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**Appendix L**

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This appendix describes the USRDS database and its standardized working datasets, specialized code definitions, and common data processing practices. It also details the statistical methods used in this 2002 Annual Data Report. The recently updated Researcher’s Guide to the USRDS Database, published separately, provides additional detail about the USRDS database and Standard Analysis Files.

DATA SOURCES
The USRDS maintains a stand-alone database that includes data on the demographics and diagnoses of ESRD patients, along with biochemical data, dialysis claims, and information on treatment history, hospitalization events, deaths, and physician/supplier services.

REBUS/PMMIS database
The major source of ESRD patient information for the USRDS is the CMS (formerly HCFA) Renal Beneficiary and Utilization System (REBUS), which was adopted in 1995 as the Online Transaction Processing (OLTP) 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.

CMS regularly updates the REBUS/PMMIS database, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the United Network for Organ Sharing (UNOS) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notification forms (2746) obtained from renal providers.

CMS Medicare Enrollment Database (EDB)
CMS’s Enrollment Database is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on beneficiary residence, Medicare as Secondary Payor (MSP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

CMS paid claims records
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, who are most likely non-Medicare patients or beneficiaries who develop ESRD while already on Medicare because of age or disability, will eventually be entered into the 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 service dates for ESRD. These paid claims records are, however, only a supplement to—not a replacement of—other sources of information on incidence and prevalence.

It is important to note that some Medicare-eligible patients may not have bills submitted to and paid by Medicare, including MSP patients covered by private insurance, HMOs, Medicaid, or the Department of Veterans Affairs (DVA).

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

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

♦ All UNOS transplants are accepted into the database.
♦ All CMS transplants before 1988 are accepted.
♦ CMS transplants from 1988 to 1993 are accepted if there is no UNOS transplant record for that patient within 30 days of the CMS transplant.
♦ Transplants indicated on the Medical Evidence 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 Medical Evidence form.

CMS Standard Analytic Files (SAFs)
CMS’s Standard Analytic Files contain data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved.

For Part A institutional claims the USRDS uses the following data:
♦ inpatient, 100 percent SAF
♦ outpatient, 100 percent SAF
♦ home health agency (HHA), 100 percent SAF
♦ hospice, 100 percent SAF
♦ skilled nursing facility (SNF), 100 percent SAF

For Part B physician/supplier claims:
♦ physician/supplier, 100 percent SAF
♦ 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 2002 ADR includes all claims up to December 31, 2000. Patient-specific demographic and diagnosis information, however, includes data as recent as October 2001.

**Annual Facility Survey (AFS)**
In addition to the CMS ESRD databases, independent ESRD patient counts are available from CMS’s Annual Facility Survey, which all dialysis units and transplant centers must complete at the end of each year. The AFS reports counts of patients being 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 information, they do provide independent patient counts used to complement the CMS patient-specific records.

**CDC surveillance**
The Centers for Disease Control and Prevention use their National Surveillance of Dialysis-Associated Diseases to collect information from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination and conversion rates for staff and patients, and the incidence of HIV, AIDS, and tuberculosis. None of the information is patient-specific. The CDC did not conduct a survey in 1998.

**DATA MANAGEMENT & PREPARATION**
The USRDS main computer system is a Compaq Alpha system consisting of one Compaq AlphaServer ES45 with dual EV-68 (1 GHz) and two Compaq AlphaServers DS20 with dual EV-6 (500 MHz) processors, with a total of 11 GB of RAM memory and 1.5 terabytes (1,500 gigabytes) of disk farms, all managed by four interconnecting clusters.

We use the 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 has been integrated into the new database, and its continuity and completeness have been maintained.

**Data loading & cleaning**
All data files come to the USRDS in IBM 3480 cartridges/CD-ROMs with EBCDIC, ASCII, or SAS® formats. Once loaded into the system, files are converted into SAS® data sets for further processing, and a series of data verification steps is exercised to ensure data quality and integrity before updating the USRDS database system.

**Database updates**
For this ADR, patient demographic and diagnosis data are updated through October 2001, and Medicare Part A and Part B claims are collected through December 31, 2000.

**ESRD patient determination**
A person is identified as having ESRD when a physician certifies the disease on the CMS Medical Evidence form (2728), or when there is other evidence that the person has received chronic dialysis or a kidney transplant. Patients who experience acute renal failure and are on dialysis for days or weeks, but who subsequently recover kidney function, are excluded from the database as much as possible. Patients who die soon after kidney failure without receiving dialysis treatment are occasionally missed.

The first ESRD 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 patient survival analyses.

The FSD is derived by taking the earliest of:
- the date of the start of dialysis for chronic renal failure, as reported on the Medical Evidence form,
- the date of a kidney transplant, as reported on a CMS or UNOS transplant form, a Medical Evidence form, or a hospital inpatient claim, or
- the date of the first Medicare dialysis claim.

Most FSDs are obtained from the Medical Evidence form. In the absence of this form, the date of the first Medicare dialysis claim or transplantation 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 Medical Evidence form, the earliest claim date is used as the FSD.

**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 entitlement:
- age 65 and over
- disabled
- ESRD program
- Railroad Retirement Board (RRB)

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. There are, however, some patients who 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), and must wait 30–33 months before becoming eligible to have Medicare as their primary payor. They are therefore not in the EDB database during the waiting period. 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 these patients are designated ‘ZZ’ or non-Medicare (the REBUS/PMMIS group assigns ‘ZZ’ in the two-character Beneficiary Identification Code field to identify all non-Medicare ESRD patients). 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 available in the first 30–33 months after their first ESRD service. Furthermore, it may or may not be possible to link ‘ZZ’ patients to their ESRD Death Notification forms (CMS 2746) or to the UNOS transplant data, and it may be impossible to determine comorbid conditions or Part A and Part B services. Because these data are limited, event rates that include these patients must be assessed with caution.

In order to duplicate the methods used by the previous USRDS contractor we continue to include ‘ZZ’ patients in the mortality rate calculations of the ADR. We are collaborating with CMS and other interested researchers to establish a consistent approach to managing the data for these patients.

**Lost-to-followup methodology**

The USRDS draws on all available data to create a “treatment history” for each patient in the database, showing 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. When these gaps occur the USRDS assumes that a treatment modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain that transplant 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-followup 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 appearance of Medicare dialysis claims, lost-to-followup categorization cannot begin until the end of the third year after first ESRD service. This ‘first three-year rule’ is particularly important for non-Medicare patients. Since it is now 30–33 months before these patients have Medicare as their primary payor, some patients may be followed for up to three years with limited amounts of event or death data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data to the numerator. In comparison to the two-year rule used in the 2001 ADR, this new three-year rule has significantly reduced the number of lost-to-followup patients in the prevalent population (see Figure p.7 in the Précis). Non-Medicare patients, who have been included in the database since 1995, pose a significant challenge to the USRDS and CMS, and methods of tracking them are currently being explored.

A number of events can result in a lack of dialysis data and eventual reclassification of a patient as lost-to-followup:

- The patient may have recovered renal function and no longer have ESRD.
- The patient may have left the country.
- The patient’s dialysis therapy may be covered by a payor other than Medicare, or the patient may have received a transplant not paid for by Medicare and not reported to UNOS.
- The patient may be enrolled in a Medicare HMO, so that Medicare claims for dialysis are not generated even though the patient is eligible for Medicare coverage.
- The patient’s death may not have been reported to the Social Security Administration or to CMS.

### 60-day stable modality rule

This rule requires that a treatment 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. All descriptive data appearing in the incident, prevalent, and modality sections of the 2002 ADR are based on incident and prevalent cohorts produced from the modality sequence without using this rule, making this year’s counts much closer to the numbers reported by the CMS Facility Survey and the ESRD networks’ SIMS census file (see the Précis and Chapter Three). In analyses of patient outcomes such as hospitalization and mortality, in contrast, this 60-day rule is applied.

### 90-day rule

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, this rule is used primarily when calculating survival rates and comparing outcomes by modality at several points in time. Use of this 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 modalities), and from center hemodialysis patients younger than 65 and not disabled, who cannot bill Medicare for their dialysis treatments and hospitalization 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.

### DATABASE DEFINITIONS

#### Modalities

Because different patient modality categories are used throughout the ADR, these categories are defined in the methods sections for each chapter.

#### Primary cause of renal failure

Information on the primary cause of renal failure is obtained directly from the Medicare Evidence form. For the Annual Data Report these disease codes have been grouped into 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
Less commonly occurring diseases

The chapters on incidence, clinical indicators, hospitalization, and mortality present new analyses of patients whose ESRD is caused by one of the less commonly occurring diseases. These diseases are identified by the following ICD-9-CM codes: IgA nephropathy, Berger’s disease, IgM nephropathy, 583.81; Goodpasture’s syndrome, 583.4; lupus erythematosus, 710.0; other secondary glomerulonephritis/vasculitis, 287.0, 283.1, 446.0, 446.4, 583.9, and 446.2; scleroderma, 710.1; Alport’s and other hereditary/familial diseases, 759.8; multiple myeloma and light chain nephropathy, 203.0; and AIDS nephropathy, 042.9.

Race & ethnicity

Information on patient race and ethnicity is obtained from the Medical Evidence form, the CMS Medicare Enrollment Database, and the REBUS identification file. Because they are addressed in separate questions on the Medical Evidence form, racial and ethnic categories can overlap.

Throughout the ADR we have included information on Hispanic patients. Most rate calculations that include these data begin with 1996, the first full year after the introduction of the revised Medical Evidence form, in which patient ethnicity is a required field. Reference tables, however, contain Hispanic data starting in 1995, though these data may be incomplete. The non-Hispanic category includes all non-Hispanics and patients whose ethnicity is unknown.

Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we have concentrated throughout the ADR on white, black, Native American/Alaskan Native, and Asian/Pacific Islander populations. As the numbers of patients of other races increase, data on them will be presented in the ADR.

PRÉCIS

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

Figures p.9–16 contain information on ESRD patients age 67 or older without Medicare as a secondary payor or HMO coverage. These patients have Medicare coverage for at least two years prior to the initiation of renal replacement therapy, allowing us to investigate delivered services by analyzing claims in this time period.

Figure p.17 addresses diabetic preventive care in the two years prior to the start of ESRD therapy, using a patient cohort of 1999 incident diabetic ESRD patients age 67 or older. Those with Medicare as a secondary payor or with HMO coverage during 1999 are omitted. Codes to identify glycosylated hemoglobin testing, diabetic eye exams, and lipid testing are described in the discussion of Chapter Five. Claims within 30 days of the last claim for each patient are excluded.

Figures p.18–23 illustrate patient complexity as defined by diabetes, chronic kidney disease (CKD), anemia, and congestive heart failure (CHF), and show as well the risks of death and of developing ESRD in the general Medicare population. Study cohorts are derived from the five percent Medicare file for 1996–1999. We include patients who were continuously enrolled in both Medicare Part A and Part B in the periods 1996–1997, 1997–1998, and 1998–1999, alive on the last day of the two-year observation periods, and resided in the 50 states or the District of Columbia. Patients are excluded if they were enrolled in a managed care program (HMO), became Medicare as secondary payor (MSP) patients, or were diagnosed with ESRD anytime between 1996 and 1999.

A previously validated methodology is used to identify patients with diabetes. According to this methodology, a patient is diabetic if, within a two-year observation period, he or she has one or more claims with a diabetes diagnostic billing code from Part A services (inpatient hospitalization, skilled nursing facility, or home health agency), or two or more claims from either Part A (outpatient institutional claims) or Part B (physician/supplier services). We apply the same methodology to determine the CKD, anemia, and CHF status for each patient. Patient age is calculated as of the first day of each two-year observation period.

Figure p.18 shows the origins of ESRD patients in the general Medicare population. To track the development of ESRD and its relationship to certain comorbid conditions, all Medicare patients without a diagnosis of ESRD during 1997–1998 are followed for one year starting January 1, 1999. Patients are characterized as having diabetes, CKD, CHF, any combination of the three, or none of them. We calculated the proportion of non-ESRD patients in each disease group, and then the proportion, by disease group, of patients who developed ESRD during the followup period.

Figures p.19–21 display the prevalence of diabetes and CKD in the general Medicare population. In Figure p.21 the percent of patients diagnosed with diabetes and CKD is calculated for each of the 50 states and the District of Columbia. Adjustments for age, gender, and race are made using the model-based adjustment method with a Poisson distribution (discussed in the statistical methods section). The reference population is the group of non-ESRD Medicare patients, 1998–1999, age 65 or older and residing in the 50 states or the District of Columbia.

Figures p.22–23 show the risks for death and development of ESRD in the general Medicare population. Non-ESRD Medicare patients during 1996–1997 are followed from January 1, 1998 to December 31, 1999 to see if they developed ESRD or died. Patients are characterized by their diabetes and CKD disease status during 1996–1997.
Figures p.26–27 show the number of hospitalizations per 1,000 patient years at risk for period prevalent hemodialysis, peritoneal dialysis, and transplant patients of different vintages. Vintage is defined as the time from the first ESRD service date until January 1 of the year for prevalent patients, or, for incident patients, as less than one year. Figure p.27 presents data by year for 1996 to 2000, with the year representing the period prevalent year, and with the vintage group representing the number of years following the first ESRD service date. A patient with a first service date of April 5, 1996, for example, is included in the <3 year group for 1996–1999, and in the 3+ year group in 2000. All-cause and cause-specific rates (CHF, ISHD, other cardiovascular, infection, and other) are defined by the principal ICD-9-CM codes used in Figures 6.9–10, listed in the discussion of Chapter Six.

Figures p.28–29 display total hospital admissions per 1,000 patient years and total hospital days per patient year, by HSA, for 2000 period prevalent dialysis and transplant patients. Calculation of these unadjusted rates follows methods used in the morbidity and hospitalization section.

Figures p.30–31 and p.33 use 1998–2000 period prevalent cohorts of hemodialysis, peritoneal dialysis, and transplant patients. Cohort definitions are similar to those used in Reference Tables H.2–6. Cause of death categories are as follows:

- CHF: cardiomyopathy or pulmonary edema due to exogenous fluid
- ISHD: acute myocardial infarction or atherosclerotic heart disease
- Other cardiovascular: pericarditis, cardiac dysrhythmia, cardiac arrest, valvular heart disease, cerebrovascular accident, and ischemic brain damage
- Infection: pulmonary infection, septicemia, viral hepatitis, tuberculosis, AIDS, fungal peritonitis, and other infections
- Other causes: all other causes of death, including missing and unknown causes

Mortality rates in Figure p.32 are estimated using the same methods used for Tables H.14–16. Methods for Figures p.36–37 are presented in the section describing Chapter Twelve, under the discussion of the “CMS model.”

HEALTHY PEOPLE 2010

The 2010 targets in Figure hp.1 came directly or were estimated from data supplied in the Healthy People 2010 chapter on chronic kidney disease. The 2000 data in this figure are obtained using the methods specified for each objective.

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

Objective 4.2: Data for this objective include prevalent dialysis patients, 1996–2000. Cardiovascular death and disease are defined using CMS codes: for death, 27 and 31 (CHF), 26 (ASHD), 02 and 23 (MI), and 01, 04, 25, 28–30, and 36–37 (other), and for disease, 01, 02, 04, 23, 25, 26, 27, 28–31, 36–37.

Objective 4.4: For Figures hp.8–10, the calculation of fistula insertion rates follows methods similar to those described for Chapter Four. For Table hp.c, data are obtained from the Dialysis Morbidity and Mortality Study (DMMS) Wave 1 and Wave 2, and from the CMS Clinical Performance Measures (CPM) Project, also described in the discussion of Chapter Four. To obtain consistent information on race and ethnicity, patients included in the DMMS and CPM datasets are matched to the ESRD database using UID numbers.

Objective 4.5: Medicare patients younger than 70 from 1998–2000 are included in the study cohort for Figures hp.14–15 and Table hp.e. Proportions are calculated as the number of patients on the transplant waiting list on December 31 of the calendar year divided by all prevalent dialysis patients alive on the same day. Waiting list counts are obtained from UNOS data.

Objective 4.6: The study cohort includes Medicare patients, 1995–1997, who are younger than 70 and receive first-time transplants from cadaveric donors. Data from 1992–1994 are combined to determine a baseline. Patients are followed for three years, from placement on the waiting list until the first of: removal from the waiting list, death, transplant, or censoring at three years post-transplant. Waiting list counts are obtained from UNOS data.

Objective 4.7: Incident rates for Figures hp.18–20 and Table hp.g are calculated using the methods described for Chapter One.

Objective 4.8: The calculation of percentages and selection of the study population in these analyses follow methods similar to those used in Chapter Five. For this study, the population includes individuals diagnosed with diabetes in 1997, 1998, or 1999, continuously enrolled in Medicare between 1996–1997, 1997–1998, or 1998–1999, age 67 and older on the last day of 1997, 1998, or 1999, and residing in one of the 50 states. Patients are excluded if they are enrolled in a managed care program (HMO), become a Medicare as secondary payor patient, or are diagnosed with ESRD during any of the two-year periods.

INCIDENCE & PREVALENCE · CHAPTER ONE & REFERENCE SECTIONS A & B

Incidence is defined as the number of people in a population who are newly diagnosed with a disease in a given time period,
typically a year. Prevalence is characterized as the number of people in a population who have the disease at a given point in time (point prevalence) or during a given time period (period prevalence). The USRDS generally reports point prevalence—the type of prevalence used throughout most of the Annual Data Report—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 year’s end.

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. The terms incidence and prevalence are thus qualified as incidence and prevalence of reported ESRD. Some ESRD registries, such as the European Dialysis and Transplantation Association, use the term “acceptance into ESRD therapy.” The USRDS, however, believes 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.

As discussed earlier, patients are classified as lost-to-followup if they have had ESRD for at least three years but have had no reported data on dialysis, death, or transplant for one year. Beginning with the 1992 ADR, lost-to-followup patients are not included in the point prevalent counts; they are, however, reported separately in Tables B.1 and B.a of the Reference Tables.

Because it measures the current burden of a disease on the health care delivery system, point prevalence is a useful measure for public health research. Period prevalence is appropriate for cost analysis, since it indicates total disease burden over the course of a year. We have chosen, however, to focus primarily on the incidence of ESRD, as we believe that it is the most useful measure for medical and epidemiological research examining disease causality and its effect on different subpopulations.

For Figure 1.1, a map of the odds ratios of developing ESRD, incident data are obtained from CMS, while population counts are obtained from the U.S. Census Bureau. A logistic regression is used to compare the incidence of ESRD by location, with ESRD (yes or no) as the dependent variable. Explanatory variables include incident year, race (white and black), gender, age (20–44, 45–64, 65–74, and 75+), and location (50 states plus the District of Columbia).

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-followup patients.

Because the U.S. population figures (presented in Reference Section L) used for this report include only residents of the 50 states and the District of Columbia, tables focus on patients from these areas as well. The exceptions are Tables A.1, A.a, A.9–15, and A.c–i, 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.

Reference Section B

With the exception of Tables B.1, B.2, B.11, and B.b, these tables focus on patients who are residents of the 50 states and the District of Columbia. Age is calculated as of December 31.

PATIENT CHARACTERISTICS · CHAPTER TWO & REFERENCE SECTION C

Data used in both Chapter Two and Reference Section C are obtained from the CMS Medical Evidence form (2728). This form is completed at the dialysis unit for each new ESRD patient treated at that unit, and is sent to CMS through the ESRD networks. It serves to establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, reclassify previously eligible Medicare beneficiaries as ESRD patients, and provide 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 the revised form in 1995, however, dialysis providers are now required to complete the form for all new ESRD patients, regardless of Medicare eligibility. The revision also contains new fields for comorbid 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 was revised for the new form, the USRDS stores the codes reported on each version so that detail is not lost through trying to convert one set of codes to the other.

The data in Tables C.4–16 are restricted to patients for whom the first Medical Evidence form (2728) is a new form and is certified within 12 months of the first service date; total patient counts for this group, and for patients with no 2728 form, are in Table C.3.

Figures 2.32–33 display, by estimated glomerular filtration rate, event curves for hospitalization and survival in 1998 and 1999 incident dialysis patients. Patient inclusion criteria, as well as the modeling strategy used to produce adjusted survival rates, follow those used for the adjusted rates in Figures 6.16–19 and 9.10–13, described later in this appendix. Adjusted survival probabilities presented by eGFR are adjusted for age, gender, race, ethnicity, primary cause of ESRD, and BMI. Kaplan-Meier estimates are used to create the unadjusted survival curves.

TREATMENT MODALITIES · CHAPTER THREE & REFERENCE SECTION D

Chapter Three and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-
followup. In this year’s ADR, we have introduced many tables describing modality-specific data on incident patients, using analyses applied in the past primarily to point prevalent patients.

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, and 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)

The third section, Tables D.9–10, presents counts of prevalent patients alive at the end of each year, by ESRD exposure time and modality. Table D.9 shows counts by the number of years the patient has had ESRD, while Table D.10 shows 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 INDICATORS OF CARE · CHAPTER FOUR**

Data underlying the figures in this chapter are obtained from several sources. Erythropoietin (EPO) dose information and hemoglobin values (calculated from hematocrit values) in Figures 4.1–21 and 4.34–49 are obtained from EPO claims data, while in Figures 4.21 and 4.30–33 Part B physician/supplier claims data supply the CPT codes indicating the insertion of temporary and permanent central venous access and simple fistulas. The information in Table 4.a and Figures 4.8, 4.9, 4.22, and 4.26–28 is obtained from the CMS ESRD Clinical Performance Measures Project (CPM, formerly the ESRD Core Indicators Project). Data on urea reduction ratios (URRs) in Figures 4.22–25 come from Part A institutional outpatient claims. And Figures 4.28–29 contain data from the CDC’s annual National Surveillance of Dialysis-Associated Diseases. All figures include data from Medicare patients only.

Figure 4.1 shows the mean hemoglobin, weekly EPO dose, and number of monthly iron vials for hemodialysis patients, 1991–2000. The data for each year include prevalent hemodialysis patients with at least one EPO claim during the year and ≤20 EPO administrations per month. Time at risk begins on January 1 for prevalent patients and on day 91 of ESRD for incident patients, and is censored at the earliest of modality change, loss-to-followup, death, or December 31. Each patient’s yearly mean hemoglobin is calculated from claims during the time at risk, and the average of these values is calculated for each year.

The weekly EPO dose for each patient is calculated as the total units in the year divided by the number of weeks at risk during the year. (This mean dose does not, however, take into account the actual number of weeks that EPO is administered, for there may be gaps in administrations due to missed or held doses. These averages may thus overestimate the weeks in the denominator and underestimate the true EPO dose per week.) To obtain the yearly average of EPO dose per week across all patients, the patient averages are weighted based on the average number of administrations per month (calculated as the total number of administrations divided by the total time at risk in months), and a weighted mean weekly EPO dose is obtained for each year. For hemodialysis patients, a weight of 1 is given to patients with an average of >11–14 administrations per month. Time at risk begins on January 1 for prevalent patients and on day 91 of ESRD for incident patients, and is censored at the earliest of modality change, loss-to-followup, death, or December 31. Each patient’s yearly mean hemoglobin is calculated from claims during the time at risk, and the average of these values is calculated for each year.

The following weights are assigned to hemodialysis patients with at least one EPO claim during the year and ≤20 EPO administrations per month. Time at risk begins on January 1 for prevalent patients and on day 91 of ESRD for incident patients, and is censored at the earliest of modality change, loss-to-followup, death, or December 31. Each patient’s yearly mean hemoglobin is calculated from claims during the time at risk, and the average of these values is calculated for each year.

The second section, Table D.8, shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 1996 to 1998. 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 date of first ESRD service.
Figures 4.2–4 include data from all incident hemodialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each month for the following six months. In Figure 4.2, 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 each patient in each month, the total number of months divided by the number of weeks at risk during the month (patients may not be at risk during the entire first month of dialysis if they became incident in the middle of the month). For each month, a weighted mean weekly EPO dose is calculated across patients by weighting each patient’s mean weekly dose by the number of administrations during the month. The weights used are the same as those in Figure 4.1, with the exception that for each month the actual number of EPO administrations is used to determine the weighting, as opposed to the average number of EPO administrations per month across the entire time period, as in Figure 4.1. In Figure 4.4, for each month, each patient is classified as receiving iron if he or she has an iron claim in that month or in one of the previous months (but after becoming ESRD). The percent of patients receiving iron then represents a cumulative percent of patients receiving iron since starting ESRD therapy. (Because iron data is complete only through the end of 2000, Figure 4.4 includes only those patients incident on or before June 1, 2000.)

Figures 4.5–7 include incident dialysis patients who have an EPO claim within the first 30 days of becoming ESRD, at least one EPO claim during each month for the following six months, and a hematocrit listed on the Medical Evidence form. Patients are placed into hemoglobin groups (hematocrit divided by three) based on this hematocrit value. Monthly hemoglobin, iron dose, and EPO dose are calculated as in Figures 4.2–4, except that the values shown represent data from 1995–2000 combined. For Figure 4.6, the weights assigned to hemodialysis patients for each month are the same as in previous figures; for peritoneal dialysis patients, the following weights are assigned to patients with the given number of monthly EPO administrations: 1 for >4–7; $\frac{4}{7}$ for >3–4 or >7–8; $\frac{3}{7}$ for >2–3 or >8–9; $\frac{2}{7}$ for >1–2 or >9–10; and $\frac{1}{7}$ for >0–1 or >10–20.

Table 4.a presents data from the Clinical Performance Measures Project and the USRDS database. The table includes only patients appearing in both databases, and compares the classification of patients in each. Using each database separately, we have categorized patients by modality, age, gender, race, ethnicity, and primary diagnosis. The “Medicare/non-Medicare” classification in the CPM data is, however, done using the USRDS database: patients who are in both databases are classified as “Medicare” if they have at least one Medicare claim during 1999, or are identified in the USRDS database as being enrolled in an HMO or having Medicare as secondary payor status at any point in 1999.

Figures 4.8–9 include patients from both Medicare claims data and the Clinical Performance Measures Project. To make the two cohorts as similar as possible we selected Medicare claims from each year (1997–2000) for all prevalent hemodialysis and peritoneal dialysis patients who, in the previous year, were age 18 or older as of September 30, began dialysis on or before April 1, and were alive and still on dialysis as of December 31. Claims included are only those for services performed during the CPM survey periods (for hemodialysis: October–December of previous year; for peritoneal dialysis in 1997–1998: November of previous year through April of prevalent year; for peritoneal dialysis in 1999 and 2000: October of previous year through March of prevalent year). Iron use is defined as at least one iron claim during the CPM survey periods; mean hemoglobin and mean EPO dose per week are calculated and weighted using the same methods used in Figures 4.2–4. For the CPM data, the average EPO dose per week represents the prescribed dose.

Figures 4.10–11 display hemoglobin and EPO dose information by modality and patient demographics. Mean hemoglobin and mean EPO dose per week are calculated as in previous figures.

Figures 4.12–13 present the distribution of patients by mean hemoglobin group. Figure 4.12 illustrates this distribution on a monthly basis, in which each month contains all patients with at least one EPO claim during the month. Figure 4.13 shows this distribution on a rolling three-month basis, in which each month contains all patients who have three consecutive months with at least one EPO claim in each month; the average for each patient is the average hemoglobin on the claims from all three months.

Figure 4.14 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for prevalent dialysis patients with EPO claims and ≤20 administrations per month.

Figures 4.15–16 display mean hemoglobin level and EPO dose per week by geographic region, calculated as in previous figures. The maps are smoothed using the iterative head-banging method, described in the discussion of statistical methods at the end of this appendix.

Figures 4.17–20 show mean hemoglobin level and EPO dose per week by the number of infections per patient year. Data include period prevalent hemodialysis patients with at least one EPO claim in 2000, and exclude MSP patients. For each patient, the number of infections represents the number of inpatient hospital stays, per patient year at risk, with an infection as the principal diagnosis. Figures 4.17–19 show all-cause infections (ICD-9-CM codes are listed in the discussion of the methods used in Chapter Six), while Figure 4.20 shows catheter infections (ICD-9-CM diagnosis code of 996.62). Figures 4.19–20 include only those patients with at least 0.3 patient years at risk—that is, they must be prevalent hemodialysis patients who are alive and not in the hospital for at least 30 percent of the year. The maps in Figures 4.17–18 are smoothed using the Bayesian method, described later in this appendix.

Figure 4.21 displays mean hemoglobin level and EPO dose per week by the number of catheter (temporary and permanent) insertions per patient year at risk. Data include period prevalent hemodialysis patients with at least one EPO claim in 2000, and exclude MSP patients. Part B physician/supplier claims provide
the CPT codes for insertions (36489, 36491, 36800, and 36533). Additional methods are used to exclude catheters inserted for purposes other than dialysis. A CPT code of 36489, 36491, or 36533 is included only if it is associated with either a line-level diagnosis code or a claim-level principal diagnosis code among the following ICD-9-CM codes related to dialysis or renal failure: 250, 403, 580–589, 593, 996.1, 996.62, 996.73, V45.1, and V56. Additionally, Part B physician/supplier and durable medical equipment claims are searched for chemotherapy (CPT codes 96408, 96410, and 96412) and parenteral nutrition (CPT codes B4164–B5200, B9004, B9006, and B9999) claims. Patients with any of these codes during the year are excluded.

Figure 4.22 illustrates trends in urea reduction ratios (URRs), using data from Medicare claims and the CPM Project. Claims data include period prevalent hemodialysis patients with at least one claim containing URR information during October through December of their prevalent year, beginning regular dialysis on or before April 1, and alive and still on dialysis as of December 31. To closely mirror the CPM data collection methodology, only the first claim containing URR information each month (October, November, December) is used. Each patient’s URR range is obtained from the “G” modifier attached to CPT code 90999 with revenue codes of 821 or 825. For each patient, a median URR range is calculated from these claims; for patients with an even number of URR ranges, the two middle values are given a weight of 0.5. The CPM data is calculated in the same way; each URR measurement is categorized into ranges, and a median range is determined for each patient. The URR is calculated from the reported pre- and post-BUN measurements, which represent the first pre- and post-BUN for the month. For the CPM data in this figure, the years reported represent the year the data was collected (e.g. 1999 data comes from the “2000 CPM data set”).

Figures 4.23–25 display trends in URR levels, using Medicare claims data. The methods are the same as those used in Figure 4.22, except that all claims during the entire year are used. Figure 4.24 is smoothed using the Bayesian method, described in later in this appendix.

Figures 4.26–27 use CPM data, and show trends in weekly Kt/V (peritoneal dialysis patients) and weekly creatinine clearance (hemodialysis patients) by unit profit status and type.

Figures 4.28–33 display information about access insertion rates. Data from the CPM Project are used for Figure 4.28, data from the CDC’s National Surveillance of Dialysis-Associated Diseases in the United States are used for Figures 4.28–29, and Medicare claims data are used for Figures 4.30–33. The maps in Figure 4.33 are smoothed using the Bayesian method, discussed later in this appendix.

Figures 4.30–33 show rates per 1,000 patient years at risk, using event information obtained from Part B physician/supplier claims with the following CPT codes:

- temporary catheters: 36489, 36491, and 36800
- permanent catheters: 36533
- fistulas: 36819, 36821, and 36825
- grafts: 36830
- angioplasty: 35460, 35476, and 75978
- declot procedures: 35875, 36831, 36860, 36861, 37201, and 75896
- revisions: 35190, 35876, 35900, 35903, 35910, 36534, 36535, 36815, 36832, 36834, 37190, 37607, M0900, and 36833
- stents: 37205, 75960, 37206, 37207, and 37208

In the calculation of insertion rates for temporary and permanent central venous catheters, additional methods are used to exclude catheters inserted for purposes other than dialysis; see the discussion of Figure 4.21.

For Figure 4.32, physician specialty is obtained from the physician specialty code on Part B physician/supplier claims:

- surgery: 02, 23, 33, 77, and 78
- radiology: 30 and 94
- anesthesiology: 05 and 43
- nephrology: 39

Figures 4.34–49 display hemoglobin levels, iron use, and EPO dose per week by rare disease status. Prevalent hemodialysis and peritoneal dialysis patients, 1999–2000 combined, are classified each year based on mean EPO dose, mean hemoglobin, and iron use for that year; the values in the figures are aggregated across both years. The mean EPO dose per week is calculated and weighted with the same methods used in previous figures. Diseases are identified using the principal diagnosis codes and trailer codes in the USRDS database.

PREVENTIVE HEALTH CARE MEASURES · CHAPTER FIVE

Methods and codes used to determine screening rates for breast and cervical cancer, diabetic eye exams, and glycosylated hemoglobin testing (HbA1c) are taken directly from HEDIS® 2002 specifications (HEDIS® 2002 is a program of the National Committee for Quality Assurance, and is used to monitor the performance of managed health care plans). Because HEDIS® 2002 does not address prostate cancer, lipid testing, or influenza or pneumococcal vaccinations, algorithms for these analyses have been created by the USRDS. Screening rates are determined for both incident and prevalent ESRD patients.

Patients who have Medicare as a secondary payor, who are not eligible for Medicare, or who are enrolled in an HMO are omitted from all analyses. Also omitted are those 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, and, for diabetic eye exams, HbA1c, and lipid testing, who are non-diabetic. Data on influenza and pneumococcal vaccinations exclude those without Part B eligibility during the reporting period.

Age is generally calculated based on the last date of the reporting period. For patients selected for comparisons of pre-ESRD and post-ESRD, age is calculated based as of the first date of ESRD.

Analyses of pre- and post-ESRD preventive care include only patients age 67 or older; the 90-day rule (described under “Data Management and Preparation” at the beginning of this appendix) is not applied to this cohort. Patients age 65–75 constitute
the study cohort for analyses of diabetic care in ESRD and non-ESRD populations. The population examined for breast cancer screening includes females age 52–69; for cervical cancer screening, females 21–64; and for prostate cancer screening, males 50 or older. All ages are calculated as of the last date of the reporting year. Data for the non-ESRD population are obtained from the five percent general Medicare sample, with ESRD patients excluded.

In Figure 5.1 the numerator includes all patients receiving an influenza vaccination in the last four months of 1999, while the denominator includes all prevalent hemodialysis patients initiating therapy before September 1, 1999. Figures 5.2–3 display rates of hospitalization and death in the winter of 2000 (January 1–March 31). For these figures we use the same denominator used in Figure 5.1, except that patients dying during the winter of 2000 are excluded in Figure 5.2.

Figure 5.4 presents the percentage of patients vaccinated against influenza before and after the start of ESRD therapy. The cohort includes patients initiating therapy between January 1 and August 31, 1999, and vaccination rates are calculated for patients receiving one vaccination between September 1 and December 31 (of 1998 for pre-ESRD, and 1999 for post-ESRD).

The analysis of pneumococcal pneumonia vaccination rates (Figures 5.5–6) includes patients initiating therapy in 1997. Rates are calculated for the two years prior to and following the start of ESRD therapy; in Figure 5.6, the numerator includes vaccinations given any time during this four-year period.

Influenza vaccinations are identified through CPT codes of 90724, 90657, 90658, 90659, and 90660, and through a HCPCS code of G0008, while pneumococcal vaccinations are established through CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009. Lipid testing is identified through CPT codes 80061, 82465, 83715–83721, and 84478.

Analyses of diabetic care in the pre- and post-ESRD periods (Figures 5.7–9) include patients whose diabetes is diagnosed at least one year prior to the start of ESRD. For patients whose primary cause of ESRD is diabetes, diabetic eye examinations are counted in the one year prior to or following ESRD; for other diabetic patients, examinations are counted in the prior or following two years. Lipid and glycosylated hemoglobin (HbA1c) testing rates are calculated for the one year prior to and one year following the start of ESRD.

Figure 5.10 illustrates rates of diabetic eye examinations in the ESRD and non-ESRD populations. The ESRD cohort includes patients initiating therapy prior to January 1, 1998, alive on December 31, 1999, and with diabetes in 1999. The non-ESRD population includes patients continuously enrolled in both Medicare Part A and Part B in 1998 and 1999, and with diabetes in 1999. Examinations are counted during 1998 and 1999.

For comparisons of lipid monitoring and glycosylated hemoglobin testing (Figures 5.12, 5.14, and 5.16), the ESRD population includes patients initiating therapy prior to January 1, 1999, alive on December 31, 1999, and with diabetes in 1999. The non-ESRD population consists of patients continuously enrolled in both Medicare Part A and Part B in 1999, and with diabetes in 1999. Rates include patients receiving at least one test during 1999. In Figure 5.16, glycosylated hemoglobin claims made within 30 days of the last claim for each patient are excluded.

Figures 5.11, 5.13, and 5.15 compare diabetic testing in the dialysis and transplant populations. For eye examinations, the cohort includes patients initiating therapy prior to January 1, 1999, alive on December 31, 2000, and carrying a diagnosis of diabetes in 2000. For patients whose primary cause of ESRD is diabetes, examination rates are calculated for patients receiving one examination in 2000; for other diabetic patients, rates are calculated for 1999–2000. Cohorts for lipid and glycosylated hemoglobin testing include patients initiating therapy prior to January 1, 2000, and with diabetes in 2000; rates are calculated for patients receiving one test during 2000.

The cohort for breast cancer screening includes patients initiating therapy prior to January 1, 1999; data are searched for patients receiving one mammogram during 1999 or 2000. Cohorts for cervical and prostate cancer screening include patients starting therapy before January 1, 1998; data are searched for patients receiving one screening test during the 1998–2000 period.

Cancer screening rates in the ESRD and non-ESRD populations are compared in Figures 5.21, 5.23, and 5.25. In the ESRD populations, the cohort for breast cancer screening includes patients initiating therapy prior to January 1, 1998, while the cohorts for cervical and prostate cancer screening include patients starting before January 1, 1997. The non-ESRD population includes patients continuously enrolled in both Medicare Part A and Part B during 1998–1999 (breast cancer screening) or 1997–1999 (cervical and prostate cancer screening); rates include patients who received one screening during that same period.

For prostate cancer screening, patients are excluded if their claims contain any of the following codes: ICD-9-CM procedure codes of 60.2, 60.21, 60.29, 60.3, 60.4, 60.5, and 60.62, or CPT codes of 52601, 52612, 52614, 55801, 55810, 55812, 55815, 55821, 55831, 55840, 55842, and 55845. Codes used to identify patients who receive screening include CPT code 84153; revenue codes of 0300 and 0310, associated with an ICD-9-CM diagnosis code of 185 or 233.4; and ICD-9-CM procedure codes of 60.11, 60.12, 60.18, 87.92, and 91.39.

Screening intervals for cervical and prostate cancer include the reporting year and the two prior years; for breast cancer, the reporting year and the prior year; for glycosylated hemoglobin and lipid testing, the reporting year only; for diabetic eye exams for ESRD patients, the reporting year and the prior year if diabetes was not the cause of renal failure, otherwise, the reporting year only; for diabetic eye exams for non-ESRD patients, the reporting year and the prior year; for influenza vaccinations, September 1 through December 31 of the reporting year; for pneumococcal pneumonia vaccinations, the reporting year and the prior year.
Morbidity & Hospitalization: Chapter Six & Reference Section E

Methods used for this chapter generally echo those used for the tables in Reference Section E (described below). Inclusion and exclusion criteria are the same, as are the methods for computing hospitalization rates. Part A inpatient institutional claims are used for the analyses unless otherwise specified, and the methodologies for excluding MSP and HMO patients are applied here as well, as detailed in the discussion of Section E.

New to this year’s ADR, only certain consecutive hospitalizations that occur with no days between discharge and the following admission are combined into one hospitalization, defined from the first admission date to the last discharge date. All overlapping hospitalizations, as well as those consecutive hospitalizations with a discharge transfer code or interim claim status, are combined, while consecutive hospitalizations without a discharge transfer code or interim claim status are defined as separate events. This method is described further under the Section E methods.

Also new to this year’s ADR, Figures 6.2 and 6.10–15 present hospitalization data for general Medicare patients, using the Medicare five percent data. We selected prevalent patients from 1998 and 1999 who had Medicare Part A or B coverage during the year, excluding those with inconsistent coverage that ended and then resumed during the year. ESRD patients and patients with HMO coverage anytime during the year are also excluded for that year. Included general Medicare patients are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. A two-year entry period (1996–1997 for 1998 patients and 1997–1998 for 1999 patients) is used to characterize patients as diabetic/non-diabetic and CKD/non-CKD. Only patients meeting the following criteria during the entire two-year entry period are selected: non-ESRD, with no HMO coverage, alive, and with Medicare Part A or B coverage. Patients are classified as having diabetes or CKD based on entry-period claims; at least one inpatient, home health, or skilled nursing claim, at least two outpatient claims, or at least two Part B claims for the condition are required for classification. Patients are followed from the first day of the first month of the year with Medicare Part A or B coverage until the earliest of death, the last day of the last month with coverage during the year, or December 31. Medicare institutional inpatient claims provide hospitalization data, and all overlapping and selected consecutive hospitalizations are combined using the same method described above for ESRD patients.

Where patients are classified by primary cause of ESRD as diabetic and non-diabetic, the non-diabetic category includes patients with causes that are missing, unknown, or other than diabetes. The “other” race category includes patients with missing race, or races other than white or black. Figures 6.3–4, 6.6, 6.15–19, and 6.22 present data for Hispanic patients according to the ethnicity classification on the CMS Medical Evidence form. Patients whose ethnicity is reported as unknown, missing, or other than Hispanic are included in the non-Hispanic category.

Figure 6.1 presents admission rates per 1,000 patient years for 1991–2000 period prevalent ESRD patients, with corresponding patient distributions by age and diabetic status, and Figure 6.2 presents the same for non-ESRD general Medicare patients in 1998 and 1999. Both unadjusted and adjusted rates are presented, with 1999 ESRD patients as the reference population for the adjusted rates. Rates are adjusted using the direct adjustment method for age (0–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other), and primary cause of renal failure (diabetes and non-diabetes).

Data for Figures 6.3–4 are calculated using different methods. Data on hospital days per patient year at risk include only days within the analysis period, while data on hospital days per admission include all days for hospitalizations in which the admissions occur within the analysis period, even days occurring after the period has ended. The number of days per admission in Figure 6.3 thus represents the mean length of stay per admission for hospitalizations beginning within the time at risk for the given year. The number of days per patient year at risk in Figure 6.4, however, includes only those hospital days that fall within the time at risk, regardless of the admission date.

Data from 1998 to 2000 are combined in Figures 6.5–6, which illustrate the mean number of hospital admissions per year at risk by gender and modality in combination with age, race, or ethnicity. Figures 6.5–6 exclude patients with missing gender, while Figure 6.5 also excludes those with missing age. Figure 6.6 includes only patients who are white, black, Native American, Asian, or of Hispanic ethnicity.

Data on the frequency of principal procedures and diagnoses (Figures 6.7–8) are obtained from Part A inpatient institutional claims. Patients with missing values for gender or age are excluded. The time at risk for each procedure is censored at the end of the year, death, or three days prior to transplant. As in the total admission rates presented in the hospitalization reference tables, inpatient rates are calculated by subtracting the days spent in the hospital for each procedure or diagnosis from the total time at risk for admission for that procedure or diagnosis.


Figure 6.9 displays unadjusted total admission rates per 1,000 patient years for 1999 prevalent dialysis patients age 65 and older. Rates are presented by primary cause of ESRD (diabetes, hypertension, glomerulonephritis, cystic kidney, and other, which includes missing or unknown causes). Infectious hospitalization is defined by the principal ICD-9-CM codes used in Figures 6.7–8, while cardiovascular hospitalization is defined by the following...
therefore, direct comparison of adjusted rates is appropriate only when rates are adjusted for each of the remaining variables, using all included 1998–1999 prevalent dialysis and general Medicare (non-ESRD) patients. With the exception of Figure 6.14, which includes patients younger than 65, only patients age 65 and older are included. To allow classification of CKD and non-CKD patients, general Medicare patients who satisfy the two-year entry period criteria (described previously) are selected. Figure 6.10 displays cardiovascular admission rates per 1,000 patient years for ISHD, CHF, and other cardiovascular admissions. ISHD hospitalization is defined by principal ICD-9-CM codes of 410–414, while CHF hospitalization is defined by the following principal ICD-9-CM codes: 425.9, 425.11, 425.21, 425.31, and 425.41. The remaining codes listed above for cardiovascular hospitalization are included in the “other cardiovascular” category. In Figures 6.12–15, the categories of cardiovascular, infectious, and other hospitalizations are defined as in Figure 6.9. Figure 6.13 excludes patients with missing gender, while 6.14 excludes those with missing age.

Figures 6.16–19 show adjusted first-year first hospitalization rates per 1,000 patient years for 1998 and 1999 (combined) incident dialysis patients. Patients are followed from day 91 of ESRD until the earliest of the following: first hospitalization, death, transplant, loss-to-followup, or the end of one year. Measures of height, weight, and serum creatinine at the initiation of dialysis are obtained from the CMS Medical Evidence form (2728) in order to calculate body mass index (BMI) and estimated glomerular filtration rate (eGFR, from the Levey four-variable formula). The following patients are excluded from the cohorts: patients with missing age, BMI, or eGFR, patients age 0–19, non-residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories; non-Medicare patients; patients with MSP or HMO status anytime during followup; and patients with a bridge hospitalization that spans the start of the followup period. Adjusted first hospitalization rates are obtained from the model-based adjustment method described later in this appendix. The Cox proportional hazards model is used with all possible two-way interactions of the following variables: age (20–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other), primary cause of ESRD (diabetes and non-diabetes), ethnicity (Hispanic and non-Hispanic), body mass index (<20, 20–<25, 25–<30, and 30+ kg/m²), and eGFR (<5, 5–<7, 7–<10, and 10+ ml/min). Adjusted rates presented by a subset of these variables are adjusted for each of the remaining variables. The reference is the patient distribution in the included 1998 and 1999 (combined) incident dialysis patient cohort.

Comparison of adjusted rates is appropriate only when rates are adjusted for the same variables. In Figure 6.16, for example, rates are adjusted for eGFR, BMI, and the primary cause of ESRD. Rates for the “all” group, however, are also adjusted for race and ethnicity, while rates by race are also adjusted for ethnicity, and rates by ethnicity are also adjusted for race. In Figures 6.16–19, therefore, direct comparison of adjusted rates is appropriate only between rates within the “all” group, the three race groups, or the two ethnicity groups (e.g. comparisons of rates between whites and Hispanics would be inappropriate).

Table 6.a displays relative risks of first hospitalization by diabetic status. Separate Cox proportional hazards models are used for diabetics and non-diabetics. The models include the following covariates as main effects only: age, gender, race, ethnicity, BMI, eGFR, albumin (as a continuous variable), and comorbidities from the Medical Evidence form, including CHF, ASHD (defined as ischemic heart disease or myocardial infarction), other cardiac disease (defined as cardiac arrest, dysrhythmia, or pericarditis), CVA/TIA, PVD, history of hypertension, COPD, cancer, tobacco use, alcohol dependence, drug dependence, inability to ambulate, and inability to transfer. Patient inclusion criteria follow those of Figures 6.16–19, with the additional exclusion of patients with missing albumin or missing comorbidities on the Medical Evidence form.

Figures 6.20–22 show adjusted first-year first hospitalization rates, per 1,000 patient years at risk, by hemoglobin, URR, and BMI. The study includes adult (>19 years of age) incident hemodialysis patients, 1998–1999 combined, for whom the incident date is defined as the first ESRD service date plus 90 days. Included patients survive the first 90 days plus a full six-month entry period, and have at least four EPO claims and three URR measurements during the entry period. The following patients are excluded from the cohort: patients with a bridge hospitalization spanning the start of the followup period; patients with missing values for age or BMI; non-residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories; non-Medicare patients; and patients with MSP or HMO classification any time during the entry or followup periods. The range of each patient’s URR is obtained from the “G” modifier attached to CPT code 90999, with revenue code 821 or 825. For each patient the median URR of the last three entry-period URR values is selected, and the mean entry-period hemoglobin is computed. Patients are followed from the end of the entry period until the earliest of death, first hospitalization, modality change, loss-to-followup, one year following the end of the entry period, or December 31, 2000. Adjusted first hospitalization rates are obtained using a model-based adjustment method with the Cox proportional hazards model and direct adjustment. All possible two-way interactions of the following variables are included in the model for these figures: age (20–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other race), primary cause of ESRD (diabetes and non-diabetes), ethnicity (Hispanic and non-Hispanic), BMI (<20, 20–<25, 25–<30, and 30+ kg/m²), URR (<60, 60–<65, 65–<70, 70–<75, and 75+ percent), and hemoglobin (<9, 9–<10, 10–<11, 11–<12, and 12+ g/dl). As in Figures 6.16–19, adjusted rates presented by subgroups are adjusted for all of the remaining variables, using all included 1998–1999 incident hemodialysis patients as the reference population.

Also as in Figures 6.16–19, direct comparisons among rates are limited due to adjustments for different groups of variables. In Figures 6.20–21, in addition to the adjustment factors listed in the figure captions, rates by gender are also adjusted for race and primary cause of ESRD, while rates by race are also adjusted for
gender and primary cause of ESRD, and rates by primary cause of ESRD are also adjusted for gender and race. Direct comparison of rates in these figures is thus appropriate only within the groups by gender, race, and primary cause of ESRD, and not between these groups. As in Figures 6.16–19, Figure 6.22 also presents rates that are comparable only within the “all,” race, or ethnicity groups.

Tables 6.b–d present relative risks and 95 percent confidence intervals by gender, race, and diabetic status, respectively. While the patients included in these tables are identical to those in Figures 6.20–22, the Cox models here contain only main effects for the variables in the figures, as well as for ten comorbidities and the entry-period indicators of disease severity. Severity of disease is measured by the number of blood transfusions (0, 1–2, and 3+), hospitalization days (0, 1–10, 11–20, and 21+), and vascular access procedures (0, 1–3, and 4+). Separate models are run in Table 6.b for males and females (without gender as a covariate), in Table 6.c for whites and blacks (without race as a covariate), and in Table 6.d for diabetics and non-diabetics (without diabetic status as a covariate). Since separate analyses are used to assess the impact of hemoglobin and URR on hospitalization within gender, race, and diabetic groups, it is inappropriate to compare relative risks across these groups.

The methods of Tables 6.a–d and Figures 6.16–22 are repeated in Tables 9.a–d and Figures 9.10–16 for all-cause death. Chapter Nine data, however, do not exclude patients with a bridge hospitalization or those with MSP or HMO status, and followup time is not censored at the first hospitalization.

Figures 6.23–38 display rates of total admissions and hospital days per patient year at risk for patients with less common causes of ESRD. Eight diseases are defined from the indication of primary cause of renal failure on the Medical Evidence form. The cohort includes period prevalent ESRD patients, 1996–2000 combined; patients with missing age or gender are excluded. Consistent with the methods of Chapter Six and Section E, patients with AIDS as a primary or secondary cause of death are excluded (with the exception of Figures 6.37–38, which present rates for AIDS patients including those who die of AIDS). Both unadjusted and adjusted rates for each disease are presented for all patients, with the adjusted rates adjusted for age and gender. Rates by age are adjusted for gender, and rates by gender are adjusted for age. Adjustments are made with the direct adjustment method, using all 1999 prevalent patients with any of the eight diseases as the common reference population; this allows for comparison of rates across diseases. Due to the small number of pediatric or older patients with some diseases, the younger age groups are combined into 0–44 for patients with scleroderma, myeloma, or AIDS, and the older age groups are combined into 65+ for AIDS patients.

Reference Section E

Because hospitalization data may be incomplete for non-Medicare patients, the analyses in this section include Medicare patients only. Hospitalization data are obtained from Part A institutional inpatient claims, and Table E.27 includes REBUS hospitalization data as well.

Tables E.1–26 include dialysis and transplant patients who have been on their modality for at least 60 days, who have reached day 91 of ESRD by the end of the year, and who are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. 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, black, Native American, or Asian are excluded. Age is classified on January 1 of each year. Patients are also classified according to the 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 using the following categories:
- all-dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as patients who have been on more than one modality in the past 60 days
- hemodialysis: patients who have been on hemodialysis for at least 60 days at the start of the period at risk
- CAPD/CCPD: patients who have been on CAPD/CCPD for at least 60 days at the start of the period at risk
- 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 bills are excluded from Tables E.1–26. 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 is at least $675 of Medicare paid dialysis claims
- end date: the end of a three-month period in which there is 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. This method is similar to that used in the economic analysis section, except that here the paid claims dates are analyzed only for the dialysis patient start date. The dialysis patient end date remains the earliest of death, three days prior to transplant, or December 31 of the year.

MSP patients and, new to this year’s ADR, HMO patients (because of potentially incomplete Medicare claims) are also excluded from the dataset through use of the enrollment database. Patients for whom the database indicates MSP or HMO status anytime during the period at risk are excluded for 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 for hosp-
tization is censored only at death or December 31 of the year; modality change is not used as a censoring event. For transplant patients in the all-ESRD and transplant categories, the analysis 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.

In the case of a hospitalization that begins prior to January 1 or day 91 of ESRD and continues into the analysis year, the time at risk for first admission begins on the day of discharge from this bridge hospitalization. Patients with a bridge hospitalization that spans the entire analysis period are excluded from the first admission rates.

Time at risk is calculated differently for length of stay 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 on 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 stay days during the analysis period are included, respectively, in the total admissions and length of stay 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 analysis period, and only the hospitalization days within the period are counted in the total days for length of stay rates. The minimum length of stay is one day, and hospitalizations with admission and discharge on the same day, as well as hospitalizations with discharge the day after admission, are both counted as one day.

In the hospitalization reference tables in previous Annual Data Reports, overlapping hospitalizations and hospitalizations that occurred with no days between discharge and the following admission were combined into one hospitalization that spanned the first admission date to the last discharge date. In this year's Tables E.1–26, however, 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 only combined when there is a discharge transfer code or indication of an interim claim. In the 1991–2000 institutional inpatient claims, for example, 3.6 percent (0.1 percent overlapping, 2.2 percent adjacent with a discharge transfer, and 1.3 percent adjacent with an interim claim) of the hospitalizations were combined using these criteria. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

Table E.27, in contrast, includes all hospitalizations in the total discharges reported, and no overlapping or adjacent hospitalizations are combined. These tables present total hospital discharges by diagnostic related groups (DRGs), and no exclusions are made for patients dying of AIDS or for MSP status. Total discharges are presented by modality group and the year of discharge. For each year the total discharges are counted from January 1 or the first ESRD service date until the end of the period at risk, as defined previously. In this case, however, the period at risk for transplant patients in the transplant and all-ESRD groups is not censored at three years following the date of transplant. Inpatient REBUS data are combined with Part A institutional inpatient claims data, and duplicate observations from both sources with identical hospitalization start dates, end dates, and DRG codes are omitted.

The methodology used for computing first admission rates (Tables E.1–5) uses a generalized mixed model (discussed in the statistical methods section later in this appendix). Smoothed rates are used to calculate the expected number of first hospitalizations, a number then used to obtain standardized hospitalization ratios (SHRs). New to this year's ADR, SHRs by state (Table E.6) now compare observed events to expected events from the same year. In Table E.6 in the 2001 ADR, the expected number of first hospitalizations in the denominators of the 1997, 1998, 1999, and 1997–1999 SHRs were each calculated based on 1999 national predicted first hospitalization rates by age, gender, race, and primary cause of renal failure. This year, however, expected events for the 1998, 1999, and 2000 SHRs are calculated based on predicted rates for 1998, 1999, and 2000, which are obtained from generalized mixed models containing 1996–1998, 1997–1999, and 1998–2000 data, respectively. The expected events for the 1998–2000 (combined) SHRs are now calculated from the 1998–2000 predicted rates, obtained from the model using equally weighted 1998–2000 data. These methods are described further in the discussion of standardized mortality ratios, later in this appendix.

The methods used to compute total admissions and days hospitalized are the same as those used in prior ADRs. The total admission rate is expressed per 1,000 patient years at risk, while the rate of hospital days is given per patient year at risk. Data from 1998 to 2000 are pooled to increase stability, but followup is for single calendar year periods using cohorts of patients alive at the beginning of each year. The number of hospital admissions and days, and the number of years at risk for each event, are computed separately for each year and summed over the three years; rates are then computed by dividing the total admissions or days by the total time at risk. A patient who is alive at the beginning of 1998, dies in 2000, and has two hospitalizations each year, for example, will contribute two and a fraction years at risk and six admissions. These calculations are discussed further in the statistical methods section of this appendix.

**PEDIATRIC ESRD · CHAPTER SEVEN**

Information on pediatric patients is a subset of the ESRD patient data used throughout the ADR; methods used to create most figures in this chapter are therefore the same as those described in the related chapter discussions.
Figure 7.24 shows the cumulative percentage of patients with a diagnosis of diabetes and cancer following transplantation. Patients with known diabetes or cancer at the time of transplantation, and those with a history of either disease (identified through Medicare claims) in the previous two years, are excluded from the respective measures. Medicare claims are searched for diabetes or cancer claims in the three years following transplantation; non-malignant skin cancers are not included in the definition of cancer. Graphed curves are inverse Kaplan-Meier estimates.

Figure 7.25 shows the percent of pediatric patients receiving Epstein-Barr testing in the three years after initiation of ESRD therapy. Patients incident during 1994–1997 and alive for at least three years are included, and followed for three years. Epstein-Barr tests are identified through CPT codes 86663–86665.

Methods used for the hospitalization data presented in Figures 7.26–27 generally follow those described for Chapter Six and Reference Section E. Rates are unadjusted total admission rates per 100 patient years for hospitalizations in which the principal ICD-9-CM code indicates an infection, and patients with missing age or gender information are excluded. Time on ESRD is calculated as the time from the first ESRD service date until the first of the year for prevalent patients, or from day 91 of ESRD for incident patients. Principal ICD-9-CM diagnosis codes used for overall infection are listed in the discussion of Figures 6.7–8.

The cohort used for Figures 7.28–29 is a subset of that used in Tables H.2–12.

Mean hemoglobin, mean EPO dose per week, and iron use (Figures 7.30–32) are, for the most part, calculated with the methods described for Chapter Four. URR and Kt/V data (Figure 7.33) are obtained from all available CPM data, with each patient’s URR calculated from pre- and post-BUN values.

The information in Figure 7.30 comes from both CPM and USRDS data. “Medicare” patients in the CPM data are those with a Medicare claim during 1999, identified in the USRDS database as having Medicare as secondary payor, or enrolled in a group health plan during 1999. USRDS data include hemodialysis patients age 12–17 as of September 30, 1999 with an EPO claim during October, November, or December of 1999. Iron use, EPO dose, and hemoglobin are calculated from claims during this same time period.

In Figure 7.32, since the mean EPO dose per week is always a weighted average (see the discussion of Chapter Four), the cut-off for EPO dose is calculated as the weighted median dose, where the weights for each patient are determined by the average number of monthly EPO administrations, and the weighted median represents the dose(s) where, once ordered, the cumulative sum of the weights from the lowest dose on up equals one-half of the total sum of all of the weights.

For Figure 7.34, catheter days during the time at risk are counted by summing the days from a catheter insertion (CPT code 36533) until a catheter removal (CPT code 36535). Since insertions and removals occur on claims on separate lines with different expense dates, it is possible for two insertions or two removals to occur consecutively, in which case the days are counted from the first insertion or until the last removal. When the first code during the time at risk indicates a removal, catheter days are counted from the beginning of the time at risk until the removal. Similarly, in the case of an insertion as the last code of the time at risk, catheter days are counted from the insertion until the end of the risk period. An insertion and removal occurring on the same day are counted as one catheter day. Rates of catheter days per year at risk are then calculated by dividing the total catheter days during the time at risk by the total years at risk, and the number of days per insertion is computed by dividing the total days by the number of insertions during the time at risk.

The cohort examined for influenza vaccinations (Figure 7.35) includes patients starting ESRD therapy at least 90 days prior to September 1, 2000, alive on December 31, 2000, and with Part B eligibility during the last four months of 2000; age is calculated on September 1, 2000. Influenza vaccinations are identified through CPT codes of 90724, 90657, 90658, 90659, and 90660, and a HCPCS code of G0008; rates are calculated for patients receiving a vaccination in the last four months of 2000. The same rules are used to select the cohort for hepatitis vaccinations, though age is calculated here on December 31, 2000. Hepatitis vaccinations are identified through CPT codes of 90636, 90740, 90743–90744 and 90746–90748, and rates are calculated for patients receiving one vaccination in 2000. For pneumococcal vaccinations, the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1, 1999, alive on December 31, 2000, and with Part B eligibility during 1999–2000. Vaccinations are identified through CPT codes of 90669 and 90732 and HCPCS codes J6065 and G0009, and rates are calculated for patients receiving one pneumococcal vaccination during 1999–2000.

The cohort analyzed for glycosylated hemoglobin testing (Figure 7.36) includes all prevalent patients initiating ESRD at least 90 days prior to January 1, 2000, alive on December 31, 2000, and carrying a diagnosis of diabetes in 2000. Age is calculated on December 31, 2000. Testing is identified through CPT code 83036, and rates are calculated for patients receiving one HbA1c test in 2000. Patients with Medicare as secondary payor, or enrolled in an HMO, are excluded.

**TRANSPLANTATION · CHAPTER EIGHT & REFERENCE SECTIONS F & G**

**Chapter Eight**

In addition to the analyses conducted for the reference tables (discussed below), several additional methods are used for the figures in this chapter.

Figure 8.1 presents transplant counts by donor source. These counts are obtained through a combination of UNOS data and data from CMS. For patients with a living donor of unknown type (related or distant/unrelated), a living related donor is assumed.

Figure 8.5 illustrates median waiting times by various demographic characteristics for patients receiving their transplants between 1995 and 2000. Only first-time, kidney-only recipients of
a cadaveric kidney are included in the measure, and pre-emptive transplants are omitted. Times are calculated from date of listing to the date of transplantation. Median times are mapped by state in Figure 8.4.

For organ donation rates (Figure 8.6), the numerators include all donors younger than 70 whose kidneys are not discarded. Denominators are estimated from the 1990 U.S. census. Rates are calculated as the number of donated kidneys (excluding discarded organs) divided by the population, and multiplied by one million to yield donations per million population. These rates are mapped by HSA in Figure 8.7.

Figure 8.8 presents organ shipping and sharing practices by organ procurement organization (OPO). Each OPO is represented on the map by a pie chart that details the percentage of harvested organs that are transplanted locally, transplanted regionally, designated as payback organs, or transplanted as part of the zero-antigen mismatch program. All first-time, kidney-only, cadaveric transplants between 1995 and 2000 are included in the calculation. Each OPO’s pie chart is mapped over the city in which the OPO operates, and this chart contains a four-character code, designated by UNOS, to identify the OPO.

Table 8.1 lists results from three separate Cox proportional hazards models, modeling all-cause graft failure (including death), death-censored graft failure (return to dialysis), and patient death (not censored at graft failure). All first-time, kidney-only transplants between 1994 and 2000 with known recipient age and donor type are included. The table presents all characteristics used in the models, followed by the percent of patients with the characteristic and the modeled hazard ratio, 95 percent confidence interval, and p-value. Hazard ratios designated by “(ref)” are the reference level for the particular covariate and represent a ratio of 1.00. Note that some of the covariates include “unknown” levels. Because these levels are excluded from the table, the associated percentages do not add to 100 percent.

Figures 8.9–62 provide more detail on certain covariates listed in Table 8.1. Included are Kaplan–Meier graft survival curves, along with adjusted graft survival curves obtained from the all-cause graft failure Cox proportional hazards model used in Table 8.1. The adjusted curves are calculated as the expected survival of the average patient in the population, adjusted for all covariates detailed in the table. Following these curves are trends in one-year survival probabilities, estimated using the Kaplan–Meier method, and trends in estimated conditional graft half-lives. These half-life estimates are conditional on one year of graft survival, and use an exponential approximation to the survival curve. They can be interpreted as the estimated time until 50 percent of kidneys transplanted in the given year would fail, given that a graft survives the first year post-transplant. Note that, since cold ischemia time applies only to recipients of cadaveric kidneys, this covariate is not included in Table 8.1. To produce Figures 8.60–62, models are rerun using only recipients of cadaveric kidneys.

Reference Section F
Transplant events are presented in Tables F.1–16. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients.

Calculations of transplant rates per 100 patient years on dialysis begin in Table F.17, and include only patients reaching day 91 of ESRD service. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. Patients who die of AIDS or whose age is unknown at transplant, are excluded. 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-followup in a given year are not censored at the lost-to-followup date, but are followed until the end of the calendar year. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year.

Table F.19, first transplant rates per 1,000 patient-years at risk, is calculated using a generalized mixed model to stabilize the rates. (This model is detailed later in this appendix.)

Table F.24 displays standardized first transplant ratios by state and territory for 1998–2000. A state’s observed first transplant rate, calculated using a generalized mixed model as in Table F.19, is compared to the rate expected from national rates for patients with similar characteristics. The standardized first transplant ratio is calculated as the ratio of the observed number of first transplants in the state to the expected number.

Reference Section G
This section presents graft survival probabilities for various demographic groups and lengths of followup. Patients are followed from the transplant date to graft failure, death, or the end of the followup period (December 31, 2000); death in this analysis is considered a graft failure. Because a minimum of one year of followup is required, 1999 is the most recent year reported.

To produce a standard patient cohort, patients with unknown age, gender, or race 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. Non-Medicare patients are excluded from all tables in this section due to the lack of followup information; the renal transplant counts presented here differ, therefore, from those in Section F.

Unadjusted survival probabilities are estimated with the Kaplan–Meier method and Greenwood’s formula, while the Cox model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, and primary diagnosis, standardized to 1998 patient characteristics, and expressed as percentages.

SURVIVAL, MORTALITY, & CAUSES OF DEATH - CHAPTER NINE & REFERENCE SECTIONS H & I
The analytical methods for adjusted mortality and death rate calculations are described in the statistical methods section of this appendix. Figures created with the same methodologies and patient populations as the related reference tables are described below, and methods unique to the figures are discussed here.
Figures 9.1–2 include incident and period prevalent patients, 1991–2000. Incident patients are followed from the onset of ESRD to death or the end of the first year of treatment, while prevalent patients are followed from January 1 to December 31 of each prevalent year. Mean age and the percent of patients with diabetes as the primary cause of ESRD are calculated at the onset of ESRD (Figure 9.1) or the beginning of the prevalent year (Figure 9.2). Unadjusted mortality rates are presented as number of deaths per 1,000 patient-years at risk. Adjusted mortality rates for incident patients are calculated with the same method used in Table H.14, and rates for prevalent patients use the methods of Tables H.8–12.

Figures 9.3–9 further characterize mortality in period prevalent dialysis patients who survive the entry period of July 1 to December 31, 1999. These patients are followed from January 1, 2000 to the earliest of death, transplant, or December 31, 2000.

Figure 9.5 shows unadjusted death rates (per 1,000 dialysis patient years), by HSA, for the general Medicare and dialysis populations. The five percent Medicare cohort includes 1999 period prevalent patients who are age 65 or older on January 1, do not have ESRD, have at least one month of Medicare entitlement in 1999, and are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. This cohort is followed from January 1 or the first day of the first month with Medicare eligibility until death or December 31, 1999.

Figures 9.4 and 9.6–9 illustrate mortality rates related to cardiovascular disease (CVD) in dialysis and general Medicare patients. CVD is defined from primary and secondary ICD-9-CM diagnosis codes in Part A and Part B claims during the six-month entry period: ischemic heart disease (410.x–414.x); cerebrovascular disease (430.x–438.x); conduction disorders and cardiac dysrhythmias (426.x–427.x); congestive heart failure, fluid overload, and cardiomyopathy (276.6, 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 425.x, and 428.x); other cardiac disease (394.x–398.99, 415.1–415.9, 416.x, 424.x, and 429.x); hypertensive heart disease (401.x–405.x); and other circulatory system diseases (440.x–459.x).

The methods used in Tables 9.a–d and Figures 9.10–16 parallel those used for similar data on hospitalization (Tables 6.a–d and Figures 6.16–22). Figures 9.10–13 present adjusted first-year all-cause mortality in 1998–1999 (combined) incident dialysis patients. Patients are followed from day 91 of ESRD until the earliest of death, transplant, or loss-to-followup. Body mass index (BMI) and estimated glomerular filtration rate (eGFR, from the Levey four-variable formula) are calculated from height, weight, and serum creatinine at the initiation of dialysis, data available on the CMS Medical Evidence form (2728). Excluded are patients under age 20 or with missing BMI or eGFR, non-residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories, and non-Medicare patients. Adjusted first-year mortality is calculated by the model-based adjustment method. The Cox proportional hazards model includes age (20–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other races), primary cause of ESRD (diabetes and non-diabetes), ethnicity (Hispanic and non-Hispanic), body mass index (BMI, <20, 20–<25, 25–<30, and 30+ kg/m²), and eGFR (<5, 5–<7, 7–<10, and 10+ ml/min), and all possible two-way interactions of these variables. Adjusted rates presented by a subset of these variables are adjusted for each of the remaining variables. The reference is the patient distribution in the included 1998–1999 incident dialysis patient cohort. As noted in the discussion of Chapter Six, comparisons of these adjusted rates should be made with caution.

Table 9.a displays relative risks of mortality by diabetic status. Separate Cox proportional hazards models are used for diabetics and non-diabetics. The models include the following covariates as main effects only: age, gender, race, ethnicity, BMI, eGFR, albumin (as a continuous variable), and comorbidities from the Medical Evidence form, including CHF, ASHD (defined as ischemic heart disease or myocardial infarction), other cardiac disease (defined as cardiac arrest, dysrhythmia, or pericarditis), CVA/TIA, PVD, history of hypertension, COPD, cancer, tobacco use, alcohol dependence, drug dependence, inability to ambulate, and inability to transfer. Patient inclusion criteria follow those of Figures 9.10–13, with the additional exclusion of patients with missing albumin levels on the Medical Evidence form.

Figures 9.14–16 show adjusted first-year mortality rates by URR and hemoglobin. The cohort consists of 1998–1999 (combined) incident hemodialysis patients, age 20 or above, who survive both the first 90 days after ESRD onset and an additional six-month entry period. Excluded are patients with fewer than four EPO claims or three URR measurements during the entry period; patients with missing values for age or BMI; non-residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories; and non-Medicare patients. The range of each patient’s URR is obtained from the “G” modifier attached to CPT code 90999, with revenue codes 821 or 825. For each patient the median URR of the last three entry-period URR values is selected, and the mean entry-period hemoglobin is computed. Patients are followed from the end of the entry period until the earliest of death, modality change, loss-to-followup, or December 31, 2000. Adjusted first-year mortality is calculated by the model-based adjustment method with the Cox proportional hazards model and direct adjustment. The main effects and all possible two-way interactions of the following variables are included in the model: age (20–44, 45–64, 65–74, and 75+ years), gender, race (white, black, and other race), primary cause of ESRD (diabetes and non-diabetes), ethnicity (Hispanic and non-Hispanic), BMI (<20, 20–<25, 25–<30, and 30+ kg/m²), URR (<60, 60–<65, 65–<70, 70–<75, and 75+ percent), and hemoglobin (<9.9–<10, 10–<11, 11–<12, and 12+ g/dl). Adjusted rates presented by subgroups are adjusted for all remaining variables, using all 1998–1999 incident hemodialysis patients as the reference population. Comparisons of these adjusted rates should be made with caution.

Tables 9.b–d present relative risks and ninety-five percent confidence intervals by gender, race, and diabetic status. While patient cohorts are identical to those used in Figures 9.14–16, the Cox models here contain only main effects for the variables listed for Figures 9.14–16, plus ten comorbidities and measures of disease severity during the entry period (number of blood transfusions (0, 1–2, and 3+), hospital days (0, 1–10, 11–20, and 21+), and vascular access procedures (0, 1–3, and 4+)). Separate Cox mod-
els are used in Table 9.1 for males and females (without gender as a covariate in the model), in Table 9.1 for males and females (without race as a covariate), and in Table 9.1 for diabetics and non-diabetics (without diabetic status as a covariate). Since separate analyses are performed to assess the impact of hemoglobin and URR on mortality by gender, race, and diabetic groups, it is inappropriate to compare relative risks across these groups.

Figures 9.17–24 illustrate survival probabilities by age and gender for incident dialysis patients, 1980–2000, whose renal failure is due to one of the less frequently occurring diseases. The model-based adjustment method is used, including age (0–19, 20–44, 45–64, 65–74, 75+), gender, and race (white, black, and other races). Probabilities by age are adjusted for gender and race, and those by gender are adjusted for age and race.

Table 9.e presents expected remaining lifetimes for the ESRD and general populations. For year 2000 period prevalent ESRD patients, expected lifetimes are calculated using the adjusted death rates in Reference Tables H.3 and H.6, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.3 and H.6, and the method for calculating expected remaining lifetimes is described in the general analytical methods section. Deaths due to AIDS, accidents (“accidents unrelated to treatment” on the ESRD Death Notification), and illegal drugs (“drug overdose (street drugs)”), are excluded, so the reported lifetimes correspond to hypothetical populations in which these causes of death do not occur. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

Figures 9.25–26 present expected remaining lifetimes for the dialysis and general Medicare populations. The general Medicare cohort includes non-ESRD patients with at least one month of Medicare entitlement in 1999, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. A two-year period (1997–1998) is used to identify patients with diabetes, chronic kidney disease, and, in Figure 9.26, congestive heart failure. Patients are classified as having these diseases based on entry-period claims: at least one inpatient, home health, or skilled nursing claim, at least two outpatient claims, or at least two Part B claims for the condition are required for classification.

Figure 9.27 displays, by state, expected remaining lifetimes for prevalent dialysis and transplant patients in 2000 and for 1999 general Medicare patients. For ESRD patients, the cohort definitions are the same as those used in Table 9.e, excluding patients who are not residents of the 50 states or the District of Columbia. For the Medicare population, age is defined on January 1, 1999, and patients with a listed age greater than 110 are excluded. The Medicare cohort includes patients without ESRD, with at least one month of Medicare entitlement in 1999, and who reside in the 50 states or the District of Columbia. This cohort is followed from January 1 or the first day of the first month with Medicare eligibility until death or December 31, 1999.

Expected remaining lifetimes for general Medicare patients (Figures 9.25–27) are computed using smoothed death rates from the generalized mixed model. This process is described in the discussion of statistical methods.

Reference Section H
PATIENT POPULATIONS
Counts of deaths (Table H.1) are reported for 1991 to 2000, while adjusted death rates for period prevalent cohorts (Tables H.2–6) are presented for the year 2000. Standardized mortality ratios (SMRs, Table H.7) and cause-specific death rates (Tables H.8–13 and H.a.1–4, supplemental tables on our website) are reported for prevalent cohorts of 1998 to 2000. Adjusted first-, second-, and third-year death rates for incident cohorts are reported in Tables H.14–16. Residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories are included in each of these tables, as are all non-Medicare patients.

Tables H.1, H.8–13, H.a.1–4, and H.14–16 include all causes of death. Tables H.2–6 exclude patients dying of AIDS. While patients dying of street drug overdoses or accidents unrelated to treatment are not counted in the rates, their time at risk is counted until death.

Tables H.2–13 include both incident and prevalent patients. As defined earlier, prevalent cohorts include patients who are 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. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year. Because calculations in these tables include only one-year of followup, a prevalent patient surviving until 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 of these 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-followup at the beginning of the year are excluded from the analysis. The period at risk is not censored at the start of a lost-to-followup period, however; if a patient enters the lost-to-followup 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 day, 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.

Both adjusted and unadjusted death rates for prevalent cohorts are reported for the following groups (definitions are the same as those used in the hospitalization analyses; see the discussion of Section E):

- **all-dialysis**: if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
• hemodialysis; if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
• CAPD/CCPD; if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
• functioning transplant: patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored only at the end of the year
• all-ESRD; the period at risk is censored only at the end of the year

Patient populations for tables H.14–16 are the same as those used in Reference Section I. The population groups include all dialysis, hemodialysis, CAPD/CCPD, and first transplant (known cadaver and living only).

METHODS

Generalized mixed models are used to calculate the smoothed rates in Tables H.2–6; these methods are described later in this appendix, as is the method used to calculate standardized mortality ratios (SMRs) in Table H.7. Patients whose gender or date of birth is missing, or who are of races other than white, black, Native American, or Asian, are excluded from these populations, while those with no listed diagnosis are included in the “other” diagnosis group.

In Tables H.8–13 death rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 1998–2000. Subgroups are characterized by age, gender, race, and modality at the start of each cohort year for prevalent patients, and at 90 days of ESRD for incident patients. Dialysis patients are censored at transplant or the end of the calendar year, while transplant patients and patients in the all-ESRD category are censored only at the end of the calendar year. The death 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 followup time. The sum of death rates for each cause in a subgroup is equal to the overall death rate of that subgroup. Death rates for collapsed categories of death (Table a.a. below) are presented in Tables H.8–12, while Tables H.a.1–4 (supplemental tables available on the USRDS website) list rates for each specific cause of death. Table H.13 presents rates by cause of withdrawal.

In Tables H.14–16 the adjusted first-, second-, and third-year death rates for incident cohorts—including 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. A separate Cox model is used for each incident year. These death rates are presented using aggregate categories for age, gender, race, and primary disease, and a death rate presented for one of these variables is adjusted for the remaining three. Overall death rates for all patients are adjusted for each of the four variables. Death rates for Hispanic and non-Hispanic patients, however, are unadjusted (crude) death rates calculated as the number of deaths over patient-years at risk. The reference population for adjusted rates consists of 1995 incident patients in each cohort.

Reference Section I

PATIENT POPULATIONS

These tables, which include only incident cohorts, present patient counts, counts of first renal transplants, and patient 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.

#### a.a - Collapsed categories of death

<table>
<thead>
<tr>
<th>Collapsed categories</th>
<th>Individual categories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute myocardial infarction</td>
<td>Myocardial infarction, acute</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>Hyperkalemia</td>
</tr>
<tr>
<td>Pericarditis</td>
<td>Pericarditis, including cardiac tamponade</td>
</tr>
<tr>
<td>Atherosclerotic heart disease</td>
<td>Atherosclerotic heart disease</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>Cardiomyopathy</td>
</tr>
<tr>
<td>Cardiac dysrhythmia</td>
<td>Cardiac dysrhythmia</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>Cardiac arrest, cause unknown</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>Valvular heart disease</td>
</tr>
<tr>
<td>Pulmonary edema</td>
<td>Pulmonary edema</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>Cerebrovascular accident including intracranial hemorrhage; ischemic brain damage/anoxic encephalopathy</td>
</tr>
<tr>
<td>G. I. hemorrhage</td>
<td>Hemorrhage from transplant site; hemorrhage from vascular access; hemorrhage from dialysis circuit; hemorrhage from ruptured vascular aneurysm; hemorrhage from surgery; other</td>
</tr>
<tr>
<td>Septicemia</td>
<td>Septicemia, due to peritonitis; septicemia, due to peripheral vascular disease; gangrene; septicemia, other</td>
</tr>
<tr>
<td>Pulmonary infection</td>
<td>Pulmonary infection (bacterial); pulmonary infection (fungal); pulmonary infection (other); tuberculosis</td>
</tr>
<tr>
<td>Viral infection</td>
<td>Viral infection, CMV; viral infection, other; Hepatitis B; other viral hepatitis</td>
</tr>
<tr>
<td>AIDS</td>
<td>AIDS</td>
</tr>
<tr>
<td>Other infection</td>
<td>Infection, other; fungal peritonitis</td>
</tr>
<tr>
<td>Cachexia</td>
<td>Cachexia</td>
</tr>
<tr>
<td>Malignant disease</td>
<td>Malignant disease; patient ever on immunosuppressive therapy; malignant disease</td>
</tr>
<tr>
<td>Other cause</td>
<td>Pulmonary embolus; mesenteric infarction/ischemic bowel; liver-drug toxicity; cirrhosis; polycystic liver disease; liver failure, cause unknown or other; pancreatitis; perforation of peptic ulcer; perforation of bowel; bone marrow depression; dementia, including dialysis dementia, Alzheimer’s; seizures; diabetic coma, hyperglycemia, hypoglycemia; chronic obstructive pulmonary disease (COPD); complications of surgery; air embolism; accident related to treatment; accident unrelated to treatment; suicide; drug overdose (street drugs); drug overdose; other identified cause of death.</td>
</tr>
<tr>
<td>Unknown cause</td>
<td>Unknown</td>
</tr>
<tr>
<td>Missing forms</td>
<td>Missing forms</td>
</tr>
</tbody>
</table>
with unknown gender or age, or whose age is listed as greater than 110, are excluded from the cohorts.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients with a first ESRD service date between January 1, 1980, and December 31, 1999, are included in the analysis. These patients are followed until December 31, 2000, a maximum followup time of 20 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 followup
- 65 and over at start of ESRD: all ESRD patients age 65 and over who begin renal replacement therapy in a calendar year; patients are grouped in two-year periods to increase cell size, and are censored only at the end of followup
- dialysis only: all ESRD patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or at the end of followup
- first renal transplant (cadaveric): patients receiving their first transplant in a calendar year, and receiving that kidney from a cadaveric donor
- first renal transplant (living): patients receiving their first transplant in a calendar year, and receiving that kidney from a living donor

In both transplant categories, patients for whom the donor type is other or unknown are excluded. The cohort is defined by the year of first transplant, regardless of the year of first ESRD service date. These patients are followed from the date of transplant (also the date at which age is computed), and are censored only at the end of followup.

**METHODS**

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. Unadjusted probabilities for Hispanics are new to this report.

To limit imprecision due to small cell sizes, adjusted survival probabilities are presented using 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 discussion of statistical methods. The reference population consists of 1995 incident patients for each cohort.

**CARDIOVASCULAR SPECIAL STUDIES • CHAPTER TEN**

This chapter addresses cardiovascular events in ESRD patients, outcomes following these events, and the incidence of major cardiovascular diseases after the onset of ESRD. The study cohort consists of incident dialysis patients, 1995–1999, who survive the first year (the entry period) of dialysis after the onset of ESRD. To limit the impact of non-Medicare patients with incomplete claims data, analyses of the incidence of cardiovascular events and the use of evaluation procedures are restricted to incident dialysis patients who are Medicare-eligible on day 91 of ESRD. A patient is excluded if he or she has not been on dialysis a full year, or has no information on age, gender, or race listed on the Medical Evidence form. Missing age is defined as a missing date of birth or an age calculated to be less than zero or greater than 110.

Patients are classified into four study groups according to the primary cause of ESRD and to diabetic status (determined from the Medical Evidence form and from diabetes-related Part A (institutional) or Part B (physician/provider) claims during the entry period).

- Group 1: patients with diabetes as the primary cause of ESRD
- Group 2: patients whose ESRD is not due to diabetes, but for whom diabetes is listed as a comorbid condition on the Medical Evidence form
- Group 3: patients who do not have diabetic ESRD or diabetes as a comorbid condition at the initiation of dialysis, but who have diabetes-related Part A or Part B claims; patients are classified into this group if they have one inpatient or skilled nursing facility claim in which diabetes is indicated by either primary or secondary ICD-9-CM diagnosis codes, or two outpatient or Part B physician service claims with ICD-9-CM diabetes codes
- Group 4: patients who have no indications of diabetes

Figures 10.1–8 present overall descriptions of the four study groups. For the incidence of cardiovascular diseases or events, patients are followed up to one year after the initiation of dialysis until December 31, 2000 or the first occurrence of cardiovascular disease, transplant, or loss-to-followup. Age and major comorbid conditions are determined at the beginning of followup. Major comorbid conditions are defined from either the Medical Evidence form at the initiation of dialysis or from Part A and B claims during the entry period, and include atherosclerotic heart disease (ASHD), congestive heart failure (CHF), peripheral vascular disease (PVD), cerebrovascular accident/transient ischemic attack (CVA/TIA), other cardiac disease (valvular heart disease, dysrhythmia, and pacemaker), chronic obstructive pulmonary disease (COPD), cancer, and gastrointestinal bleeding (GI).

Figure 10.3 presents cardiac and all-cause mortality, adjusted for age, gender, race, and eight major comorbidities. The adjustment method is that used for Figures 10.9–18, below.

Figures 10.9–18 use event-free survival probabilities to describe the likelihood of cardiovascular diseases and events among incident dialysis patients. Probabilities are again adjusted for age, gender, race, and eight major comorbidities. Patients are classified as having a particular cardiovascular event as of the first occurrence of claims (Part A or B) with ICD-9-CM diagnosis or procedure codes.

For non-fatal cardiovascular events of acute myocardial infarction, congestive heart failure, or cerebrovascular accident/transient ischemic attack, the event date is defined as the first appearance of an ICD-9-CM diagnosis code in the Part A in-
stitutional claims, while for a non-fatal cardiac arrest the date is that on which an ICD-9-CM diagnosis code first appears in either Part A or B claims. The event date for a coronary revascularization is defined as the first appearance of an ICD-9-CM procedure code in Part A institutional claims. For fatal events, the event date is the date of death due to the event. For peripheral vascular disease the date is defined through ICD-9-CM diagnosis codes in Part A claims and/or Current Procedural Terminology (CPT) codes in Part B claims data, and the date of major amputation is identified through CPT codes in Part B claims. Codes used to identify patients with cardiovascular disease are as follows:

- acute myocardial infarction: 410, 410.X0, and 410.X1 (ICD-9-CM diagnosis codes)
- congestive heart failure: 428 (ICD-9-CM diagnosis codes)
- cerebrovascular accident or transient ischemic attack: 430–437 (ICD-9-CM diagnosis codes)
- cardiac arrest: 475 (ICD-9-CM diagnosis codes)
- peripheral vascular disease: 440–444, 447, 451–453, and 557 (ICD-9-CM diagnosis codes); 23900, 23920, 24920, 24940, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, and 28805 (CPT codes)
- coronary revascularization: 36.01, 36.02, 36.05, 36.06, and 36.1x (ICD-9-CM procedure codes)

For each endpoint, including cardiovascular events, combined cardiovascular events, cardiac death, and all-cause death, a separate Cox proportional hazards model with age, gender, race, and eight major comorbidities is used to estimate event-free survival probabilities. Using the model-based adjustment method (described in the section on statistical methods), and with the entire study cohort as the reference population, these probabilities are further adjusted for age, gender, race, and comorbidities. The cardiac and all-cause mortalities in Figure 10.3 are adjusted using a similar method.

Figures 10.19–26 present all-cause mortality following cardiovascular events. For each event, only those patients who experience the event are included in the analysis. Patients are followed from the event to the earliest of death, transplant, loss-to-followup, or December 31, 2000. Age and major comorbid conditions are recalculated at the beginning of the new followup. Comorbid conditions are again defined either from the Medical Evidence form at the initiation of dialysis or from Part A and B claims prior to the event. The method for calculating adjusted survival probabilities here is similar to that used in Figures 10.9–18, with adjustments for age, gender, race, and ESRD vintage (the time between the onset of ESRD and the cardiovascular event). Figures 10.20 and 10.24 illustrate geographic patterns of mortality rates, by HSA, in Group 1 patients with acute myocardial infarction and cardiac arrest, respectively. These rates are not adjusted for demographic risk factors.

Figures 10.27–29 and 10.31–33 display cardiovascular event rates for prevalent general Medicare and ESRD patients. The study cohort for the Medicare population is derived from the five percent Medicare Standard Analytic Files, 1997–1999. We include patients enrolled in both Part A and Part B on January 1, 1997 or any time during 1997, age 65 or older on January 1, 1997 or at the time of Medicare enrollment in 1997, and without a diagnosis code for ESRD prior to followup. Each patient is followed from January 1, 1997 or the time of Medicare enrollment in 1997 to the earliest of a cardiovascular event, diagnosis of ESRD, end of Medicare entitlement, or December 31, 2000. The ESRD population consists of 1997 prevalent dialysis patients who survive the first 90 days of ESRD and are either on dialysis on January 1, 1997 or start dialysis during 1997. Patients are followed from January 1, 1997 or the ninety-first day of ESRD to the earliest of a cardiovascular event, death, transplant, loss-to-followup, or December 31, 2000. Cardiovascular events are again defined from Part A and Part B claims. Rates are not adjusted for demographic risk factors.

Using similar methods, Figure 10.30 illustrates cardiovascular event rates for 1997 period prevalent cohorts of hemodialysis, peritoneal dialysis, transplant, and general Medicare patients. These cohorts are defined in ways similar to those described in the previous paragraph, except that dialysis patients are censored at a change in modality, and transplant patients are censored at graft failure. Rates are estimated as the number of events per 1,000 patient years at risk.

Figure 10.34 presents trends of cardiovascular event rates in transplant patients. Patients are followed from the transplant date to the earliest of a cardiovascular event, death, loss-to-followup, or December 31, 2000. The Cox proportional hazards model, stratified on the year of transplantation, is used to calculate adjusted cardiovascular event rates, with age, gender, race, and diabetic status as covariates. Event rates are adjusted using the model-based method (described in the section on analytical methods).

**PROVIDER CHARACTERISTICS · CHAPTER ELEVEN & REFERENCE SECTION J**

In previous ADRs chain ownership of dialysis units was presented only in data on state and network distribution of chain-affiliated and non-chain units; no specific chains were identified. In this year’s ADR, however, we identify the five chains with the greatest numbers of dialysis patients, and present data for patients treated in these chains, other chains, units not affiliated with chains, hospital-based units, and units of unknown affiliation. We define a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units owned by a corporation and located in more than one state.

Data are obtained from the CMS Annual Facility Survey, the CMS Independent Renal Facility Cost Report (Form 265-94), and the CDC National Surveillance of Dialysis-Associated Diseases in the United States (the CDC did not conduct a survey in 1998). The CMS data is available at www.cms.hhs.gov/data/download.

This chapter summarizes data from facilities that have returned a CMS and/or CDC survey. Chain identification is determined from the “Provider Name” field of the Facility Survey and from the “Chain Organization Name” field of the Cost Report. The third and fourth digits of the provider number assigned to each dialysis unit by CMS indicate whether that unit is hospital-
based or freestanding. Profit status is indicated on the CMS facility survey, which is also the source for staffing data.

Only facilities which have returned a CMS and/or CDC survey are included in the analyses. There were 4,091 unique provider units submitting surveys in 2000; 3,615 were common to both the CMS and CDC data. Sixty-eight providers submitted a survey to the CDC but not to CMS, while 408 submitted a survey to CMS but not to the CDC.

Data on urea reduction ratios, hemoglobin levels, and iron use are obtained with the same methods used in Chapter Four.

**ECONOMIC COSTS OF ESRD · CHAPTER TWELVE & REFERENCE SECTION K**

**Chapter Twelve**

The majority of the economic analyses in this year’s ADR use the as-treated model, described in detail in the discussion of Reference Section K, below.

**HCFA MODEL**

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Table 12.c and for Figures 12.11–14 and p.36–37. 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 who have a kidney transplant during the calendar year
- functioning graft: ESRD patients who have 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, 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 always classified in the transplant category

Patients are categorized as having Medicare as secondary payor on the basis of the “Primary payor amount” on Part A and Part B claims.

**METHODS**

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total Medicare spending in 2000 is calculated from the claims data, and includes all paid claims for ESRD patients in theUSRDS database. Cost aggregation begins at the first ESRD service date for each patient. Total 2000 Medicare spending is inflated by two 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 2000 (obtained from the CMS managed care organization file) in conjunction with the 2000 AAPCC rate.

Non-Medicare spending by Employer Group Health Plans (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 2000. Patient obligations are estimated as 17.3 percent of the sum of Medicare payments, non-federal EGHP costs, and patient obligations (1999 ADR, page 149). Because non-Medicare patients are estimated to constitute seven percent of all ESRD patients in the U.S. (1999 ADR, Table ES-1), costs are estimated as seven percent of the total costs of Medicare patients.

Changes in Medicare spending from 1999 to 2000 are obtained from Table K.1, without the two percent adjustment for late claims. Calculations per patient year at risk are based on patients never MSP during the study period (Tables K.19–20), again using non-inflated results. The apparent decrease in per patient per year costs is likely artifactual, and due to the absence of late claims affecting the 2000 claims dataset. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (3.4 percent) and the Medical Consumer Price Index (4.2 percent). Calculations by modality for per patient per year at risk, 1996–2000, are taken directly from Table K.4; these data include non-MSP patients only, and are not adjusted for late claims.

For the overall costs of ESRD (Tables 12.a–b and Figures 12.3–6), we analyze Medicare allowable expenditures for 1999 incident adult dialysis patients. Data are obtained from Medicare Part A and Part B claims data in the CMS Standard Analytic File. Patients are followed from day 91 after the initiation of ESRD therapy until one year after day 91, and censored at death, transplant, loss-to-followup, or the end of the followup period. Medicare allowable per member per month (PMPM) costs in 1999 are calculated for each patient by dividing the total Medicare allowable costs by the months of risk. Data on patient demographic and clinical characteristics at the initiation of ESRD, such as height, weight, serum albumin, serum creatinine, and hematocrit, are obtained from the Identification and Medical Evidence portions of the CMS Renal Beneficiary Utilization System (REBUS). Patients younger than 20 or with Medicare as secondary payor, missing or unknown demographic status, missing biochemical values (e.g. serum albumin, serum creatinine, and hematocrit), or unknown dialysis modality at the initiation of ESRD are excluded.

Multiple linear regressions are used for these analyses of ESRD costs, with the dependent variable of logged Medicare allowable PMPM. In addition to the logged transformation, the lower 0.25 percent and upper 0.25 percent of observations are trimmed, based on the distribution of the Medicare allowable PMPM. Separate multiple linear regression models are fitted for Part A, Part B, and overall expenditures, and are also fitted by diabetic status and modality type. Explanatory variables include age (20–44, 45–64, 65–74, and 75+), race (white, black, and other), gender, diabetes as a primary cause of renal failure, known dialysis modality at the initiation of ESRD, height, weight, serum albumin, serum creatinine, and hematocrit, or unknown demographic status, missing biochemical values (e.g. serum albumin, serum creatinine, and hematocrit), or unknown dialysis modality at the initiation of ESRD are excluded.
The predicted relative cost, or percentage of effect on Medicare expenditures for each risk factor or variable, is calculated by the exponential of the coefficient, and compared to the reference in that variable. Compared to the cost of patients age 45–64, for example, the relative cost for patients age 20–44 is 0.9234, or 7.7 percent less. Compared to hemodialysis patients, peritoneal dialysis patients incur a relative cost of 0.8485—15.15 percent less.

Data on costs for vascular access services (Figures 12.26–36) are obtained from event-based analyses. Part B (physician/supplier) vascular access procedures and costs are easily identified through CPT codes (Table a.b, below). Facility costs, however, are more difficult to identify. For inpatient facility costs, vascular access procedures in the inpatient setting 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 these 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, below). Such hospitalizations are labeled “pure” inpatient vascular access events.

For outpatient facility costs, Part B 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 Part B and outpatient claims. Once again, all procedures and costs for the entire matching 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.

Information about the construction of other figures and tables is provided in the captions.

**Reference Section K**

**MEDICARE CLAIMS DATA**

Cost information in this section is derived from Medicare Part A and Part B claims data in the CMS Standard Analytic Files, which are created annually six months after the end of each calendar year. The data for 1996 to 2000 are comprised of approximately 30 million institutional claims for hospital inpatient and outpatient facilities, outpatient dialysis facilities, skilled nursing facilities, hospice facilities, and home health agencies, as well as over 200 million line items from physician/supplier claims. Claims data are obtained for all patient ID numbers in the USRDS database, and the Renal Beneficiary Utilization System (REBUS) is used to gather all CMS ID numbers under which patients may have claims. The claims data are then merged with patient demographic data and modality information in the USRDS database.

The economic analysis for this reference section focuses on two amounts found in the claims data: the claim payment amount, which is the amount of payment made from the Medicare trust fund for the services covered by the claim record; and the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and kidney acquisition costs. Chapter Twelve includes another dollar amount called Medicare Allowable, defined here as the amount of allowed charges for the services covered by the claim record. For institutional claims, this amount is calculated as the sum of the amounts from the Medicare payment, coinsurance, deductible, and any payment provided by a payor other than Medicare. For physician/supplier claims, the Medicare Allowable amount is provided by CMS as a separate data element.

**PAYMENT CATEGORIES**

Medicare payments are broken down into several categories, as shown in Table a.d (next page). Estimates of costs from the Outpatient SAF are derived for the individual services provided. Since actual payment amounts are provided only for the entire claim, cost estimates for dialysis, EPO, iron and so forth are calculated from the claim-level “Total Charge,” the payment amount, and the revenue line-level “Total Charge,” as follows: payment (line) = [total charge (line) / total charge (claim)] * payment (claim).

### a.b - CPT codes for vascular access services

| Used for Figures 12.26–36 | Complication: 35190, 35460, 35476, 35875, 35876, 35900, 35903, 35910, 36005, 36105, 36145, 36534, 36535, 36831, 36832, 36833, 36834, 36860, 36861, 37190, 37201, 37205, 37206, 37207, 37208, 37607, 49422, 75790, 75820, 75860, 75896, 75960, 75962, 75978, 00532, 01784, 01844, and M0900 | Hemodialysis catheter insertion: 36011, 36488, 36490, 36491, 36533, and 36800 | Peritoneal dialysis catheter insertion: 49420 and 49421 | Synthetic graft insertion: 36830 | Fistula insertion: 36810, 36815, 36819, 36820, 36821, and 36825 |

### a.c - DRG & ICD-9-CM codes for vascular access services

<table>
<thead>
<tr>
<th>Used for Figures 12.26–36</th>
<th>DRG codes(^a)</th>
<th>112</th>
<th>Percutaneous cardiovascular procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>120</td>
<td>Other circulatory system OR procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>315</td>
<td>Other kidney and urinary tract OR procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>442</td>
<td>Other OR procedure for injuries with complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>443</td>
<td>Other OR procedure for injuries without complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>478</td>
<td>Other vascular procedure with complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>479</td>
<td>Other vascular procedure without complication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD-9-CM procedure codes(^a)</td>
<td>38.95</td>
<td>Venous catheterization for renal dialysis</td>
<td></td>
</tr>
<tr>
<td>39.27</td>
<td>Arteriovenostomy for renal dialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.42</td>
<td>Revision of arteriovenous shunt for renal dialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.43</td>
<td>Removal of arteriovenous shunt for renal dialysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.93</td>
<td>Insertion of vessel-to-vessel cannula</td>
<td></td>
<td></td>
</tr>
<tr>
<td>39.94</td>
<td>Replacement of vessel-to-vessel cannula</td>
<td></td>
<td></td>
</tr>
<tr>
<td>86.07</td>
<td>Insertion of totally implantable vascular access device</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICD-9-CM diagnosis codes(^a)</td>
<td>996.1</td>
<td>Mechanical complication of vascular device, implant, graft</td>
<td></td>
</tr>
<tr>
<td>996.62</td>
<td>Infectious complication of vascular device, implant, graft</td>
<td></td>
<td></td>
</tr>
<tr>
<td>996.73</td>
<td>Other complication due to renal dialysis device, implant, graft</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present).

\(^b\)the presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access event.
In an as-treated model patients are initially classified by their modality at entry into the analysis, and they retain that classification until a change in modality. When such 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 in order to account for any carryover effects. If the change is from dialysis to transplantation, 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.

Patients are classified in these tables 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 five years from January 1, 1996 to December 31, 2000, and ESRD patients prevalent on January 1, 1996 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 the following:
- January 1, 1996
- thirty days after the first ESRD service date in the USRDS database for that patient
- for dialysis patients, 30 days after the first month in which dialysis payments exceed $675

Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payer (MSP) at any time during the study period, as determined from the Medicare Enrollment Database, are excluded from the analysis.

### AS-TREATED MODEL

#### Medicare payment categories

<table>
<thead>
<tr>
<th>Medicare payment categories</th>
<th>Basis for categorizing claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>Sum of all payments</td>
</tr>
<tr>
<td><strong>Total inpatient</strong></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</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, calculated from per diem &amp; covered days</td>
</tr>
<tr>
<td>Total outpatient</td>
<td>Sum of all payments originating from the Outpatient SAF</td>
</tr>
<tr>
<td>Outpatient hemodialysis</td>
<td>Outpatient SAF, hemodialysis revenue codes</td>
</tr>
<tr>
<td>Outpatient peritoneal dialysis</td>
<td>Outpatient SAF, peritoneal dialysis revenue codes</td>
</tr>
<tr>
<td>Outpatient other dialysis</td>
<td>Outpatient SAF, dialysis revenue codes other than HD or PD</td>
</tr>
<tr>
<td>Outpatient EPO</td>
<td>Outpatient SAF, revenue codes and/or HCPCS code</td>
</tr>
<tr>
<td>Outpatient Calcijex</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient iron</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient 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>Outpatient other</td>
<td>Outpatient SAF, does not qualify for any other cost category</td>
</tr>
<tr>
<td>Skilled nursing facility</td>
<td>Skilled nursing facility SAF</td>
</tr>
<tr>
<td>Home health agency</td>
<td>Home health SAF</td>
</tr>
<tr>
<td>Hospice</td>
<td>Hospice SAF</td>
</tr>
<tr>
<td><strong>Total physician/supplier</strong></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, CPT 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, EPO</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 category</td>
</tr>
</tbody>
</table>

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss-to-followup, or December 31, 2000. Dialysis patients are defined as being lost-to-followup after a period of three consecutive months in which their dialysis payments (institutional plus physician/supplier) fall below $675/month, and patients incurring no Part A or Part B Medicare costs for the entire period are excluded.

Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

In order to express the costs as dollars per year at risk (YAR), total costs during the followup period are divided by the length of the followup 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 disease causing ESRD, 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.

INTERNATIONAL COMPARISONS - CHAPTER THIRTEEN
The international dialysis and transplant data for 2000 have been collected from the following countries, using a data form designed by the USRDS: the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA), the Austria OEDTR, the Bangabandhu Sheikh Mujib Medical University (Bangladesh), the Ripas Hospital of Brunei, Bulgaria First Hemodialysis Center, the Canadian Organ Replacement Registry, the Catalan Renal Registry, the Chilean Renal Registry, the Czech Society of Nephrology, the Finnish Registry for Kidney Diseases, the QuaSi-Niere in Germany, the Greek Hellenic Renal Registry, the Hungarian Transplant Registry, the Israeli Renal Registry, the Italian Registry of Dialysis and Transplantation, the Japanese Society of Dialysis Therapy, the Netherlands Dialysis Registry, the Norwegian National Hospital, the Philippines Renal Disease Registry Project, the Polish Dialysis Registry, the Society of Dialysis in Russia, the Swedish Renal Registry, the Taiwan Society of Nephrology, the Thailand Renal Replacement Therapy Registry, the United Kingdom Transplant Support Service Authority, the Uruguay Dialysis and Transplant Renal Registry, the Institute of Nephrology in Yugoslavia, and the USRDS.

New to this year’s ADR, we report age-specific incidence, prevalence, dialysis, and transplant data from reporting countries.

CENSUS POPULATION BASE · REFERENCE SECTION L
Census data, used to calculate rates throughout the ADR, are obtained from the United States Census Bureau. Updated population estimates are available at www.census.gov.

As noted in the introductory chapter, because population counts in the 2000 U.S. census are considerably different from those estimated in the 1990 census, and because the most recent census form introduced a new category for race, any rates using the most recent data would not be comparable to those in previous Annual Data Reports. We have chosen, therefore, to continue using population estimates based on 1990 census data to calculate all incident, prevalent, and other rates which incorporate data on the U.S. population, and will further address the issue in the 2003 ADR.

STATISTICAL METHODS
Methods for calculating rates
RAW RATE (OBSERVED RATE)
The calculation of observed rates is straightforward. Some rates are based on counts, and others on followup time. The ESRD incident rate in 2000, for example, is the observed incident count divided by the population in 2000, and multiplied by one million if the unit is per million population; the 2000 death rate for prevalent ESRD patients is the number of deaths in 2000 divided by the total followup time (patient years) of the 2000 prevalent patients, and multiplied by a thousand if the unit is per thousand patient years. Standard deviations 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. A model-based method can improve the stability of these estimates. Two examples of model-based methods in this ADR are the generalized mixed model, used to estimate prevalent patient death rates in Reference Section H, and the log-normal model, used to produce mapped costs in Chapter Twelve.

MEASUREMENT UNITS FOR RATES
Both raw and model-based rates are often calculated per unit of followup time (such as the patient year) to account for varying lengths of followup among patients. Patient years are calculated as the total number of years, or fractions of a year, of followup time for a group of patients.

Take, for example, a calculation of 1997 first hospitalization rates per 1,000 patient years at risk for two groups of dialysis 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 peritoneal 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 patient years at risk, respectively. The resulting first hospitalization rate for 1997 for Group A is 1,143 hospitalizations per 1,000 patient years at risk (calculated as \( \frac{2 \text{ total events}}{1.75 \text{ total patient years at risk}} \times 1,000 \)), while the rate for Group B is 727 hospitalizations per 1,000 patient years at risk (calculated as \( \frac{2 \text{ total events}}{2.75 \text{ patient years at risk}} \times 1,000 \)). While 67 percent of patients have a first hospitalization within both Group A and Group B, the resulting rate per patient year at risk is lower for Group B, due to the longer total followup time.

Rates per patient may be influenced by the proportion of patients who are followed for only a fraction of a year. The percentage of patients with an event 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 patient year at risk, in contrast, count only the actual time that a patient is at risk for an event. Many of the death, hospitalization, and transplant rates in this ADR are thus calculated per patient year (or per 100 or 1,000 patient years) at risk.

Methods for adjusting rates
DIRECT ADJUSTMENT
There are several rate adjustment methods, but only the direct method allows rates to be compared (Pickle LW, White AA). With this method, 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. The 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, black, and other) and two gender groups (male and female), there are six categories: white males, white females, black males, black females, males of other races, and females of other races. This method is used to produce some adjusted incident and prevalent rates in Chapters One and Two and in Reference Sections A and B. It is also used in the model-based adjustment method.

**MODEL-BASED ADJUSTMENT**

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating death 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 death rate will be unstable, likely making the adjusted death rate unstable as well. In addition, if one category in a group has no patients, the method is not valid for calculating an adjusted death 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 directly calculate adjusted rates using these estimates with a given reference population. There is unfortunately no straightforward way in this method to calculate standard deviations for the adjusted rates; the bootstrap approach works well, but is time consuming.

Model-based adjustments are used in the ADR to calculate adjusted death rates, adjusted survival probabilities based on the Cox regression model, adjusted incident and prevalent rates based on the Bayesian spatial model, and some other rates.

**Death rates & survival probabilities**

**UNADJUSTED SURVIVAL PROBABILITIES**

In this ADR, unadjusted survival probabilities are calculated using the Kaplan–Meier method, and corresponding standard deviations are calculated with Greenwood’s formula (Kalbfleisch JD, Prentice RL). Survival probabilities are expressed as percentages varying from 0 to 100.

**ADJUSTED SURVIVAL PROBABILITIES**

Because of the different mix of patients each year, unadjusted probabilities may not be comparable across cohort years. Adjusted analyses make results comparable by reporting probabilities that would have arisen had each incident cohort contained patients with the same distribution of age, gender, race, and primary diagnosis as the reference population. 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 the survival probabilities that would have arisen in each year for patients in the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among years are due to factors other than age, gender, race, and primary diagnosis. The adjusted death rates in Reference Section H are calculated using similar methods.

**Generalized mixed model**

The generalized mixed model with log link and Poisson sampling distribution is used to calculate death rates, first hospitalization rates, and first transplant rates for prevalent patients. While rates are reported only for 2000, three years of prevalent data (1998–2000) with different weights are used to improve the stability of the estimates.

The generalized mixed model, which considers both fixed and random effects, is implemented using the SAS® macro GLIMMIX. The Poisson rates for the intersections of age, gender, race, and diagnosis are estimated using the log linear equation $\log(\text{rate}) = (\text{fixed effects}) + (\text{random effect})$. Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and diagnosis. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction of age, gender, race, and primary diagnosis.

For the 2002 ADR we have used a single model to calculate all rates (for both intersecting and marginal groups) in a single table. The marginal rates are simply the weighted averages of the estimated, cross-classified rates, with cell-specific patient years as weights. For this approach the use of a single model means that GLIMMIX cannot give the standard deviations for some of these estimated rates; the bootstrap was therefore used instead.

**Standardized mortality ratios**

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm (reference), and is derived by dividing the observed number of deaths by the expected number of deaths, e.g. the number of deaths in a dialysis unit if that unit experienced the same death rate as the reference population.

In Table H.7, for example, SMRs are used to compare the mortality for prevalent dialysis patients in each state to national mortality rates from 1998 to 2000, and to show how relative death rates have changed, using as the reference the national dialysis population in the corresponding year. The SMR accounts for patient age, gender, race, and primary diagnosis. The expected number of deaths in each category of the observed population is calculated by multiplying the category-specific standard rates by the total followup time at risk of the observed patients. Category-specific standard rates come directly from the generalized mixed model. The total expected number in a state is then calculated by summing the expected numbers in all categories. An SMR of 1.05 for a state indicates that patients in this state have a risk of death approximately five percent higher than patients in the reference population of all U.S. dialysis patients.

First admission standardized hospitalization ratios (SHRs) and standardized first transplantation ratios (STRs), calculated using similar methods, are reported in Tables E.6 and F.24.

**Expected remaining lifetimes**

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients within
that group. Some patients in the cohort will live longer than, and some less than, the average lifetime. 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, which is in turn calculated using observed death rates. Let r(X) denote the death rate for a five-year age group, with X identifying one of the listed age ranges. Death rates for successive age intervals, r(X), are plotted versus age, X, and the area under the curve up through age A is denoted by R(A). The survival function at age A, S(A), is related to the death rates by the equation S(A) = exp(-R(A)), where “exp” denotes the exponential function. Among patients alive at age A, the probability of surviving X more years is S(X|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(X|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. Geographic 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 researchers stabilize data and show geographic patterns while still maintaining geographic resolution. The methods described here have been used in most of maps presented in the 2002 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.

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.”

In many figures, data ranges have been standardized to invite comparisons across years, modalities, or patient characteristics. In the remaining maps, HSAs have been 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, and, 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 DATA**

To smooth map data we use a Bayesian spatial hierarchical model (Waller LA 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 relative risks for the regions, as random effects, follow the Conditional Autoregressive (CAR) Normal distribution, and the precision of the relative risks has a beta distribution (Waller LA, Carlin BP, Xia H, Gelfand AE). The model smoothes 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. The exponential offsets in the model are the internally standardized incident counts. 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 for smoothing prevalent rates and for calculating some percentages.

To smooth maps of mean hemoglobin, estimated glomerular filtration rates, and creatinine levels, this model is extended to assume that the means have a normal distribution of gamma precision; the model used for rates assumes a Poisson distribution.

**MISCELLANEOUS**

**Special studies & data collection forms**

The USRDS website includes copies of the CMS Medical Evidence form (2728) and Death Notification orm (2746); the UNOS Transplant Candidate Registration form, Kidney Transplant Recipient Registration form, and Kidney Transplant Recipient Followup form; and forms used for data collection in past USRDS special studies.

**Captions**

Captions in the Annual Data Report 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.

**BIBLIOGRAPHY**


### Abbreviations

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<td>AAPCC</td>
<td>Adjusted average per capita costs</td>
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<td>AMI</td>
<td>Acute myocardial infarction</td>
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<td>ASHD</td>
<td>Atherosclerotic heart disease</td>
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<td>BMI</td>
<td>Body mass index</td>
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<td>BUN</td>
<td>Blood urea nitrogen</td>
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<td>CAPD</td>
<td>Continuous ambulatory peritoneal dialysis</td>
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<td>CCPD</td>
<td>Continuous cycler peritoneal dialysis</td>
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<td>CHF</td>
<td>Congestive heart failure</td>
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<td>CK</td>
<td>Cystic kidney disease</td>
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<td>CMS</td>
<td>Centers for Medicare &amp; Medicaid Services</td>
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<td>CVA/TIA</td>
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<td>CVD</td>
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<td>eGFR</td>
<td>Estimated glomerular filtration rate</td>
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<td>GN</td>
<td>Glomerulonephritis</td>
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<td>Health Care Financing Administration</td>
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<td>Health Plan Employer Data Information Set</td>
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<td>Health service area</td>
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<td>Hypertension</td>
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<td>ICD-9-CM</td>
<td>International Classification of Diseases, 9th revision, Clinical Modification</td>
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<td>Intermittent peritoneal dialysis</td>
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<td>ISHD</td>
<td>Ischemic heart disease</td>
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<td>Kidney Disease Outcomes Quality Initiative</td>
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<td>Myocardial infarction</td>
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<td>MSP</td>
<td>Medicare as secondary payor</td>
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<td>NKF</td>
<td>National Kidney Foundation</td>
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<td>PD</td>
<td>Peritoneal dialysis</td>
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<td>PVD</td>
<td>Peripheral vascular disease</td>
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<td>Tx</td>
<td>Transplant</td>
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<td>UNOS</td>
<td>United Network for Organ Sharing</td>
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<tr>
<td>URR</td>
<td>Urea reduction ratio</td>
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</table>

**Acquired immunodeficiency syndrome (AIDS)**

An epidemic disease caused by the human immunodeficiency retrovirus that leads to immune system failure.

**Adjusted average per capita costs (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.

**Angioplasty**

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

**Atherosclerotic heart disease (ASHD)**

A disease of the arteries of the heart, characterized by a thickening and/or loss of elasticity of the arterial walls.

**Blood urea nitrogen (BUN)**

A by-product of the breakdown of amino acids and endogenous and injected protein.

**Body mass index (BMI)**

A measure of height to weight ratio: Weight (kg)/Height (m²).

**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 four to five times each day.

**Continuous cycler-assisted peritoneal dialysis (CCPD)**

A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automated cycler machine.

**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.

**Centers for Disease Control & Prevention (CDC)**

The lead federal agency for protecting the health and safety of people at home and abroad; serves as the national focus for disease prevention by developing and applying programs designed to improve the health of the people of the United States.
Centers for Medicare & 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 the brain. Cerebrovascular accidents (CVA) and transient ischemic attacks (TIA) are two events that can result from this condition.

Chain provider
A single business entity that owns 20 or more dialysis units located in more than one state. This definition applies to all chain affiliation references in the USRDS’s 2000–2002 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 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 Part A and Part B 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.

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

Creatinine
A waste product of protein metabolism found in the urine and often used to evaluate kidney function. Abnormally high creatinine levels are seen in people with kidney failure or 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.

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.

DVA
Department of Veterans Affairs.

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 an individual’s kidney function is not adequate to support life.

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 network
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.

Erythropoietin (EPO)
A hormone secreted chiefly by the adult kidney; acts on the bone marrow to stimulate red cell production.

For-profit facility
A dialysis facility which is 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 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.

Health Care Financing Administration (HCFA)
Created in 1977, the federal agency responsible for administration of Medicare and Medicaid, the nation’s largest healthcare
Appendix B

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+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 2010
A nationwide agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people (www.health.gov/healthypeople).

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.

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

High-flux hemodialysis
Dialysis therapy provided 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.

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

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

Incident patient
A patient starting renal replacement therapy for ESRD during the 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.

Ischemic heart disease (ISHD)
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.

Kt/V
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 patient demographics, primary cause of renal disease, comorbidity, 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 risk patient
A patient enrolled in a Managed Care Organization (MCO) under contract with CMS and for whom health care costs are paid by CMS on a per capita basis.

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

National Claims History (NCH) 100 percent Nearline File
A file which contains all Common Working File (CWF) Part A (provider) and Part B (physician/supplier) Medicare claims and adjusted claims information.

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.

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 & Information System for ESRD, & Renal Beneficiary & Utilization System (PMMIS/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 2746), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.

**Prevalent patient**
A patient on renal replacement therapy or with a functioning kidney transplant (regardless of when the transplant was performed). 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.

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

**Pyrogen reaction**
A condition in which a patient afebrile 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.

**REMIS**
CMS's Renal Management Information System (REMIS) is replacing the existing Renal Beneficiary and Utilization System (REBUS) in 2002. REMIS will include 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 Analytical Files (SAFs)**
CMS files containing final action Medicare Part A claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and five 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, race, gender, and diabetes as a cause of ESRD.

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

**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. \( \text{URR} = \frac{(\text{pre-dialysis} - \text{post-dialysis BUN})}{\text{pre-dialysis BUN}} * 100 \).

**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, 820, 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, maintained by the United Network for Organ Sharing (UNOS), of patients awaiting an organ transplant.
The timely fulfillment of data requests. In many cases these 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.

DATA FILES AVAILABLE TO RESEARCHERS
The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to the data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding a new group of 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.

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

STANDARD ANALYSIS FILES (SAFs)
The use of Standard Analysis files is governed by the USRDS policy on data release for investigator-initiated research, which appears later in this appendix. Research proposals must be approved by the USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data” (page 257). Prices for these files are listed in Table c.c (page 252).

Most SAFs provide patient-specific data. All patient identifiers (name, address,
Social Security number, and so on) are removed from the files or encrypted, but confidentiality of the data is still a serious concern. The “Agreement for Release of Data” therefore includes restrictions on the use and disposition of the SAFs. The SAFs do include an encrypted ID number to allow patient data from multiple SAFs to be merged when needed.

**Core Standard Analysis File CD**

The USRDS has carried out a number of Special Studies. Topics are approved by the NIDDK, with recommendations from CMS, the USRDS Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. For each study, design and sampling plans are developed, samples are selected, and data collection forms and instructions are drafted, tested, and finalized. The main studies to date are summarized below, and are detailed in the Researcher’s Guide.

The Core Standard Analysis File CD contains the most frequently used SAFs, including those from the USRDS Special Studies, and is needed for use of the Transplant CD, the Hospital CD, or any CD based on Medicare claims data. The files included on this Core CD are as follows (and are also listed in Table c.b, next page):

**PATIENT**
Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.

**RESIDENCE**
Provides a longitudinal record, to ZIP code level, of each patient’s place of residence.

**TREATMENT HISTORY**
The Modality Sequence file; contains a new record for each patient's place of residence.

**MEDICAL EVIDENCE**
Contains full data from the 1995 version of the CMS Chronic Renal Disease Medical Evidence form (2728), the source of data about the primary disease causing renal failure and the start date of chronic renal dialysis. In April 1995 a new version of the form went into use that includes data on comorbidity, employment status, laboratory values at the start of dialysis, and Hispanic ethnicity.

**TRANSPLANT**
Contains basic data for all transplants, including the date of graft failure (detailed transplant data are contained on a separate transplant CD).

**TRANSPLANT WAITING LIST**
Includes one record for each patient in the USRDS database who can also be identified in the UNOS transplant waiting list file, and contains only the date on which the patient was first placed on the waiting list. Because of the complexity and variability of the patterns of patient movement on and off the waiting list, we have not attempted to derive more complex indicators of the transplant waiting list experience.

**DIALYSIS MORBIDITY & MORTALITY STUDY (DMMS)**
The DMMS was an observational study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected for a random sample of U.S. dialysis patients, using dialysis records. 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 true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

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<td>Most USRDS research studies result in published papers or presentations at national meetings. Figures from presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.</td>
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CASE MIX ADEQUACY STUDY OF DIALYSIS

The objectives of this 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 the dialysis dose
♦ assess how this relationship is affected by dialyzer reuse
♦ assess 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 study data were collected on 5,255 patients incident in 1986–87 at 328 dialysis units nationwide. The objectives of the study were to:

♦ estimate the correlation of comorbidity and other factors existing at the onset of ESRD to subsequent 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 using different treatment modalities
♦ 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 pediatric ESRD patient growth and sexual maturation to modality
♦ 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 Rates Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors. The study population in-
cluded 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.

**FACILITY**
The CMS annual 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. Because of this link, geographic variables that could be used to identify facilities have been deleted. The survey period is January 1 through December 31.

**FACILITY COST REPORTS**
The CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993 are available as Standard Analysis Files. All geographic variables are deleted to ensure confidentiality. The file may be linked with the Facility SAF by using the USRDS provider ID, though geographic analyses at less than a regional or network level are not possible. Because of the minimal use of these files, additional data will be added only if there is sufficient demand.

**DIALYZERS**
The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies all collected information on patient dialyzers. The SAFs for these studies describe the dialyzer through a code, which must be matched to information in the Dialyzer file to find the manufacturer and model of the dialyzer along with characteristics such as membrane type and clearance. The data in this file come from published sources available at the time of the study. We believe these data accurately represent the dialyzer characteristics, but they should be used with caution.

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

- **TX:** includes minimum details about all transplants from all sources
- **TXWAIT:** contains one record for each patient in the USRDS database who also can be identified on the kidney transplant waiting list maintained by the United Network for Organ Sharing (UNOS)
- **TXHCFA:** includes transplant information collected by CMS’s PMMIS system prior to 1994
- **TXUNOS:** includes transplant information collected by UNOS, currently the main source of transplant data for the USRDS, since 1987
- **TXFUHCFA:** includes transplant followup 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 followup reports collected by UNOS since 1987
- **TXIRUNOS:** includes information on immunosuppressive medications collected by UNOS at the time of transplant since 1987
- **TXIFUNOS:** includes information on immunosuppressive medications collected by UNOS at followup visits since 1987

The tables in Section F of the reference section are produced primarily from the main and UNOS transplant files.

In July 1994 HCFA (now CMS) and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its contract with HRSA. The 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.

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

**Hospital CD**
Hospitalization inpatient data from the USRDS database are a subset of the Institutional Claims file. No payment or cost variables are included on this CD, which is for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but who do not need payment data.

**Dialysis Morbidity & Mortality CD**
This CD contains files from the Dialysis Morbidity and Mortality Study, with data extracted from all other SAFs for the patients in this study. All data on Medicare payments for these patients are followed to the currently reported claims year.

**Case Mix Adequacy CD**
This CD contains the Case Mix Adequacy Special Study file and extracts data from all other SAFs for the patients in this study. All data on Medicare payments for these patients are followed to the currently reported claims year. Along with analyses related to the study itself, this file is useful for developing analyses that will later be run on the full Medicare payments files.

**CDs of Medicare payment data**
Medicare payment data on institutional claims are available for pre-1989 through 2000, while data on physician/supplier claims are available for 1991–2000. The 2000 claims will be available, along with other updated USRDS SAF CDs, by the end of 2002. These data sets can be purchased by year.

Institutional claims consist of all Part A claims (Inpatient, Outpatient, Skilled Nursing Facility, Home Health Agency, and
Hospice) and some Part B claims, notably outpatient dialysis. All physician/supplier claims are Part B; these 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 are different, as are the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, which indicates 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, which contains details such as diagnosis and procedure codes. Many analyses will 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.

File media & formats
The SAFs are provided on CD-ROM disks as SAS® (Statistical Analysis System) files, and can be used directly by SAS® on any 486 or Pentium PC with a CD-ROM reader.

A SAS® format was chosen for the USRDS SAFs because it 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, from mainframes to PCs, and it is almost universally available on university computer systems. The USRDS SAFs take full advantage of the program’s ability to incorporate a large amount of documentation into the file.

Researchers who require a different program format or a medium other than CD-ROM need to arrange for the conversion themselves. The USRDS also may be able to convert files to alternative formats or media, but the cost will be substantially greater.

What is needed to use the SAFs
- Computer: at a minimum, a 486 or Pentium PC. Smaller runs have been done on 486/100 PCs. The files can be converted to SAS® transport format for use on any computer with access to SAS®.
- CD-ROM drive: Any PC with a CD-ROM drive should be able to read the SAF CDs.
- Disk storage: 10–600 megabytes are needed for use of the Core CD, depending on the files used. The data on each CD require 550–650 megabytes of disk storage. Keep in mind that you will need space for temporary work files and for the files you create.
- Software: SAS®. Files converted to SAS® transport format can be used by SPSS.
- People with software experience: The SAF documentation provides some of the basics of loading the files into SAS® and using them, but further work with the files requires SAS® experience.

Costs
File prices (Table c.c, right) cover the cost of reproducing and shipping the files and their documentation, the administrative cost of handling the sales, and the cost of technical support to researchers. These prices are subject to change.

Documentation
The Researcher’s Guide to the USRDS Database provides most of the documentation of the SAFs. It includes a codebook of variables, copies of the data collection forms used by the Special Studies, and a chapter on techniques for using the SAFs in SAS®. Copies of the Researcher’s Guide may be downloaded from the USRDS website, or requested from the Coordinating Center by phone or e-mail.

ACKNOWLEDGMENT FOR USE OF USRDS DATA
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 U.S. government.

DATA RELEASE POLICY & PROCEDURE
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.

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*CDs for years prior to 1989 include only hospital inpatient stays and quarterly summaries of outpatient dialysis; no cost data are included.
at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators should do the following:

♦ Provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation (see Table c.d, above). The summary must include goals, background data, an in-depth description of the 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,” page 257.

♦ Indicate which USRDS SAFs will be needed. If the USRDS SAFs cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.

♦ If the project is approved, return a signed copy of the USRDS “Agreement for Release of Data” to the PO. The investigator and the 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 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 USRDS CC. The process of reviewing the data request, generating the data file, and releasing the data will take the CC approximately three months.

When both a copy of the signed “Agreement for Release of Data” and payment for the files have 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 the 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 with the Act 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 the released data must contain the standard acknowledgement and disclaimer presented on page 252. The investigator is requested to send copies of all final publications resulting from this research to both the PO and the USRDS 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 the data in the SAFs, 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, however, other than review of the proposal and preparation of the data file, will not be provided under the USRDS contract, though USRDS CC personnel may participate in analyses funded by other sources.

Standard Analysis Files or other data files from USRDS Special Studies will become available one year after the data have been collected, edited, and entered into the database.
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United States Renal Data System (USRDS)
Agreement for Release of Data

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. 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.
Project title

Recipient typed name, title, & organization

Recipient telephone number

Recipient signature & date

Contractor typed name, title, & organization, as appropriate

Contractor telephone number

Contractor signature & date

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

USRDS Project Officer signature & date

Revised June 1994
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) The subset of total incident patients whose failure is due to diabetic nephropathy. Subtracting B2 from B1 should give the total number of incident patients for all non-diabetic nephropathy causes.

B2) Patients with a functioning kidney transplant as of December 31.

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, 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.

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### Table

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| **B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year** |       |       |       |       |     |
| 1998   |       |       |       |       |     |
| 1999   |       |       |       |       |     |
| 2000   |       |       |       |       |     |
| 2001   |       |       |       |       |     |

| **B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes** |       |       |       |       |     |
| 1998   |       |       |       |       |     |
| 1999   |       |       |       |       |     |
| 2000   |       |       |       |       |     |
| 2001   |       |       |       |       |     |
## C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

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## C2) Prevalence: Total number of ESRD patients with a functioning graft at the end of the year (December 31)

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## C3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31)

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## C4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31)

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## C5) Prevalence: Total number of ESRD patients on CAPD/CCPD at the end of the year (December 31)

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## C6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31)

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## D1) Transplant: Total number of cadaveric transplants during the year

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## D2) Transplant: Total number of living donor transplants during the year

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