applying the ME method to incident patients entering into the ESRD program on or after January 1, 1995.

**Medicare & Non-Medicare (‘ZZ’) Patients**
Beneficiaries are enrolled in Medicare based on criteria defined in Title XVIII of the Social Security Act of 1965, and in subsequent amendments to the act. A person in one of these four categories is eligible to apply for Medicare: age 65 and over, disabled, ESRD program, and Railroad Retirement Board (RRB).

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by Employer Group Health Plans (EGHPs), must wait 30–33 months before becoming eligible to have Medicare as their primary payor. Some of these patients, particularly new patients since 1995, have FSDs established by Medical Evidence forms, but have no dialysis claims or hospitalization events in the CMS claims database. In the REBUS/PMMIS database all non-Medicare ESRD patients are assigned a code of ‘ZZ’ in the two-character Beneficiary Identification Code field. CMS does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that ‘ZZ’ patients are true ESRD patients, and should therefore be included in patient counts for incidence, prevalence, and treatment modality. Calculations of standardized mortality ratios (SMRs), standardized hospitalization ratios (SHRs), and standardized transplantation ratios (STRs), however, should not include these patients because of the small number of claims.
After this period the patient is declared lost-to-follow-up until the next modality-determining event. A patient with plant failure or death notification is encountered in the data. In the incident, prevalent, and modality sections are based on incident and prevalent patients are known to have stable and established modalities. Starting with the 2003 ADR, all descriptive data on non-Medicare “lost-to-follow-up” patients are substituted with available SIMS treatment information.

LOST-TO-FOLLOW-UP METHODOLOGY
The USRDS uses all available data to create a treatment history for each patient in the database, including all modality events, their duration, and the renal providers involved in each patient’s care. Gaps frequently exist in the billing data upon which modality periods are based. The USRDS assumes that a modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain it unless a transplant failure or death notification is encountered in the data. In the absence of a death notification, dialysis claims, or other confirmation of a continuing modality, a dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim. After this period the patient is declared lost-to-follow-up until the occurrence of a dialysis claim or transplant event.

Because Medicare may be the secondary payor for up to the first 30–33 months of ESRD, delaying the submission of Medicare dialysis claims, lost-to-follow-up categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data for duplicate records, consolidated these records, and integrated the databases. These integrated data were then re-analyzed for duplicates, which were themselves consolidated. This consolidation of patients is an ongoing collaborative effort between the ESRD Networks, CMS, and the USRDS.

Patient treatment histories compiled by the USRDS rely on Medicare dialysis billing records, which contain no information on dialysis therapy or modality changes in non-Medicare patients. Beginning with the 2003 ADR, we incorporate treatment-specific information from the ESRD Networks’ SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-follow-up. The consolidation efforts from database integration among USRDS, SIMS, and REMIS continue to pay dividends in reducing the number of lost-to-follow-up patients—10,289 for the 2002 data reported in the 2008 ADR, for example, compared to 24,726 for the 2002 data reported in 2004.

We continue to take a conservative approach to incorporating SIMS Event History data into the USRDS treatment history; as we learn more about the data, we may expand this approach. We currently make the following updates on an annual basis:

- The USRDS database is updated with mortality data from the SIMS event database.
- The database is updated for each incident patient whose initial modality is listed as “unknown dialysis,” and for whom the SIMS database lists a known dialytic modality within 90 days of the established first ESRD service date.
- Data on non-Medicare “lost-to-follow-up” patients are substituted with available SIMS treatment information.

Since the 2007 ADR we have included the recovered renal function (RRF) event in the modality sequence, which in turn will directly reduce the lost-to-follow-up episodes within the prevalent population. Presently, an RRF event is established in the USRDS database only if such an event occurs within the first 180 days of FSD and lasts for at least 90 days. This definition is much more conservative than that in the SIMS event database.

60-DAY STABLE MODALITY RULE: TREATMENT HISTORY
This rule requires that a modality continue for at least 60 days before it is considered a primary or switched modality. It is used to construct a patient’s modality sequence, or treatment history, so that incident and prevalent patients are known to have stable and established modalities. Starting with the 2003 ADR, all descriptive data in the incident, prevalent, and modality sections are based on incident and prevalent cohorts produced from the modality sequence without using this rule. In analyses of patient outcomes such as hospitalization and mortality, in contrast, this rule is applied.

90-DAY RULE: OUTCOMES ANALYSES
This rule defines each patient’s start date, for data analyses, as day 91 of ESRD. Allowing outcomes to be compared among all ESRD patients at a stable and logical point in time, it is used primarily to calculate survival rates and compare outcomes by modality at several points in time. Use of the rule overcomes the difficulties of examining data from the first three months of ESRD service (an unstable time for new patients as renal providers try to determine the best treatment modality), and from in-center hemodialysis patients younger than 65 and not disabled, who cannot bill Medicare for their dialysis treatments and hospitalizations until 90 days after the first ESRD service date. Patients on peritoneal dialysis or home dialysis, or with transplant as the first modality, can bill immediately.

INTEGRATION OF THE USRDS, SIMS, & REMIS DATABASES
We continue working to reconcile ESRD patients in the SIMS, REMIS, and USRDS databases. We have analyzed each database
SERUM ALBUMIN DATA
The Medical Evidence form reports a patient’s albumin level along with the test’s lower limit, which indicates the testing method. There are currently two methods in use: brom cresol purple and brom cresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

While producing the 2004 ADR we uncovered severe problems in data quality related to albumin information on the ME form. We found that, from 1995 to 2003, almost 50 percent of forms contained lower limit values equal to “zero,” while another 25 percent reported values other than the expected 3.2 and 3.5 g/dl. Only 25 percent (n=173,000) of incident patients had legitimate lower limit values for determining normal serum albumin. Further analyses have shown that these patients are a representative cohort sample, with similar demographic distributions by age, gender, race, and cause of ESRD to that of the overall ESRD population. For all figures in the 2005 and later ADRs which present data on serum albumin from the ME form, we have therefore included only those incident patients with both an albumin lower limit of 3.2 or 3.5 g/dl and an albumin value.

Database definitions
MODALITIES
The Coordinating Center and the ESRD group at CMS have worked extensively on methods of categorizing patients by ESRD modality. While the Medical Evidence form is the primary source of data on modality at ESRD initiation, the modality it indicates may be temporary, as patients often change to a new one within the first 90 days, and it can be difficult to track modality during this time. Patients age 65 and older have Medicare claims in the first 90 days; these claims contain revenue codes that designate modality. Patients younger than 65 who are in employer group health plans or Medicare risk programs, however, have no such claims. Modality may thus not be determined until Medicare becomes the primary payor at day 91 or, for EGHP patients, at 30–33 months after the first ESRD service date. These limitations influence our ability to determine a patient’s exact modality at any one point in time.

Of particular concern are patients categorized as having an unstable modality (i.e. on a modality for fewer than 60 consecutive days) in the first 90 days, and who are therefore not recognized as being hemodialysis or peritoneal dialysis patients. These patients tend to have higher death and hospitalization rates, and unless they are identified and assigned to modalities, interpretations of modality-specific outcomes should be viewed with caution. These patients are included in the “all ESRD” category, which provides a more complete view of mortality and hospitalization with the least biasing of the data.

As mentioned earlier, a new modality/event—recovered renal function (RRF)—has been introduced in the 2007 ADR. RRF can only be established if it occurs within first 180 days of FSD and the RRF period persists for at least 90 days. The RRF modality (i.e. event) is similar to the lost-to-follow-up event in that patients with an RRF event will not be included in the prevalent populations for outcomes analyses. However, as with the lost-to-follow-up events, we have kept them in the modality sequence so that subsequent renal failure episodes can be closely tracked in a timely manner.

Individual analyses categorize modalities in different ways; these are defined in the methods sections for each chapter.

PAYORS
Information on payors is obtained from the CMS Medicare Enrollment Database (EDB). We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payor (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payor sequence file to provide payor history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors.

The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP, Medicare as secondary payor, Medicare+Choice, Medicaid, or a combination of payors. With this approach, the USRDS is now able to apply payor status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Eleven).

PRIMARY CAUSE OF RENAL FAILURE
Information on the primary cause of renal failure is obtained directly from the Medical Evidence form. For the ADR we use eight categories, with ICD-9-CM codes as follows:

- diabetes: 250.00 and 250.01
- hypertension: 403.9, 440.1, and 593.81
- glomerulonephritis: 580.0, 580.4, 582.0, 582.1, 582.9, 583.1, 583.2, 583.4, and 583.81
- cystic kidney: 753.13, 753.14, and 753.16
- other urologic: 223.0, 223.9, 590.0, 592.0, 592.9, and 599.6
- other cause: all other ICD-9-CM codes covered in the list of primary causes on the Medical Evidence form, with the exception of 799.9-
- unknown cause: 799.9 and ICD-9-CM codes not covered in the list of primary causes on the Medical Evidence form
- missing cause: no ICD-9-CM code listed

RACE & ETHNICITY
Data on patient race and ethnicity are obtained from the ME form, the CMS Medicare Enrollment Database, and the REMIS/REBUS identification file. Because they are addressed in separate questions on the Medical Evidence form, racial and ethnic categories can overlap.

Patient ethnicity became a required field on the 1995 revised ME form; because data for 1995 are incomplete, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients with unknown ethnicity. Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we concentrate on white, African American, Native American (includes Alaskan Native), and Asian (includes Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase.

EGHP COHORT
EGHP data in this year’s ADR are derived, as mentioned above, from Medstat MarketScan and Ingenix i3 databases. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication...
analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

ESRD COHORT IN THE EGHP POPULATION

Because the Medstat and I3 databases do not provide identifiable data elements, we are unable to link them directly to the USRDS ESRD registry. To identify ESRD patients, we therefore use a process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

The first ESRD service date is set to the earliest of the first dialysis service date or the transplant date. If neither is available, the start of enrollment is used. Incidence is defined by a first ESRD service date at least 60 days after the start of enrollment.

Précis

For Figure p.1 we identify chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in patients from the 5 percent Medicare sample using methods described for Chapter Eleven; these methods are also used to determine diabetic status and CHF in the ESRD population. Costs for the “cost year” are determined for the ESRD registry. To identify ESRD patients, we therefore use a process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

The first ESRD service date is set to the earliest of the first dialysis service date or the transplant date. If neither is available, the start of enrollment is used. Incidence is defined by a first ESRD service date at least 60 days after the start of enrollment.

TRENDS IN QUALITY OF CARE

Figure p.11 presents the distribution of patients by mean hemoglobin group on a monthly basis, in which each month contains all patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by three. Figure p.12 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. The mean EPO dose is adjusted in the same way used in Chapter Five, with a patient’s time at risk including only those days in which he or she is not in an inpatient hospital setting.

For Figure p.13, an archived PMMIS quarterly dialysis record is used to track transfusions in ESRD patients in years prior to 1991. The percentage of hemodialysis patients receiving transfusions is calculated as the number receiving at least one transfusion in a given quarter divided by the number with at least one dialysis record in that quarter. Since the archived data are current only to the third quarter of 1995, we emulate this method, using Medicare claims generated by ESRD facilities, to update the trend.

Figure p.14 includes prevalent hemodialysis patients in the ESRD CPM database with at least one valid URR measurement. For each patient, we calculate a mean URR measurement from all measurements available, then the percentage of patients whose mean URR is in each category. Figure p.15 includes prevalent peritoneal dialysis patients in the ESRD CPM database with at least one valid Kt/V measurement. For each patient, we calculate a mean Kt/V measurement from all those available, then the percentage of patients whose mean Kt/V is in each category.

HOSPITALIZATION & MORTALITY

Figure p.16 shows the percent change in admission rates for period prevalent ESRD patients. Included patients have Medicare as a primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or gender information. Methods generally follow those described for the prevalent patient cohorts in Chapter Six and Reference Section G. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2005. Principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. Vascular access and peritoneal dialysis access hospitalizations are those defined as “pure” inpatient vascular/dialysis access events, as described for Tables G.11-15.

Figure p.17 illustrates trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2005 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Methods for the portion of Table p.a that addresses Medicare spending are addressed in the discussion of Chapter Eleven.

ESRD EXPENDITURES

Methods used for Figures p.20–25 and Table p.c are described in the text for Chapter Eleven and in the figure captions.
Healthy People 2010

Objectives:

Objective 4.1: Incident rates in Figures hp.2–3, hp.4 (first graph), and hp.26, and in Table hp.a, are calculated using the methods described for Chapter Two. Rates of diabetes in the general population (second graph in Figure hp.4) are obtained from the CDC’s Behavioral Risk Factor Surveillance System, at www.cdc.gov/brfss.

Objective 4.2: The study cohort includes period prevalent ESRD patients, 1991–2006. Cause-specific cardiovascular mortality is defined using CMS codes 27, 31, and 32 (congestive heart failure), 26 (atherosclerotic heart disease), 02 and 23 (myocardial infarction), and 01, 04, 25, 28–30, and 36–37 (other cardiovascular disease). Age is calculated for point prevalent patients as of January 1, and for incident patients as of the first ESRD service date. We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.3: Table hp.c and figure hp.8 use data from the newest version of the Medical Evidence form for patients initiating ESRD on hemodialysis. Information on pre-ESRD care is obtained directly from the Medical Evidence form. The cohort for Figures hp.9–10 includes incident ESRD patients, age 67 and older at initiation; pre-ESRD nephrologist care is identified through at least one physician/supplier claim with a physician specialty code of “nephrologist.” Albumin tests are identified from Medicare claims during the two-year period prior to ESRD.

Objective 4.4: For Figures hp.12–13, the calculation of placement rates follows methods used in Chapter Five. For Table hp.d (ESRD CPM year 2006) and Figures hp.11 and hp.32 (ESRD CPM years 1999–2006), data are obtained from the CMS ESRD Clinical Performance Measures (CPM) Project. Patients included in these two figures and the table are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and the access type represents the access used during the last quarter of the year. To obtain consistent information on race and ethnicity, patients included in the CPM dataset are matched to those in the ESRD database using UID numbers.

Objective 4.5: The cohort for Figures hp.14–15 and Table hp.e includes patients younger than 70 in 1991–2005. Percentages are calculated as the number of patients placed on the deceased donor organ wait list or receiving a deceased donor transplant within one year of initiating ESRD therapy, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier method. Note that this method differs from those used in previous ADRs, which showed the percent of point prevalent dialysis patients on the wait list as of December 31 of the given year.

Objective 4.6: The study cohort here includes patients from 1991–2003 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

Objective 4.7: Incident rates of ESRD due to diabetes are calculated using the methods described for Chapter Two.

Objective 4.8: Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) testing and eye exams are taken from HEDIS 2002 specifications (HEDIS 2002, an NCQA program, is used to monitor the performance of managed health care plans). CPT code 83016 is used to identify diabetic HbA1c testing (claims made within 30 days of the last claim for each patient are excluded, and at least two HbA1c claims must be counted). Codes used to identify diabetic eye exams include CPT codes 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 92287, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, and 67228, ICD-9-CM procedure codes 141.1–141.4, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16, and ICD-9-CM diagnosis code V80.2. Lipid testing is identified through CPT codes 80066, 82465, 83715–83721, and 84478. The general Medicare population includes patients diagnosed with CKD and diabetes in each year, continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the whole year, and age 65 or older at the beginning of the year. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD and diabetes are described under the “CKD population & costs” section in the CKD volume.

Figure hp.36 illustrates diabetic preventive care among pre-ESRD population by network. The cohort is 2006 incident ESRD patients, age 67 or older at initiation, with diabetes one year prior to start of ESRD, and with Medicare inpatient/outpatient and physician/supplier coverage during the two years prior. Eye exams are tracked in the two years prior to ESRD, while lipid and HbA1c testing are tracked in the one year prior.

Figures hp.21–22 and Table hp.h also show ACE-I/ARB use for diabetic CKD patients in the Medicare population. We use Cost and Use data from the Medicare Current Beneficiary Survey (MCBS)—a national, continuous, multipurpose survey of older, disabled, and institutionalized beneficiaries—to measure cost in Medicare patients age 65 and older. To ensure that we obtain information on all therapy received by each person during each study year, included patients are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the entire year, survive until the end of the year, have a completed survey, are not enrolled in a managed care organization, and do not have ESRD; they also reside in the 50 states or the District of Columbia and are community-dwelling respondents. Comorbidities, including CKD and diabetes, are defined from the claims, using the same method used with the 5 percent data. Drug use information is obtained from the MCBS Cost and Use data file “Prescribed Medicine Events,” and SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data.

Objective 5.11: The cohort for Figures hp.23–25 and hp.37, and for Table hp.i, is the same as that used for Objective 4.8. CPT codes used for urinary microalbumin measurement are also identified from HEDIS 2002 specifications, and include 82042, 82043, and 82044. Testing is tracked during each year.

Objective 14.29: The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to September 1 of each year and alive on December 31. For pneumococcal
The population for Figures 1.1–4 and Tables 1.a–c includes 1993–2005 data cleaning and counting of admissions and time at risk for years. For each cohort, claims prior to initiation as well as after. Emerging issues: First-year mortality

Chapter One

The population for Figures 1.1–4 and Tables 1.a–c includes 1993–2005 incident dialysis patients who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, or primary diagnosis are excluded. Patients are followed from the first service date up to one year, and are censored at transplant, loss-to-follow-up, or December 31, 2006. The reference cohort consists of 2005 incident dialysis patients. Overall mortalities are adjusted for age, gender, race, and primary cause of ESRD; mortalities by primary diagnosis are adjusted for age, gender, and race.

Figures 1.5–7 and Tables 1.d–f present all-cause and cause-specific admission rates in the first months of dialysis. Cohorts include incident dialysis patients age 20 and older, 1993–2005. Included patients have Medicare as a primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. As in the hospitalization analyses (Chapter Six), patients with missing data for age or gender, or with AIDS as a primary or secondary cause of death, are excluded. Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalization until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after dialysis initiation, and are followed for admissions up to one year after day 90. Data cleaning and counting of admissions and time at risk for admissions generally follow that described for Reference Section G; here, however, incident patients are followed during intervals following day 90 rather than during prevalent years. Censoring occurs at death, loss to follow-up, three days prior to transplant, end of payor status, or December 31, 2006. Cardiovascular and infectious admissions in Tables 1.e–f and Figures 1.6–7 are identified by principal ICD-9-CM diagnosis codes listed in the discussion of Figure 6.6. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. Incident dialysis patients during 2005 comprise the reference cohort. Similarly to the previous mortality figures and tables, admission rates by primary diagnosis are adjusted for age, gender, and race, and overall rates are also adjusted for primary diagnosis.

Figures 1.8–12 include Medicare patients who initiate hemodialysis at age 67 or older during 2000 or 2005 and who are Medicare eligible during the two years prior to initiation, along with patients from the Medstat dataset who initiate dialysis during those same years. For each cohort, claims prior to initiation as well as after the start of dialysis are searched to identify insertions for dialysis catheters, fistulas, or grafts, as identified by codes listed in Table 1.c later in this appendix. Cumulative probabilities are calculated using Kaplan-Meier survival methods, censoring at death, a change in eligibility or payor status, renal transplant, or at a change to peritoneal dialysis (Medicare patients only). Tables 1.g–i use Medicare patient cohorts that match those for used in Figures 1.8–12.

The Reference Tables present parallel sets of counts and rates for the start of dialysis are searched to identify insertions for dialysis catheters, fistulas, or grafts, as identified by codes listed in Table 1.c later in this appendix. Cumulative probabilities are calculated using Kaplan-Meier survival methods, censoring at death, a change in eligibility or payor status, renal transplant, or at a change to peritoneal dialysis (Medicare patients only). Tables 1.g–i use Medicare patient cohorts that match those for used in Figures 1.8–12.

Table 1.j includes 2005 incident dialysis patients. Patients are followed from ESRD date to death, transplant, or end of follow-up (one, three, six, and 12 months from the date of ESRD initiation). Hazard ratios are estimated from Cox proportional hazard models and adjusted for age, gender, race, and other comorbidities. Comorbidities are obtained from the Medical Evidence form.

Incidence & prevalence

Chapter Two: A & B Tables

Here and throughout the ADR, the USRDS generally reports point prevalence—the type of prevalence used throughout most of the book—as of December 31, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of patients who have the disease at the end of the year and those who have the disease during the year and die before the year’s end. Because the USRDS treats successful transplantation as a therapy rather than as a “recovery” from ESRD, patients with a functioning transplant are counted as prevalent patients.

Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS are not included in the database. We therefore qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term “acceptance into ESRD therapy.” We believe, however, that “incidence of reported ESRD therapy” is more precise, because “acceptance” implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS.

Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

REFERENCE SECTION A

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalent counts and counts of lost-to-follow-up patients.

Because the U.S. population figures (shown in Reference Section M) used in the ADR include only residents of the 50 states and the District of Columbia, tables also focus on patients from these areas. Exceptions are Tables A.1, A.a, A.6, A.8, A.10, and A.c, all of which present data specific to patients in Puerto Rico and the Territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Rates in Table A.9 are calculated using the model-based method (described in the Statistical Methods section later in this appendix), and adjusted for age, race, and gender, with the 2006 national population as reference.

REFERENCE SECTION B

With the exception of Tables B.1, B.6, B.8, and B.10, these tables focus on patients residing in the 50 states and the District of Columbia. Age is calculated as of December 31. Table B.9 is constructed similarly to Table A.9.
Treatment modalities
Chapter Four: C tables

Data used here are obtained from the Medical Evidence form, completed at the dialysis unit for each new ESRD patient treated at that unit and sent to CMS through the ESRD networks. This form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible Medicare beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new ESRD patients.

Before 1995, units were required to file the Medical Evidence form only for Medicare-eligible patients. With the adoption of a revised form in 1995, however, providers are now required to complete the form for all new ESRD patients, regardless of their Medicare eligibility. The 1995 revision also introduced new fields for comorbidity conditions, employment status, race, ethnicity, and biochemical data at the start of ESRD therapy.

This form is the only source of information about the cause of a patient’s ESRD. Because the list of diseases has been revised, the USRDS stores the codes from each version so that detail is not lost through trying to convert one set of codes to the other.

A new revision of the Medical Evidence form was released in the spring of 2005, introducing new fields related to comorbidity, laboratory test values, pre-ESRD care, and vascular access.

Figure 3.5 includes incident hemodialysis patients who have valid EPO claims during each of the first four months after initiation.

Treatment modalities are defined here as follows:
- center hemodialysis: hemodialysis treatment received at a dialysis center
- center self-hemodialysis: hemodialysis administered by the patient at a dialysis center; a category usually combined with center hemodialysis
- home hemodialysis: hemodialysis administered by the patient at home; cannot always be reliably identified in the database
- CAPD: continuous ambulatory peritoneal dialysis; usually combined with CCPD
- CCPD: continuous cycling peritoneal dialysis; usually combined with CAPD
- other peritoneal dialysis: primarily intermittent peritoneal dialysis (IPD), a small category except among very young children; usually combined with unknown dialysis and uncertain dialysis to form an other/unknown dialysis category
- uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but none last 60 days; usually combined with other peritoneal dialysis (IPD) and unknown dialysis to form an other/unknown dialysis category
- unknown dialysis: a period in which the dialysis modality is not known (e.g. when dialysis sessions are performed in a hospital); usually combined with other peritoneal dialysis (IPD) and uncertain dialysis to form an other/unknown dialysis category
- renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a cadaveric donor
- death: a category not appearing in the year-end modality tables, which report only living patients, but used as an outcome (e.g. in tables showing living patients followed for a period of time for their modality treatment history)

Modality and provider characteristics are presented in Figures 4.3 and 4.6. For a description of the provider data used in these figures, please see the discussion of Chapter Ten. All provider-related figures include only dialysis patients. Figures 4.4 and 4.7 show modality and payor information, while Tables C–D and Figures 4.9–14 provide a closer look at the demographic and geographic variations of home hemodialysis patients.

Reference Section D is divided into three sections. The first, Tables D.1–11 and D.15–16, provides counts and percentages—by demographics, geographic location, and treatment modality—of incident and prevalent patients alive at the end of each year. Age is computed as of the start of ESRD for incident patients, and as of December 31 for point prevalent patients.

Table D.12 shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 2001 to 2003. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

The third section, Tables D.13–14, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.13 shows counts by the number of years of ESRD, while Table D.14 presents counts by the number of years on the end-of-year treatment modality. For the duration of ESRD exposure, zero should be read as less than one year, one as at least one full year but less than two, and so on.

Clinical care & preventive health
Chapter Five

In Figure 5.1, for both Kt/V measurements, 2005 ESRD CPM data are used to calculate a mean Kt/V value for each patient from the 1–3 values present for each, and the percent of patients with a mean Kt/V over a certain threshold is determined. For prevalent hemodialysis patients in 2006, each patient’s URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Each measurement is categorized into one of five ranges, and the median URR is calculated; for patients whose median lies between two ranges, we assign a weight of 0.5 to each. Information on new hemodialysis patients with an arteriovenous fistula as the first access is calculated as described for Figure 5.11. Hemoglobin levels are calculated for EPO-treated, 2006 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500 or greater than 80,000 units, or with a hematocrit value less than 10 or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hematocrit values divided by three.
Data on albumin are obtained for incident hemodialysis patients in 2006 who have a valid value on their Medical Evidence form; those with a lower limit equal to zero are omitted.

ANEMIA TREATMENT

The methods for Figures 5.2–3 are described in the discussion of Figures p.11-12. Figures 5.4–6 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. EPO claims with a dose per administration of less than 500 units or more than 80,000 units are omitted, as are those with an average dose per day (calculated as the total EPO units on the claim divided by the number of days spanned by the claim) of less than 100 units or greater than 10,000 units. For 2006, patients are incident prior to June 1, to allow them to have six months of EPO and/or iron claims after their incident date. For graphs by starting hemoglobin, patients are included only if they have a hematocrit listed on the Medical Evidence form, and their starting hemoglobin is determined from this value. In Figure 5.4, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 5.5, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only. And for Figure 5.6, the cumulative percent receiving at least one IV Iron administration during the first six months of dialysis is calculated.

Figure 5.7 includes incident dialysis patients with a first service date in 1992, 1997, 2002, or 2006; Medicare as primary payor; and age greater than or equal to 65. Patients who die in the first twelve months are excluded. Probabilities are calculated using the Kaplan-Meier method, and patients are censored at death date. Figure 5.8 includes point prevalent dialysis patients, 1992–2005, with a first service date 90 days prior to January 1 of each year and alive through the end of the following year. Transfusion events are examined from January 1 of each year to December 31 of the following year. Table 5.4 includes point prevalent dialysis patients in 1992, 1997, 2002, and 2006 with a first service date 90 days prior to January 1 of each year and alive through the end of the year. Odds ratios are calculated using simple logistic regression.

In the case of an overlap in transfusion dates, only one transfusion event is used. If an inpatient and outpatient claim both indicate transfusion events and have the same “from” date, the inpatient claim is used; if inpatient and outpatient claims indicating a transfusion partially overlap, the claim with the earliest “from” date is used; and if one or more short period claims indicating a transfusion are within a long period claim, the long period claim is used.

OUT-OF-TARGET HEMOGLOBIN LEVELS

Cumulative probabilities here are calculated using the Kaplan-Meier method, and patients are censored at a missing hemoglobin value.

The cohort for Figures 5.9 and 5.11 includes incident dialysis patients with a first service date between June 1, 2005, and May 31, 2006, with Medicare as primary payor, and receiving EPO during the first six months after incidence. Patients who die or are transplanted in the first six months are excluded. Figures 5.12 and 5.14 include incident dialysis patients with a first service date between July 1, 2005, and June 30, 2006, with Medicare as primary payor, and receiving EPO during the first six months. Patients who die or are transplanted in the first six months are excluded. And Figures 5.10 and 5.13 include point prevalent dialysis patients, 2006, with a valid hemoglobin value in each of the first six months. The 90-day rule is applied.

PREVENTIVE CARE

Figures 5.15–17 present data on comprehensive diabetic monitoring and in patients age 18–75. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted from these analyses, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost-to-follow-up during the study period. Patients who reside in the District of Columbia, Puerto Rico, and the Territories are also omitted from the maps. Age is generally calculated at the end of the study period.

Methods and codes used to determine rates of diabetic glycosylated hemoglobin (HbA1c) testing, lipid testing, and eye exam are described in the methods for Chapter HP2010 Objective 4.8. Patients are defined as having diabetes either through medical claims (one inpatient/outpatient, two physician/supplier, two outpatient, or one physician/supplier and one outpatient), or through a listing of diabetes on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define diabetes are described under the “CKD population & costs” section in CKD volume.

Figure 5.15 show rates by HSA in 2006, Figure 5.16 show the amount of diabetic monitoring by modality, and Figure 5.17 compare rates in dialysis and transplant patients. The population for Figures 5.15 and 5.17 includes ESRD patients initiating therapy at least 90 days prior to January 1, 2005, alive on December 31 of 2005, and with diabetes defined in 2005. Testing is tracked in 2006. Rates include patients receiving at least four HbA1c tests, at least two lipid tests, and at least one eye exam. HbA1c & lipid tests are at least 30 days apart.

The cohort for Figure 5.16 includes patients starting therapy at least 90 days prior to January 1 of the first year of each study period and with diabetes in the first year. Testing is tracked in second year of each study period, and tests are at least 30 days apart.

Figures 5.18–23 show rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality, age, race/ethnicity, and time period. Cohorts for Figures 5.18–21 are the same as those described for Objective 14.29 in the HP2010 chapter, while the cohorts for Figures 5.22–23 are the same as those for Figures 5.36 and 5.35, respectively. Patients who reside in Puerto Rico and the Territories are omitted from the maps. Age is generally calculated at the end of the study period. Hepatitis B vaccinations are identified through CPT codes 90636, 90740, 90743–90744, 90748, 90731, and 90723.

VASCULAR ACCESS IN PREVALENT PATIENTS

Figures 5.24–30 include prevalent hemodialysis patients who are in both the USRDS and ESRD CPM databases, and whose day 91 begins prior to October 1 of the prevalent year. The access represents the current access being used according to the CPM data. Claims are then searched during the following calendar year for events and complications. Figure 5.30 includes incident peritoneal dialysis patients from the USRDS database. For Figures 5.27–30, complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the place-
ment of a different type of access. Vascular access codes are listed in the methods for Chapter Eleven.

**Morbidity & mortality**

Chapter Six: G, H, & I tables

**HOSPITALIZATION**

Methods used for the prevalent patient hospitalization figures in this chapter generally echo those used for the tables in Reference Section G (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Reference Section G of patients of races that are unknown or other than white, African American, Native American, or Asian; these patients are included in the Chapter Six figures, except where data are presented by race.

Inpatient institutional claims are used for the analyses, and methods for cleaning claims follow those described for Section G. Adjusted rates are calculated using the model-based adjustment method on the observed category-specific rates. This method is described further in the discussion of Section G, and in the statistical methods section later in this appendix.

Methods for rates in Figures 6.2–3 follow those described for Reference Section G. In Figure 6.2, methods are similar to those described for Figure p.16 in the Précis, with admissions for pneumonia, bacteremia/septicemia, and cellulitis in Figure 6.2 replacing the categories of all-cause, infection, and cardiovascular disease in p.16. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: pneumonia, 480–486 and 487.0; bacteremia/septicemia, 058.0–058.9 and 790.7; and cellulitis, 682. Vascular access hospitalizations are “pure” inpatient vascular access events, as described in the discussions of Tables G.11–15 (in Reference Section G) and in Table a.c later in this appendix. Due to new dialysis access codes for peritoneal dialysis patients in 1998, vascular access hospitalizations are shown for hemodialysis patients only. Figure 6.3 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, with the 2005 ESRD cohort used as the reference.

Figure 6.4 presents unadjusted rates for period prevalent ESRD patients in 2006 by HSA and state. (Rates for peritoneal dialysis and transplant patients are presented by state rather than by HSA due to fewer patients and events in many HSAs.) Maps by HSA are smoothed using the Bayesian method.

Figure 6.5 shows adjusted admission rates for principal diagnoses for prevalent ESRD patients. Principal ICD-9-CM codes for pneumonia, bacteremia/septicemia, and cellulitis are listed above for Figure 6.2. Other principal ICD-9-CM codes are as follows: for vascular access infection (hemodialysis patients only), 996.62; and for peritonitis (peritoneal dialysis patients only), 567.

Figure 6.6 presents the percent change in adjusted hospital admission rates for period prevalent patients, 1996–2006. Values presented for all patients are adjusted for age, gender, race, and primary diagnosis, while rates presented by one of these factors are adjusted for the remaining three. As noted in the caption, these adjustments for different factors mean that rates across the individual graphs are not directly comparable. We use the model-based adjustment method here, with 2005 dialysis patients as the reference cohort. Vascular access hospitalizations (hemodialysis patients only) are “pure” inpatient vascular access events, as listed later in this appendix in Table a.c. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 423–438, and 440–459, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 610.1, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Table 6.4 presents adjusted hospital admission rates by vintage and modality for adult (age 20 and older) period prevalent ESRD patients in 2006. Patient vintage is calculated as the time from the first ESRD service date to the first of the year for prevalent patients, or as less than one year for incident patients. Rates in the “all” row are adjusted for age, gender, race, and primary ESRD diagnosis, while rates presented by one factor are adjusted for the other three.

Figures 6.11–13 show rates by age, adjusted for gender, race, and primary diagnosis using the model-based adjustment method. These figures include period prevalent dialysis patients age 20 and older, with the 2005 dialysis cohort as the reference. Figure 6.11 presents adjusted rates of cause-specific hospital admissions per patient year. The categories for cardiovascular disease and infection are defined by the codes listed for Figure 6.6; the infection codes for Figure 6.11, however, exclude those due to internal device. The principal ICD-9-CM diagnosis codes used for infection due to internal device (related to a vascular access device or peritoneal dialysis catheter) are 996.62 and 996.68.

Figure 6.12 shows adjusted event rates for inpatient coronary revascularization. Patients are followed until the first coronary revascularization event, and are censored at the earliest of death, three days prior to transplant, or the end of the calendar year. Events are identified from inpatient and physician/supplier claims occurring within a hospital stay. The following ICD-9-CM procedure and CPT codes are used to identify events: angioplasty, procedure codes 36.06, 36.07, 36.08, 36.09, and 36.10, and CPT codes 92982, 92984, 92985, and 92996; coronary stents, procedure code 36.06 and CPT codes 92980–92981; and bypass, procedure codes 36.10 and CPT codes 33510–33523, 33533–33536.

Figure 6.13 displays adjusted vascular access placement rates for period prevalent adult hemodialysis patients. These are not hospital admission rates, but procedure rates for vascular access placements in an inpatient setting. Vascular access placements are obtained from CPT codes on physician/supplier claims, and are restricted to those occurring in the hospital (during an inpatient stay or emergency room visit). Categories include catheters, fistulas, and grafts, and the CPT codes used to define them are found in Table a.b later in this appendix. The category for all vascular access placements includes the CPT codes for all of the above categories. Methods are also used to exclude vascular access used for purposes other than dialysis. Catheter placement codes that are not specific for dialysis are included only if they are accompanied by an ICD-9-CM renal diagnosis code. Also, rates for catheter and all vascular access placements exclude patients with specific chemotherapy or parenteral nutrition claims during the year. Inpatient/outpatient institutional, physician/supplier, and durable medical equipment claims indicate
MORTALITY

Patient cohorts for all mortality figures here include both Medicare and non–Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Figure 6.1 shows trends in mortality rates by modality for incident ESRD patients, 1980–2005. The population groups include all-ESRD, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, third-, fourth-, and fifth-year mortality rates for incident cohorts—including all-ESRD, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method, described later in this appendix. Mortality rates for all patients are adjusted for age, gender, race, and primary diagnosis. The reference population for adjusted rates consists of 2005 incident ESRD patients.

Figure 6.7 presents unadjusted all-cause mortality, by HSA, for 2006 prevalent ESRD, dialysis, transplant, and general Medicare patients age 65 and older. General Medicare patients are non-ESRD patients with at least one month of Medicare eligibility in 2006; they are followed from the first day of the first month with Medicare eligibility until death or December 31, 2006. ESRD patients are followed from January 1 until December 31, 2006.

Figure 6.8 shows all-cause mortality by age for 2006 prevalent ESRD, dialysis, transplant, and general Medicare patients. All-cause mortality rates by age are calculated using generalized mixed models, and are adjusted for gender and race. Medicare patients from 2006 are used as the reference cohort.

Table 6.6 shows expected remaining lifetimes for dialysis patients, renal transplant patients, and the general U.S. population. For period prevalent ESRD patients in 2006, expected lifetimes are calculated using the death rates from the mixed model with 16 age groups, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.4.4 and H.28.4, and the method for calculating expected remaining lifetimes is described in the section on statistical methods at the end of this appendix. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

Figure 6.9 illustrates trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2005 prevalent dialysis patients, and adjusted mortality rates across vintages are comparable.

Figure 6.10 presents five-year survival by modality for 1992–1996 and 1997–2001 incident patients, with modality defined on the first ESRD service date. Transplant is defined as the first transplant in the incident year. Patients with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110, are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2006, while transplant patients are followed from the first transplant date until death or the end of 2006. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. New for this ADR, the reference population consists of 2005 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figure 6.14 displays adjusted all-cause and cause-specific mortality in incident dialysis patients. The cohort includes dialysis patients, 1991–2005, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year, and censored at transplant or recovery of kidney function. Overall mortality rates are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 2005 incident dialysis patients, and adjusted mortality rates can be compared across year and cause of mortality.

Figures 6.15–16 display adjusted mortality due to cardiovascular disease and infection, respectively by age. Populations are same as in Figure 6.14. Mortality rates by age are adjusted for gender, race, and primary diagnosis. The reference population consists of 2005 incident dialysis patients.

WITHDRAWAL & HOSPICE CARE

IN THE MEDICARE ESRD POPULATION

Data on withdrawal & hospice care in the Medicare ESRD population (Figures 6.17–23 and Tables 6.c–f) compare the use of dialysis withdrawal and hospice between the 2000–2001 and 2005–2006 ESRD patient cohorts. The first cohort is comprised of incident and prevalent ESRD patients who died between January 1, 2000, and December 31, 2001, who were on dialysis (including hemodialysis, peritoneal dialysis, and unspecified dialysis) immediately prior to death, and who had Medicare as primary payor coverage; this cohort contains 109,484 patients. The 2005–2006 cohort, constructed in the same way for patients dying between January 1, 2005, and December 31, 2006, contains 126,907 patients. A secondary set of two six-month cohorts—with the additional criteria that patients be on dialysis and have Medicare as primary payor coverage for the entire six months prior to death—is used in analyses examining costs and site of death; the 2000–2001 six-month cohort contains 86,975 patients, while the 2005–2006 six-month cohort contains 101,584 patients. Figure 6.23 uses these latter cohorts. Withdrawal status is determined from the ESRD Death Notification form, which indicates whether a patient withdrew, and, if so, identifies a withdrawal cause (as described in Figure 6.22). Hospice status is determined from the CMS hospice claims Standard Analytical Files. A patient is classified as using hospice if a claim exists showing the patient was in hospice on the date of death, or the discharge code from hospice is “death.”

BURDEN OF WALKING DISABILITY

Table 6.g and Figures 6.24–27 display data on walking disability in incident dialysis patients, obtained from several sources. Those identified as “unable to ambulate” are those for whom it is indicated as such on their Medical Evidence form. A “walking disability” represents the presence of a Medicare claim during the first year after initiation with an ICD-9-CM diagnosis code of 782.1 (abnormal gait), 719.7 (difficulty walking), V13.88 (history of fall), or for a specific type of fall: E88.01, E88.09, E88.42–46, E88.59, E88.88, and E88.89. Those with “assistive devices” are those who have a DME claim during the first year after initiation for a cane (E01.00, E01.05), a walker (E01.10–E01.49), or a wheelchair (E09.50–E10.30, E10.50–E12.98, K00.01–K00.12, and K00.14–K0108). Comorbidities...
are identified from Medicare claims during the one-year period prior to initiation, except for dementia (ICD-9-CM diagnosis codes 290.x or 331.x), which is identified from claims during the two-year period prior to initiation. Institutional status in Figures 6.24–25 is obtained from the Medical Evidence form.

Table 6.28 and Figures 6.28–31 utilize point prevalent dialysis patients from 2005 who have Medicare as their primary payor from 2003 through 2005, and who survive through the end of 2005. Walking disabilities are identified from claims during 2005. Comorbidities are identified from Medicare claims during 2004, except for dementia, which is identified from claims during 2003–2004. Figures 6.26 and 6.30 are calculated as unadjusted Kaplan-Meier survival curves.

REFERENCE SECTION G
Hospitalization reference tables present adjusted total admission and hospital day rates by year from 1993 to 2006. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section at the end of this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from inpatient/outpatient institutional inpatient claims, with the following exceptions: supplementary tables G.1–G.10.5 (on our website and CD-ROM) use only REBUS inpatient data.

Tables G.1–18 include dialysis and transplant patients on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, gender, or race; and patients of races that are unknown or other than white, African American, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the “other” category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:
- all-dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days
- hemodialysis: patients who have been on hemodialysis for at least 60 days
- CAPD/CCPD: patients who have been on CAPD/CCPD for at least 60 days
- transplant: patients with a functioning transplant, and who received the transplant less than three years prior to the start of the period at risk
- all-ESRD: all patients

To limit the contribution of patient years at risk from patients who are classified as MSP, and who therefore have incomplete hospitalization data, dialysis patients failing to reach a certain level of Medicare paid dialysis claims are excluded from Tables G.1–18. Dialysis patient start dates (January 1 for prevalent patients and day 91 of ESRD for incident patients) must fall between start and end dates based on Medicare paid dialysis claims, as follows:
- start date: the first day of the first month in which there are at least $675 of Medicare paid dialysis claims
- end date: the end of a three-month period in which there are less than $675 of paid claims in each month

If a patient’s start date does not fall between these dates, he or she is excluded from the analysis for that year. The paid claims dates are analyzed only for the dialysis patient start date. The end date remains the earliest of death, three days prior to transplant, or December 31 of the year.

For patients in the all-dialysis, hemodialysis, and peritoneal dialysis categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, or December 31. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period is censored only at death or December 31 of the year, a modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories,
the period is censored at the earliest of death, three years after the transplant date, or December 31 of the year. The censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of hospitalizations in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When bridge hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

All admissions and hospital days during the analysis period are included, respectively, in the total admissions and hospital days for each year. An admission for a hospitalization that occurs before and spans the start of the analysis period is excluded from the total admissions for that period, and only the hospitalization days within the period are counted in the total days for hospital day rates. The minimum length of stay is one day, and hospitalizations with an admission and discharge on the same day, as well as those with a discharge the day after admission, are both counted as one day.

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the 1991–2006 institutional inpatient claims, for example, 4.3 percent of the counts of the total admissions or hospital days, patient years at risk, and total patients, are computed similarly to the unadjusted rates in G.1–5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and peritoneal dialysis access hospitalizations are those classified as “pure” inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain DRG code. Codes are listed later in this appendix in Table a.c. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–491; infectious diseases, 001–199; and cancer, 140–208, 140–230, and 233–234. Hospitalizations that do not fall under any of these categories are counted under all others.

Tables G.16–18 display hospital admission rates for infections including bacteremia/septicemia, pneumonia, and urinary tract infection. Rates reflect hospital admissions for the purpose of these infections and are therefore categorized by principal ICD-9-CM diagnosis codes. Codes for bacteremia/septicemia and pneumonia are listed under the discussion of figure 6.2; codes for urinary tract infection include 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1–2, 608.0, 608.4, 616.1, 616.3–4, and 616.8. Rates are unadjusted and show admissions per 100 patient years by modality for prevalent ESRD patients pooled across years.

Supplementary tables providing additional rates and counts are available on our website and CD-ROM. Standardized hospitalization ratios by state (Table G.a) are calculated using the Bayesian method, also described in the statistical methods section. Tables G.1.1–10.1 present adjusted rates similar to those shown in G.1–10, but include more patient subgroups. Rates of admissions per 1,000 patients and days per patient, rather than per patient year, are also available. The rates in these tables (G.1.2–10.2) are calculated with denominators consisting of the total patients, rather than the total time at risk in patient years. Additional tables (G.1.3–10.3) display the counts of the total admissions or hospital days, patient years at risk, and total patients that are used to calculate the rates.

Long-term trends in hospitalization data are also available in supplementary tables (G.1.4–10.4). Total admission rates per 1,000 patient years and hospital day rates per patient year from 1980–2006 are presented in G.1.4–3.4 and G.6.4–8.4. Due to the instability of rates in earlier years, these rates are presented from 1983 in G.4.4 and G.9.4 for peritoneal dialysis patients, and from 1986 in G.5.4 and G.10.4 for transplant patients. Rather than using institutional inpatient claims data, which are unavailable for earlier years, these tables use only REBUS inpatient claims data. All one-day hospitalizations with a discharge date on the same day or the next day as the admission date are excluded from these tables, since, prior to 1991, the REBUS data include no hospitalizations of less than 24 hours. To enable comparison of rates across years, therefore, only hospitalizations with a length of at least two days are included. As a result, these rates are lower than those in Tables G.1.1–10.1, which use all institutional inpatient claims. Other methods (rate calculation, model-based adjustment, etc.) generally follow those discussed for Tables G.1–10.

In supplemental tables G.1.4–10.4, however, we do not exclude dialysis patients failing to reach a certain level of Medicare paid dialysis bills, since this economic information is unavailable for the earlier years. Additionally, supplementary tables G.1.5–10.5 present counts of total admissions or days, patient years at risk, and total patients, which correspond with the rates presented in G.1.4–10.4.

REFERENCE SECTION H

Cohorts for tables in Section H include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.
Cohorts in Tables H.1–31 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year, while prevalent cohorts include patients alive on renal replacement therapy on January 1 and whose first service date is at least 90 days prior to the beginning of the year. Because calculations include only one year of follow-up, a prevalent patient surviving to the end of the year contributes one year at risk, while a prevalent patient dying during the year contributes less than one year. Since the calculation for incident patients begins on day 91 of ESRD, most patients contribute less than one year at risk; a full year is contributed only if day 91 of ESRD is January 1 and the patient survives to the end of the year. Patients considered lost-to-follow-up at the beginning of the year are excluded. The period at risk is not censored at the start of a lost-to-follow-up period, however; if a patient enters the lost-to-follow-up category during a calendar year, he or she remains in the death rate computation until the end of that year. Patient cohort populations often overlap. Patients with a functioning transplant on the start date, for example, are included in the all-ESRD and functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two subgroups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD, or who have been on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

Cohorts in Tables H.32–46 include incident ESRD, dialysis, hemodialysis, CAPD/CCPD, and transplant patients who survive the first 90 days. Patient selection criteria are the same for both unadjusted and adjusted mortality rates. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2005, are included in the analysis. For incident ESRD and transplant cohorts, these patients are followed from day 91 until death or December 31, 2006, for incident dialysis, hemodialysis, and CAPD/CCPD cohorts, patients are followed from day 91 until death, transplant, or December 31, 2006.

Tables H.1, H.2, and H.2.1–2.4 present mortality information for all-ESRD patients. Total patient deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, gender, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. The unadjusted mortality rates are calculated by dividing total patient deaths in a category—male, for example—by total follow-up time in the same category. For the adjusted rates, generalized mixed models are used to calculate the smoothed rates; these methods are described later in this appendix. After obtaining smoothed rates from the generalized mixed models, direct adjustment methods are used. Overall mortality rates are adjusted for age, gender, race/ethnicity, primary diagnosis, and vintage, while rates for each category (age, gender, race, primary diagnosis, and vintage) are adjusted for the remaining four categories. The reference population includes 2005 prevalent ESRD patients.

Table H.2.1 presents adjusted mortality rates by primary diagnosis. The method for calculating the adjusted rate is same as that in Table H.2, except that vintage is not included. Overall mortality rates are adjusted for age, gender, race, and primary diagnosis, while rates for diabetes, hypertension, glomerulonephritis, and other causes of ESRD are adjusted for age, gender, and race. The difference between Table H.2.1 and H.2.2 is that the mortality rate is expressed as per 1,000 patients years in H.2.1 and per 1,000 patients in H.2.2. Table H.2.3 shows total death counts, total follow-up years, and total patient counts. Table H.2.4 presents mortality rate by patient age, gender, race, and primary diagnosis for 2005 prevalent ESRD patients. Mortality rates in Table H.2.4 are smoothed and unadjusted using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1–4.4 (dialysis); Tables H.11, H.12, and H.12.1–4 (hemodialysis); Tables H.19, H.20, and H.20.1–20.4 (CAPD/CCPD); and Tables H.27, H.28, and H.28.1–4 (transplant).

Tables H.5–10 (dialysis), H.13–18 (hemodialysis), and H.21–26 (CAPD/CCPD) include total patient deaths and annual unadjusted and adjusted mortality rates for patients who have never been on the transplant waitlist, for those who have been listed, and for those who have returned to the modality after a transplant.

In Table H.29, unadjusted mortality rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 2004–2006. The unadjusted mortality rate for a specific primary cause of death in each subgroup is obtained by dividing the total deaths from that cause by the subgroup's total follow-up time, and the sum of rates for each cause in a subgroup is equal to the overall mortality rate of that subgroup. Two new categories of primary cause of death due to congestive heart failure and withdrawal from dialysis have been added, based on the new ESRD Death Notification form introduced in October, 2005.

Patient populations for Tables H.32–46 are the same as those used in Reference Section I. The population groups include all-ESRD, all-dialysis, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, and third-year mortality rates for incident cohorts—including all-ESRD, all-dialysis, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method, described later in this appendix. These rates are presented using aggregate categories for age, gender, race, and primary diagnosis, and a rate presented for one of these variables is adjusted for the remaining three. Overall mortality rates for all patients are adjusted for each of the four variables. Mortality rates for Hispanic and non-Hispanic patients, however, are unadjusted (crude) rates calculated as the number of deaths over patient-years at risk. The reference population for adjusted rates consists of 2005 incident ESRD patients.

REFERENCE SECTION I

These tables, which include only incident cohorts, present patient counts and survival probabilities. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown gender or age, or whose listed age is greater than 110, are excluded.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2005, are included in the analysis. These patients are followed until December 31, 2006, a maximum follow-up time of 24 years and a minimum of one year.

Results are reported for the following groups:

- all-ESRD: all ESRD patients beginning renal replacement therapy in a calendar year and surviving beyond day 90; patients are censored only at the end of follow-up
regression analysis considers all years for which the median is observed. For each cohort, a probability presented for one variable is adjusted for each of the four variables, as described later in the statistical methods section. New for this ADR, the reference population consists of 2005 incident ESRD patients.

Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while the Cox model and the model-based adjustment method are used for adjusted probabilities.

To limit imprecision due to small cell sizes, adjusted probabilities use aggregate categories for age, gender, race, and primary diagnosis. For each cohort, a probability presented for one variable is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables, as described later in the statistical methods section. New for this ADR, the reference population consists of 2005 incident ESRD patients.

Transplantation
Chapter Seven: E & F tables

TRANSPLANT WAIT LIST

Figures 7.1–2 presents transplant counts by donor type, obtained through a combination of OPTN and CMS data. Living-related donors include parents, children, identical twins, full siblings, and half siblings, while living distant/unrelated donors include other relatives, spouses, and others. Figure 7.2 provides more detail regarding the relation of the donor to the recipient of a living donor transplant.

Data on living donor relations are obtained from the OPTN.

Figure 7.3 shows the number of patients on the OPTN kidney or kidney-pancreas wait list on December 31 of the year. Because patients may list at multiple transplant centers, Figure 7.3 shows the number of unique patients on the list and the proportion of patients listed at multiple centers. Similar data are presented for patients classified as “active” listings. Distributions shown in 7.4 are based on active and inactive listings.

Figure 7.5 shows observed and projected median wait times in patients age 18 or older at the time of transplant, by race, blood type, and PRA. Median wait times are estimated for each year using the Kaplan-Meier methodology. Years for which the median is observed are plotted, while for cases in which a subgroup has fewer than 15 patients the median is not plotted and is left as unknown. For more recent years in which the median has not yet been observed—i.e., more than 50 percent of the patients listed in that year have yet to be transplanted—the median time is estimated using a linear regression model. These projections are plotted with a dotted line. The regression analysis considers all years for which the median is observed, excluding cells with fewer than 15 patients, as described above. A regression line is estimated using the year of transplantation as an independent variable. To improve the fit of this line, a quadratic term for the year of transplantation is included in the model. Predicted medians are then estimated from the resulting regression line.

Figure 7.6 shows median wait times by state for adult patients receiving a deceased donor kidney during 2006. Wait time is calculated as the transplant date minus the date the patient is added to the kidney or kidney-pancreas wait list, not necessarily the date he or she is first listed at the center where the transplant is performed. State is the state where the transplant took place, not the state of the patient’s primary residence.

Figure 7.7 shows projected median wait times by state for adult patients listed for a deceased donor kidney transplant in 2006. Projections are estimated using the same methods as in Figure 7.5. State is the state in which the patient is listed, not the state of the patient’s primary residence.

In 2003, OPTN started the expanded criteria donor (ECD) program, to allow patients to indicate their willingness to accept a kidney from a “marginal” donor. Figure 7.8 shows the percent of adult patients—new and prevalent listings—willing to accept an ECD kidney, by OPTN region; prevalent listings include all patients on the list in the 2005–2006 interval regardless of when they initially list. OPTN regions are as follows:

1. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island
2. District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania, West Virginia
3. Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
4. Oklahoma, Texas
5. Arizona, California, Nevada, New Mexico, Utah
7. Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
8. Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming
9. New York, Vermont
10. Indiana, Michigan, Ohio
11. Kentucky, North Carolina, South Carolina, Tennessee, Virginia

Figure 7.9 shows the likelihood of adult patients dying while awaiting transplant in the first five years after listing among patients first listed between 1991 and 2005. The likelihood of dying is estimated using the Kaplan-Meier method. Patients are censored at removal from list and the end of the follow-up period.

Figure 7.10 illustrates outcomes for adult patients first listed in 2001. Patients are classified at five years post-listing as having received a transplant, having died awaiting a transplant, having been removed from the list prior to transplantation, or still waiting.

TRANSPLANTATION & DONATION

Figure 7.11 juxtaposes the growing rate of ESRD with the falling rate of transplantation in patients 20 years and older at transplant, for transplants in 1991–2006. Most adult-only figures are limited to patients 18 years and older, but since census population data are provided in five-year increments, this figure is limited to patients 20 and older. Figure 7.12 presents transplant counts per million population by the state in which the transplant occurs, for transplants occurring in 2006. Figure 7.13 presents transplant rates per 100 dialysis patient years, by state, in 2006. Transplant rates are estimated from a Poisson regression, adjusting for age, gender, race, and primary cause of renal failure, then standardized to the age, gender, race, and primary cause of renal disease makeup of the national population of dialysis patients incident in 2006. The state is the recipient’s last known state of residence, not necessarily the state where the transplant was performed.
Immunosuppression

Figures 7.17–22 present data on immunosuppressive medications used in adult recipients at the time of transplantation, 1995–2006, as reported on the OPTN Immunosuppression Treatment form. All such medications (apart from induction antibodies) are indicated as maintenance immunosuppression on the form. Figure 7.18 highlights the switch over time from Azathioprine to Mycophenolate Mofetil or Mycophenolate Sodium as the common anti-metabolite. Figure 7.19 contrasts the percent of patients using mTOR inhibitors, Sirolimus or Everolimus, at baseline and one year after transplant. Figure 7.20 contrasts the percent of patients using steroids at baseline and one year after transplant. Figure 7.21 shows changes in trends of antibody induction use over time, and Figure 7.22 shows the most common immunosuppression regimes in adult patients transplanted from 2004–2006.

Graft survival

Figures 7.23–24 present five- and ten-year graft survival, as well as conditional half-lives for adult recipients of kidneys from deceased and living donors. All estimates are made from Cox proportional hazards models, adjusted for transplant year, age, gender, race, and primary diagnosis, and based on the population’s average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and estimated from the cumulative hazard between years one and two. Conditional half-lives are interpreted as the estimated median survival of grafts surviving the first year, while half-lives are interpreted as the estimated median survival of all grafts.

Figure 7.25 shows the percentage of adult transplants with primary non-function, defined as kidney failure within seven days of transplantation. Figures 7.26 looks at patients with evidence of delayed graft function (defined by a need for dialysis in the first week after transplantation) by donor status and ECD and DCD status, as reported to the OPTN.

Figure 7.27 presents statistics on graft failures in adults that necessitate long-term dialysis; graft failures due to death and preemptive retransplantations are excluded from these counts. Subsequent treatment is determined from a combination of Medicare claims and OPTN data. Figure 7.28 describes the length of time a transplant survives prior to failure in adult patients. The median time of kidney function is displayed along with first and third quartiles of the distribution. The year is the year of graft failure, and failures due to death are excluded.

In Figure 7.29 we present the rate of return to dialysis/preemptive retransplantation, the rate of death with a functioning graft, and the rate of any graft failure, which includes failure due to death. Rates are limited to adult patients, and estimated from a Poisson regression, adjusting for age, gender, and race.

Figure 7.30 displays causes of death for adult patients transplanted between 1997 and 2006 who subsequently die with a functioning graft. Causes of death are ascertained from OPTN transplant follow-up data, or, if unknown, from the ESRD Death Notification form. Figure 7.31 shows trends in causes of death as a function of time post-transplant.

Pediatric transplantation

Figure 7.32 shows the number of patients age 0–17 at transplant who are on the OPTN kidney or kidney-pancreas wait list on December 31 of the year. Similar data are presented for patients classified as “active” listings.

Figure 7.33 presents median wait times in patients age 17 or younger at the time of transplant, estimated with the same methodology as for Figure 7.5. Figure 7.34 shows transplant counts in pediatric patients by donor type, obtained through a combination of OPTN and CMS data. And Figures 7.35–36 present trends in pediatric transplant rates, 1991–2006, by donor type and age group. These unadjusted rates are calculated as the number of each type of transplant divided by the total dialysis patient time during the year.

Figure 7.37 illustrates data on the most common immunosuppressive regimes used in pediatric recipients at the time of transplantation, 2002–2006, as reported on the OPTN Immunosuppression Treatment form.

Figure 7.38 shows graft survival among pediatric patients transplanted in 2002–2006, while Figure 7.39 illustrates death-censored graft survival in the same population. Survival is estimated using the Kaplan-Meier methodology.

Figure 7.40 displays causes of graft failure in pediatric patients whose grafts failed before the age of 26, and in the interval 2002–2006. Failures due to death are not counted in this figure. Causes of graft failure are ascertained from OPTN transplant follow-up data. Also shown are the proportions of graft failures in which non-compliance was indicated as a primary or contributory cause of failure.

Reference section E

Tables E.1–6 present various measures regarding the wait list for renal transplantation. Wait list data prior to 1988 are not shown; the OPTN wait list began in earnest in 1987. Table E.1 presents counts of patients newly added to the wait list for a kidney or kidney-pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents wait times, defined as the median time, in days, from first listing to transplant among patients listed for a kidney-alone transplant. Kaplan-Meier methodology is used to estimate median wait times. Table E.3 presents counts of patients on the wait list on December 31 of the given year, regardless of when first listing occurred. Table E.4 presents counts for patients that have been certified as having ESRD, and Table E.5 the percent of prevalent dialysis patients on the kidney wait list. In Table E.5, point prevalent dialysis patients on December 31 of the given year are included. Table E.6 presents...
the percent of patients wait-listed or receiving a transplant within one year of ESRD initiation; patients receiving a transplant from a living donor excluded from the measure in the first half of the table and included in the second half. Percentages are calculated using the Kaplan-Meier methodology. This measure is modeled after Healthy People 2010 Objective 4.4.

Transplant counts are presented in Tables E.7-10. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients.

Transplant rates per 100 patient years on dialysis are shown in Table E.11. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. A patient’s dialysis days are counted from the beginning of the specified year, or day one of ESRD dialysis therapy if treatment begins mid-year, until the first of transplant, death, or the end of the year. Patients lost-to-follow-up in a given year are not censored at the lost-to-follow-up date, but are followed until the end of the calendar year. Dialysis time for patients returning from transplant is counted. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year.

Table E.12 shows the distribution of transplanted patients by donor type and PRA level, determined from the OPTN Recipient Histocompatibility form. Table E.13 presents a cross-tabulation of recipients and donors in terms of CMV antibody status at the time of transplantation. A recipient/donor is considered positive if any applicable OPTN data source indicates positive, and “unknown” status is applied only in the event that no applicable test is performed. Table E.14 presents similar data for Hepatitis C antibody status. And Table E.15 presents transplant counts based on cold ischemia times (hours) among deceased donor transplants. Cold ischemia times are taken from OPTN Transplant Recipient Registration form.

REFERENCE SECTION F
This section presents probabilities of graft survival and graft failure necessitating dialysis or retransplantation, by donor type, for various groups and follow-up times. In previous ADRs, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to some confusion regarding terminology, we have decided to rename this outcome. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2006). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or retransplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier methodology, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, primary diagnosis, and first versus subsequent transplant, and standardized to 2005 patient characteristics.

Tables E.25–26 present the relative risk of graft failure, return to dialysis (including preemptive retransplantation), and death with a functioning graft for first-time recipients of deceased donor and living donor kidneys, respectively. Relative risks are estimated from Cox proportional hazards models, one for each donor type and outcome. Patients transplanted between 2001 and 2006 are included. Follow-up is censored at December 31, 2006, for a maximum follow-up of six years. For the graft failure outcome, death is considered a graft failure; for return to dialysis, patients are censored at death with a functioning graft; and for death with function, follow-up is censored at return to dialysis.

Pediatric ESRD
Chapter Eight
Information on pediatric patients is a subset of ESRD patient data used throughout the ADR; methods used for most figures are therefore the same as those described in the related chapter discussions.

ANEMIA & OUT-OF-TARGET HEMOGLOBIN LEVELS
For Figures 8.14–15, the mean hemoglobin and mean weekly EPO dose are calculated on a quarterly basis, and each quarter includes only patients with at least one valid EPO claim during that time. Doses are adjusted for inpatient days. Figure 8.16 includes prevalent hemodialysis and peritoneal dialysis patients who are alive and remain on the modality for the entire prevalent year. Patients are identified as receiving iron if they have at least one claim for it during the year.

The cohort for Figure 8.17 includes incident dialysis patients, age 0–19, with a first service date 90 days prior to June 1, 2001, or May 31, 2006, with Medicare as primary payor, and receiving EPO during the first six months after day 91. Patients who die or are transplanted in the first six months are excluded. Patients are censored at a missing hemoglobin value, and cumulative probabilities are calculated using Kaplan-Meier method.

The cohort for Figure 8.19 includes incident dialysis patients, age 0–19, with a first service date 90 days prior to July 1, 2001, or June 30, 2006, with Medicare as primary payor, and receiving EPO during the first six months after day 91. Patients who die or are transplanted in the first six months are excluded. Patients are censored at a missing hemoglobin value, and cumulative probabilities are calculated using Kaplan-Meier method.

Figures 8.18 and 8.20 includes prevalent dialysis patients, age 0–19, 2006, with a valid hemoglobin value in each of the first six months. The 90-day rule is applied in this analysis.

PREVENTIVE CARE
Figures 8.21–23 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine vaccination rates are similar to those described for Chapter Five. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare inpatient/outpatient and physician/supplier coverage for the entire period.

For influenza vaccinations (Figure 8.21), the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients vaccinated in the last four months of each year. For pneumococcal pneumonia vaccinations (Figure 8.22), the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year; rates are calculated for patients receiving one vaccination in each period. And for hepatitis B vaccinations (Figures 8.23), cohorts include prevalent patients initiating therapy 90 days prior to January 1 and alive on December 31 of each year;

Data on infectious complications in Figure 8.36 include incident dialysis patients with Medicare as primary payor at ESRD initiation. Infectious hospitalizations represent inpatient stays with a principal diagnosis of infection. Pneumonia represents diagnosis codes 480.x–486.x, and device infections include diagnosis codes of 996.62 (hemodialysis) and 996.68 (peritoneal dialysis).

VASCULAR ACCESS

Figure 8.25 includes incident hemodialysis patients from the 2001–2006 ESRD CPM data. Year represents the incident year, and access the access reported as being used at the time of data collection during that year. Figures 8.26–27 include incident hemodialysis patients in both the USRDS and ESRD CPM datasets. Patients are age 0–19 at dialysis initiation, and have Medicare as primary payor on January 1 of the following year. CPM data are used to determine the access used at the time of data collection in the incident year. Patients are followed from January 1 of the year following incidence, and Medicare claims are used to identify access infections and sepsis. Included events occur between January 1 and the censoring date, which is the earliest of death, modality change, change in payer status, placement of a different vascular access, or December 31. For Figure 8.27, time at risk is calculated as the number of days between January 1 and the censoring date. Figure 8.26 also includes incident peritoneal dialysis patients from the USRDS database who are age 0–19 and have Medicare as primary payor on day 91 after incidence. Medicare claims during the one-year period after day 91 are used to identify the first occurrence of either sepsis or an infection of the peritoneal dialysis catheter, censored by death, modality change, change in payer status, or placement of a hemodialysis access. For Figure 8.26, the event-free probability represents the survival probability from an unadjusted Kaplan-Meier curve, using patients from 2000–2005 combined.

HOSPITALIZATION & SURVIVAL

Methods used for the hospitalization data in Figures 8.28–30 and 8.33–35 generally follow those described for Chapter Six, with adjusted rates computed using the model-based adjustment method. Included period prevalent dialysis patients have Medicare as primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, and those with missing age or gender information, are excluded. Rates by primary diagnosis are adjusted for gender and race, and overall rates are adjusted for gender, race, and primary diagnosis. The reference cohort includes period prevalent ESRD patients, age 0–19, in 2005. For Figures 8.33–35, principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. In Figure 8.34, principal ICD-9-CM diagnosis codes are as follows: for CHF: 398.91, 402.X1, 404.X1, 404.X3, 422, 425, and 428; and for dysrhythmia, 426–427. Codes in Figure 8.35 are listed in the discussion of Figure 6.2 for pneumonia and bacteremia/septicemia and in Figure 6.11 for infection due to internal device.

Figure 8.31 presents one- and five-year survival probabilities, by age and modality, adjusted for gender, race, and primary cause of ESRD. The reference consists of 2005 ESRD patients age 0–19.

Figure 8.32 presents five-year survival by modality for 1992–1996 and 1997–2001 incident patients age 0–19. Patients with unknown age, gender, or primary diagnosis are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplant, or the end of 2006; transplant patients are followed from the first transplant date until death or the end of 2006. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 2004–2005 incident pediatric ESRD patients, and adjusted probabilities can be compared across modalities.

Figure 8.37 presents adjusted all-cause and cause-specific mortality, by age, for prevalent dialysis patients, 1991–2006. These rates are also computed from the generalized mixed model. Rates for all patients are adjusted for gender, race, and primary cause of ESRD. The reference population consists of 2005 ESRD patients age 0–19.

GROWTH & DEVELOPMENT

Figures 8.38–41 and Tables 8.b–c utilize the 2002 ESRD CPM data and supplement. Heights reported in the CPM data are standardized for age and gender using a method developed by the CDC and based on their 2000 growth charts. We incorporated some SAS code provided on the CDC’s website, at http://www.cdc.gov/nccdphp/dnpa/growthcharts/sas.htm. Included patients have a standardized height more than two standard deviations below the mean. This cutoff was chosen because it is included as one of the criteria for recombinant human growth hormone (rhGH) use in the “Guidelines for use of Human Growth Hormone,” published by the American Society of Pediatric Nephrology. Biochemical data and information about rhGH prescriptions are obtained from the 2002 ESRD CPM supplement. The percentage of patients with growth hormone prescription includes only those patients for whom it is known whether or not they were prescribed rhGH. “Z-scores” in Figure 8.38 represent the number of standard deviations away from the mean standardized heights of the U.S. pediatric population, assuming a Normal Distribution. Insurance status (Medicare as primary payor) in Table 8.b and Figures 8.40–41 is obtained for patients also in the USRDS database.

Special Studies

Chapter Nine

CARDIOVASCULAR SPECIAL STUDIES

Figure 9.1 displays trends in the use of diagnostic tests and treatment for cardiovascular disease in the year beginning on day 90 after dialysis initiation (incident dialysis patients) or the first transplant date (transplant patients) for the 1995–2005 cohorts. It also displays the probability of receiving tests or treatment in the three years beginning on day 90 after dialysis initiation or the first transplant date for the combined 2001–2003 (Period 1) and 2004–2006 (Period 2) cohorts. The dialysis cohort includes incident ESRD patients receiving hemodialysis or peritoneal dialysis on day 90 after ESRD onset, 1995–2005, age 20 and older, and enrolled in Medicare inpatient/outpatient and physician/supplier programs on day 90 after onset. The transplant cohort includes first renal transplant patients, 1995–2005, age 20 and older, regardless of first ESRD service year, with Medicare as primary payor. Patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories are excluded. These exclusion criteria also apply in the following figures.
Dialysis patients 1995–2005 are followed from day 90 after dialysis initiation to the earliest of one year after initiation, December 31, 2006, or the date of censoring due to death, transplant, loss to follow-up, recovery of renal function, end of Medicare as primary payor status, or modality change. Transplant patients 1995–2005 are followed from the first transplant date to the earliest of one year after the first transplant date, December 31, 2006, or the date of censoring due to death, graft failure, or end of Medicare as primary payor status. Dialysis patients 2001–2003 are followed from day 90 after dialysis initiation to three years after day 90, December 31, 2003, or the date of censoring. Dialysis patients 2004–2006 are followed from day 90 after dialysis initiation to three years after day 90, December 31, 2006, or the date of censoring. Transplant patients 2001–2003 are followed from the first transplant date to the earliest of three years after first transplant date, December 31, 2003, or the date of censoring. And transplant patients 2004–2006 are followed from the first transplant date to the earliest of three years after first transplant date, December 31, 2006, or the date of censoring. Age is computed as of the beginning of follow-up.

Diagnostic tests include stress testing, coronary angiography, and stress testing/coronary angiography. Treatments include percutaneous coronary interventions (PCI), coronary artery bypass graft (CABG) surgery, and implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy with defibrillator (CRT-D). For each endpoint, the Kaplan-Meier method is used to estimate the event probability.

Figures 9.2–3 illustrate comorbidity in patients receiving their first diagnostic tests and treatment for cardiovascular disease. The dialysis and transplant cohorts are constructed as described for Figure 9.1, except the cohort year is 2004–2006 combined. Incident hemodialysis and peritoneal dialysis patients are followed from day 90 of dialysis initiation to the earliest of December 31, 2006, or the date of censoring due to death, transplant, loss to follow-up, recovery of renal function, end of Medicare as primary payor status, or modality change. First-transplant patients are followed from the first transplant date to the earliest of December 31, 2006, or their date of censoring due to death, graft failure, or end of Medicare as primary payor status.

Major comorbid conditions are defined from Medicare claims in the year before the first date of diagnostic testing, and the Medical Evidence form, which lists the primary cause of ESRD, is also used to identify comorbidity.

A previously validated methodology for using Medicare claims to identify diabetic patients defines a patient as diabetic if, within a one-year observation period, an ICD-9-CM diagnosis code for diabetes appears on one or more inpatient institutional claims (hospitalization, skilled nursing facility, or home health agency), or two or more outpatient institutional claims or physician/supplier claims. We use this methodology to identify patients with comorbid conditions, with the following ICD-9-CM diagnosis codes: A110, 250, 251, 360, 401, and 410; CHF, 350.91, 422, 425, 428, 429, 430.x1, 430.x2, 430.x3, and V42.1; and diabetes, 250, 357.2, 362.0x, and 366.41.

Figures 9.4–12 describe the cumulative percent of incident hemodialysis, peritoneal dialysis, and first-transplant patients receiving diagnostic tests and treatment for cardiovascular disease. The cohorts are similar to those described for Figure 9.1. Data for echocardiograms, electrocardiograms (ECGs), and lipid testing are presented in addition to data for the procedures described in Figure 9.1.

The cumulative percentage is calculated as the cumulative number of patients receiving diagnostic tests or treatment divided by the total number of patients at the beginning of follow-up.

Diagnostic tests and treatment for cardiovascular disease are identified using several sources. Echocardiograms, lipid testing, and ECGs are identified by CPT codes in physician/supplier claims; ICDs and CRT-D by ICD-9-CM procedure codes in inpatient/outpatient patient claims; and stress tests (including stress echocardiogram, stress nuclear test, and stress ECG), coronary angiography and/or catheterization, PCI, and CABG surgery by ICD-9-CM procedure codes in inpatient/outpatient claims or CPT codes in physician/supplier claims. The following codes are used:
- Echocardiograms: 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93318, 93320, 93321, and 93325 (CPT codes)
- Lipid testing: 80061, 80465, 84478, and 83715–83721 (CPT codes)
- ECG: 93000, 93005, 93010, 93012, 93014, 93224–93227, 93230–93233, 93235–93237, 93268, 93270–93272, and 93278 (CPT codes)
- ICD: 37.94 (ICD-9-CM procedure code)
- CRT-D: 00.51 (ICD-9-CM procedure code)
- Stress tests: 89.41–89.44 (ICD-9-CM procedure codes); 78459–78461, 78464, 78465, 78469, 78472, 78473, 78478, 78480, 78481, 78483, 78491, 78492, 93015–93018, and 93350 (CPT codes)
- Coronary angiography and/or catheterization: 37.22–37.23 and 38.53–38.57 (ICD-9-CM procedure codes); 93508, 93510, 93511, 93524, 93526, 93527, 93529, 93531–93533, 93539, 93540, 93543, 93545, and 93555 (CPT codes)
- PCI: 00.66, 36.01, 36.02, 36.05, and 36.06 (ICD-9-CM procedure codes); 92980–92982, 92984, and 92995–92996 (CPT codes)
- CABG surgery: 36.1x (ICD-9-CM procedure codes); 33510–33523 and 33533–33536 (CPT codes)

REHABILITATION/QUALITY OF LIFE
& NUTRITION SPECIAL STUDIES

Work & disability

The Comprehensive Dialysis Study (CDS) includes 1,646 incident dialysis patients. In the data summarized in this chapter, age is defined as of the date of the patient’s baseline interview. Educational status is obtained from question 9 of the CDS Patient Questionnaire. The first four response categories (0–6 years completed, 7–9 years completed, some high school completed, college degree completed) are collapsed to form the category of “high school or less.” The last three response categories (vocational school or some college completed, college degree completed, professional or graduate degree completed) are collapsed to form the category of “college.” Educational status information is missing for 6 patients. Of those remaining, the distribution was 910 (55.5 percent) “high school or less” and 730 (44.5 percent) “college.”

Data for Figure 9.15 are obtained from question 71 of the Patient Questionnaire: Were you working for pay (receiving taxable wages) at any time during the year before you started dialysis? Data for Figure 9.16 are obtained from question 73: Are you now working for pay (receiving taxable wages)? Data for Figure 9.17 are obtained from question 72: Are you now able to work for pay (receiving taxable wages)? Data for Figure 9.18 are obtained from question 75 (Are you receiving disability benefits (SSDI, SSI) from Social Security?) and question 77 (IF NO, have you applied for Social Security disability benefits since you began dialysis?) of the Patient Questionnaire.
total of 16 patients had missing values for question 75 and/or question 77. After excluding these patients, data for Figure 9.18 were available for 1,630 incident dialysis patients.

Perceived physical status and mental status
The Physical Component Summary (PCS) score and the Mental Component Summary (MCS) score were calculated from the Medical Outcomes Study Short Form-12 (SF-12), v.2 (questions 14–25 of the CDS Patient Questionnaire). See http://www.sf-36.org/tools/sf12.shtml.

A total of 33 patients had missing values for one or more of the SF-12 questions on the baseline CDS Patient Questionnaire. After excluding these patients, data were available for 1,613 incident dialysis patients.

Figure 9.19 shows mean scores for the PCS, by age and gender, and Figure 9.21 shows mean scores for the MCS, by age and gender.

Figure 9.20 shows the percentage of patients who reported that they often take walks (question 68 on the CDS Patient Questionnaire). A total of ten patients had missing values for question 68. After excluding these patients, data were available for 1,629 incident dialysis patients.

Figure 9.22 shows the percentage of patients who screened positive for probable/possible depression, based on the Patient Health Questionnaire-2 (PHQ-2), a two-item depression screening instrument (questions 26–27 of the CDS Patient Questionnaire). The PHQ-2 inquires about the frequency of depressed mood and anhedonia over the last two weeks, scoring each as 0 (not at all) to 3 (nearly every day). PHQ-2 scores can range from 0 to 6. A PHQ-2 score $\geq 3$ indicates a positive screen. A total of 17 patients had missing values for questions 26–27. After excluding these patients, data were available for 1,636 incident dialysis patients.

Nutrition
Laboratory data: Serum samples were obtained at baseline for 269 patients at 66 facilities (76 percent of participants in the nutrition substudy). Serum specimens were obtained in conjunction with routine monthly laboratory studies for patients at facilities in the nutrition substudy. Blood was centrifuged according to routine dialysis unit procedures and then shipped on wet ice via overnight delivery to the laboratory in Davis, California, without further processing at the facilities. Serum was separated by centrifugation upon receipt, and one aliquot was analyzed for albumin, prealbumin, C-reactive protein (CRP), and $\alpha_1$ acid glycoprotein ($\alpha_1$AG) by rate nephelometry using a Beckman Array 360 nephelometer. The measured range for serum albumin is 0 to 6 g/dl with a normal range of 3.5 to 5.5 g/dl. The measured range for prealbumin is 1.2 to 1800 mg/dl with normal range of 18 to 45 mg/dl. The measured range for CRP is 0.4 to 12 mg/dl with a normal range of $\leq$ 8 mg/dl. All nephelometric measurements were made in duplicate in each of two optical systems. The average of these values is reported and shown in Figures 9.23–26. The median CRP for each group is depicted; all other analytes are shown as means.

Nutrition data: Three hundred sixty-one patients completed the Block Brief 2000 Food Frequency Questionnaire (NutritionQuest, Berkeley, CA). The questionnaire was designed to provide estimates of usual and customary dietary intake. The questionnaire contains approximately 70 food items and asks about portion sizes for each. The food list for this questionnaire was developed from the NHANES III dietary recall data. The questionnaire was administered in English or Spanish by trained interviewers from DataBankue Research Services (Pittsburgh, Pennsylvania) using computer-assisted telephone interviewing. The Food Frequency Questionnaire portion of the interview took an average of 24 minutes to complete.

ESRD providers
Chapter Ten: J tables
This is the second year in which the USRDS has used its new definition of a dialysis chain. Throughout the atlas and in Reference Section J, we now define a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units which are owned or operated by a corporation at the end of a year. The affiliation category of “small dialysis organization,” or SDO, includes all organizations meeting our definition of a chain but having fewer than 100 units. Chain affiliation is determined from the “Provider Name” field of the Facility Survey, the “Chain Name” field of the Dialysis Facility Compare database, and the “Chain Organization Name” field of the Cost Report.


A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each dialysis unit by CMS. For years prior to 2002, we determine facility profit status through the ownership type field on the CMS survey. In the 2002 CMS Survey the profit status variable was dropped, so for that and subsequent years we use the profit status field of the Dialysis Facility Compare (DFC) database. There are, however, a small number of facilities in the CMS survey that are not in the DFC database; these facilities have an unknown profit status, and are omitted from any graph showing profit status.

For provider specific analyses, unless otherwise specified, the dialysis provider for individual patients is assigned as follows: for prevalent studies, the patient is assigned to the facility providing dialysis services at the prevalent date, as determined from the treatment history. For incident studies, the patient is assigned to the facility providing dialysis services at the incident date, as determined from the treatment history. In either case, if provider data is unavailable from the treatment history, the patient is assigned to “Unknown Provider” or excluded, depending on the analysis.

ANEMIA TREATMENT & VASCULAR ACCESS
Figure 10.7 includes period prevalent dialysis patients in 2001 and 2006. Data for mean hemoglobin include only patients with valid EPO claims. A mean is calculated for each patient from all valid claims during the year. Figure 10.8 shows the number of months in which patients have a hemoglobin value of 10–12 g/dl. The study cohort includes point prevalent dialysis patients, 2006, with a valid hemoglobin value in each of the first six months after January 1, 2006.
The cohorts for Figure 10.9–10 include incident dialysis patients with a first service date between July 1, 2005, and June 30, 2006 (Figure 10.9), or May 31, 2006 (Figure 10.10), with Medicare as primary payor, and receiving EPO during the first six months after incidence. Patients who die or are transplanted in the first six months are excluded. Hazard ratios are calculated using a proportional hazards model with the independent unit affiliation as the reference group.

Figure 10.11 displays the prevalence of IV iron administration, by dialysis unit affiliation and product type. The cohort consists of patients initiating ESRD therapy at least 90 days prior to the start of 2006, and receiving dialysis on December 31, 2005. All patients survive, continue dialysis, and carry Medicare as primary payor during all of 2006. Iron use is indicated by inpatient/outpatient claims with HCPCS codes J0635–J0636, J1270, and J2500–2501. Chain affiliation is defined at the beginning of follow-up for iron use.

Figure 10.12 includes period prevalent dialysis patients, 2001 and 2006, treated with EPO, and the standard deviation represents the standard deviation of the yearly individual mean hemoglobin values for all patients.

Figure 10.13 includes point prevalent dialysis patients in 2001 and 2006 with a first service date 90 days prior to January 1 of each year and alive through the end of the year. Rates represent patients with one or more transfusions within the year. Figure 10.14 includes point prevalent dialysis patients with a first service date 90 days prior to January 1, 2005 and alive through the end of 2006. Transfusion events are identified from January 1, 2005, to December 31, 2006. For both figures, at any overlap in transfusion dates only one event is used. If both inpatient and outpatient claims indicate a transfusion event and have the same “from” date, the inpatient claim is used; if inpatient and outpatient claims partially overlap, the claim with the earliest date is used; and if one or more short period claims indicating a transfusion are within a long period claim indicating a transfusion, the long period claim is used.

**CLINICAL MONITORING**
Figures 10.15–20 include incident hemodialysis patients in 2001 and 2006, and show the cumulative probability of testing in the first six months of dialysis, by unit affiliation. Tests are identified from outpatient and physician/supplier claims during the year, using the following HCPCS codes: calcium/phosphorus tests, 82310, 80048, 80050, 80053, 80069, and 84100; parathyroid hormone testing, 83970; ferritin, 82728; iron saturation, 83550, 83540, and 84466; complete blood cell (CBC), 85025, 85027, 80050, and 80055; and prothrombin time, 85610.

**PREVENTIVE CARE & VASCULAR ACCESS**
Figures 10.21–23 use the same cohort as Figure 5.16, here for periods 2002–2003 and 2005–2006; Figure 10.24 uses the cohort from Figure 5.18, here for 2003 and 2006; Figure 10.25 uses the 2005–2006 cohort from Figure 5.20, and the same criterion to define the cohort for 2002–2003; and Figure 10.26 uses the cohort from Figure 5.22, here for 2003 and 2006. All are limited to dialysis patients.

Figures 10.27–29 illustrate the prevalence of intravenous vitamin D administration during 2001 and 2006. For Figure 10.27, the cohort consists of ESRD patients surviving at least nine months following incidence, and whose months 4–9 of ESRD fall entirely within calendar year 2006. All patients survive, continue dialysis, and carry Medicare as primary payor during months 4–9. For Figures 10.28–29, the cohort consists of patients initiating ESRD therapy at least 90 days prior to the start of the noted year, and receiving dialysis on December 31 of the previous year. All patients survive, continue dialysis, and carry Medicare as primary payor during all of the noted year. Vitamin D use is indicated by HCPCS codes J0635–J0636, J1270, and J2500–2501. Chain affiliation is defined at the beginning of follow-up for vitamin D use.

**HOSPITALIZATION & MORTALITY RATIOS**
Figures 10.32–39 compare mortality and hospitalization ratios among dialysis provider types, chains, and regions, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). The SMRs and SHRs are estimated by the traditional SMR calculation method. A patient’s dialysis provider is defined on January 1, 2006. Patients are followed from January 1, 2006, to the first of death, transplant, or December 31, 2006. Patients dying of AIDS are excluded; those dying of drug overdose (street drugs) or an accident not related to treatment are censored at the date of death. SMR calculations include all January 1, 2006 point prevalent hemodialysis patients, while SHR calculations include only hemodialysis patients with Medicare as primary payer, and use the number of hospital admissions as the end-point. Both SMRs and SHRs are adjusted for age, gender, race, primary diagnosis, and vintage, with 2006 national point prevalent hemodialysis patients used as reference.

**Costs of ESRD**
Chapter Eleven: K tables
The majority of the economic analyses in this year’s ADR use the as-treated model, described in detail later in this section.

**PAYOR SEQUENCE**
The payor sequence is similar in concept to the USRDS treatment history. Payor status is tracked for each ESRD patient from the first ESRD service date until death or the end of the study period. Data from the Medicare Enrollment Database, as well as dialysis claims information, are used to categorize payor status as Medicare primary payor (MPP), Medicare secondary payor (MSP), Medicare Advantage (HMO), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, since it is impossible to determine the complete cost of care for ESRD patients with MSP coverage, most analyses exclude patients during the periods when they have this coverage.

**CHAPTER ELEVEN**
Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total 2006 Medicare spending is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation for each patient begins at the first ESRD service date. Total 2006 Medicare spending is inflated by 2 percent to account for incomplete claims, and organ acquisition costs are estimated with the same methods used in the 1999 ADR (pages 149–150). HMO costs are estimated using the total HMO months for 2006 (obtained from the CMS managed care organization file) in conjunction with the 2006 AAPC rate.

Non-Medicare spending by EGHPs is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multiplying the difference by the EGHP years at risk for 2006. Patient obligations are estimated as the difference between Medicare allowable and net payment amounts. Non-Medicare patient spending is estimated as the number of patient months
at risk for non-Medicare patients (determined from the USRDS payer sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2005 to 2006 are obtained from Table K.2, without the 2 percent adjustment for late claims. Calculations of PPPY at-risk costs are based on patients for whom Medicare is primary payor during the study period (Table K.e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (3.2 percent) and Medical Consumer Price Index (4.0 percent).

Data on costs for vascular access physician/supplier services (Figures 11.21 and 11.24) are obtained directly from the physician/supplier Standard Analytical Files (SAF), and do not include any facility charges. Physician/supplier vascular access procedures and costs are identified through CPT codes (Table a.b). Because some CPT codes are not specific to an ESRD access (e.g., central venous catheter, radiological procedures), our selection process requires that certain CPT codes be accompanied by a renal-related diagnosis code for inclusion in the analysis (these codes are identified with an asterisk in Table a.b). Per patient per year total vascular access costs (Figure 11.23) are obtained from event-based analyses, and include both physician/supplier costs as described above, and facility costs that can be attributed to vascular access services. Facility costs are difficult to identify. For inpatient facility costs, vascular access procedures in the inpatient setting (identified from the physician/supplier SAF) are matched with inpatient claims, and all procedures performed during a given inpatient stay (admission date through discharge date) are considered a single vascular access event. Because vascular access procedures are often performed when a patient is hospitalized for another reason, costs for inpatient facilities are included in the analysis only if the cause of hospitalization can be reasonably attributed to vascular access, using Diagnosis Related Grouping (DRG) and ICD-9-CM principal procedure codes, or ICD-9-CM principal diagnosis codes (Table a.c). Such hospitalizations are labeled “pure” inpatient vascular access events.

For outpatient facility costs, physician/supplier claims with vascular access procedures performed in the outpatient setting are linked to outpatient claims, using service dates and CPT codes. These costs are included in the analysis only if a matching CPT code is found on both physician/supplier and outpatient claims. Once again, all procedures and costs for the entire matching outpatient claim are considered part of a single vascular access event. Since the CPT code is not a required element on outpatient claims, not all outpatient facility costs for vascular access can be identified. Events that can be identified in the outpatient claims are labeled “pure” outpatient vascular access events.

Although vascular access procedures can be identified from claims data, it is not possible to determine with certainty the type of vascular access being used for dialysis at any given time. In order to compare overall and vascular access costs by type of vascular access, data are analyzed for the hemodialysis cohort from the CMS ESRD Clinical Performance Measures Project (CPM) for 1999 through 2006. The CPM project collects data annually on a random sample of hemodialysis and peritoneal dialysis patients, including the type of vascular access being used for hemodialysis at the time of data collection. The CPM data for hemodialysis patients are collected from October through December of the year prior to the cohort year (e.g., CPM data were collected from October through December, 2005 for the 2006 cohort). For Figures 11.22–23 we classify patients by the vascular access in use at the time of the CPM data collection, and aggregate costs for the following calendar year, with follow-up until the earliest of death, transplant, modality change, or the end of the calendar year. This analysis is limited to patients with Medicare as primary payor.

For Figure 11.25, prevalent hemodialysis patients from 1998–2005 are matched to the ESRD CPM data to obtain their current vascular access in use at the end of their prevalent year. Inpatient hospital stays during the following calendar year (censored by change in modality or a placement event for a different type of access) are identified as being for a vascular access infection if the principle diagnosis is 996.62, “Infection of Internal Device.” The total payment amount from that inpatient stay is used to calculate a raw PPPY cost. These costs are then adjusted for inflation to 2000 dollars using the Consumer Price Index published by the Bureau of Labor Statistics so that costs could be compared across years.

### Table a.b

<table>
<thead>
<tr>
<th>Complication</th>
<th>CPT codes for vascular access &amp; peritoneal dialysis access services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peritoneal catheter placement</td>
<td>49419, 49420, and 49421</td>
</tr>
<tr>
<td>Synthetic graft placement</td>
<td>36830</td>
</tr>
<tr>
<td>Fistula placement</td>
<td>36118, 36119, 36820, 36821, and 36825</td>
</tr>
</tbody>
</table>

1. Requires accompanying renal diagnosis code for inclusion.

### Table a.c

<table>
<thead>
<tr>
<th>DRG &amp; ICD-9-CM codes for vascular access &amp; peritoneal dialysis access services</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRG codes</td>
</tr>
<tr>
<td>112 Percutaneous cardiovascular procedure</td>
</tr>
<tr>
<td>315 Other kidney and urinary tract OR procedure</td>
</tr>
<tr>
<td>442 Other OR procedure for injuries with complication</td>
</tr>
<tr>
<td>443 Other OR procedure for injuries without complication</td>
</tr>
<tr>
<td>478 Other vascular procedure without complication</td>
</tr>
</tbody>
</table>

2. Identification as being for a vascular access infection if the principal diagnosis is 996.62, “Infection of Internal Device.”

3. The presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.
**a.d. Medicare categories of payment & basis for categorizing claim**

<table>
<thead>
<tr>
<th>Total</th>
<th>Sum of all payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient</td>
<td>Sum of all payments originating from the inpatient SAF, including pass-throughs</td>
</tr>
<tr>
<td>Medical DRG</td>
<td>Inpatient SAF, DRG</td>
</tr>
<tr>
<td>Surgical DRG</td>
<td>Inpatient SAF, DRG</td>
</tr>
<tr>
<td>Transplant DRG</td>
<td>Inpatient SAF, DRG 302 &amp; 512</td>
</tr>
<tr>
<td>Other DRG</td>
<td>Inpatient SAF, DRG not included in the above categories</td>
</tr>
<tr>
<td>Non-transplant pass-throughs</td>
<td>Inpatient SAF, DRG not 302 or 512, calculated from per diem and covered days</td>
</tr>
<tr>
<td>Transplant pass-throughs</td>
<td>Inpatient SAF, DRG 302, calculated from per diem and covered days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total outpatient</th>
<th>Sum of all payments originating from the Outpatient SAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodialysis</td>
<td>Outpatient SAF, hemodialysis revenue codes</td>
</tr>
<tr>
<td>Peritoneal dialysis</td>
<td>Outpatient SAF, peritoneal dialysis revenue codes</td>
</tr>
<tr>
<td>Other dialysis</td>
<td>Outpatient SAF, dialysis revenue codes other than HD or PD</td>
</tr>
<tr>
<td>ESA</td>
<td>Outpatient SAF, revenue codes and/or HCPCS code</td>
</tr>
<tr>
<td>Vitamin D hormones</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Iron</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Other injectables</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Radiology</td>
<td>Outpatient SAF, revenue and/or CPT codes</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Ambulance</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Laboratory/pathology</td>
<td>Outpatient SAF, revenue and/or CPT codes</td>
</tr>
<tr>
<td>Other</td>
<td>Outpatient SAF, does not qualify for any other cost category</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skilled nursing facility</th>
<th>Skilled nursing facility SAF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospice</td>
<td>Hospice SAF</td>
</tr>
<tr>
<td>Total physician/supplier</td>
<td>Sum of physician/supplier payments</td>
</tr>
<tr>
<td>Transplant surgery</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Inpatient surgery</td>
<td>Physician/supplier SAF, CPT, and place of service codes</td>
</tr>
<tr>
<td>Outpatient surgery</td>
<td>Physician/supplier SAF, CPT and place of service codes</td>
</tr>
<tr>
<td>E&amp;M nephrologist inpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M non-nephrologist inpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M non-nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>Dialysis capitation</td>
<td>Physician/supplier SAF, CPT and/or type of service codes</td>
</tr>
<tr>
<td>Inpatient dialysis</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Home dialysis</td>
<td>Physician/supplier SAF, HCPCS and place of service codes</td>
</tr>
<tr>
<td>Vascular access</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Peritoneal access</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Physician/supplier ESA</td>
<td>Physician/supplier SAF, HCPCS codes</td>
</tr>
<tr>
<td>Physician/supplier iron</td>
<td>Physician/supplier SAF, HCPCS codes</td>
</tr>
<tr>
<td>Immunosuppressive drugs</td>
<td>Physician/supplier SAF, HCPCS codes</td>
</tr>
<tr>
<td>Durable medical equipment</td>
<td>Physician/supplier SAF, HCPCS codes</td>
</tr>
<tr>
<td>Physician/supplier radiology</td>
<td>Physician/supplier SAF, CPT and specialty codes</td>
</tr>
<tr>
<td>Physician/supplier lab/pathology</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Physician/supplier ambulance</td>
<td>Physician/supplier SAF, HCPCS and place of service codes</td>
</tr>
<tr>
<td>Other physician/supplier</td>
<td>Physician/supplier SAF, does not qualify for any other cost category</td>
</tr>
<tr>
<td>E&amp;M: Evaluation and management</td>
<td></td>
</tr>
</tbody>
</table>
SAF a field containing line item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line item cost is discounted by the ratio of the sum of line item payment amounts to the total paid amount for the claim. Since complete data on line item payments are available for the 2001 Outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2001–2006, with adjustments as noted.

MODEL 1: AS-TREATED ACTUARIAL MODEL
In an as-treated model patients are first classified by their modality at entry into the analysis, and retain that classification until a modality change. When a change is encountered in the data, the beginning modality is censored at the change date plus 60 days, and a new observation with the new modality is created. The first 60 days after a change are attributed to the previous modality to account for any carryover effects. If the change is from dialysis to transplant, however, the modality is censored, and the transplant modality begins on the date of the transplant hospital admission. In the case of changes involving only a change from one type of dialysis to another, the new modality must last at least 60 days in order to be counted. Aggregation of Medicare payments is done on an as-treated basis, attributing all payments to the patient’s modality at the time of the claim.

In Section K we classify patients into four as-treated modality categories: hemodialysis, CAPD/CCPD, other dialysis, and transplant. The “other dialysis” category includes cases in which the dialysis modality is unknown or is not hemodialysis or CAPD/CCPD, while the transplant category includes patients who have a functioning graft at the start of the period or who receive a transplant during the period. Some tables also include categories for all-dialysis (hemodialysis, CAPD/CCPD, and other dialysis) and all-ESRD (all-dialysis and transplant).

The study spans the 16 years from January 1, 1991, to December 31, 2006, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payor sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor at any time during the study period are classified as MSP for the duration of the MSP status in the payor sequence. If the payor status changes to Medicare as primary payor, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare Advantage program are excluded until payor status changes to Medicare (either as primary or secondary payor). Patients classified as MSP are included in Tables K.1–3, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2006. Patients incurring no inpatient/outpatient or physician/supplier Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

To express costs as dollars per year at risk, total costs during the follow-up period are divided by the length of the period. Costs per year at risk are calculated by patient category, and stratified by age, gender, race, modality, and diabetic status. Diabetic status is based on the primary diagnosis, as recorded on the Medical Evidence form. A patient with a non-diabetic cause of renal failure may have diabetes, but the disease is not judged to be the cause of ESRD. Patient age is calculated at the study start date, and patients with a missing date of birth are excluded from the analysis.

MODEL 2: CATEGORICAL CALENDAR YEAR MODEL
This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figures 11.13–14, and in the Précis, Table p.c, as well as Reference Tables K.9–12. With this method, patients are classified into four mutually exclusive treatment groups:

- dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled.
- transplant: ESRD patients with a kidney transplant during the calendar year.
- functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled.
- graft failure: ESRD patients who have had a transplant, but return to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are classified in the transplant category.

New this year, Tables K.14–18 present estimates of per person per year costs for general Medicare patients, derived from the 5 percent Medicare sample. The cohorts include those who survive all of year one, are continuously enrolled in Medicare Parts A and B, are not enrolled in a managed care program (HMO), and do not have ESRD during year one. Costs for this portion of the cohort are aggregated for year two, with censoring at the earliest of death, development of ESRD, change in payor status, or the end of year two. The cohorts also include those who survive at least three months of year two, with continuous enrollment in Medicare Parts A and B, and not enrolled in an HMO during year two; costs for this portion of the cohort are also aggregated for year two. Important comorbidities (congestive heart failure (CHF), diabetes mellitus (DM), and chronic kidney disease (CKD)) are determined for these cohorts from Medicare claims using a previously validated method. A patient is defined as having one of these comorbidities if, within the one-year observation period (year one or year two), he or she has a qualifying ICD-9-CM diagnosis code on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency) or two or more Part A institutional claims (outpatient) and/or Part B physician/supplier claims. Qualifying diagnosis codes for DM are 250.xx, 357.2, 362.xx, and 366.41. Qualifying diagnosis codes for CKD are 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 547.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4. Qualifying diagnosis codes for CHF are 398.91, 422.xx, 425.x, 428.xxx, 420.x1, 404.x1, 404.x3, and V42.1. Per person per year expenditures are presented for 1992–1993 through 2005–2006 cohorts. The cost year is always year two of the cohort. The 2005–2006 general Medicare cohort is also combined with the ESRD period prevalent 2006 cohort for Figure p.1.
EGHP PATIENTS
Several figures in the Précis and Chapter Eleven include data for EGHP patients. Patients in the Medstat database who are identified as ESRD (as described previously), are under 65 years of age, and do not have evidence of Medicare payments (either as primary or secondary payor) are included in these analyses. Medicare payments are identified in the Medstat database, and patients are excluded on the basis of these payments in order to obtain a more accurate estimate of ESRD costs in the private sector. The payment amounts presented are the net payments are do not include deductibles and copayments.

International comparisons
Chapter Twelve
The international data for this ADR have been collected from the following sources, using the data form at the end of this section:
• the Argentina National Dialysis Registry
• the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA)
• the Austria OEDTR
• the Bangladesh Renal Registry
• the French-Belgian Nephrologists Registry
• Centre Hospitalier Etterbeek-Ixelles, Belgium
• Clinical Center University of Sarajevo, Bosnia and Herzegovina
• the Canadian Organ Replacement Registry (CORR)
• the Chilean Renal Registry
• the Croatian Society of Nephrology, Dialysis, and Transplantation
• the Czech Society of Nephrology
• the Danish Society of Nephrology
• the ERA-EDTA Registry
• the Finnish Registry for Kidney Diseases
• the French Renal Epidemiology and Information Network (REIN) Registry
• the QuaSi-Niere, Germany
• the Hellenic Renal Registry, Greece
• the Hong Kong Renal Registry
• the Department of Transplantation and Surgery in Hungary
• the Landspitali University Hospital, Iceland
• the Transplantation Research Center & Iranian Tissue Bank, Iran
• the Israeli Renal Registry
• the Italian Registry of Dialysis and Transplantation
• the Jalisco State Dialysis and Transplant Registry, Mexico
• the Japanese Society of Dialysis Therapy
• the Korean Society of Nephrology ESRD registry
• Registre Néphrologique du Grand Duché de Luxembourg
• the Malaysian Dialysis and Transplant Registry
• the Netherlands Dialysis Registry
• the Norwegian National Hospital
• the Kidney Foundation of Pakistan
• the Philippines Renal Disease Registry Project
• the Romanian Renal Registry
• the Society of Dialysis, Russia
• the Scottish Renal Registry
• the Shanghai Jiao Tong University
• Spanish National Renal Diseases Registry
• the Swedish Renal Registry
• the Taiwan Society of Nephrology
• the Thailand Registration of Renal Replacement Therapy
• the Turkish Society of Nephrology
• the United Kingdom Renal Registry
• the Uruguayan Registry of Dialysis
• the U. S. Census Bureau International Database

Thank you to all who provided data for this year’s Annual Data Report. We are especially grateful to Dr. Kitty Jager and Anneke Kramer at the ERA-EDTA Registry for their help in coordinating much of the European data presented in this chapter. Data for some countries do not represent 100 percent of the ESRD population; interpretation of changes in incident and prevalent rates must therefore be performed with caution. Notations are made in the captions for those countries reporting only dialysis patients.

To contribute data from your country’s registry, please complete the International Data Collection Form and return it to the USRDS.

Vascular access
L tables
Tables L.1–3 include period prevalent hemodialysis patients from 1999 to 2006 who have Medicare as their primary payor. Place -
ments are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, change in modality, change in payor status, or the end of the prevalent year. Tables L.4–6 include point prevalent hemodialysis patients, and data from 2006 is used. Vintage represents the amount of time between the first service date and January 1, 2006.

Tables L.7–14 include point prevalent hemodialysis patients with Medicare as their primary payor who are also in the ESRD CPM report for the corresponding year. Their current access is determined from the CPM data as the access used at the time of the most recent data collection, i.e., during the months of October, November, and December of the year prior to the prevalent year. Complications and intervention events are obtained from claims during the time at risk during the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a different hemodialysis vascular access. Patients who have a placement claim after the time of the CPM data collection but prior to the start of the prevalent year are excluded.

Tables L.14–15 include point prevalent peritoneal dialysis patients with Medicare as primary payor. Complications and intervention events are obtained from claims during the time at risk in the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the placement of a hemodialysis vascular access.

Census populations
The 2000 U.S. census, available in 2002, introduced a new race category with additional racial groupings. Census estimates for 1990–1999 were back-calculated based on the actual 2000 census. For 2000–2006, however, the actual data include racial groups that do not coincide with those in the ESRD data. For 2000–2006 rate calculations throughout the ADR, we thus use the CDC’s Bridged Race Dataset, which estimates white, African American, Native American, and Asian populations. The data and methods for these estimates are available at www.cdc.gov/nchs/about/major/dvs/popbridge/popbridge.
Statistical methods

METHODS FOR CALCULATING RATES

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2002, for example, is the observed incident count divided by the 2002 population size and, if the unit is per million population, multiplied by one million; the 2002 death rate for prevalent ESRD patients is the number of deaths in 2002 divided by the total follow-up time (patient years) of the 2002 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution.

model-based rates

Some patient groups may be very small, and their observed rates therefore unstable. If follow-up time is considered, the hazard of an event may change over time. A model-based method can improve the stability of these estimates and incorporate changes of hazard over time. In this ADR, for example, we have used the generalized linear mixed Poisson model to estimate prevalent patient mortality rates for Reference Section H.

measurement unit for rates

Both raw and model-based rates are calculated per unit of population (such as per 1,000 patients) or per unit of follow-up time (such as per 1,000 patient years). Calculating rates per unit of follow-up time can account for varying lengths of follow-up among patients. Patient years are calculated as the total number of years, or fractions of a year, of follow-up time for a group of patients.

Take, for example, a calculation of 1997 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 1997. Group A consists of three patients: Patient 1 had a first hospitalization on March 31, 1997;Patient 2 was hospitalized on June 30, 1997; and Patient 3 was on dialysis through December 31, 1997, with no hospitalizations. Group B also has three patients: Patient 4 was first hospitalized on December 31, 1997; Patient 5 was hospitalized on September 30, 1997; and Patient 6 was on hemodialysis the entire year, with no hospitalizations through December 31, 1997.

Patients 1 to 6 contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 1997. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as [2 total events / 1.75 total patient years at risk] x 1,000 for Group A and [2 total events / 2.75 patient years at risk] x 1,000 for Group B). The resulting rate is lower for Group B because of the longer total follow-up time.

Rates per unit of population may be influenced by the proportion of patients who are followed for only a fraction of a year. The event rate per unit of population is likely to be lower, for example, in a group of patients followed for only one month until censoring than in a group whose patients are each followed for up to a full year. Rates per unit of follow-up time at risk, in contrast, count only the actual time that a patient is at risk for the event.

METHODS FOR ADJUSTING RATES

Because each cohort contains a different patient mix, unadjusted event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders—such as age, gender, race, and primary diagnosis—as the reference population.

direct adjustment

There are several rate adjustment methods, but only the direct method allows rates to be compared (Pickle LW, White AA). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the adjusted rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. Categories are defined by the adjusting variables. For example, if a rate is adjusted for race and gender and there are three race groups (white, African American, and other) and two gender groups, there are six categories: white males, white females, African American males, African American females, males of other races, and females of other races.

Suppose we try to compare state-level incident rates in 2001 after removing the difference caused by race. To do this, we need to calculate the adjusted incident rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population—here, the population at the end of 2001—with five race groups (white, African American, Native American, Asian/Pacific Islander, and other).

Assuming the incident rate of state A in 2001 is 173 per million population, and the race-specific rates and national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is (153 x 75.1%) + (250 x 12.3%) + (303 x 0.9%) + (174 x 3.6%) + (220 x 8%) = 158.73 per million population. This means that if state A had the same racial distribution as the entire country, its incident rate would be 158.73 instead of 173. If state B had an adjusted incident rate of 205, we could say that state B had a higher incident rate than state A if they both had the same racial distribution as the whole country.

<table>
<thead>
<tr>
<th>Race</th>
<th>Incidence Rate</th>
<th>National Population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>153</td>
<td>75.1</td>
</tr>
<tr>
<td>African American</td>
<td>250</td>
<td>12.3</td>
</tr>
<tr>
<td>Native American</td>
<td>303</td>
<td>9.9</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>174</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>220</td>
<td>8.0</td>
</tr>
</tbody>
</table>

This method is used to produce some adjusted incident and prevalent rates in Chapters Two and Three and in Reference Sections A and B, as well as in the model-based adjustment method.

model-based adjustment

Under some circumstances there are disadvantages to the direct adjustment method described above. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one includes category no patients, the method is not valid for calculating an adjusted mortality rate for the group. An attractive alternative is a model-based approach, in which we find a good model to calculate category-specific estimated rates for each group and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). There is, unfortu-
Adjusted survival probabilities are reported in Reference Sections G and I, with age, gender, race, and primary diagnosis used as adjusting risk factors. The model-based adjustment method is used with survival probabilities predicted from the Cox regression model (Kalbfleisch JD, Prentice RL). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, and primary diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

**STANDARDIZED MORTALITY RATIOS**

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the state-level SMR is used to compare mortality in prevalent dialysis patients—after adjusting for age, gender, race, primary diagnosis, and ESRD vintage—in each state using the national dialysis population in the corresponding year as the reference. An SMR of 1.05 for a state indicates that patients in this state have a risk of death approximately five percent higher than that of patients in the reference population of all U.S. dialysis patients.

The adjusted mortality rates for prevalent cohorts are calculated using the direct adjustment method based on the category-specific mortality rates from the generalized linear mixed models.

The adjusted mortality rates for prevalent cohorts are calculated using the direct adjustment method based on the category-specific mortality rates from the generalized linear mixed models.

**EXPECTED REMAINING LIFETIMES**

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients in that group. Some patients will live longer than, and some will live less than, the average. Although the average cannot be known until all patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients. For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let \( S(A) \) denote the survival function of patients at time \( A \). Among patients alive at age \( A \), the probability of surviving \( X \) more years is \( S(A) = S(A+X)/S(A) \). For a given starting age \( A \), the expected remaining lifetime is then equal to the area under the curve of \( S(A) \) plotted versus \( X \). Because few patients live beyond 100, this area is truncated at the upper age limit \( A + X = 100 \).

**MAPPING METHODS**

Mapping is an important tool for assessing environmental determinants and illustrating spatial patterns and temporal trends.
graphic resolution is enhanced by mapping at the level of small regions, but this can increase data instability. The use of smoothing methods, however, can help stabilize data and show geographic patterns while still maintaining geographic resolution.

The majority of disease mapping within the ADR is by Health Service Area (HSA), an approach we continue to adopt from the Atlas of United States Mortality (Centers for Disease Control and Prevention). Each HSA is a group of counties described by the CDC authors as “an area that is relatively self-contained with respect to hospital care.” The methods described here have been used for all HSA-level maps in the ADR. Because the distribution of age, gender, and race in a population can affect incident and prevalent ESRD rates, we have included maps in which data are adjusted for these variables as well as smoothed.

In many figures, data ranges have been standardized to invite comparisons across years, modalities, or patient characteristics. In remaining maps, HSAs are divided into quintiles.

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. HSA-level information is mapped according to the patient’s residence (with the exception of some maps of organ donation rates in Chapter Seven). Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. Territories are not included in the maps.

methods for smoothing & adjusting map data
To smooth map data we use a Bayesian spatial hierarchical model (Waller et al.). This method is a statistical approach that uses the log linear model (Poisson regression model) to fit the incident counts of the regions. The region effects, as random effects, follow the Conditional Autoregressive (CAR) Normal distribution, and the precision of the effects has a Gamma distribution. The model smooths the incident counts by borrowing information for each HSA from its neighbors through the relationship defined by CAR; neighbors, in our definition, are HSAs sharing a boundary. Smoothed incident rates are obtained by dividing the predicted counts by the corresponding population sizes. For adjusted maps, an almost non-informative prior is assigned to fixed effects of age, gender, and race with the Bayesian model. Adjusted incident rates are calculated using the model-based adjustment method based on the predicted values from the Bayesian spatial hierarchical model, with the national population as reference.

This model is also used to smooth prevalent rates and calculate some percentages. To smooth maps of mean hemoglobin, eGFRs, and creatinine levels, the model is extended to assume that the means have a normal distribution.

Miscellaneous
SPECIAL STUDIES & DATA COLLECTION FORMS
The USRDS website includes complete copies of the CMS Medical Evidence (2728) and Death Notification forms (2746); the OPTN Transplant Candidate Registration form, Kidney Transplant Recipient Registration form and Kidney Transplant Recipient Follow-up form; and forms used for data collection in USRDS Special Studies.

CAPTIONS
Captions in the ADR provide descriptions of patient cohorts and data adjustments, along with other general information regarding the figures and tables, and should be read in conjunction with the explanations provided in this appendix.


National Kidney Foundation K/DOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients. AJKD 2005; 45: St–St54 (Suppl 3).


roducts and services provided by the USRDS to support the work of the renal community are detailed in Table b.a. The entire ADR is available at www.usrds.org, with PowerPoint slides of all figures and Excel files of the data behind the graphs; included as well are PDF files of the Researcher’s Guide. The site’s RenDER system allows users to create customized data sets and regional maps. Data on website use are presented in Figure b.1.

Data requests
Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases requests can be answered by providing data published in the ADR or elsewhere. Requests for data not available in material published by the USRDS, but that require two hours or less of staff time, are fulfilled by the Coordinating Center without charge, usually within one week. More complex requests—those requiring more than two hours of staff time—as well as requests for Standard Analysis Files and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the NIDDK Project Officer.

Research files
The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding new grants focusing on research using the USRDS data. The result has been an annual increase in the number of files provided by the USRDS.

Prior to 1994 all researcher files were created for specific projects. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a patient finder file to be matched with the USRDS database. For more information on merged data requests, please contact the Coordinating Center at usrds@usrds.org.

The three-CD Core SAF set contains basic patient data, and is needed to use any of the other SAFs. Included are each patient’s demographic information, payor and treatment history, limited transplant data, provider data, and all data from the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this CD set. Full transplant information is provided on a separate CD that contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD. All Medicare billing data are available by individual year (see Table b.c).

Standard Analysis Files
The use of Standard Analysis Files is governed by the USRDS policy on data release for investigator-initiated research, found later in these appendices. Research proposals must be approved by a USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data,” on the same page. File prices are listed in Table b.c.

Most SAFs provide patient-specific data. All patient identifiers are removed or encrypted, but data confidentiality remains a serious concern. The “Agreement for Release of Data” describes restrictions on SAF use and disposition. The SAFs include an encrypted ID number to allow patient data from multiple SAFs to be merged.

CORE CDS
The Core Standard Analysis File CDs contain the most frequently used SAFs, including those from the Special Studies, and are needed for use of the Transplant and Hospital CDs, or any CD based on Medicare claims data. Included files are as follows (also listed in Table b.b).

• Patient Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.
• Payor History Contains a new record for each patient at each change in insurance payor.
• Modality Sequence Contains a new record for each patient at each change in modality or dialysis provider.
• Transplant Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant CD).
• Transplant Wait List Beginning with 2001 data (used in the 2002 ADR), this CD has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.
• Facility Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.
• Facility Cost Reports CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level
Dr. Jane Smith

Professor of Medicine

University of California, Los Angeles

Abstract

The objective of this study was to investigate the relationship between the dose of delivered dialysis therapy and mortality rates among patients on different dialysis modalities. The study was conducted using data from the USRDS special study on transplant follow-up reports collected by CMS and UNOS. The data were collected from January 1, 1990, to December 31, 1999, and included all patients prevalent in 1990 and born after December 31, 1970.

The study consisted of two groups: a historical prospective study of patients on hemodialysis in 1990, and a prevalent sample of dialysis patients for 1996 and early 1997. Patient growth and hospitalization rates were compared for patients on hemodialysis with those on peritoneal dialysis.

The study found a statistically significant difference in patient growth and hospitalization rates, with patients on hemodialysis having lower rates than those on peritoneal dialysis. The study also found that the relationship between dose and mortality was affected by dialyzer reuse, and that the impact of different dialysis membranes on patient morbidity and mortality was significant.

Conclusion

The results of this study suggest that the relationship between dose and mortality is affected by dialyzer reuse and the impact of different dialysis membranes on patient morbidity and mortality. These findings highlight the importance of considering these factors when evaluating the effectiveness of different dialysis modalities.

Data from Special Studies

Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. The main studies to date are summarized below, and are detailed in the Researcher’s Guide.

**Dialysis Morbidity & Mortality Study (DMMS)**

The DMMS was a USRDS Special Study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected, using dialysis records, for a random sample of U.S. patients. Waves 1, 3, and 4 are historical prospective studies in which data were collected for patients on in-center hemodialysis on December 31, 1993. Data were abstracted from medical records, and patients were followed to the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a prospective study of incident hemodialysis and peritoneal dialysis patients for 1996 and early 1997.

**Case Mix Adequacy Study of Dialysis**

The objectives of this USRDS Special Study were to establish the relationship between the dose of delivered dialysis therapy and mortality, determine the strength of this relationship when data are adjusted for comorbidity, assess how this relationship changes with dialysis dose, assess how this relationship is affected by dialyzer reuse, and examine the impact of different dialysis membranes on patient morbidity and mortality.

The study consisted of two groups: an incident sample of ESRD patients who began hemodialysis in 1990, and a prevalent sample of hemodialysis patients whose ESRD began prior to 1990. A total of 7,096 patients from 523 dialysis units were included, with approximately 3,300 patients having both the pre- and post-BUN values needed to calculate delivered dialysis dose. Ninety-four percent of these cases were matched to the USRDS database. The ESRD networks collected these data in conjunction with their Medical Case Review data abstraction.

**Case Mix Severity Study**

For this USRDS Special Study, data were collected on 5,355 patients incident in 1986–87 at 328 dialysis units nationwide. Objectives were to estimate the correlation of comorbidity and other factors existing at the onset of ESRD to mortality and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis; evaluate possible associations of these factors with reported causes of death; assess the distribution of comorbidity and other factors among patients on different modalities; and compare relative mortality rates by treatment modality, adjusting for comorbid conditions and other factors.

**Pediatric Growth & Development**

The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relation of patient growth and sexual maturation to modality, and establish a prototype for the ongoing collection of pediatric data. All patients prevalent in 1990 and born after December 31, 1970 were included in the study, a total of 3,067 patients at 548 units.

**CAPD & Peritonitis Study**

The USRDS CAPD and Peritonitis Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors. The study population included all patients newly starting CAPD in the first six months of 1989, a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains data on 3,385 patients from 706 units.

**Transplant CDS**

Due to changes in data collection sources over the years, data related to transplants are now presented in eight separate SAFs. The first two are included on the Core CD, and the remaining six are included on two separate Transplant CDSs.

- **TX** includes minimum details about all transplants from all sources
- **TXWAIT** contains one record for each patient in the USRDS database per wait list event
- **TXICFA** includes transplant information collected by CMS’s PMMIS system prior to 1994
- **TXUNOS** includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- **TXIRUNOS** includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- **TXFUHCAF** includes transplant follow-up reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- **TXFUUNOS** includes transplant follow-up reports collected by UNOS since 1988
- **TXFUHCAF** includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

The tables in Reference Sections E and F are produced primarily from the CMS and UNOS transplant files.

In July 1994, CMS and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its HRSA contract. Expanded transplant data are shared among HRSA, CMS, and the NIH, and are thus available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplant patients, including children.

CMS and UNOS transplant files overlap for 1988–1993, and some Medical Evidence (ME) forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all pre-1988 CMS transplants accepted next. CMS transplants from 1988–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the CMS transplant (it is common for dates between sources to differ by one day). Finally, transplants indicated on the ME form are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

**Hospital CDS**

Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on
Reports & guides
Annual Data Reports Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.564.4415, nkudicinfo.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Diseases.
Annual Data Report CD Contains the text and graphics of the ADR, data tables, PowerPoint slides, and the Researcher’s Guide.

Researcher’s Guide to the USRDS database
Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files; the basic reference for researchers who use USRDS data files.

www.usrds.org
Contains PDF files of the chapters, reference tables, and the Researcher’s Guide; PowerPoint slides of atlas figures and USRDS conference presentations; Excel files of the data tables; notices regarding current news and analyses; links to related Internet sites; and email addresses for contacting the USRDS.

RenDER
The USRDS Renal Data Extraction and Referencing (RenDER) System is a querying application that allows users to create data tables and interactive maps. It can be accessed at www.usrds.org/odr/rendert_home.asp following a short registration; a tutorial is also available on this site to help new users.

Requests for data
Data requests: two-hour Questions and data requests that are not answered directly by the ADR can be addressed to the Coordinating Center; those that require less than two hours of staff time to fulfill will be processed without charge.

Data requests: more than two hours Questions and data requests that require over two hours of staff time must be submitted in writing and approved by the NIDDK Project Officer. Fulfillment of these requests is subject to staff availability, and costs are assessed on a case-by-case basis.

Standard Analysis Files SAFs provide patient-specific data from the USRDS to support ESRD research. A standard price list has been established for the files (Table b.c), and users must sign a Data Release Agreement with the NIDDK.

Custom data files Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of $103.97 will be assessed for time spent answering directly by the ADR.

Publications & presentations
Most USRDS research studies result in published papers or presentations at national meetings. Figures from abstracts and presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.

Contact information
Data requests & publication orders USRDS Coordinating Center 914 South 8th Street, Suite 5-206 Minneapolis, MN 55404 612.347.7776 or 1.888.99USRDS Fax 612.347.5878 www.usrds.org Data file contact Shu-Cheng Chen, MS, schen@usrds.org

USRDS products & services

Contents of the USRDS Core Standard Analysis CD-ROM
File name, unit of observation, & uses; this two-CD set is needed in order to use any of the other Standard Analysis Files.

Patient one record for each ESRD patient Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.

Residence for each patient, one record for each period in a different residence Regional analyses.

Treatment History one record for each period a patient is on one modality Modality distribution and treatment patterns.

Payor History one record for each period a patient is covered by one payor; each patient can have many records The impact of insurance payors on clinical outcomes.

Medical Evidence one record for each 2728 form filed (1995 version) ESRD first service date, initial treatment modality, comorbid conditions, patient status at start of ESRD.

Transplant one record for each transplant event; patients can have multiple events Transplant and transplant outcome analyses.

Transplant Wait List one or more records for each patient ever on list Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to wait list.

Dialysis Morbidity and Mortality (DMMS; Special Study) Wave 1: 3,670 patients; Wave 2: 4,024 patients; Wave 3: 11,245 patients Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.

Case Mix Adequacy (Special Study) 7,096 patients Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Case Mix Severity (Special Study) 5,235 patients Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Pediatric Growth and Development (Special Study) 3,087 patients Growth, development, and other issues relating to pediatric ESRD patients.

CAPD Peritonitis (Special Study) 3,185 patients CAPD and peritonitis.

Facility one record for each year facility has operated merged with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.


Dialyzers information on dialyzer characteristics; be matched to patient dialyzer information in other files on CD Relation of dialyzer characteristics to patient outcomes.

CLMCOODES one record for each diagnosis, procedure, or HCPCS code appearing in claims files Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.

FORMAT5.SC2 all USRDS-defined SAS formats used by SAFs Format library used to format values of categorical variables.
The Clinical Performance Measures (CPM) data is a CMS project. This CD contains the Case Mix Adequacy Special Study file, and all data on Medicare payments for these patients are followed to the currently reported claims year.

CASE MIX ADEQUACY CLAIMS CD
This CD contains the Case Mix Adequacy Special Study file, and extracts data for the study patients from all CMS Medicare payment data. Medicare payment data for these patients are followed to the currently reported claims year. This file is useful for developing analyses to be run on full Medicare payment files.

MEDICARE PAYMENT DATA CDS
Medicare payment data on institutional claims are available for pre-1989 through 2005, while data on physician/supplier claims are available for 1991–2005. The 2005 claims will be available, along with other updated USRDS SAF CDs, by the end of 2007.

Institutional claims consist of all inpatient/outpatient claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), including outpatient dialysis claims. Physician/supplier claims account for 80 percent of the claims but only 20 percent of the dollars. The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating the type of claim, the dollar amounts, the DRG code, the type of dialysis involved (if any), and the dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

CLINICAL PERFORMANCE MEASURES SURVEY CDS
The Clinical Performance Measures (CPM) data is a CMS project developed to collect information on the quality of care provided to the ESRD dialysis population. The data originates from yearly surveys of approximately 10,000 people completed by the patients’ primary care facilities, and was formerly known as the ESRD Core Indicators Project. This project results in a rich source of detailed information, useful in analyses of healthcare delivery in a sample of the dialysis population.

To further expand the value and use of the CPM data, we have linked patient data from the USRDS SAFs, enabling complete claims extraction from the SAFs for all identified patients. The resulting claims history has been combined with the CPM data to form a complete mini-set of the USRDS data products with supporting files. This enables researchers to add patient-level laboratory and dialysis prescription detail to a broad range of healthcare service event data over many years.

The USRDS Coordinating Center has made the CPM data available as USRDS Standard Analysis Files (SAF). The dataset contains CPM data collected in surveys from 1994–2004. A listing of available files and the corresponding costs can be found in Table b.e, or you may contact the USRDS Coordinating Center for further information.

DISEASE-BASED COHORT CDS & 5 PERCENT GENERAL MEDICARE PAYMENT DATA CDS
Three disease-based cohort CD sets—for CKD, diabetes, and CHF—are built from the 5 percent general Medicare Claims SAFs. Each CD contains a patient master file, a payor sequence file, and a set of comorbidity files.

Separately, 5 percent general Medicare claims SAFs (IP, OP, SNF, HH, HS, PB, and DME) are also available for single or multiple years from 1992 to 2005. Data are derived from the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

PRE-ESRD MEDICARE CLAIMS CD S
The pre-ESRD claims (also known as “back-casted claims”) are a collection of Medicare institutional and physician/supplier (Part B, durable medical equipment) billing records incurred prior to the onset of ESRD. Included in these claims are any and all claims available from Medicare for incident patients during their incident years and for the two calendar years prior to the incident year.

The USRDS has made the pre-ESRD data available as Standard Analysis Files (SAF). This dataset includes Medicare claims of ESRD patients from incident years 1995–2005. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payor sequence is provided so...
**II.b.c** Prices for the USRDS Standard Analysis Files

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The Case Mix Adequacy Claims CD contains all institutional and physician/supplier claims data for patients in the USRDS Case Mix Adequacy Special Study. The data from the Special Study data collection forms are included on the Core CD.

The DMMS claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. The data from the Special Study data collection forms are included on the Core CD.

**II.b.d** Outline for research proposals using USRDS data

A data request applies only to the project stated in the proposal; a new proposal must be submitted for each additional use of the data.

1. **Research topic title and submission date.**
2. **Background information.**
3. **Study design:** objectives, hypothesis(es), analytical methods.
4. **Data being requested:**
   1. List of Standard Analysis Files needed (if multiple years, please specify), or fields needed in custom data file.
   2. Description of data security: responsible party, computer access, etc.
   3. **Time frame for the project.**

5. **To address patient privacy issues,** to be consistent with HIPAA policies, and to ensure that researchers are adhering to local privacy standards as well as to USRDS and CMS privacy policies, the USRDS now requires IRB approval for all research proposals. IRB approval is not required from those requesting aggregate data.

6. **Outline of estimated costs of requested data; source of funding.**
7. **Agreement for Release of Data,** signed by all researchers.
8. **Investigator information:** For Principal Investigator and co-authors, supply:
   - Name
   - Affiliation
   - Business address
   - Business phone & fax
   - Email address

**Submit to**

Paul Eggers, PhD
NIDDK
6707 Democracy Blvd, Room 3B37
Bethesda, MD  20892-5458
Phone 301.594.8305
Fax 301.480.3510
eggersp@extra.niddk.nih.gov

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**II.b** Prices for the 5 percent Medicare Sample Standard Analysis File CD-ROMs

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**III** Chronic kidney disease / Pt cohort finder $750

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**Diabetes / Patient cohort finder $750**

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**CHF/ Patient cohort finder $750**

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the researcher can determine patient Medicare enrollment for the periods prior to first ESRD service date. A listing of available files and the corresponding costs can be found in Table b.e.

**FILE MEDIA & FORMATS**

SAFs are provided on CDs and DVDs as SAS files, and can be used by SAS on any 486 or Pentium PC with a CD/DVD reader. The SAS format is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, and is almost universally available on university computer systems. The SAFs take full advantage of the program’s ability to incorporate detailed documentation into the file. Researchers needing another format or medium must arrange for the conversion.

**COSTS**

File prices cover file reproduction, documentation, administrative costs, and costs of technical support. Prices are subject to change.

**DOCUMENTATION**

The Researcher’s Guide to the USRDS Database provides most of the SAF documentation. It includes a codebook of variables, copies of data collection forms used by CMS, UNOS, and the USRDS Special Studies, and a chapter on using the SAFs in SAS. The guide may be downloaded from the USRDS website, and a copy on CD-ROM will be sent to researchers with the purchase of the SAFs.

**Data use acknowledgement**

Publications using USRDS data should include an acknowledgment and this notice: The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the United States government.

**Data release policy**

Since the SAFs and custom data files contain confidential, patient-specific data, their release requires the approval process described here. Investigators may contact the USRDS Project Officer (PO) at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators must provide the PO with a detailed description of the proposed investigation (see Table b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the “Agreement for Release of Data,” later in the appendices. With your completed research proposal, please include a signed agreement for release of information from each investigator and analyst who will use the data files.

Investigators must also indicate needed USRDS SAFs by name. If these files cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.

The investigator and the Coordinating Center (CC) will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation.

The NIH will review the project for technical merit and for conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the outcome, and if the project is not approved will discuss reasons for the decision. The PO will send a copy of the approval letters to the CC. When payment for the files has been received by the CC, the CC will prepare the files and documentation and send them to the investigator.

Any reports or articles resulting from use of USRDS data must be submitted to the PO prior to submission for publication to assure adherence to the Privacy Act. The PO must respond within 30 days. If a report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO’s approval indicate government endorsement of the investigator’s opinions and conclusions.

All publications using released data must contain the standard acknowledgement and disclaimer presented above. Investigators are requested to send copies of all final publications resulting from this research to both the PO and the CC.

**Caveats**

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research.

The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS “Agreement for Release of Data” contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in any of the usual media (tape, disk, or hard copy). Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.

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<th>Prices for the ESRD CPM/USRDS files checks must be made payable to the Minneapolis Medical Research Foundation</th>
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<tr>
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<tr>
<td>ESRD CPM Medicare participant Institutional &amp; Physician/Supplier claims are available for the years pre-1989 through 2005; $100–300/year</td>
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</table>
ACE inhibitors  Antihypertensive agents that inhibit the production of angiotensin II. Can delay progression to diabetes or kidney disease.

Acquired immunodeficiency syndrome (AIDS) An epidemic disease caused by the human immunodeficiency retrovirus that leads to immune system failure.

Acute myocardial infarction (AMI) An event causing injury to the heart muscle.

Adjusted average per capita cost (AAPCC) An estimate of how much Medicare will spend in a year for an average beneficiary.

Adult polycystic kidney disease An inherited disease in which the kidneys contain multiple cysts.

Anemia A condition marked by a reduced number of red cells in the bloodstream.

Angioplasty A procedure in which a balloon catheter is inserted into a blocked or narrowed vessel in order to reopen the vessel and allow normal blood flow.

ARB Angiotensin II receptor blockers; antihypertensive agents that inhibit the actions of angiotensin II, a substance which causes narrowing of blood vessels.

Arteriovenous fistula A type of vascular access used in hemodialysis patients, and created by the anastomosis of the radial artery and the cephalic vein.

Arteriovenous graft A type of vascular access used in hemodialysis patients and created via a connection between an artery and vein using either a native vessel (saphenous vein) or a synthetic material such as Teflon.

Atherosclerotic heart disease (ASHD) A disease of the arteries of the heart, characterized by a thickening and/or loss of elasticity of the arterial wall.

Beta blockers Antihypertensive medications that block production of noradrenaline, slowing the heart rate and preventing the constriction of blood vessels.

Blood urea nitrogen (BUN) A by-product of the breakdown of amino acids and endogenous and ingested protein.

Body mass index (BMI) A measure of height to weight ratio: weight (kg)/height (m2).

C-reactive protein A protein produced by the liver in response to infection or injury; high levels are associated with an increased risk of heart disease and stroke.

Calcium channel blockers Antihypertensive agents that work by blocking the access of calcium to muscle cells in artery walls.

Cancer A disease that causes abnormal cell growth.

Cardiac arrest A complete cessation of cardiac activity.

Cardiomyopathy A general diagnostic term indicating a primary non-inflammatory disease of the heart muscle.

Catheter A vascular access used in hemodialysis patients, commonly implanted into the jugular or subclavian vein.

Centers for Disease Control & Prevention (CDC) The lead federal agency for protecting the health and safety of people at home and abroad; develops and applies programs designed to improve the health of the people of the United States.

Centers for Medicare and Medicaid Services (CMS) Formerly the Health Care Financing Administration (HCFA). Federal agency that administers the Medicare, Medicaid, and State Children’s Health Insurance programs.

Cerebrovascular disease (CVD) A disease that causes narrowing or occlusion of the arteries supplying blood to the brain. Cerebrovascular accidents (CVA) and transient ischemic attacks (TIA) can result from this condition.

Chain provider A single business entity that owns 20 or more dialysis units located in more than one state (USRDS definition). This definition applies to all chain affiliations referenced in the USRDS Annual Data Reports. An alternative definition from the Centers for Medicare and Medicaid Services can be found under “definitions” in the Health Care Provider/Supplier Application Form, CMS 855.

Chronic obstructive pulmonary disease (COPD) A progressive disease characterized by coughing, wheezing, or difficulty in breathing.

Clinical Performance Measures (CPM) Project Formerly the Core Indicator Project. A project in which CMS and the ESRD networks cooperatively maintain a clinical database of key elements related to the quality of dialysis care. These elements are used as indicators in quality improvement initiatives.

Common Working File (CWF) System The Medicare inpatient/outpatient and physician/supplier benefit coordination and claims validation system. Under the CWF, CMS maintains both institutional and physician supplier claims-level data. CWF claims records are the data source for most claims and utilization files used by the USRDS.

Comprehensive Dialysis Study (CDS) A special data collection study that focuses on physical activity level, health-related quality of life, and work/disability status reported by patients who have recently started maintenance dialysis.

Congestive heart failure (CHF) A condition caused by ineffective pumping of the heart and subsequent fluid accumulation in the lungs.

Conventional hemodialysis Dialysis therapy using small surface area hemodialyzers that are made with conventional membranes and have low solute clearance and low fluid removal capabilities. Does not require the use of delivery systems with ultrafiltration control.

Coronary artery disease A disease that causes narrowing or occlusion of the arteries surrounding the heart.

Continuous ambulatory peritoneal dialysis (CAPD) A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity 4–5 times each day.

Continuous cyclic-assisted peritoneal dialysis (CCPD) A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automated cycler machine.

Creatinine A waste product of protein metabolism found in the urine; often used to evaluate kidney function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

Creatinine clearance Used as an indicator to predict the onset of uremia, which develops when creatinine clearance falls below 10 ml/minute/1.73 m2.

Darbepoetin alfa (DPO) One of a class of medications called erythropoietic proteins. Used to treat anemia in patient with serious kidney disease.

Death Notification Form (CMS-2746) A form submitted following the death of an ESRD patient, and containing basic patient demographic information in addition to information on the primary cause of death.

Diabetes mellitus, insulin-dependent A condition in which insulin is necessary to regulate abnormally high levels of glucose (sugar) in the blood.

Diagnosis Related Groups (DRGs) Used by Medicare to determine payment for inpatient hospital stays; based on diagnosis, age, gender, and complications.

Dialysis & transplant center A facility that combines the functions of a dialysis center and a transplant center.

Dually enrolled Patients enrolled in both Medicare and Medicaid.

Employer group health plan (EGHP) A health plan of or contributed to by an employer, providing medical care directly or through other methods such as insurance or reimbursement to current or former employees, or to these employees and their families.

End-stage renal disease (ESRD) A condition in which a person’s kidney function is inadequate to support life.

Erythropoiesis stimulating agent (ESA) Used to increase the production of red blood cells; includes erythropoietin (EPO) and darbepoetin alfa (DPO).

Erythropoietin (EPO) A hormone secreted chiefly by the adult kidney; acts on bone marrow to stimulate red cell production. Also produced in a formulat ed version to treat anemia.

ESRD Facility Survey Data for this survey are collected annually by CMS from all facilities certified to provide Medicare-covered renal dialysis and transplantation. The survey uses CMS form 2744, and encompasses the full calendar year. Geographic data are included to the level of facility ZIP code. Each record contains facility information and data on the number of patients served, dialysis treatments provided, and kidney transplants performed. The data
include services to both Medicare and non-Medicare patients.

ESRD networks Regional organizations, established by law in 1978, contracted by CMS to perform quality oversight activities to assure the appropriateness of services and protection for dialysis patients.

Expanded criteria donors (ECDs) Older kidney donors or donors whose health issues in the past would have prevented their acceptance into the donor program.

For-profit facility A dialysis facility owned, leased, or, through any other devices, controlled by a single business entity.

Freestanding facility A unit licensed to provide outpatient and home maintenance dialysis; sometimes referred to as an independent unit.

Glomerular filtration rate (eGFR) Estimated rate in ml/min/1.73 m² of the volume of plasma filtered by the kidney. Rates of filtration are based on an individual’s age, gender, and height, and on levels of serum creatinine, serum blood urea nitrogen, and serum albumin. GFR is traditionally considered the best overall index to determine renal function.

Glycosylated hemoglobin (HbA1c) test Used to help determine how well a patient’s diabetes is being controlled, this test measures the level of glucose-bound hemoglobin in the bloodstream.

Health Care Financing Administration (HCFA) Created in 1977, the federal agency responsible for administration of Medicare and Medicaid, the nation’s largest healthcare programs. HCFA was renamed the Centers for Medicare and Medicaid Services (CMS) in June 2001.

Health Maintenance Organization (HMO) A competitive medical plan, such as Medicare’s Choice, that has contracts with CMS on a prospective capitation payment basis for providing healthcare to Medicare beneficiaries.

Health Plan Employer Data & Information Set (HEDIS) Established by the National Committee for Quality Assurance, HEDIS 2002 is a set of standardized performance measures created to aid consumers in comparing managed healthcare plans.

Health Service Area (HSA) A group of counties described by the authors of the CDC Atlas of United States Mortality as “an area that is relatively self-contained with respect to hospital care.”

Healthy People 2000 A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people (www.health.gov/healthypeople).

Hemoglobin Oxygen-carrying protein in the erythrocyte (red blood cell).

Hepatitis An inflammation of the liver that may be caused by a viral infection, poisons, or the use of alcohol or other drugs. Forms include Hepatitis A, usually transmitted by contaminated food or water; Hepatitis B, more serious than Hepatitis A and transmitted through blood and body fluids; Hepatitis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an individual is already infected with the Hepatitis B virus.

HgC Hierarchical condition category. A risk adjustment methodology used by CMS and developed to address severity of illness and actual expenditures.

High-efficiency hemodialysis Dialysis therapy that uses hemodialyzers with larger surface areas than conventional hemodialyzers. Enhanced solute clearance is achieved through increased blood flow rates, 300–400 milliliters per minute, allowing treatment times to be reduced to approximately three hours.

High-flux hemodialysis Dialysis therapy using hemodialyzers with synthetic membranes and large surface areas that, combined with high blood and dialysate flow rates, allow enhanced solute clearance and fluid removal. Delivery systems with ultrafiltration control are required for this therapy.

Homocysteine An amino acid present in the blood. High levels can accompany kidney disease, and can indicate an increased risk of cardiovascular disease and stroke.

Hospital-based facility A dialysis unit attached to or located in a hospital and licensed to provide outpatient dialysis services directly to ESRD patients.

Hospital center unit A dialysis unit located or attached to a hospital and licensed to furnish inpatient and outpatient dialysis plus diagnostic, rehabilitative, and therapeutic services.

Incident ESRD patient A patient starting renal replacement therapy for ESRD during a calendar year. Excludes patients with acute renal failure, those with chronic renal failure who die before starting ESRD treatment, and those whose treatments are not reported to CMS.

Incident population The people in a population who are newly diagnosed with a disease in a given time period, typically a year.

Ischemic heart disease (IHD) A disease of the heart evidenced by a lowered oxygen supply to the heart tissue, caused by occlusion or narrowing of the arteries supplying the heart muscle.

Kidney Disease Outcomes Quality Initiative (K/DOQI) Established in 1995 by the National Kidney Foundation to improve patient outcomes and survival by providing recommendations for optimal clinical practices in the areas of dialysis adequacy, vascular access, and anemia.

K/DOQI An indicator of the dialysis dose per treatment, calculated by multiplying the urea clearance (K) by the treatment duration (T) and dividing by the urea distribution (V). The urea distribution volume is approximately equal to the volume of total body water.

Medical Evidence form (CMS-2728) A form which provides source data about ESRD patients, including information on demographics, primary cause of renal disease, comorbidities, biochemical data, dialysis treatment, transplant, dialysis training, employment status, initial insurance coverage, and first ESRD service date.

Medicare as Secondary Payor (MSP) patient A Medicare beneficiary with a health insurer other than Medicare (e.g. an Employer Group Health Plan) that has primary responsibility for payment of the beneficiary’s medical bills.

Medicare Current Beneficiary Survey (HCBS) An ongoing national survey of aged, disabled, and institutionalized Medicare beneficiaries. Sponsored by the Centers for Medicare and Medicaid Services, and used to study the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of Medicare beneficiaries.

Medicare risk patient A patient enrolled in a Managed Care Organization under contract with CMS and for whom healthcare costs are paid by CMS on a per capita basis.

Medication possession ratio (MPR) Used to measure patient compliance with medication regimens.

Microalbuminuria A condition in which small amounts of albumin are present in the urine; indicates early kidney damage.

Modality A method of treatment. Treatment for end-stage renal disease (ESRD) is comprised of three modalities: hemodialysis, peritoneal dialysis, and transplantation.

Myocardial infarction (MI) An event which causes injury to the heart muscle.

National Claims History (NCH) A file which contains all Common Working File (CWiff patient/outpatient (provider) and physician/supplier Medicare claims and adjusted claims information.

National Health and Nutrition Examination Survey (NHANES) A survey conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention; uses home interviews and health tests to collect information on health and diet in the United States.

National Institutes of Health (NIH) The federal focal point for medical research in the U.S. and one of eight health agencies of the Public Health Services, which are part of the Department of Health and Human Services.

Period prevalent patient A patient receiving treatment for ESRD at some point during a period of time, usually six months or a year. Patients may die during the period or be point prevalent at the end of the period. Period prevalence is a useful measure for cost analysis, since it indicates total disease burden over the course of a year.

Peripheral vascular disease (PVD) A progressive disease that causes narrowing or occlusion of the arteries supplying the extremities of the body.

Peritoneal dialysis Dialysis in which fluid (dialysate) is introduced into the abdominal cavity and uremic toxins are removed across the peritoneum.

Point prevalent patient A patient reported as receiving treatment for ESRD on a particular day of the calendar year (e.g. December 31).

Program Medical Management and Information System for ESRD, and Renal Beneficiary and Utilization System (PAMMS/REBUS) The major source of data for the USRDS. This CMS file incorporates data from the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2764), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.
Prevalent ESRD patient: A patient on renal replacement therapy or with a functioning kidney transplant (regardless of the transplant date). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving treatment for ESRD, and those whose ESRD treatments are not reported to CMS.

Prevalent population: The people in a population who have a disease at a given point in time (point prevalence) or during a given time period (period prevalence).

Proteinuria: The existence of protein in the urine; indicative of kidney damage.

Pyrogen: A substance which is bacterial in nature and capable of producing low-grade fevers.

Pyrogen reaction: A condition in which a patient is afibrile prior to dialysis experiences a low-grade fever during the run, caused by pyrogens in the dialysate fluid. The fever disappears after the dialysis is complete, distinguishing the reaction from an actual infection.

Recombinant human growth hormone (rhGH): Also called somatropin; a substance used to treat growth hormone deficiency.

REMIS: CMS’s Renal Management Information System (REMIS), which has replaced the Renal Beneficiary and Utilization System (REBUS). Includes an operational interface to the SIMS Central Repository.

Reuse: A process through which a hemodialyzer is cleaned and disinfected, allowing it to be used multiple times on the same patient.

Reuse germicide: A chemical used during the reuse process to disinfect the hemodialyzer.

SIMS: CMS’s Standard Information Management System (SIMS), which became operational at the beginning of 2000. Supports CMS reporting requirements and the business processes of the ESRD networks; provides communication and data exchange links for the networks, CMS, and other parts of the renal community; supplies standard core data functionality for previous network data systems; and provides improved electronic communication capabilities, data standardization, and information management tools.

Standard Analysis Files (SAFs): CMS files containing final action Medicare inpatient/outpatient claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and a percent Sample Beneficiary.

Standardized hospitalization ratio (SHR): Used to compare hospitalization rates for a selected group of patients by computing the ratio of the group’s observed hospitalization rate to the expected hospitalization rate for the national ESRD population.

Standardized mortality ratio (SMR): Used to compare dialysis patient mortality rates from year to year. Mortality rates for a subgroup of patients are compared to a set of reference rates, with adjustments for age, gender, race, primary diagnosis, and ESRD vintage.

Standardized transplantation ratio (STR): Used to compare transplant rates for a subgroup of patients to national transplant rates.

Statins: Medications that lower cholesterol through action on an enzyme in the liver.

Transplant center: A hospital unit licensed to provide transplantation and other medical and surgical specialty services for the care of kidney transplant patients, including inpatient dialysis furnished directly or under arrangement.

United Network for Organ Sharing (UNOS): A private, non-profit organization that maintains the organ transplant list for the nation and coordinates the matching and distribution of organs to patients awaiting transplant.

Urea reduction ratio (URR): A means of measuring dialysis dose by calculating the change in BUN over the course of a dialysis treatment. URR = (pre-dialysis - post-dialysis BUN) / pre-dialysis BUN * 100.

Valvular heart disease (VHD): A condition in which a patient has one or more abnormal heart valves.

Vintage: Time in years that a patient has had ESRD.

The VISION project: CMS’s Vital Information System to Improve Outcomes in Nephrology (VISION) will provide customized data entry and reporting for the nearly 4,000 U.S. dialysis facilities, and will capture and securely communicate ESRD patient and provider data collected via the CMS 2728, 2746, 2744, 82c, and 821 forms. This project is designed to meet the goals of the Hemodialysis Facilities of Achievement Project (FOA) as outlined in the Federal Register (April 29, 1997).

Wait list: A list of patients awaiting an organ transplant; maintained by the United Network for Organ Sharing (UNOS).

Some of these definitions are obtained from the On-Line Medical Dictionary, found at http://can-cerweb.ncl.ac.uk/omd/.
United States Renal Data System (USRDS)
Agreement for Release of Data

Project title _____________________________________________________________

In this agreement, “Recipient” means _________________________________________

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copies containing data extracted from the USRDS research database.

B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.

C. The Recipient shall not use the data to identify individuals on the file.

D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.

E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the data may not be used include, but are not limited to,
   • the identification and targeting of under- or over-served health service markets primarily for commercial benefit
   • the obtaining of information about providers or facilities for commercial benefit
   • insurance purposes such as redlining areas deemed to offer bad health insurance risks
   • adverse selection (e.g., identifying patients with high risk diagnoses)

Any use of the data for research not in the original proposal must be approved by the USRDS Project Officer (PO).

F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten individuals or fewer than five providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor, and (2) the contractor has signed a data release agreement with the PO.

G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.

H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III—Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. The USRDS data files covered in this data use agreement may be retained by the Recipient until _______________. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient’s expense, and any derivative files and copies shall be destroyed.

J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon request, be granted access to premises where data in this file are kept.
May 2004

Lawrence Y. C. Agodoa, MD, NIDDK, NIH or Paul W. Eggers, PhD, NIDDK, NIH
USRDS Project Officer

USRDS Project Officer signature & date
United States Renal Data System (USRDS)  
International Data Collection Form

This form is designed to solicit information on the population of End-Stage Renal Disease (ESRD) patients in your country. The information you provide will be returned to you along with comparable information from other countries participating in the voluntary effort.

The form has been changed and expanded to provide more detail in age-specific categories. If you cannot provide data in the age categories listed, please provide the total numbers. The format has also been changed to more clearly separate incident and prevalent population counts from transplant counts.

A) Population: the population of your country for the most recent year available

B) Incidence: the count of patients who start any form of renal replacement therapy during the year. These are first-time patients only; patients who start dialysis after a failed transplant, for example, should not be included.

B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year

B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes

C) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).

C1) All patients on some form of treatment, dialysis or transplantation.

C2) Patients with a functioning kidney transplant as of December 31.

C3) All dialysis patients. C2 and C3 should sum to C1 unless there are lost-to-follow-up patients. If there are lost-to-follow-up patients, please note this fact and whether these patients are captured in C2.

C4) All patients treated with in-center hemodialysis as of December 31.

C5) All patients treated with CAPD or CCPD as of December 31.

C6) All patients treated with home hemodialysis as of December 31.

C4, C5, and C6 are subsets of all dialysis patients (C3). They should not total to more than C3. They may, however, sum to less than C3 due to unknown or other types of dialysis.

D) Transplant activity: This is meant to be a count of transplants, not transplanted patients. If a patient receives multiple transplants during the year, all should be counted. If you report only transplanted patients, please provide these numbers and note that they refer to patients. D1 (cadaveric transplants) and D2 (living donor transplants) should sum to the total number of transplants. If there are a number of transplants with unknown donor types, or if you cannot separate transplants by donor type, please report the total number of transplants.

You may return this form to us by email or fax: usrds@usrds.org, and 1.612.347.5878.

<table>
<thead>
<tr>
<th>Country</th>
</tr>
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<table>
<thead>
<tr>
<th>A) Population of country</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
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</table>

<table>
<thead>
<tr>
<th>B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
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<tbody>
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<td>2004</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
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<tr>
<td>C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)</td>
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<tr>
<td>0–19</td>
<td>20–44</td>
<td>45–64</td>
<td>65–74</td>
<td>75+</td>
<td>Total</td>
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<td>2004</td>
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<td>2005</td>
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<td>2007</td>
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</tbody>
</table>

| C2) Prevalence: Total number of ESRD patients with a functioning graft at the end of the year (December 31) |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| C3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31) |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| C4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31) |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| C5) Prevalence: Total number of ESRD patients on CAPD/CCPD at the end of the year (December 31) |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| C6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31) |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| D1) Transplant: Total number of cadaveric transplants during the year |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |

| D2) Transplant: Total number of living donor transplants during the year |
|-----------------------------------------|---------|---------|---------|---------|---------|---------|
| 0–19 | 20–44 | 45–64 | 65–74 | 75+ | Total |
| 2004 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2005 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2006 | _______ | _______ | _______ | _______ | _______ | _______ |
| 2007 | _______ | _______ | _______ | _______ | _______ | _______ |
# END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT

**MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION**

## A. COMPLETE FOR ALL ESRD PATIENTS

**Check one:**
- Initial
- Re-entitlement
- Supplemental

### 1. Name (Last, First, Middle Initial)

### 2. Medicare Claim Number

### 3. Social Security Number

### 4. Date of Birth

### 5. Patient Mailing Address (Include City, State and Zip)

### 6. Phone Number

### 7. Sex
- Male
- Female

### 8. Ethnicity
- Not Hispanic or Latino
- Hispanic or Latino

### 9. Country/Area of Origin or Ancestry

### 10. Race (Check all that apply)
- White
- Black or African American
- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander

### 11. Is patient applying for ESRD Medicare coverage?
- Yes
- No

### 12. Current Medical Coverage (Check all that apply)
- Medicaid
- Medicare
- Employer Group Health Insurance
- DVA
- Medicare Advantage
- Other
- None

### 13. Height

### 14. Dry Weight

### 15. Primary Cause of Renal Failure (Use code from back of form)

### 16. Employment Status (6 mos prior and current status)

### 17. Co-Morbid Conditions (Check all that apply currently and/or during last 10 years)*See instructions

### 18. Prior to ESRD therapy:

### 19. Laboratory Values Within 45 Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

<table>
<thead>
<tr>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Serum Albumin (g/dl)</td>
<td>_____</td>
<td>-</td>
<td>d. HbA1c</td>
<td>_____</td>
<td>-%</td>
</tr>
<tr>
<td>b. Serum Albumin Lower Limit</td>
<td>_____</td>
<td>-</td>
<td>e. Lipid Profile</td>
<td>TC</td>
<td></td>
</tr>
<tr>
<td>c. Hemoglobin (g/dl)</td>
<td>_____</td>
<td>-</td>
<td>LDL</td>
<td>_____</td>
<td></td>
</tr>
<tr>
<td>b. Serum Creatinine (mg/dl)</td>
<td>_____</td>
<td>-</td>
<td>HDL</td>
<td>_____</td>
<td></td>
</tr>
<tr>
<td>c. Lipid Profile</td>
<td>_____</td>
<td>-</td>
<td>TG</td>
<td>_____</td>
<td></td>
</tr>
</tbody>
</table>

## B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

### 20. Name of Dialysis Facility

### 21. Medicare Provider Number (for item 20)

### 22. Primary Dialysis Setting
- Home
- Dialysis Facility/Center
- SNF/Long Term Care Facility

### 23. Primary Type of Dialysis
- Hemodialysis (Sessions per week __/hours per session ___)
- CAPD
- CCPD
- Other

### 24. Date Regular Chronic Dialysis Began

### 25. Date Patient Started Chronic Dialysis at Current Facility

### 26. Has patient been informed of kidney transplant options?
- Yes
- No

### 27. If patient NOT informed of transplant options, please check all that apply:
- Medically unfit
- Patient declines information
- Unsuitable due to age
- Patient has not been assessed
- Psychologically unfit
- Other
C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

28. Date of Transplant

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

31. Enter Date

32. Name of Preparation Hospital

34. Current Status of Transplant (if functioning, skip items 36 and 37)

☐ Functioning ☐ Non-Functioning

35. Type of Donor:

☐ Deceased ☐ Living Related ☐ Living Unrelated

36. If Non-Functioning, Date of Return to Regular Dialysis

37. Current Dialysis Treatment Site

☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

38. Name of Training Provider

40. Date Training Began

42. This Patient is Expected to Complete (or has completed) Training and will Self-dialyze on a Regular Basis.

☐ Yes ☐ No

39. Medicare Provider Number of Training Provider (for Item 38)

41. Type of Training

☐ Hemodialysis a. ☐ Home b. ☐ In Center

☐ CAPD ☐ CCPD ☐ Other

43. Date When Patient Completed, or is Expected to Complete, Training

E. PHYSICIAN IDENTIFICATION

46. Attending Physician (Print)

47. Physician's Phone No.

48. UPIN of Physician in Item 46

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

54. Signature of Patient (Signature by mark must be witnessed.)

55. Date

51. Physician Recertification Signature

52. Date

E. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)" published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

FORM CMS-2728-U3 (06/04) EF(03/2005)
# LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 15. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **Code effective as of September 2003.**

<table>
<thead>
<tr>
<th>DIABETES</th>
<th>CYSTIC/HEREDITARY/CONGENITAL DISEASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>25040</td>
<td>Diabetes with renal manifestations Type 2</td>
</tr>
<tr>
<td>25041</td>
<td>Diabetes with renal manifestations Type 1</td>
</tr>
<tr>
<td>75313</td>
<td>Polycystic kidneys, adult type (dominant)</td>
</tr>
<tr>
<td>75314</td>
<td>Polycystic, infantile (recessive)</td>
</tr>
<tr>
<td>75316</td>
<td>Medullary cystic disease, including nephronophthisis</td>
</tr>
<tr>
<td>7595</td>
<td>Tuberous sclerosis</td>
</tr>
<tr>
<td>7598</td>
<td>Hereditary nephritis, Alport’s syndrome</td>
</tr>
<tr>
<td>2700</td>
<td>Cystinosis</td>
</tr>
<tr>
<td>2718</td>
<td>Primary oxalosis</td>
</tr>
<tr>
<td>2727</td>
<td>Fabry’s disease</td>
</tr>
<tr>
<td>7533</td>
<td>Congenital nephrotic syndrome</td>
</tr>
<tr>
<td>5839</td>
<td>Drash syndrome, mesangial sclerosis</td>
</tr>
<tr>
<td>75321</td>
<td>Congenital obstruction of urerteropelvic junction</td>
</tr>
<tr>
<td>75322</td>
<td>Congenital obstruction of ureterovesical junction</td>
</tr>
<tr>
<td>75329</td>
<td>Other Congenital obstructive uropathy</td>
</tr>
<tr>
<td>7530</td>
<td>Renal hypoplasia, dysplasia, oligonephronia</td>
</tr>
<tr>
<td>75671</td>
<td>Prune belly syndrome</td>
</tr>
<tr>
<td>75989</td>
<td>Other (congenital malformation syndromes)</td>
</tr>
</tbody>
</table>

| GLOMERULONEPHRITIS | 5829 | Glomerulonephritis (GN) |
|                    | (histologically not examined) |
| 5821 | Focal glomerulosclerosis, focal sclerosing GN |
| 5831 | Membranous nephropathy |
| 58321 | Membranoproliferative GN type 1, diffuse MPGN |
| 58322 | Dense deposit disease, MPGN type 2 |
| 58381 | IgA nephropathy, Berger’s disease |
| (proven by immunofluorescence) |
| 58382 | IgM nephropathy (proven by immunofluorescence) |
| 5834 | With lesion of rapidly progressive GN |
| 5800 | Post infectious GN, SBE |
| 5820 | Other proliferative GN |
| 75321 | Congenital obstruction of ureteropelvic junction |
| 75322 | Congenital obstruction of ureterovesical junction |
| 75329 | Other Congenital obstructive uropathy |
| 7530 | Renal hypoplasia, dysplasia, oligonephronia |
| 75671 | Prune belly syndrome |
| 75989 | Other (congenital malformation syndromes) |

| SECONDARY GN/VASCULITIS | 7100 | Lupus erythematosus, (SLE nephritis) |
| 2870 | Henoch-Schonlein syndrome |
| 7101 | Scleroderma |
| 28311 | Hemolytic uremic syndrome |
| 4460 | Polyarteritis |
| 4464 | Wegener’s granulomatosis |
| 5839 | Nephropathy due to heroin abuse and related drugs |
| 44620 | Other Vasculitis and its derivatives |
| 44621 | Goodpasture’s syndrome |
| 58391 | Secondary GN, other |
| 1890 | Renal tumor (malignant) |
| 1899 | Urinary tract tumor (malignant) |
| 2239 | Urinary tract tumor (benign) |
| 23952 | Urinary tract tumor (unspecified) |
| 20280 | Lymphoma of kidneys |
| 20300 | Multiple myeloma |
| 20308 | Other immuno proliferative neoplasms |
| (including light chain nephropathy) |
| 2773 | Amyloidosis |
| 99680 | Complications of transplanted organ unspecified |
| 99681 | Complications of transplanted kidney |
| 99682 | Complications of transplanted liver |
| 99683 | Complications of transplanted heart |
| 99684 | Complications of transplanted lung |
| 99685 | Complications of transplanted bone marrow |
| 99686 | Complications of transplanted pancreas |
| 99687 | Complications of transplanted intestine |
| 99689 | Complications of other specified transplanted organ |

| INTERSTITIAL NEPHRITIS/PYELONEPHRITIS | 9659 | Analgesic abuse |
| 5830 | Radiation nephritis |
| 9849 | Lead nephropathy |
| 5909 | Nephropathy caused by other agents |
| 27410 | Gouty nephropathy |
| 5920 | Nephrolithiasis |
| 5996 | Acquired obstructive uropathy |
| 5900 | Chronic pyelonephritis, reflux nephropathy |
| 58389 | Chronic interstitial nephritis |
| 58089 | Acute interstitial nephritis |
| 5929 | Urolithiasis |
| 27549 | Other disorders of calcium metabolism |

| HYPERTENSION/LARGE VESSEL DISEASE | 40391 | Unspecified with renal failure |
| 4401 | Renal artery stenosis |
| 59381 | Renal artery occlusion |
| 59383 | Cholesterol emboli, renal emboli |
| 28260 | Sickle cell disease/anemia |
| 28269 | Sickle cell trait and other sickle cell (HbS/Hb other) |
| 44620 | Post partum renal failure |
| 042 | AIDS nephropathy |
| 8660 | Traumatic or surgical loss of kidney(s) |
| 5724 | Hepatorenal syndrome |
| 5836 | Tubular necrosis (no recovery) |
| 59389 | Other renal disorders |
| 7999 | Etiology uncertain |
**END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT**

**MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION**

### A. COMPLETE FOR ALL ESRD PATIENTS

1. Name (Last, First, Middle Initial)

2. Health Insurance Claim Number

3. Social Security Number

4. Full Address (Include City, State, and Zip)

5. Phone Number

6. Date of Birth

7. Sex
   - Male
   - Female

8. Ethnicity
   - Hispanic: Mexican
   - Hispanic: Other
   - Non-Hispanic

9. Race (Check one box only)
   - White
   - Black
   - American Indian/Alaskan Native
   - Asian
   - Pacific Islander
   - Mid-East/Arabian
   - Indian sub-Continent
   - Other, specify ______
   - Unknown

10. Medical Coverage (Check all that apply)
    - Medicaid
    - DVA
    - Medicare
    - Employer Group Health Insurance
    - Other Medical Insurance
    - None
    - Other, specify ______

11. Is Patient Applying for ESRD Medicare Coverage? (if YES, enter address of Social Security office)
    - Yes
    - No

12. Primary Cause of Renal Failure (Use code from back of form)

13. Height

14. Dry Weight

15. Employment Status (6 mos. prior and current status)
   - Unemployed
   - Employed Full Time
   - Employed Part Time
   - Homemaker
   - Retired due to Age/Preference
   - Retired (Disability)
   - Medical Leave of Absence
   - Student

16. Co-Morbid Conditions (Check ALL that apply currently or during last 10 years) *See instructions
   a. Congestive heart failure
   b. Ischemic heart disease, CAD*
   c. Myocardial infarction
   d. Cardiac arrest
   e. Cardiac dysrhythmia
   f. Pericarditis
   g. Cerebrovascular disease, CVA, TIA*
   h. Peripheral vascular disease*
   i. History of hypertension
   j. Diabetes (primary or contributing)
   k. Diabetes, currently on insulin
   l. Chronic obstructive pulmonary disease
   m. Tobacco use (current smoker)
   n. Malignant neoplasm, Cancer
   o. Alcohol dependence
   p. Drug dependence*
   q. HIV positive status
   r. AIDS
   s. Inability to ambulate
   t. Inability to transfer

17. Was pre-dialysis/transplant EPO administered?
    - Yes
    - No

18. Laboratory Values Prior to First Dialysis Treatment or Transplant  *See Instructions.

### B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Provider

20. Medicare Provider Number

21. Primary Dialysis Setting
    - Hospital Inpatient
    - Dialysis Facility/Center
    - Home
    - Hemodialysis
    - IPD
    - CAPD
    - CCPD
    - Other

22. Primary Type of Dialysis

23. Date Regular Dialysis Began

24. Date Patient Started Chronic Dialysis at Current Facility

25. Date Dialysis Stopped

26. Date of Death

---

*Instructions for filling out the ME form can be found in the Researcher's Guide & on our website, www.usrd.org.*
I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

If Nonfunctioning, Date of Return To Regular Dialysis

This Patient is Expected to Complete (or has completed) Training and Will Self-dialyze on a Regular Basis.

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

The collection of this information is authorized by section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, “End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS), published in the Privacy Act Issuance, 1991 Compilation, Vol. 1, pages 436–437, December 31, 1991, or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for a research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

For ESRD Network Use Only in Cases Referred to ESRD Medical Review Board

☐ Yes  ☐ No

☐ Hemodialysis  ☐ IPD  ☐ CAPD  ☐ CCPD
LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 12. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code plus the letter code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary.

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>LTR</th>
<th>NARRATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>25000</td>
<td>A</td>
<td>Type II, adult-onset type or unspecified type diabetes</td>
</tr>
<tr>
<td>25001</td>
<td>A</td>
<td>Type I, juvenile type, ketosis prone diabetes</td>
</tr>
<tr>
<td>5829</td>
<td>A</td>
<td>Glomerulonephritis (GN) (histologically not examined)</td>
</tr>
<tr>
<td>5821</td>
<td>A</td>
<td>Focal glomerulosclerosis, focal sclerosing GN</td>
</tr>
<tr>
<td>5831</td>
<td>A</td>
<td>Membranous nephropathy</td>
</tr>
<tr>
<td>5832</td>
<td>A</td>
<td>Membranoproliferative GN type 1, diffuse MPGN</td>
</tr>
<tr>
<td>5832</td>
<td>C</td>
<td>Dense deposit disease, MPGN type 2</td>
</tr>
<tr>
<td>58381</td>
<td>B</td>
<td>IgA nephropathy, Berger's disease (proven by immunofluorescence)</td>
</tr>
<tr>
<td>58381</td>
<td>C</td>
<td>IgM nephropathy (proven by immunofluorescence)</td>
</tr>
<tr>
<td>5804</td>
<td>B</td>
<td>Rapidly progressive GN</td>
</tr>
<tr>
<td>5834</td>
<td>C</td>
<td>Goodpasture's Syndrome</td>
</tr>
<tr>
<td>5800</td>
<td>C</td>
<td>Post infectious GN, SBE</td>
</tr>
<tr>
<td>5820</td>
<td>A</td>
<td>Other proliferative GN</td>
</tr>
<tr>
<td>7100</td>
<td>E</td>
<td>Lupus erythematosus, (SLE nephritis)</td>
</tr>
<tr>
<td>2870</td>
<td>A</td>
<td>Henoch-Schonlein syndrome</td>
</tr>
<tr>
<td>7101</td>
<td>B</td>
<td>Scleroderma</td>
</tr>
<tr>
<td>2831</td>
<td>A</td>
<td>Hemolytic uremic syndrome</td>
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<tr>
<td>4460</td>
<td>C</td>
<td>Polyarteritis</td>
</tr>
<tr>
<td>4464</td>
<td>B</td>
<td>Wegener's granulomatosis</td>
</tr>
<tr>
<td>5839</td>
<td>C</td>
<td>Nephropathy due to heroin abuse and related drugs</td>
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<tr>
<td>4462</td>
<td>A</td>
<td>Vasculitis and its derivatives</td>
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<tr>
<td>5839</td>
<td>B</td>
<td>Secondary GN, other</td>
</tr>
<tr>
<td>9659</td>
<td>A</td>
<td>Analgesic abuse</td>
</tr>
<tr>
<td>5830</td>
<td>B</td>
<td>Radiation nephritis</td>
</tr>
<tr>
<td>9849</td>
<td>A</td>
<td>Lead nephropathy</td>
</tr>
<tr>
<td>5909</td>
<td>A</td>
<td>Nephropathy caused by other agents</td>
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<tr>
<td>27410</td>
<td>A</td>
<td>Gouty nephropathy</td>
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<tr>
<td>5920</td>
<td>C</td>
<td>Nephrolithiasis</td>
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<tr>
<td>5996</td>
<td>A</td>
<td>Acquired obstructive uropathy</td>
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<tr>
<td>5900</td>
<td>A</td>
<td>Chronic pyelonephritis, reflux nephropathy</td>
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<td>58389</td>
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<td>Chronic interstitial nephritis</td>
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<td>58089</td>
<td>A</td>
<td>Acute interstitial nephritis</td>
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<td>5929</td>
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<td>Urolithiasis</td>
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<tr>
<td>2754</td>
<td>A</td>
<td>Nephrocalcinosis</td>
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<tbody>
<tr>
<td>4039</td>
<td>D</td>
<td>Renal disease due to hypertension (no primary renal disease)</td>
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<tr>
<td>4401</td>
<td>A</td>
<td>Renal artery stenosis</td>
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<tr>
<td>59381</td>
<td>B</td>
<td>Renal artery occlusion</td>
</tr>
<tr>
<td>59381</td>
<td>E</td>
<td>Cholesterol emboli, renal emboli</td>
</tr>
<tr>
<td>75313</td>
<td>A</td>
<td>Polycystic kidneys, adult type (dominant)</td>
</tr>
<tr>
<td>75314</td>
<td>A</td>
<td>Polycystic, infantile (recessive)</td>
</tr>
<tr>
<td>75316</td>
<td>A</td>
<td>Medullary cystic disease, including neoprophathesis</td>
</tr>
<tr>
<td>7595</td>
<td>A</td>
<td>Tuberous sclerosis</td>
</tr>
<tr>
<td>7598</td>
<td>A</td>
<td>Hereditary nephritis, Alport's syndrome</td>
</tr>
<tr>
<td>2700</td>
<td>A</td>
<td>Cystinosis</td>
</tr>
<tr>
<td>2718</td>
<td>B</td>
<td>Primary oxalosis</td>
</tr>
<tr>
<td>2727</td>
<td>A</td>
<td>Fabry's disease</td>
</tr>
<tr>
<td>7533</td>
<td>A</td>
<td>Congenital nephrotic syndrome</td>
</tr>
<tr>
<td>5839</td>
<td>D</td>
<td>Drash syndrome, mesangial sclerosis</td>
</tr>
<tr>
<td>7532</td>
<td>A</td>
<td>Congenital obstructive uropathy</td>
</tr>
<tr>
<td>7530</td>
<td>B</td>
<td>Renal hypoplasia, dysplasia, oligonephronia</td>
</tr>
<tr>
<td>7567</td>
<td>A</td>
<td>Prune belly syndrome</td>
</tr>
<tr>
<td>7598</td>
<td>B</td>
<td>Hereditary/familial nephropathy</td>
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<tr>
<td>1890</td>
<td>B</td>
<td>Renal tumor (malignant)</td>
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<tr>
<td>1899</td>
<td>A</td>
<td>Urinary tract tumor (malignant)</td>
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<tr>
<td>2230</td>
<td>A</td>
<td>Renal tumor (benign)</td>
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<tr>
<td>2239</td>
<td>A</td>
<td>Urinary tract tumor (benign)</td>
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<tr>
<td>2395</td>
<td>A</td>
<td>Renal tumor (unspecified)</td>
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<tr>
<td>2395</td>
<td>B</td>
<td>Urinary tract tumor (unspecified)</td>
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<tr>
<td>20280</td>
<td>A</td>
<td>Lymphoma of kidneys</td>
</tr>
<tr>
<td>2030</td>
<td>A</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>2030</td>
<td>B</td>
<td>Light chain nephropathy</td>
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<tr>
<td>2773</td>
<td>A</td>
<td>Amyloidosis</td>
</tr>
<tr>
<td>99680</td>
<td>A</td>
<td>Complication post bone marrow or other transplant</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9</th>
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<th>NARRATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td>28260</td>
<td>A</td>
<td>Sickle cell disease/anemia</td>
</tr>
<tr>
<td>28269</td>
<td>A</td>
<td>Sickle cell trait and other sickle cell (HbS/Hb other)</td>
</tr>
<tr>
<td>64620</td>
<td>A</td>
<td>Post partum renal failure</td>
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<tr>
<td>0429</td>
<td>A</td>
<td>AIDS nephropathy</td>
</tr>
<tr>
<td>8660</td>
<td>A</td>
<td>Traumatic or surgical loss of kidney(s)</td>
</tr>
<tr>
<td>5724</td>
<td>A</td>
<td>Hepatorenal syndrome</td>
</tr>
<tr>
<td>5836</td>
<td>A</td>
<td>Tubular necrosis (no recovery)</td>
</tr>
<tr>
<td>59389</td>
<td>A</td>
<td>Other renal disorders</td>
</tr>
<tr>
<td>7999</td>
<td>A</td>
<td>Etiology uncertain</td>
</tr>
</tbody>
</table>
**CHRONIC RENAL DISEASE MEDICAL EVIDENCE REPORT**

**IDENTIFYING INFORMATION**

1. **PATIENT'S NAME (LAST, FIRST, MIDDLE INITIAL)**
2. **PATIENT'S OWN SOCIAL SECURITY NUMBER**

3. **PATIENT'S ADDRESS (STREET, CITY, STATE, ZIP)**
4. **PATIENT'S CLAIM NUMBER**

5. **PHONE NO.**
6. **DATE OF BIRTH**
7. **RACE**
   - A. AMERICAN INDIAN OR ALASKAN NATIVE
   - B. ASIAN OR PACIFIC ISLANDER
   - C. BLACK
   - D. WHITE
   - E. UNKOWN

8. **ADDRESS OF SOCIAL SECURITY OFFICE**
9. **PATIENT'S SEX**
   - A. MALE
   - B. FEMALE

10. **PRIMARY DIAGNOSIS (CAUSE OF ESRD)**

11. **NAME, ADDRESS AND PHONE NUMBER OF PHYSICIAN RESPONSIBLE FOR RENAL TREATMENT AT TIME OF CLAIM**

**TREATMENT INFORMATION—DIALYSIS**

<table>
<thead>
<tr>
<th>TYPE OF DIALYSIS</th>
<th>DATE REGULAR DIALYSIS BEGAN</th>
<th>FREQUENCY SINCE REGULAR DIALYSIS BEGAN (TIMES PER WEEK)</th>
<th>HAS DIALYSIS ENDED?</th>
<th>IF ENDED, DATE OF LAST DIALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEMODIALYSIS</td>
<td>1987-01-01</td>
<td>3 TIMES PER WEEK</td>
<td>YES</td>
<td>1987-01-01</td>
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<tr>
<td>PENTORAL CAPD</td>
<td>1987-01-02</td>
<td>2 TIMES PER WEEK</td>
<td>YES</td>
<td>1987-01-02</td>
</tr>
</tbody>
</table>

**TREATMENT INFORMATION—TRANSPLANT**

16. **DATE OF TRANSPLANT**
17. **NAME OF TRANSPLANT HOSPITAL**
18. **PROVIDER NO**

19. **WAS THE PATIENT ADMITTED AS AN INPATIENT TO A HOSPITAL IN PREPARATION FOR OR ANTICIPATION OF A KIDNEY TRANSPLANT PRIOR TO THE DATE OF ACTUAL TRANSPLANTATION?**
   - YES
   - NO

20. **CURRENT STATUS OF TRANSPLANT (IF B. CLEARED, ANSWER 21 OR EXPLAIN IN REMARKS)**
   - a. FUNCTIONING
   - b. REJECTED

21. **DATE OF RETURN TO REGULAR DIALYSIS**
22. **CURRENT TREATMENT SITE**
   - a. HOME
   - b. FACILITY

**MEDICAL CERTIFICATION**

23. **DO YOU CERTIFY THAT THIS PATIENT HAS REACHED THE STATE OF RENAL IMPAIRMENT THAT APPEARS IRREVERSIBLE AND PERMANENT AND REQUIRES A REGULAR COURSE OF DIALYSIS OR KIDNEY TRANSPLANTATION TO MAINTAIN LIFE?**
   - YES
   - NO

24. **SIGNATURE AND TITLE OF ATTENDING PHYSICIAN**
25. **DATE**

**CERTIFICATION OF SELF CARE DIALYSIS TRAINING**

26. **NAME ADDRESS OF TRAINING PROVIDER**
27. **PROVIDER NO**
28. **DATE TRAINING BEGAN**
29. **TYPE OF TRAINING**
   - a. HEMODIALYSIS
   - b. IPC
   - c. CAPD
   - d. CORP

30. **HAS THE PATIENT COMPLETED THE TRAINING PROGRAM?**
   - YES
   - NO

31. **IF NO., WHEN IS THE PATIENT EXPECTED TO COMPLETE THE PROGRAM?**
32. **I CERTIFY THAT THE ABOVE SELF-DIALYSIS TRAINING INFORMATION IS BASED ON CONSIDERATION OF ALL PERTINENT MEDICAL, PSYCHOLOGICAL, AND SOCIODEMOGRAPHIC FACTORS AS REFLECTED IN RECORDS KEPT BY THIS TRAINING FACILITY, AND IS CORRECT.**
   - SIGNATURE OF PHYSICIAN PERSONALLY FAMILIAR WITH THE PATIENT'S TRAINING
   - TITLE
   - DATE

33. **REMARKS**

34. **I HEREBY AUTHORIZE ANY PHYSICIAN, HOSPITAL, AGENCY, OR OTHER ORGANIZATION TO DISCLOSE TO THE SOCIAL SECURITY ADMINISTRATION FOR PURPOSES OF REVIEWS MY APPLICATION FOR MEDICARE BENEFITS PERMITTED UNDER THE SOCIAL SECURITY ACT, ANY MEDICAL RECORDS OR OTHER INFORMATION ABOUT MY MEDICAL CONDITION**

**SIGNATURE OF PATIENT (SIGNATURE BY MARK MUST BE WITNESSED)**

**DATE**

---

Form MCFA-2728-LM (6-67)
# ESRD DEATH NOTIFICATION

## END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient's Last Name</td>
<td>First</td>
<td>MI</td>
<td>2. Medicare Claim Number</td>
<td></td>
</tr>
<tr>
<td>3. Patient's Sex</td>
<td>a. ☐ Male</td>
<td>b. ☐ Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Date of Birth</td>
<td></td>
<td></td>
<td>5. Social Security Number</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Month</td>
<td>Day</td>
<td>Year</td>
<td></td>
</tr>
<tr>
<td>7. Place of Death</td>
<td>a. ☐ Hospital</td>
<td>b. ☐ Dialysis Unit</td>
<td>c. ☐ Home</td>
<td>d. ☐ Nursing Home</td>
</tr>
<tr>
<td></td>
<td>Month</td>
<td>Day</td>
<td>Year</td>
<td></td>
</tr>
<tr>
<td>8. Date of Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Month</td>
<td>Day</td>
<td>Year</td>
<td></td>
</tr>
</tbody>
</table>

## Causes of Death (enter codes from list on back of form)

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>a. Primary Cause</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Were there secondary causes?</td>
<td>☐ No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Yes, specify: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Renal replacement therapy discontinued prior to death:

| ☐ Yes | ☐ No |

### If yes, check one of the following:

- ☐ Following HD and/or PD access failure
- ☐ Following transplant failure
- ☐ Following chronic failure to thrive
- ☐ Following acute medical complication
- ☐ Other

| ☐ Yes | ☐ No | ☐ Unknown | ☐ Not Applicable |

## Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?

| ☐ Yes | ☐ No | ☐ Unknown | ☐ Not Applicable |

## Was patient receiving Hospice care prior to death?

| ☐ Yes | ☐ No | ☐ Unknown |

## Name of Physician (Please print complete name)

| Signature of Person Completing This Form | Date |

---


Form CMS-2746-U2 (08/06) EF 08/2006
ESRD DEATH NOTIFICATION FORM
LIST OF CAUSES

CARDIAC
23 Myocardial infarction, acute
25 Pericarditis, incl. Cardiac tamponade
26 Atherosclerotic heart disease
27 Cardiomyopathy
28 Cardiac arrhythmia
29 Cardiac arrest, cause unknown
30 Valvular heart disease
31 Pulmonary edema due to exogenous fluid
32 Congestive Heart Failure

VASCULAR
35 Pulmonary embolus
36 Cerebrovascular accident including intracranial hemorrhage
37 Ischemic brain damage/Anoxic encephalopathy
38 Hemorrhage from transplant site
39 Hemorrhage from vascular access
40 Hemorrhage from dialysis circuit
41 Hemorrhage from ruptured vascular aneurysm
42 Hemorrhage from surgery (not 38, 39, or 41)
43 Other hemorrhage (not 38-42, 72)
44 Mesenteric infarction/ischemic bowel

INFECTION
33 Septicemia due to internal vascular access
34 Septicemia due to vascular access catheter
45 Peritoneal access infectious complication, bacterial
46 Peritoneal access infectious complication, fungal
47 Peritonitis (complication of peritoneal dialysis)
48 Central nervous system infection (brain abscess, meningitis, encephalitis, etc.)
51 Septicemia due to peripheral vascular disease, gangrene
52 Septicemia, other
61 Cardiac infection (endocarditis)
62 Pulmonary infection (pneumonia, influenza)
63 Abdominal infection (peritonitis (not comp of PD), perforated bowel, diverticular disease, gallbladder)
70 Genito-urinary infection (urinary tract infection, pyelonephritis, renal abscess)

LIVER DISEASE
64 Hepatitis B
71 Hepatitis C
65 Other viral hepatitis
66 Liver-drug toxicity
67 Cirrhosis
68 Polycystic liver disease
69 Liver failure, cause unknown or other

GASTRO-INTESTINAL
72 Gastro-intestinal hemorrhage
73 Pancreatitis
75 Perforation of peptic ulcer
76 Perforation of bowel (not 75)

METABOLIC
24 Hyperkalemia
77 Hypokalemia
78 Hypernatremia
79 Hyponatremia
100 Hypoglycemia
101 Hyperglycemia
102 Diabetic coma
95 Acidosis

ENDOCRINE
96 Adrenal insufficiency
97 Hypothyroidism
103 Hyperthyroidism

OTHER
80 Bone marrow depression
81 Cachexia/failure to thrive
82 Malignant disease, patient ever on immunosuppressive therapy
83 Malignant disease (not 82)
84 Dementia, incl. dialysis dementia, Alzheimer’s
85 Seizures
87 Chronic obstructive lung disease (COPD)
88 Complications of surgery
89 Air embolism
104 Withdrawal from dialysis/uremia
90 Accident related to treatment
91 Accident unrelated to treatment
92 Suicide
93 Drug overdose (street drugs)
94 Drug overdose (not 92 or 93)
98 Other cause of death
99 Unknown

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0448. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.
# ESRD DEATH NOTIFICATION

## END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient's Last Name</td>
<td>First</td>
<td>MI</td>
<td>2</td>
<td>Medicare Claim Number</td>
</tr>
<tr>
<td>3</td>
<td>Patient's Sex</td>
<td></td>
<td></td>
<td>4</td>
<td>Date of Birth</td>
</tr>
<tr>
<td></td>
<td>a. ☐ Male</td>
<td>b. ☐ Female</td>
<td></td>
<td></td>
<td>Month</td>
</tr>
<tr>
<td>6</td>
<td>Patient's State of Residence</td>
<td></td>
<td></td>
<td>7</td>
<td>Place of Death</td>
</tr>
<tr>
<td></td>
<td>a. □ Hospital</td>
<td>c. □ Home</td>
<td>e. □ Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. □ Dialysis Unit</td>
<td>d. □ Nursing Home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Modality at Time of Death</td>
<td></td>
<td></td>
<td>10</td>
<td>Date of Death</td>
</tr>
<tr>
<td></td>
<td>a. ☐ Incenter Hemodialysis</td>
<td>b. ☐ Home Hemodialysis</td>
<td>c. ☐ CAPD</td>
<td>d. ☐ CCPD</td>
<td>e. ☐ Transplant</td>
</tr>
<tr>
<td>12</td>
<td>Causes of Death (enter codes from list on back of form)</td>
<td></td>
<td></td>
<td>13</td>
<td>Renal replacement therapy discontinued prior to death: ☐ Yes ☐ No</td>
</tr>
<tr>
<td></td>
<td>a. Primary Cause</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Were there secondary causes?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Yes, specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. If cause is other (98) please specify:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?</td>
<td></td>
<td></td>
<td>15</td>
<td>Date of most recent transplant</td>
</tr>
<tr>
<td></td>
<td>☐ Yes ☐ No</td>
<td></td>
<td></td>
<td>a. Date of most recent transplant</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Unknown</td>
<td></td>
<td></td>
<td></td>
<td>Month</td>
</tr>
<tr>
<td></td>
<td>b. Type of transplant received</td>
<td></td>
<td></td>
<td>b. Type of transplant received</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Living Related</td>
<td>☐ Living Unrelated</td>
<td>☐ Deceased</td>
<td>☐ Unknown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Was graft functioning (patient not on dialysis) at time of death?</td>
<td></td>
<td></td>
<td>c. Was graft functioning (patient not on dialysis) at time of death?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ Unknown</td>
<td>☐ Unknown</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Did transplant patient resume chronic maintenance dialysis prior to death?</td>
<td></td>
<td></td>
<td>d. Did transplant patient resume chronic maintenance dialysis prior to death?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>☐ Unknown</td>
<td>☐ Unknown</td>
<td></td>
</tr>
<tr>
<td>17</td>
<td>Name of Physician (Please print complete name)</td>
<td></td>
<td></td>
<td>18</td>
<td>Signature of Person Completing This Form Date</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# ESRD Death Notification Form

## List of Causes

### Cardiac
- 23 Myocardial infarction, acute
- 25 Pericarditis, incl. Cardiac tamponade
- 26 Atherosclerotic heart disease
- 27 Cardiomyopathy
- 28 Cardiac arrhythmia
- 29 Cardiac arrest, cause unknown
- 30 Valvular heart disease
- 31 Pulmonary edema due to exogenous fluid
- 32 Congestive Heart Failure

### Liver Disease
- 64 Hepatitis B
- 71 Hepatitis C
- 65 Other viral hepatitis
- 66 Liver-drug toxicity
- 67 Cirrhosis
- 68 Polycystic liver disease
- 69 Liver failure, cause unknown or other

### Gastro-Intestinal
- 72 Gastro-intestinal hemorrhage
- 73 Pancreatitis
- 75 Perforation of peptic ulcer
- 76 Perforation of bowel (not 75)

### Vascular
- 35 Pulmonary embolus
- 36 Cerebrovascular accident including intracranial hemorrhage
- 37 Ischemic brain damage/Anoxic encephalopathy
- 38 Hemorrhage from transplant site
- 39 Hemorrhage from vascular access
- 40 Hemorrhage from dialysis circuit
- 41 Hemorrhage from ruptured vascular aneurysm
- 42 Hemorrhage from surgery (not 38, 39, or 41)
- 43 Other hemorrhage (not 38-42, 72)
- 44 Mesenteric infarction/ischemic bowel

### Metabolic
- 24 Hyperkalemia
- 77 Hypokalemia
- 78 Hypernatremia
- 79 Hyponatremia
- 100 Hypoglycemia
- 101 Hyperglycemia
- 95 Acidosis

### Infection
- 33 Septicemia due to internal vascular access
- 34 Septicemia due to vascular access catheter
- 45 Peritoneal access infectious complication, bacterial
- 46 Peritoneal access infectious complication, fungal
- 47 Peritonitis (complication of peritoneal dialysis)
- 48 Central nervous system infection (brain abscess, meningitis, encephalitis, etc.)
- 51 Septicemia due to peripheral vascular disease, gangrene
- 52 Septicemia, other
- 61 Cardiac infection (endocarditis)
- 62 Pulmonary infection (pneumonia, influenza)
- 63 Abdominal infection (peritonitis (not comp of PD), perforated bowel, diverticular disease, gallbladder)
- 70 Genito-urinary infection (urinary tract infection, pyelonephritis, renal abscess)

### Endocrine
- 96 Adrenal insufficiency
- 97 Hypothyroidism
- 103 Hyperthyroidism

### Other
- 80 Bone marrow depression
- 81 Cachexia/failure to thrive
- 82 Malignant disease, patient ever on Immunosuppressive therapy
- 83 Malignant disease (not 82)
- 84 Dementia, incl. dialysis dementia, Alzheimer’s
- 85 Seizures
- 87 Chronic obstructive lung disease (COPD)
- 88 Complications of surgery
- 89 Air embolism
- 104 Withdrawal from dialysis/uremia
- 90 Accident related to treatment
- 91 Accident unrelated to treatment
- 92 Suicide
- 93 Drug overdose (street drugs)
- 94 Drug overdose (not 92 or 93)
- 98 Other cause of death
- 99 Unknown

---

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0448. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.
### ESRD DEATH NOTIFICATION

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0448. The time required to complete this information collection is estimated to average 17 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

#### 1. PATIENT'S LAST NAME

FIRST  
MI  
2. HEALTH INSURANCE CLAIM NUMBER

#### 3. PATIENT'S SEX

a. Male  
b. Female

#### 4. PATIENT'S STATE OF RESIDENCE

a. Hospital  
b. Dialysis  
c. Home  
d. Other

#### 5. DATE OF BIRTH

MONTH  
DAY  
YEAR

#### 6. DATE OF DEATH

MONTH  
DAY  
YEAR

#### 8. PROVIDER NUMBER

#### 9. PLACE OF DEATH (Check one)

a. Hospital  
b. Dialysis  
c. Home  
d. Other

#### 10. WAS AN AUTOPSY PERFORMED?

a. Yes  
b. No

#### 11. CAUSES OF DEATH (Enter code from List of Causes below.)

a. Primary Cause  
b. Secondary Causes?

#### LIST OF CAUSES

<table>
<thead>
<tr>
<th>CARDIAC</th>
<th>INFECTION</th>
<th>GASTRO-INTESTINAL (see also 50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>23 Myocardial infarction, acute</td>
<td>49 Septicemia, due to vascular access</td>
<td>72 Gastro-intestinal hemorrhage</td>
</tr>
<tr>
<td>24 Hyperkalemia</td>
<td>50 Septicemia, due to peritonitis</td>
<td>73 Pancreatitis</td>
</tr>
<tr>
<td>25 Pericarditis, incl. cardiac tamponade</td>
<td>51 Septicemia, due to peripheral vascular disease, gangrene</td>
<td>74 Fungal peritonitis</td>
</tr>
<tr>
<td>26 Atherosclerotic heart disease</td>
<td>52 Septicemia, other</td>
<td>75 Perforation of peptic ulcer</td>
</tr>
<tr>
<td>27 Cardiomyopathy</td>
<td>53 Pulmonary infection (bacterial)</td>
<td>76 Perforation of bowel (not 75)</td>
</tr>
<tr>
<td>28 Cardiac arrhythmia</td>
<td>54 Pulmonary infection (fungal)</td>
<td></td>
</tr>
<tr>
<td>29 Cardiac arrest, cause unknown</td>
<td>55 Pulmonary infection (other)</td>
<td></td>
</tr>
<tr>
<td>30 Valvular heart disease</td>
<td>56 Viral Infection, CMV</td>
<td></td>
</tr>
<tr>
<td>31 Pulmonary edema due to exogenous fluid</td>
<td>57 Viral Infection, Other (not 64 or 65)</td>
<td></td>
</tr>
<tr>
<td>32 Pulmonary edema</td>
<td>58 Tuberculosis</td>
<td></td>
</tr>
<tr>
<td>33 Pulmonary embolus</td>
<td>59 A.I.D.S.</td>
<td></td>
</tr>
<tr>
<td>34 Pulmonary embolus failure</td>
<td>60 Infections, other</td>
<td></td>
</tr>
<tr>
<td>35 Pulmonary embolus failure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36 Cerebrovascular accident including intracranial hemorrhage</td>
<td>61 Other viral hepatitis</td>
<td></td>
</tr>
<tr>
<td>37 Ischemic brain damage/Anoxic encephalopathy</td>
<td>62 Liver-drug toxicity</td>
<td></td>
</tr>
<tr>
<td>38 Hemorrhage from transplant site</td>
<td>63 Cirrhosis</td>
<td></td>
</tr>
<tr>
<td>39 Hemorrhage from vascular access</td>
<td>64 Polycystic liver disease</td>
<td></td>
</tr>
<tr>
<td>40 Hemorrhage from dialysis circuit</td>
<td>65 Liver failure, cause unknown other</td>
<td></td>
</tr>
<tr>
<td>41 Hemorrhage from ruptured vascular aneurysm</td>
<td>66 Other viral hepatitis</td>
<td></td>
</tr>
<tr>
<td>42 Hemorrhage from surgery (not 38, 39 or 41)</td>
<td>67 Liver-drug toxicity</td>
<td></td>
</tr>
<tr>
<td>43 Other hemorrage (not Codes 38-42, 72)</td>
<td>68 Polycystic liver disease</td>
<td></td>
</tr>
<tr>
<td>44 Mesenteric infarction/ischemic bowel</td>
<td>69 Liver failure, cause unknown other</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VASCULAR</th>
<th>LIVER DISEASE</th>
<th>OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td>35 Pulmonary embolus</td>
<td>64 Hepatitis B</td>
<td>80 Bone marrow depression</td>
</tr>
<tr>
<td>36 Cerebrovascular accident including intracranial hemorrhage</td>
<td>65 Other viral hepatitis</td>
<td>81 Cachexia</td>
</tr>
<tr>
<td>37 Ischemic brain damage/Anoxic encephalopathy</td>
<td>66 Liver-drug toxicity</td>
<td>82 Malignant disease, patient ever on immunosuppressive therapy</td>
</tr>
<tr>
<td>38 Hemorrhage from transplant site</td>
<td>67 Cirrhosis</td>
<td>83 Malignant disease (not 82)</td>
</tr>
<tr>
<td>39 Hemorrhage from vascular access</td>
<td>68 Polycystic liver disease</td>
<td>84 Dementia, incl. dialysis dementia, Alzheimer's</td>
</tr>
<tr>
<td>40 Hemorrhage from dialysis circuit</td>
<td>69 Liver failure, cause unknown other</td>
<td>85 Seizures</td>
</tr>
<tr>
<td>41 Hemorrhage from ruptured vascular aneurysm</td>
<td>70 Cholecystitis</td>
<td>86 Diabetic coma, hyperglycemia, hypoglycemia</td>
</tr>
<tr>
<td>42 Hemorrhage from surgery (not 38, 39 or 41)</td>
<td>71 Chronic obstructive lung disease (COPD)</td>
<td>87 Complications of surgery</td>
</tr>
<tr>
<td>43 Other hemorrage (not Codes 38-42, 72)</td>
<td>72 Perforation of bowel (not 75)</td>
<td>88 Air embolism</td>
</tr>
<tr>
<td>44 Mesenteric infarction/ischemic bowel</td>
<td>73 Perforation of bowel (not 75)</td>
<td>89 Seizures</td>
</tr>
</tbody>
</table>

#### 12. FOR ALL DEATHS INDICATE YES/NO

Renal replacement therapy discontinued prior to death:  

If Yes, check one of the following:  

a. Following HD and/or PD access failure  
b. Following transplant failure  
c. Following chronic failure to thrive

#### 13. IF DECEASED RECEIVED A TRANSPLANT

a. Date of most recent transplant  
b. Was kidney functioning (patient not on dialysis) at time of death?  
c. Did transplant patient resume chronic maintenance dialysis prior to death?

#### 14. REMARKS

#### 15. NAME OF PHYSICIAN

#### 16. SIGNATURE OF PERSON COMPLETING THIS FORM

FORM APPROVED

OMB NO. 0938-0448


Form CMS-2746-U3 (8-96)
### DIALYSIS PATIENTS AND TREATMENTS

#### Additions During Survey Period

<table>
<thead>
<tr>
<th>Incenter Dialysis</th>
<th>Self-Dialysis Training</th>
<th>Total Incenter Dialysis</th>
<th>Home Dialysis</th>
<th>Total Home Dialysis</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemo-Dialysis</td>
<td>CAPD</td>
<td>Fields 14 thru 19</td>
<td>Hemodialysis</td>
<td>CCPD</td>
<td>Fields 21 thru 24</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td>Other</td>
<td></td>
</tr>
<tr>
<td></td>
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<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Losses During Survey Period

<table>
<thead>
<tr>
<th>Incenter Dialysis</th>
<th>Self-Dialysis Training</th>
<th>Total Incenter Dialysis</th>
<th>Home Dialysis</th>
<th>Total Home Dialysis</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deaths</td>
<td>Recovered kidney function</td>
<td>Received transplant</td>
<td>Transferred to other dialysis unit</td>
<td>Discontinued dialysis</td>
<td>Other (LTFU)</td>
</tr>
<tr>
<td>04A</td>
<td>05A</td>
<td>06A</td>
<td>07A</td>
<td>08A</td>
<td>09A</td>
</tr>
<tr>
<td>04B</td>
<td>05B</td>
<td>06B</td>
<td></td>
<td>08B</td>
<td>09B</td>
</tr>
</tbody>
</table>

### TREATMENT AND STAFFING

#### Incenter Dialysis Treatments

<table>
<thead>
<tr>
<th>Position</th>
<th>Number of Staff</th>
<th>Number of Open Pos.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. RN</td>
<td>Full Time</td>
<td>Part Time</td>
</tr>
<tr>
<td>b. LPN/LVNs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. PCTs</td>
<td>Full Time</td>
<td>Part Time</td>
</tr>
<tr>
<td>d. APNs</td>
<td>Full Time</td>
<td>Part Time</td>
</tr>
<tr>
<td>e. Dietitians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Social Workers</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Vocational Rehabilitation

<table>
<thead>
<tr>
<th>Patients aged 18 through 54</th>
<th>Patients receiving services from Voc Rehab</th>
<th>Patients Employed full-time or part-time</th>
<th>Patients attending school full-time or part-time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Day</td>
<td>Nocturnal</td>
<td></td>
</tr>
<tr>
<td>Incenter</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THE SURVEY**

This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).

Form CMS-2744A (02/04)
<table>
<thead>
<tr>
<th>PATIENTS TRANSPLANTED AND DONOR TYPE</th>
<th>TO BE COMPLETED BY KIDNEY TRANSPLANT CENTERS ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who received transplant at this facility</td>
<td>Eligibility Status of Patients Transplanted at this Facility During the Survey Period</td>
</tr>
<tr>
<td></td>
<td>Currently enrolled in Medicare</td>
</tr>
<tr>
<td></td>
<td>Medicare Medicare Medicare</td>
</tr>
<tr>
<td></td>
<td>Other Other Other</td>
</tr>
<tr>
<td></td>
<td>42 43 44 45 46</td>
</tr>
<tr>
<td>Transplant Procedures Performed at This Facility</td>
<td>Patients Awaiting Transplant</td>
</tr>
<tr>
<td>Living Related Donor</td>
<td>Living Unrelated Donor</td>
</tr>
<tr>
<td>47 48 49 50</td>
<td>51 52</td>
</tr>
</tbody>
</table>

REMARKS/COMMENTS
access, dialysis. See vascular access
ACE inhibitors 43
acute myocardial infarction (AMI)
mortality and 37
admission rates. See hospitalization:
  admission rates
anemia. See erythropoietin therapy;
hemoglobin
anemia treatment
dialysis unit affiliation and 167
hemoglobin levels 75
hemoglobin levels and 27, 91, 92
at initiation 75

iron therapy 92
  in pediatric patients 136
angiography 151, 152
angiplasty 99, 108
angiotensin receptor blockers
  (ARBs) 43
antibody induction medications 123
antimetabolites 133
arrhythmia 142
arteriovenous fistulas
placement rates 39
arteriovenous grafts
placement rates 39
atherosclerotic heart disease
  (ASHD). See cardiovascular
disease
mortality and 37
bacteremia/septicemia
hospitalization and 104, 105
  in pediatric patients 142
vascular access and 99
Bayesian hospitalization ratios 172
Bayesian mortality ratios 172
bypass, coronary 108
Calcijex 170
calcineurin inhibitors 123
calcium/phosphorus testing 168
CAPD. See dialysis
cardiac arrest. See cardiovascular
disease
cardiovascular disease
diabetes and 52–55
diagnosis & testing 150–153
expenditures and 179
glomerulonephritis and 52, 53,
54, 55
hospitalization and 28, 54, 55, 104,
105, 108, 142, 143, 179
hypertension and 52–55
mortality and 37, 46, 51–53, 58, 59,
109, 143
  in pediatric patients 142, 143
catheters 56, 57, 73, 74, 98, 99, 108,
139, 171, 184. See also vascular
  access
placement rates 39
CBC testing 169
CCPD. See dialysis
cellulitis 104
cholesterol 134
  at initiation 76
chronic kidney disease
dietitian care and 38
expenditures 21, 91, 177
nephrologist care and 38
pre-ESRD counseling and 38
preventive care and 38, 43, 47
Comprehensive Dialysis Study (CDS)
114, 115–119
congestive heart failure (CHF). See also
cardiovascular disease
expenditures 21
hospitalization and 142
mortality and 37
  in pediatric patients 142
counts, patient. See incidence;
  prevalence; transplantation
CPM data 91, 98, 99
creatinine, serum
  at initiation 76
cystic kidney disease
hospitalization and 140
  at initiation 36
mortality and 82, 84
patient counts 22, 65, 67
rates of ESRD due to 22, 65, 67
transplantation and 40
diabetes
diabetes and 52–55
comprehensive monitoring 183
congestive heart failure and 21, 91
ESRD networks and 68
expenditures 21, 91, 180
in the general population 36
hospitalization and 54, 55
infection and 52–55
  at initiation 36
  at initiation 191
international comparisons 191
microalbumin testing 44
modality and 82, 84
monitoring, recommended 91, 96
mortality and 52, 53, 58
patient counts 22, 65, 67
prescription drug therapy and 43
pre-ESRD counseling and 43
preventive care and 43, 47
rates of ESRD due to 22, 42, 47,
55, 67, 68
recommended monitoring 170
survival and 107
transplantation and 40
transplant wait list and 40
dialysis
adequacy 27, 91
ESRD network populations 69
expenditures 30, 31, 178, 180, 182
hospitalization and 28, 104, 105,
140
infection and 104, 105
international comparisons 193
mortality and 29, 103, 106
patient counts
  incident 22, 23, 24, 65, 81, 82
  pediatric 22, 82, 84, 133
prevalent 22–24, 84
patient rates
  incident 22, 24, 25, 82, 83
  pediatric 22, 82, 84
prevalent 22, 25, 84, 85
patients returning from transplant
23, 125

index to Volume Two
patients starting or restarting 23
survival and 22, 107, 140, 141
dialysis unit affiliation
changes over time 163, 164
clinical monitoring and 168, 169
hemoglobin levels and 166
hospitalization ratios and 172, 173
iron therapy and 167
modality and 82, 84
mortality ratios and 172, 173
patient counts and 164
preventive care and 170
time managed 164
transfusions and 167
unit counts and 164
vascular access and 171
vitamin D therapy and 170
dialysis unit location 165
dialysis, withdrawal from 110, 111
dietitian care, pre-ESRD 38, 134
drug therapy, prescription 43
expenditures 31
ECD kidneys 121
ECGs 151, 152
echocardiograms 151, 152
erythropoiesis stimulating agent
(ESA) expenditures 31, 177, 181
at initiation 75
in pediatric patients 135
pre-ESRD use 26
erthropoietin (EPO) therapy, See
also anemia treatment
expenditures 177, 181, 182
in pediatric patients 136
weekly 136
erthropoietin therapy
hemoglobin levels and 92
weekly dose 92
ESRD networks
HP2010 objectives and 46, 47
patient counts, growth in 68, 69
providers and 164
expected remaining lifetimes 106
expenditures. See also Medicare
expenditures
actual and predicted costs 185
before and after initiation 31
CKD 21, 91
ESAs 177
ESRD 21, 30, 31, 91
injectables 31
inpatient 180
non-Medicare 178
outpatient 180
physician/supplier 180
during transition to ESRD 179
eye examinations, diabetic 91, 96,
170, 183
eye exams, diabetic 43, 46
ferritin testing 169
Ferrlecit 167
fistulas, arteriovenous 56, 57, 73, 74,
91, 98, 103, 130, 171, 184. See
also vascular access
glomerular filtration rate (eGFR)
at initiation 74, 76, 77
glomerular filtration rate, estimated
(eGFR)
at initiation 135
in pediatric patients 135
glomerulonephritis
ESRD networks and 68
hospitalization and 54, 55, 140
at initiation 36
modality and 82, 84
mortality and 32, 53
patient counts 22, 65, 67
rates of ESRD due to 22, 65, 67, 68
survival and 107
transplantation and 40
glycosylated hemoglobin levels
at initiation 76
glycosylated hemoglobin testing
in CKD patients 43, 46
dialysis unit affiliation and 170
expenditures 183
guidelines, patients meeting 91, 96
recommended testing 170
grafts, arteriovenous 56, 57, 73,
74, 98, 108, 139, 184. See
also vascular access
graft survival 125, 127
half-lives, graft 124
Healthy People 2010
arteriovenous fistula use 39, 46
cardiocvascular mortality rates
37, 46
diabetic preventive care 43, 46
incident rates 36, 46
incident rates, diabetes 42, 47
pre-ESRD counseling 38, 46
targets 35, 46, 47
transplant recipients 41, 46
transplant wait list 40, 46
vaccinations 45, 46
Hecotorol 170
hematocrit. See anemia treatment;
hemoglobin
hemodialysis, home 86, 87
hemoglobin
anemia treatment and 91, 92, 167
dialysis unit affiliation and 166, 167
EPO dose and 27, 92
ESAs and 75
at initiation 75
at initiation 75
at initiation 75
monthly 27, 92, 156
overshooting of target levels 91, 95,
137, 186
patient distribution and 27, 92
patient distribution by 77
in pediatric patients 135–137
pre-ESRD nephrologist care and 74
target levels 91
undershooting of target levels 94,
137, 166
hepatitis B vaccinations 91, 97, 138,
170
hospice care 110, 111
hospitalization
admission rates 104, 105, 108, 140
all-cause 28, 104, 105, 140, 172, 179
for bacteremia/sepsis 104, 105
142
cardiovascular disease 143
cardiocvascular disease and 28, 54,
55, 108, 142, 179
cause-specific 28, 108
for cellulitis 104, 105
diabetes and 54, 55
4
dialysis unit affiliation and 172, 173
expenditures 179
glomerulonephritis and 54, 55
hospital days 104, 140
hypertension and 54, 55
infection and 28, 54, 55, 108, 142,
143
modality and 104, 105
in pediatric patients 105, 140,
142, 143
for peritonitis 105
for pneumonia 104, 105, 142
ratios 172, 173
vascular access and 28, 104, 105,
108, 142
hypertension
ESRD networks and 68
hospitalization and 54, 55
at initiation 36
modality and 82, 84
mortality and 52, 53
patient counts 22, 65, 67
rates of ESRD due to 22, 65, 67, 68
survival and 107
transplantation and 40
ICDs/CRT-Ds 151, 153
immunizations 45, 47, 91, 96, 97, 138, 170
immunosuppression medications 123, 127
incidence
diabetes and 42, 47, 65
ESRD network populations 68, 69
mean age and 68
median age and 65
modality and 22, 24, 25, 82, 83, 133
patient counts 22, 24, 64, 65, 82
pediatric 22, 64, 82, 133
patient distribution
pediatric 132
patient rates 22, 24, 25, 36, 46, 64, 65, 82, 189, 190
pediatric 22, 36, 64, 82
by payer 65
international comparisons 189, 190, 191, 196, 197
primary diagnosis and 22, 65
projections 63
infection
access and 99, 105
diabetes and 52–55
due to internal device 142
glomerulonephritis and 52–55
hospitalization and 28, 54, 55, 104,
205, 308, 142, 143
hypertension and 52–55
mortality and 51, 109, 143
in pediatric patients 139, 142, 143
vascular access 139
INFeD 167
influenza vaccinations 45, 47, 91, 96,
138, 170
expenditures 183
injectables
expenditures 31, 181
insurance coverage
at initiation 83
modality and 83, 85
iron saturation testing 168
iron therapy 92
dialysis unit affiliation and 167
expenditures 31, 181, 182
in pediatric patients 136
K/DOQI targets 91
Kt/V 57, 91
lifetimes, expected remaining 106
lipid lowering agents 43
lipid testing 151, 152
in CKD patients 43–47
in diabetic patients 43, 47, 91
dialysis unit affiliation and 170
expenditures 183
guidelines, patients meeting 91, 96
in pediatric patients 134
recommended monitoring 170
Medicare expenditures
CKD 21, 91
for clinical services 182
dialysis 30, 31
ESRD 30, 31, 178, 179
growth in 22
home health 178
hospice 178
injectables 31, 181, 182
inpatient 30, 178, 179, 180
laboratory 182
modality and 22, 30
outpatient 30, 178, 180
physician/supplier 30, 178, 180
preventive care 183
skilled nursing 178
during transition to ESRD 179
transplant 30
vascular access 184
microalbumin testing 44
modality
EPO dose and 136
expenditures and 30, 178, 180
hemoglobin levels and 136
home therapies 86, 87
hospitalization and 104, 105, 140
international comparisons 193
iron therapy and 136
mortality and 29, 103
patient counts 22, 23, 82, 84, 133
patient distribution 83, 85
survival and 29, 107, 140, 141
mortality. See also survival
all-cause 29, 31, 106, 107
cardiovascular disease and 37, 46,
51–53, 58, 109, 143
cause-specific 109
diabetes and 52, 53, 58
dialysis unit affiliation and 172, 173
first-year 51–53
glomerulonephritis and 52, 53
hypertension and 52, 53
infection and 51–53, 109, 143
mortality and 29, 103, 106
in pediatric patients 127, 143
predictors of 58, 59
raising 172, 173
in transplant patients 124, 125, 127
vintage and 29, 103
nephrologist care, pre-ESRD 38, 46,
74, 134
networks. See ESRD networks
nutrition. See albumin, serum
obesity. See body mass index
parathyroid hormone (PTH) testing
168
pediatric patients
anemia treatment in 135
bacteremia/septicemia in 142
cardiovascular disease in 143
cardiorenal disease in 142
diabetes in 42
ESA use in 135
growth hormone use in 131, 144, 145
height of 131, 124, 145
hemoglobin and 136
hemoglobin in 135, 137
hospitalization in 105, 140, 142, 143
incidence 132
infection and 143
infection in 139, 142
iron therapy and 136
modality in 133
mortality in 143
patient counts
incident 22, 64, 82, 133
pediatric 133
prevalent 22, 66, 84
patient rates
incident 22, 36, 42, 64, 82
prevalent 22, 66, 84
pneumonia in 142
pre-ESRD care 134
preventive care 138
by primary diagnosis 132
survival in 140, 141
transplantation in 41, 126, 127
transplant wait list and 40
vaccinations in 138
vascular access in 139, 142
wait-listed patients 126
peritonitis 99, 105
pneumococcal pneumonia
vaccinations 45, 91, 97, 138,
370, 183
pneumonia 104, 142
pre-ESRD care
dietitian care 38, 134
survival.
stereoids
stents, coronary
revascularization
recombinant growth hormone
rates, disease.
rapamycin
projections of ESRD counts and
drug information on
prevalence
steroids
stents, coronary
survival. See also mortality
modality and 29, 107
in pediatric patients 140, 141
in transplant patients 29, 124
tacrolimus 123
transfusions, blood 27, 93, 167
transplantation
cardiovascular disease and 125, 127
counts 119, 122, 126
DCD kidneys 122
delayed graft function 124
dialysis, return to 125
donors 119, 122
ECD kidneys 121, 122
ESRD network populations 69
expenditures 30, 178-180
graft failure 124
graft survival 123, 127
hospitalization and 28, 104, 105, 140
immunosuppression 123, 127
infection and 125, 127
international comparisons 194, 195
malignancy and 125, 127
mortality and 22, 29, 103, 106, 121, 125, 127
outcomes after 124
outcomes after listing 121
patient counts
incident 22, 24, 63, 81, 82
pediatric 22, 82, 84, 133
prevalent 22, 24, 63, 81, 84
patient rates
incident 22, 24, 25, 82
pediatric 22, 82, 84
prevalent 22, 24, 25, 84
patients returning to dialysis from 23
in pediatric patient 127
in pediatric patients 126
primary non-function 124
projections 63
rates 122, 126
retransplantation 125
survival and 29, 107, 140, 141
wait list for 24, 40, 46, 63, 81, 120, 126
wait time for 24, 120, 126
within three years of registration 41, 46
transplant options, pre-ESRD
information on 38
triglycerides 134
at initiation 76
units. See dialysis unit affiliation
urea reduction ratio (URR) 27, 91
vaccinations 45, 47, 91, 97, 138, 170, 183
vascular access
current access 39, 46, 91, 98, 99
dialysis unit affiliation and 171
events and complications 99
expenditures 184
first access 39, 91
first-year 56, 57
hospitalization and 28, 104, 105, 108, 142
infection and 104, 139, 142
at initiation 26, 56, 57, 73, 139
in pediatric patients 139
nephrologist care and 74
in pediatric patients 142
placement, probability of 56
placement rates 57
pre-ESRD nephrologist care and 26
Venofer 167
vintage, patient
mortality and 29, 103, 107
vitamin D hormone
expenditures 31, 183, 182
use of 170
wait list for transplantation 24, 40, 63, 81, 120, 126
wait time for transplantation 24, 120, 126
walking disabilities 112, 113, 114, 115
Zemplar 170

ESA use 73, 135
nephrologist care 38, 46, 74, 134
prevalence
diabetes and 67
ESRD network populations 69
mean age and 68
median age and 67
modality and 22, 24, 25, 84, 85
patient counts 22, 24, 63, 66, 67, 81, 84
pediatric 22, 66, 84, 133
unit affiliation and 164
patient rates 22, 24, 25, 66, 67, 84, 189
pediatric 22, 66, 84
international comparisons 189, 192
primary diagnosis and 22, 67
projections 63
prevalence of ESRD
international comparisons 192
preventive care
in CKD patients 38, 43, 47
diabetic 43, 91, 96, 170
expenditures 183
guidelines 91, 96
lipid testing 91
in pediatric patients 138
vaccinations 45, 47, 91, 97, 170
projections of ESRD counts and
costs through 2020 63
rapamycin 123
rates, disease. See incidence;
prevalence; transplantation
recombinant growth hormone 131, 144, 145
revascularization 151, 153
stents, coronary 108
steroids 123
stress testing 151, 152
survival. See also mortality
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