“I would call your attention to the curious incident of the dog in the night-time.”

“The dog did nothing in the night-time.”

“That was the curious incident.”

Arthur Conan Doyle, “Silver Blaze”
In this appendix we describe the USRDS database and its standardized working datasets, specialized code definitions, and common data processing practices. We also detail the statistical methods used in this ADR. The *USRDS Data User’s Manual* is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (MSP) and employee group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

**CMS MEDICARE ENROLLMENT DATABASE**
CMS’s Enrollment Database (EDB) is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (MSP) and employee group health plan (EGHP) 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, primarily non-Medicare patients, or beneficiaries who develop ESRD while already on Medicare because of age or disability, will eventually be entered into the REMIS/REBUS/PMMIS—and hence the USRDS—database through the claims records. For patients without Medical Evidence forms these claims are the only reliable information from which to determine first ESRD service dates. These paid claims records are, however, only a supplement to, rather than a replacement of, other sources of information on incidence and prevalence.

The problem of timely ESRD identification has lessened since the introduction of the revised Medicare Evidence Form (CMS-2728) in April 1995, and the amended ESRD entitlement policy that now requires a Medical Evidence form to be submitted for all ESRD patients regardless of their insurance and eligibility status.

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).

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

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

- All OPTN 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 OPTN transplant record for that patient within 30 days of the CMS transplant.
- Transplants indicated on 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 ANALYSIS FILES (SAFS)**

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

For Part A institutional claims we use the following data: inpatient, 100 percent SAF; outpatient, 100 percent SAF; home health agency (HHA), 100 percent SAF; hospice, 100 percent SAF; and skilled nursing facility (SNF), 100 percent SAF. For Part B physician/supplier claims, we use: physician/supplier, 100 percent SAF; and durable medical equipment (DME), 100 percent SAF.

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized by 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2005 ADR includes all claims up to December 31, 2003. Patient-specific demographic and diagnosis information, however, includes data as recent as November 2004.

**STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS) DATABASE (ESRD NETWORKS)**

The USRDS continues to collaborate with CMS and the ESRD networks to address data tracking issues relating to non-Medicare ESRD patients. Prior to 2003, ADRs have documented the lack of consistent Medicare claims data among these patients. Working solely with data from the Medical Evidence form, the USRDS could establish the first ESRD service date for them, but could not generate more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can now address issues in the non-Medicare ESRD population such as the large and growing number of lost-to-followup patients, and look as well at patients for whom there previously were no data on initial modality or death. This new data integration is detailed on page 231.

**CMS DIALYSIS FACILITY COMPARE DATA**

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

**CMS ESRD CLINICAL PERFORMANCE MEASURES PROJECT**

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

**MINIMUM DATA SET**

The CMS Minimum Data Set (MDS) contains data on ESRD patients in long-term care facilities. Since June 22, 1998, CMS has required nursing homes participating in Medicare and/or Medicaid programs to supply MDS information, which is collected by staff at the nursing homes and reported to CMS through the Nursing Home Resident Assessment and Care Screening form.

**MEDSTAT MARKETSCAN® DATABASES (EGHP)**

We use Employer Group Health Plan (EGHP) data to illustrate healthcare trends in the younger and healthier segments of the population. These data are obtained from the Medstat MarketScan databases—specifically, the Commercial Claims and Encounters database, combined with the Medicare Supplemental and COB database—which are constructed from private sector data contributors that include approximately 45 large employers, health plans, and government and public organizations. Paid medical and prescription claims are collected from approximately 100 payors, including commercial insurance companies, Blue Cross and Blue Shield plans, and third-party administrators. These data represent healthcare utilization by insured active employees and their dependents, early retirees, and COBRA enrollees. Claims evidence includes inpatient and outpatient medical/surgical encounters as well as outpatient pharmaceutical claims, and claims are linked to person-level enrollment data including age, gender, and geographic location.

**NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY**

NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1960, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2002 were nationally representative cross-sectional surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys oversampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

**ANNUAL FACILITY SURVEY (AFS)**

Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS’s Annual Facility Survey, which all dialysis units 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 data, they provide independent patient counts used to complement the CMS patient-specific records.
CDC SURVEILLANCE
The CDC used its National Surveillance of Dialysis-Associated Diseases to collect data from U.S. dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment, therapy, vascular access use, antibiotic use, hepatitis vaccination and conversion rates for staff and patients, and the incidence of HIV, AIDS, and tuberculosis. No data are patient-specific. The CDC did not conduct a survey in 1998, and terminated this program after 2002.

UNITED STATES CENSUS
In rate calculations throughout this year’s ADR we use data from the 2000 U.S. Census, and also incorporate CDC population estimates by race. Our methods are described on page 255.

Data management & preparation
Our main computer system is a Compaq Alpha system—one Compaq AlphaServer DS20 with dual EV-6 (500 MHz) processors, with a total of 12 GB of RAM memory and 6 terabytes of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, all managed by five interconnecting high-speed storage clusters.

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

DATA LOADING & CLEANING
Data files come to the USRDS in IBM 3490 and 3490C cartridges/CD-ROMs with EBCDIC, ASCII, or SAS formats. Once loaded, files are converted into SAS data sets for processing, and a series of data verification steps is completed to ensure data quality and integrity before updating the USRDS database.
DATABASE UPDATES
For this ADR, patient demographic and diagnosis data are updated through November, 2004, and Medicare Part A and B claims are collected through December 31, 2003.

ESRD PATIENT DETERMINATION
A person is identified as having ESRD when a physician certifies the disease on the CMS Medical Evidence (ME) form, or when there is other evidence of chronic dialysis or a kidney transplant. Patients with acute kidney failure who are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database as much as possible. Patients who die soon after kidney failure without receiving dialysis are sometimes 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 survival analyses.

The FSD is derived by taking the earliest of the date of the start of dialysis for chronic kidney failure, as reported on the ME form; the date of a kidney transplant, as reported on a CMS or OPTN transplant form, an ME form, or a hospital inpatient claim; or the date of the first Medicare dialysis claim. Most FSDs are obtained from the ME form. In the absence of this form, the date of the first Medicare dialysis claim or transplant usually supplies the FSD. In the few cases in which the date of the earliest dialysis claim precedes the first dialysis date reported on the ME form, the earliest claim date is used as the FSD.

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

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by Employer Group Health Plans (EGHPs), must wait 30–33 months before becoming eligible to have Medicare as their primary payor, and 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 all non-Medicare ESRD patients are assigned a code of ‘ZZ’ in the two-character Beneficiary Identification Code field. CMS does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that ‘ZZ’ patients are true ESRD patients, and should therefore be included in patient counts for incidence, prevalence, and treatment modality. Calculations of standardized mortality ratios (SMRs), standardized hospitalization ratios (SHRs), and standardized transplantation ratios (STRs), however, should not include these patients because of the small number of claims available in the first 30–33 months after their first ESRD service. Furthermore, it may not be possible to link ‘ZZ’ patients to their ESRD Death Notification forms (CMS 2746) or the OPTN transplant data, or to determine comorbidity or Part A and B services. Because such data are limited, event rates that include these patients must be assessed with caution.

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 uses all available data to create a treatment history for each patient in the database, including all modality events, their duration, and the renal providers involved in each patient’s care.

Gaps frequently exist in the billing data upon which modality periods are based. 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 submission of Medicare dialysis claims, lost-to-followup categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data to the numerator. In comparison to the two-year rule used in the 2001 ADR, this three-year rule significantly reduces the number of lost-to-followup patients in the prevalent population.

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 may receive dialysis covered by a payor other than Medicare, or have received a transplant not paid for by Medicare or reported to OPTN.
- The patient may be enrolled in a Medicare HMO, so that Medicare dialysis claims 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.

INTEGRATION OF THE USRDS, SIMS, & REMIS DATABASES
We continue working to reconcile ESRD patients in the SIMS, REMIS, and USRDS databases. We have analyzed each database for duplicate records, consolidated these records, and integrated the databases. These integrated data were then re-analyzed for duplicates, which were themselves consolidated. This consolidation of patients is an ongoing collaborative effort between the ESRD Networks, CMS, and the USRDS.

Patient treatment histories compiled by the USRDS rely on Medicare dialysis billing records, which contain no information on dialysis therapy or modality changes in non-Medicare patients. Beginning with the 2003 ADR, we incorporate treatment-specific information from the ESRD Networks’ SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-followup. In this ADR the consolidation efforts from database integration among USRDS, SIMS, and REMIS continue to pay dividends in reducing the number of lost-to-followup patients—19,230 in 2003, compared to 24,726 in 2002.

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

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

### 60-DAY STABLE MODALITY RULE: TREATMENT HISTORY

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

### 90-DAY RULE: OUTCOMES ANALYSES

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

### SERUM ALBUMIN DATA

The Medical Evidence form reports a patient’s serum albumin level along with the lower limit of the test, which indicates the testing method used. There are currently two laboratory methods in use: brom cresol purple and brom cresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

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

### Database definitions

#### MODALITIES

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

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

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

#### PAYORS

Information on payors is obtained from the CMS Medicare Enrollment Database (EDB). We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payor (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payor sequence file to provide pay or history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors. The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP, Medicare as secondary payor, Medicare+Choice, Medicaid, or a combination of payors. With this approach, the USRDS is now able to apply pay or status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Eleven).

#### PRIMARY CAUSE OF RENAL FAILURE

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

- diabetes: 250.00 and 250.01
- hypertension: 403.9, 404.1, and 593.81
- glomerulonephritis: 580.0, 580.4, 582.0, 582.1, 582.9, 583.1, 583.2, 583.4, and 583.81
- cystic kidney: 753.13, 753.14, and 753.16
- other urologic: 223.0, 223.9, 590.0, 592.0, 592.9, and 599.6
- other cause: all other ICD-9-CM codes covered in the list of primary causes on the Medical Evidence form, with the exception of 799.9
- unknown cause: 799.9 and ICD-9-CM codes not covered in the list of primary causes on the Medical Evidence form
- missing cause: no ICD-9-CM code listed

#### RACE & ETHNICITY

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.
Patient ethnicity became a required field on the revised Medical Evidence form, released in 1995; because data for this year are incomplete, information on Hispanic patients is presented starting in 1996. 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 concentrate on white, black, Native American (includes Alaskan Native), and Asian (includes Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase.

EGHP COHORT
EGHP data in this year’s ADR are derived, as mentioned above, from Medstat Marketscan databases. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a fee-for-service plan with no more than a 40-day gap between plan changes, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

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

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

Précis
In Figure p.1, we determine CKD, CHF, and diabetic status in the 5 percent Medicare sample using methods described for Chapter One; these methods are also used to determine CHF and diabetic status in the ESRD population. Costs for the “cost year” are determined for the entire calendar year for patients who have fee-for-service coverage and Medicare as primary payer. Because this analysis combines the ESRD cohort with the 5 percent Medicare sample, ESRD patients in the 5 percent sample are excluded.

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

Figure p.12 includes prevalent hemodialysis patients in the CPM database whose current access at the time of data collection is known, while Figure p.13 includes prevalent hemodialysis patients in the CPM database with at least one valid URR measurement. For each patient, we calculate a mean URR from all measurements available, then the percentage of patients whose mean URR is in each category. Figure p.14 includes prevalent peritoneal dialysis patients in the CPM database who have at least one valid Kt/V measurement. For each patient, we calculate a mean Kt/V measurement from all those available, then the percentage of patients whose mean Kt/V is in each category.

Figure p.15 presents the distribution of patients by mean hemoglobin group on a monthly basis, in which each month contains all patients with at least one EPO claim during the month. Figure p.16 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 or fewer administrations per month. The mean EPO dose is adjusted as in Chapter Five, with a patient’s time at risk including only those days in which he or she is not in an inpatient hospital setting. (Because 2004 inpatient claims data were not available when this ADR went to press, time spent in an inpatient hospital setting is not removed from the time at risk in the 2004 EPO doses calculated with the new method.)

The method and cohort used for Figure p.17, on diabetic care in prevalent patients, are the same as those used for Figures 5.11, 5.14, and 5.17.

Figures p.18–19 include EGHP patients in the Medstat Marketscan database. The study period is divided into selection and observation periods. The selection period, the first year of the two-year window, is used to define comorbidity, including ESRD and dialysis. The observation period, the second year, is used to count prescription drug therapy. Patients included in the analyses are age 20–63, have a continuous history of fee-for-service enrollment in any two consecutive years (study period) from 1999 to 2002, with no gaps for coverage greater than 40 days, and have continuous prescription drug coverage from 2000 to 2003, the observation period. In all of this year’s drug analyses, ICD-9-CM codes during the selection period are used to identify patient comorbidities. Lists of the medications included here can be found in the Excel spreadsheet file for the Précis, on our website and CD-ROM.

Figure p.20 shows the percent of patients with at least one hospitalization during three-month intervals from 24 months prior to six months after ESRD initiation. We include Medicare ESRD patients at least 67 years old with a first ESRD service date between January 1, 2002, and June 30, 2003. To avoid inclusion of patients without Medicare coverage, we exclude patients without at least one claim of any type (Part A institutional or Part B physician/supplier) during the two-year period prior to initiation. For Figures p.20–23, principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figures 6.6–6.8. For Figure p.21, vascular access hospitalizations are those defined as “pure” inpatient vascular access events, as described for Tables G.11–15.

Figures p.21–23 show total admission rates for period prevalent ESRD patients. Methods generally follow those described for the prevalent patient cohorts in Chapter Six and Reference Section E. Included patients have Medicare as a primary payer and 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 are excluded, as are patients with missing age or gender information. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method, described in the statistical methods sections of this appendix. The reference cohort includes period prevalent ESRD patients, 2003, and vintage 2004 is calculated as the time from the first ESRD service date until the first of the year for prevalent patients, or as less than one year for incident patients.

Figure p.24 presents adjusted first-through-five-year mortality rates, by modality, for incident ESRD patients. Patients are followed from day 91 until death or December 31, 2003. For dialysis cohorts, patients are also censored at transplant. Rates are computed from the Cox model using the model-based adjustment meth-
od, described later in this appendix, and adjusted for age, gender, race, and primary cause of ESRD. The reference population consists of 1996 incident ESRD patients, and these rates are comparable across modalities.

Figure p.25 illustrates five-year survival by first modality. Populations for the 1989–1993 and 1994–1998 cohorts include incident patients on hemodialysis or peritoneal dialysis on the first ESRD service date, and patients receiving their first renal transplant in a calendar year. All cohorts include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories, and exclude those with unknown age, gender, or primary diagnosis, as well as those with a listed age greater than 110; in the dialysis cohort, patients who die or are transplanted in the first 90 days are also excluded. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2003, while transplant patients are followed from the first transplant date until death or the end of 2003. Survival probabilities are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted probabilities can be compared across modalities.

Figure p.26 shows trends in mortality rates by modality and vintage, and includes period prevalent patients on hemodialysis, on peritoneal dialysis, or with a transplant in a calendar year. All populations include both Medicare and non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown age or gender, or of races other than white, black, Native American, and Asian, are excluded. Dialysis patients are followed from January 1 until death, transplant, or the end of the year, while transplant patients are followed from January 1 until death or the end of the year. All-cause mortality rates by modality are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. All-cause mortality rates for all ESRD are adjusted for age, gender, race, primary diagnosis, and modality using generalized mixed models. Because the reference population consists of 2001 period prevalent ESRD patients, adjusted rates across modalities can be compared.

In Figures p.33–42, CKD, CHF, and diabetes are determined using the methods described for Chapter One. The population for the 5 percent Medicare data (Figures p.32–37) is limited to patients with fee-for-service coverage and Medicare as primary payor. The EGHP cohort (Figures p.38–42) is described in the “EGHP cohort” section, above. Cost aggregations are for the calendar year, and are censored at the earliest of the development of ESRD, loss of entitlement, the end of the calendar year, or death.

Healthy People 2010

Targets come directly or are estimated from published HP2010 objectives on chronic kidney disease and immunizations.

Objective 4.1: Incident rates in Figures hp.2–3, hp.4 (first graph), and hp.23, and in Table hp.a, are calculated using the methods described for Chapter Two. Rates of diabetes in the general population (second graph in Figure hp.4) are obtained from the CDC’s Behavioral Risk Factor Surveillance System, at www.cdc.gov/brfss.

Objective 4.2: The study cohort includes period prevalent ESRD patients, 1991–2003. Cause-specific cardiovascular mortality is defined using CMS codes 27 and 31 (congestive heart failure), 26 (atherosclerotic heart disease), 02 and 23 (myocardial infarction), and 01, 04, 25, 28–30, and 36–37 (other cardiovascular disease). Age is calculated for point prevalent patients as of January 1, and for incident patients as of the first ESRD service date. We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.4: For Figures hp.9–10, the calculation of insertion rates follows methods used in Chapter Five. For Table hp.c (CPM year 2003) and Figures hp.8 and hp.25 (CPM years 1999–2003), data are obtained from the CMS Clinical Performance Measures (CPM) Project. Patients included in hp.8 and hp.25 are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and the access type represents the access used at the time of data collection. Table hp.c includes prevalent patients from 1999–2003 CPM reports with a fistula as their current access, and the year represents the year of data collection. To obtain consistent information on race and ethnicity, patients included in the CPM dataset are matched to those in the ESRD database using UID numbers.

Objective 14.29: The cohort for influenza vaccinations includes all ESRD patients initiating therapy 90 days prior to September 1 of each year and alive on December 31. For pneumococcal pneumonia vaccinations, cohorts include all ESRD patients initiating therapy 90 days before January 1 of the graphed time period and alive on December 31. Patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories are omitted from the study, as are those who have a missing date of birth, who have ESRD for fewer than 90 days prior to the start of the reporting interval, or who are lost-to-follow up during the study period. Influenza vaccinations are tracked between September 1 and December 31 of each year, while pneumococcal pneumonia vaccinations are tracked during the time periods graphed. Patients in both analyses have Medicare Parts A and B coverage during the study periods. All ages are calculated at the end of the graphed time period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS codes G0088; pneumococcal vaccinations are identified through CPT codes 90669 and 90711, and HCPCS codes J6065 and G0088.

Objective 4.5: The study cohort for Figures hp.14–15 and Table hp.e includes patients from 1991–2002 who are younger than 70. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of initiating ESRD therapy, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded.) Percentages are estimated using the Kaplan-Meier method. Note that this method differs from those used in previous ADRs, which showed the percent of point prevalent dialysis patients on the waiting list as of December 31 of the given year.

Objective 4.6: The study cohort here includes patients from 1991–1999 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first of death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

Objective 4.7: Incident rates for Figures hp.18–20 and hp.29, and for Table hp.g, are calculated using the methods described for Chapter Two.

Objective 4.8: Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) testing, microalbuminuria testing, and eye exams 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), while those for lipid testing are described in the methods for Chapter One. The pre-ESRD population includes incident ESRD patients age 67 or older at the start of ESRD, with diabetes diagnosed one year prior to initiation; patients enrolled in a managed care program or with Medicare as secondary payor are excluded. Diabetic eye examinations are tracked for the two years prior to ESRD initiation, while lipid, HbA1c, and microalbuminuria testing are tracked for the one year prior. The
general Medicare population includes individuals diagnosed with diabetes in each year, continuously enrolled in Medicare Parts A and B during the diagnosis year and the previous year, and age 67 or older on the last day of each diagnosis year. Eye examinations for these patients are tracked during the diagnosis year and the previous year, while lipid, HbA1c and microalbuminuria testing are tracked during the diagnosis year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, or are diagnosed with ESRD during any of the two-year study periods. Because of categorizations in the general Medicare database, racial and ethnic categories are mutually exclusive. For both populations, patients with a missing date of birth are omitted, as are those not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories.

**Chronic kidney disease**

**CHAPTER ONE**

Figure 1.1 illustrates the size of the chronic kidney disease (CKD) population and the proportion of patients with diabetes and/or congestive heart failure (CHF), showing both general Medicare and EGHP populations in 2003. Figure 1.2 shows trends in the prevalent rate of diabetes, CHF, and combined diabetes and CHF in general Medicare and selected EGHP populations with CKD. General Medicare cohorts are derived from the 5 percent Medicare Denominator files, 1992–2003, and include patients continuously enrolled in Medicare Parts A and B for an entire calendar year and alive on the last day of the year. We exclude patients diagnosed with ESRD or enrolled in a managed care program (HMO) any time during the calendar year. EGHP cohorts are derived from the Medstat databases, 1999–2003, and include patients younger than 65 who are continuously enrolled in a fee-for-service plan for an entire calendar year with no gaps of coverage greater than 40 days.

According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-year observation period, he or she has an ICD-9-CM diagnosis code of diabetes on one or more Part A institutional claims (inpatient hospitalization, skilled nursing facility, or home health agency), or two or more Part A institutional claims (outpatient) or Part B physician/supplier claims. Using this methodology, we identify CKD patients with or without diabetes or CHF in each calendar year. Codes used to identify patients are as follows: CHF, 398.91, 422, 425, 428, 402.x1, 404.x1, 404.x3, and V42.1; CKD, 016.0, 095.4, 189.0, 189-9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 440-1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; and diabetes, 250.3, 357.2, 362.0x, and 366.41.

Figure 1.3 describes the geographic variations in prevalent CKD rates for the general Medicare population. Study cohorts are constructed with the method used for Figure 1.1, with the additional requirement that patients be continuously enrolled in Medicare during two consecutive calendar years. The prevalent rate of CKD is estimated as the number of patients with CKD per 1,000 population in each Health Service Area.

Figure 1.4 illustrates trends in population size by diabetic, CHF, and CKD status for general Medicare (1992–2005) and EGHP (1999–2005) patients. EGHP cohorts are constructed with the method used in Figure 1.1, with patients also required to be continuously enrolled in a fee-for-service plan during two consecutive calendar years with no gaps of coverage greater than 40 days.

Figures 1.5–10 compare cumulative probabilities of CKD assessments in general Medicare and EGHP at-risk populations, using the Kaplan–Meier estimation method.

The prevalent Medicare cohort includes patients entering Medicare before January 1, 2002, alive and remaining in the program through December 31, and with no CKD diagnosed during 2002. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the year are excluded, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The EGHP cohort includes patients enrolled for all of 2002 in a fee-for-service-plan, under 65 years of age, and with no CKD diagnosed during 2002. Patients diagnosed with ESRD before or during the year are excluded. For both cohorts, diabetes, CHF, and other comorbidities are defined in 2002. Methodology and codes used to define CKD and the comorbidities are described above.

Assessments of CKD include serum creatinine, microalbuminuria or proteinuria, renal ultrasound, calcium and phosphorus testing, and parathyroid hormone testing; the battery of tests in Figure 1.10 includes all of these except the renal ultrasound and PTH tests. The first testing of each assessment is tracked in 2003. Patients are censored at the end of the plan, at the end of 2003, and, for the general Medicare population, at death. Tests are identified through the following CPT codes: serum creatinine, 80069 and 82565; microalbuminuria or proteinuria (described in the HP2010 chapter), 82042, 82043, and 82044; renal ultrasound, 76770, 76775, and 76778; calcium and phosphorous, 80069, 80073, 82310, 82315, 82320, 82325, 82330, and 84100; parathyroid hormone, 83970.

Figures 1.11–12 illustrate the cumulative probabilities of bone and mineral metabolism testing in general Medicare and EGHP population with CKD, while Figures 1.13–18 show the cumulative probabilities of preventive healthcare monitoring. Methods and codes used to determine rates of glycosylated hemoglobin (HbA1c) and microalbuminuria or proteinuria testing are taken directly from HEDIS 2002 specifications, described in methods of the HP2010 chapter. Methods and codes used for lipid testing, diabetic testing strips, influenza vaccinations, and pneumococcal vaccinations are defined by the USRDS.

For Figures 1.11–16, the prevalent Medicare cohort includes patients entering Medicare before January 1, 2002, and alive and remaining in the program through December 31. For Figure 1.17, patients are alive and in the program through August 31, 2003. And for Figure 1.18, patients must enter Medicare before January 1, 2001, and remain alive and in the program though December 31, 2001. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during 2001 (for 1.18, during 2000) are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The EGHP cohort includes patients enrolled during the study period in a fee-for-service plan and younger than 65. Patients diagnosed with ESRD before or during 2002 (for 1.18, during 2001) are excluded. For Figures 1.13–15, patients are diagnosed with CKD and diabetes in 2002. For Figures 1.16–17, patients are diagnosed with CKD in 2002, and for Figure 1.18, patients are diagnosed with CKD in 2001.

The Kaplan–Meier estimation method is used to calculate cumulative probabilities. The first testing of each preventive healthcare measure is tracked in 2003. Patients are censored at the end of the plan, at the end of 2003, and, for the general Medicare population, at death, and all comorbidities are defined using methodologies and codes described above.

Codes used to identify testing are as follows: lipid testing, CPT codes 80661, 82465, 83715–83721, and 84478; HbA1c testing, CPT code 82036 (claims made within 30 days of the last claim for each patient are excluded, and at least two HbA1c claims must be counted); diabetic testing strips, HCPCS code A4253; influenza vaccinations, CPT codes 90724, 90657, 90658, and 90659, and HCPCS code G0008; pneumococcal vaccinations, CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009.

Figures 1.19–24, 1.28, and 1.30–31 present data on the NHANES III and NHANES 1999–2002 populations, age 60 and older. CKD
is defined by an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73 m², or an eGFR greater than or equal to 60 in the presence of microalbuminuria. The eGFR is estimated separately for NHANES III, NHANES 1999–2000, and NHANES 2001–2002, using the MDRD method based on adjusted creatinine value. Patients with an eGFR less than 15 ml/min/1.73 m² are excluded from the analyses. Microalbuminuria is defined by the ratio of urinary albumin to urinary creatinine (albumin/creatinine ratio, or ACR). Participants with a valid ACR if this value is not less than 30 mg/g. Hypertension, CHF, cardiovascular disease, and diabetes are self-reported comorbidities identified through the survey’s medical history questionnaires. Self-reported cardiovascular disease is defined as at least one of following self-reported diseases: coronary heart disease, angina/angina pectoris, heart attack, or stroke. Lists of the medications used in these analyses can be found in the Excel spreadsheet file for Chapter One, on our website and CD-ROM.

Figures 1.25–26 show racial disparities in serum creatinine and microalbuminuria or proteinuria testing in non-CKD patients, using the same cohorts used in Figure 1.5.

Figures 1.27 and 1.29 show racial disparities in diabetic HbA1c testing and general lipid testing for CKD and non-CKD patients. Cohorts are similar to those used in Figure 1.13, except that patients for Figure 1.27 are diagnosed with diabetes in 2002, while no specific disease is diagnosed for patients in 2002 for Figure 1.29.

Figures 1.32–37 show adjusted all-cause and cause-specific hospitalization admission rates, by the presence of diabetes and CHF, for general Medicare (1993–2003) and EGHP (2000–2003) patients with and without CKD. The prevalent Medicare cohort includes patients continuously enrolled in Medicare Parts A and B, with no HMO coverage, alive during the one-year entry period, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The prevalent EGHP cohort is comprised of patients age 20–65 with fee-for-service coverage during the entire calendar year and alive on the last day of the entry period. Patients diagnosed with ESRD before or during the entry period are omitted from the study. For Medicare patients, the period at risk for the hospitalization analysis is from January 1 until the earliest of death, end of Medicare coverage, or December 31 of the year; EGHP patients are followed up to one year from January 1 of the year after the entry period.

The same methodology described for Figure 1.1 is used to define patients with CKD, diabetes, or CHF. The all-cause hospitalization calculation excludes hospitalizations related to pregnancy or childbirth. In the Medicare data, pregnancy-related hospitalizations are identified through DRG codes of 370–391 and 469-470; in the EGHP data, hospitalizations with major diagnostic categories of 14 (pregnancy, childbirth) and 15 (newborns) are excluded in counting total hospitalizations. Principle ICD-9-CM diagnosis codes used to define cause-specific inpatient hospitalization categories are as follows: CHF, 398.91, 422, 425, 428, 402.x1, 404.x1, and 404.x3; ISHD, 410–414; pneumonia, 480–486 and 487.0; and bacteremia/septicemia, 038–038.9 and 790.7. An admission for a hospitalization spanning the start of the analysis period is excluded from the total admissions for that period. All overlapping and certain consecutive hospitalizations are combined using the methods described for Chapter Six.

For general Medicare patients, hospitalization admission rates are adjusted for age, gender, and race, using the direct adjustment method (described in the section on statistical methods), with the 2003 general Medicare cohort used as the reference group. Rates for EGHP patients are adjusted for age and gender, using the 2003 EGHP cohort as reference. Since age distribution is entirely different in the Medicare and EGHP cohorts, adjusted rates are comparable only within graphs or within the Medicare and EGHP populations individually, not between the Medicare and EGHP cohorts.

Figure 1.33 displays geographic variations in unadjusted one-year all-cause hospital admission rates for the general Medicare CKD and non-CKD populations in 2003. Patient exclusion criteria are the same as those used in Figure 1.32. Followup begins on January 1 of the year and continues until death, the last day with Medicare coverage, or one year after the start of followup.

Figures 1.38–42 present data on acute renal failure (ARF). Figure 1.38 shows the cumulative probability of hospitalization for ARF by diabetic and CHF status, for general Medicare populations with and without CKD. The study cohort consists of patients continuously enrolled in Medicare Parts A and B, with no HMO coverage during 2000; residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and alive on December 31, 2000. Patients diagnosed with ESRD before December 31, 2000, are omitted from the study. Patients are followed from January 1, 2001, until the earliest of ARF hospitalization, ESRD, death, end of Medicare coverage, or December 31, 2003. The longest followup time is three years.

The one-year entry period in 2000 is used to define patients with CKD, diabetes, or CHF. The methodology here is essentially the same as that described for Figure 1.1, with the exception of the use of the 584 ICD-9-CM code. Hospitalization for ARF is identified through this code, appearing on Medicare inpatient claims, by three methods, 1) as all diagnosis codes (A-ARF), 2) as principle diagnosis codes (P-ARF), and 3) as secondary diagnosis codes (S-ARF). The three graphs are thus generated through different methods to identify ARF hospitalizations. Patients with hospitalizations for ARF overlapping the start date of the followup period are excluded from the analysis. We use life-table estimation methods to investigate the cumulative unadjusted probability of hospitalization for ARF at years one, two, and three of the followup period.

Figures 1.39–42 display the pattern of ESRD development and death in Medicare patients after their first ARF hospitalization. A one-year entry period before the first ARF hospitalization admission date is used to define CKD, diabetes, and CHF status. Patients not continuously enrolled in Medicare Parts A and B, with HMO coverage during the entry period, or residing out of the 50 states, the District of Columbia, Puerto Rico, or the Territories, are excluded. A study period of January 1, 1999, to December 31, 2000, is used to identify patients with an ARF hospitalization any time during this time frame. The followup period extends from the first admission date for ARF hospitalization until the earliest of death, ESRD diagnosis, or December 31, 2003.

The methodology used to define patients with CKD, diabetes, or CHF is the same as that described for Figure 1.38, and hospitalization for ARF is identified through the same 584 ICD-9-CM diagnosis code on inpatient claims.

Rates for ESRD development or death in each three-month interval are estimated by the Poisson model, adjusted for the presence of CKD, diabetes, and CHF, and for baseline age, race, and gender; the entire cohort is used as the reference group. Rates in the subgroups defined by diabetes and CHF are adjusted for the remaining variables.

Incidence & prevalence of ESRD

CHAPTER TWO & REFERENCE SECTIONS A & B

Here and throughout the ADR, the USRDS generally reports point prevalence—the type of prevalence used throughout most of the book—as of December 31, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of patients who have the disease at the end of the year and those who have the disease during the year and die before the year's end. Because the USRDS treats successful transplantation as a therapy rather than as a “recovery” from ESRD, patients with a functioning transplant are counted as prevalent patients.
Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS are not included in the database. We therefore qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term “acceptance into ESRD therapy.” We believe, however, that “incidence of reported ESRD therapy” is more precise, because “acceptance” implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS.

Beginning with the 1992 ADR, lost-to-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.

ICD-9-CM codes for the diagnoses in Tables 2.a–b can be found on page 275, in the Medical Evidence (2728) form.


Figures 2.31–32 present hemoglobin and hospitalization data for incident ESRD patients. Included Medicare patients have a first ESRD service date between January 1, 2001, and June 30, 2003, and are at least 75 years old at initiation. To ensure Medicare eligibility, we exclude patients without any Medicare claims (Part A institutional or Part B physician/supplier) in the two years prior to initiation. For Figure 2.31, hemoglobin, height, weight, and creatinine at initiation are obtained from the Medical Evidence form, and patients without these data are excluded. Values are used to calculate BMI and eGFR (with the Levey formula). Length of stay is computed as total hospital days during the two years prior to initiation. Adjusted differences in mean hemoglobin are computed by age, gender, and race.

Figures 2.33 includes patients age 75 or older at the time of initiation, and Medicare-eligible with at least one claim during the two years prior to initiation. The cumulative percent represents one minus the unadjusted Kaplan-Meier survival probability for the time to fistula insertion, censored at death or change in modality.

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 M) 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.6, A.8, A.10, 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 residing in the 50 states and the District of Columbia. Age is calculated as of December 31.

Patient characteristics

CHAPTER THREE & REFERENCE SECTION C

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

Before 1995, units were required to file the Medical Evidence form only for Medicare-eligible patients. With the adoption of the revised form in 1995, however, providers are now required to complete the form for all new ESRD patients, regardless of their Medicare eligibility. The revision also introduced 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.

Tables C.4–16 are restricted to patients for whom the first Medical Evidence form is the revised form; total patient counts for them, and for patients with no 2728 form, are presented in Table C.3.

Figures 3.5–7 show cardiovascular, COPD, and cancer comorbidities in incident ESRD patients during the year after ESRD initiation. These figures include only patients who survive 90 days plus one year following initiation and have Medicare as a primary payer throughout the year. The followup year spans from 90 days after initiation until one year after day 90. Included patients have a first ESRD service date between January 1, 1991, and October 2, 2002. (The latter date is chosen to allow a complete year of followup after day 90 for all patients, since data are currently available through the end of 2003.) Comorbidities are reported as the percentages of patients hospitalized with at least one inpatient claim for the specified disease during the followup year. Comorbidity groups are determined by principal and secondary ICD-9-CM diagnosis codes. The codes for PVD and cancer are listed in the discussion of Figures 6.61–68. Other codes are as follows: for CHE, 398.91, 422, 425, 428, 402.x1, 404.x3, or V42.1; for ISHD, 411.1–411.89 or 413–414 (which excludes myocardial infarction); and for COPD, 491–494, 496, or 510.

Using EGHIP patients in the Medstat database, Figures 3.8–13 illustrate trends in the cumulative percent of incident dialysis patients receiving prescription drug therapy. Included patients have a confirmed ESRD status, a first service date not in the current year and not less than 60 days after the enrollment start date, and, for transplant patients, a transplant date later than the current year. Analyses are censored during the observation period at transplant. The method for defining comorbidity is the same as that used.
in Figures p.18–19; a list of included medications is available in the Chapter Three Excel spreadsheet on our website and CD-ROM.

Table 3.a displays the odds ratios of having a body mass index greater than 30 kg/m². Odds ratios are estimated from separate but identical logistic models for white, black, Native American, Asian, and Hispanic patients for whom a Medical Evidence (ME) form was submitted between January 1, 1996, and July 1, 2004. Patients with missing measurements for albumin or serum creatinine are excluded, as are those with a value other than 3.2 or 3.5 in the serum albumin field on the ME form. Body mass index is calculated from height and weight information on the ME form. All prognostic covariates are taken or calculated directly from this form.

Table 3.b displays the odds ratios of having an estimated glomerular filtration rate (eGFR) greater than the population's gender-specific mean. Odds ratios are estimated from separate but identical logistic models for white, black, Native American, Asian, and Hispanic patients for whom an ME form was submitted between January 1, 1996, and July 1, 2004. Patient exclusions are the same as those in Table 3.a. eGFR is estimated using the Schwartz et al. formula for patients age 0–18, and the four-variable formula of Levey et al. for patients 19 and older. The population mean eGFR is equal to 85 ml/min/1.73 m² among female patients, and 93 ml/min/1.73 m² among male patients. All prognostic covariates are taken or calculated directly from the ME form.

Treatment modalities

CHAPTER FOUR & REFERENCE SECTION D

Chapter Four 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. Unless noted otherwise, incident and prevalent cohorts without the 60-day stable modality rule are used in the analyses.

Treatment modalities are defined here as follows:

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

Figures 4.7–10 use the combined 1996–1998 incident ESRD dialysis cohort with the built-in 60-day stable modality rule. All incident dialysis patients are followed from the day of ESRD initiation to a maximum of five years. The cumulative probabilities are estimated using the Kaplan–Meier method, censoring at change in dialysis modality, transplantation, death, and the end of the follow-up period.

Modality and provider characteristics are presented in Figures 4.11–16. For a description of the provider data used in these figures, please see the discussion of Chapter Ten.

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

Table D.12 shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 1999 to 2001. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

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

Clinical care

CHAPTER FIVE

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 5.1 and 5.31–37 are obtained from EPO claims data, while in Figures 5.1 and 5.2–5.9, and in Table 5.4, information on venous accesses and fistulas is obtained from Part B physician/supplier claims data as well as the CMS ESRD Clinical Performance Measures (CPM) Project. Data on urea reduction ratios (URR) in Figure 5.1 come from Part A institutional outpatient claims data. Data on Kt/V and vascular access in Figure 5.1 come from the CPM Project, while data on albumin come from the Medical Evidence form.

In Figure 5.1, for both Kt/V measurements, 2003 CPM data are used to calculate a mean Kt/V value for each patient from the 1–3 values present for each, and the percent of patients with a mean Kt/V over a certain threshold is determined. For prevalent hemodialysis patients in 2003, each patient's URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Each measurement is categorized into one of five ranges, and the median URR is calculated; for patients whose median lies between two ranges, we assign a weight of 0.5 to each. Information on new hemodialysis patients with an arteriovenous fistula as the first access is calculated as described for Figure hp.8. Hemoglobin levels are calculated for EPO-treated, 2003 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500 or greater than 80,000 units, or with a hematocrit value less than 10 or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hemoglobin values divided by three. Data on albumin are obtained for incident hemodialysis patients in 2003 who have a valid value on their Medical Evidence form; those with a lower limit equal to zero are omitted.
Figures 5.2–7 include incident hemodialysis patients who are in both the USRDS and CPM databases, and whose day 90 begins prior to October 1 of the incident year. The access represents the access being used on day 90 according to the CPM data. Figure 5.8 includes incident peritoneal dialysis patients from the USRDS database. For Figures 5.5–8, complication rates are calculated as the number of events (from Medicare claims) divided by the time at risk, which is censored at death, change in modality, change in payment status, or the insertion of a different type of access. Vascular access codes are listed in the methods for Chapter Eleven.

Figure 5.9 and Table 5.a include prevalent hemodialysis patients who are in both the USRDS and CPM databases. The access type represents the current access being used at the time of the CPM data collection.

Figures 5.10–21 present data on diabetic preventive care in patients age 18–75. ESRD patients without Medicare Parts A and B coverage during the entire study period are omitted from these analyses, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost-to-followup during the study period. Age is generally calculated at the end of the study period.

Methods and codes used to determine screening rates for diabetic glycosylated hemoglobin (HbA1c) testing, lipid testing, and diabetic testing strips are described in the methods for Chapter One. Patients are defined as having diabetes either through medical claims (one Part A, two Part B, two outpatient, or one Part B and one outpatient), or through a listing of diabetes on the Medical Evidence form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define diabetes are described in the methods for Chapter One.

Figures 5.10, 5.13, 5.16, and 5.19 compare rates of diabetic preventive care in 1993 and 2003, while Figures 5.12, 5.15, 5.18, and 5.21 compare rates in urban and rural patients. Geographic location is determined through patient ZIP code and the Census Bureau's Urbanized Area/Cluster information from the 2000 Census. The ESRD population includes patients initiating therapy at least 90 days prior to January 1 of 1992 or 2002, alive on December 31 of 1993 or 2003, and with diabetes defined in 1992 or 2002. Rates include patients receiving at least four HbA1c tests, at least two lipid tests, at least two strips per day, or all of the above during 1993 or 2003. Figures 5.12, 5.15, 5.18, and 5.21 show diabetic preventive care in 2003 only; patients with unknown urban or rural status are excluded.

For Figures 5.11, 5.14, 5.17, and 5.20, the cohort includes patients starting therapy at least 90 days prior to January 1 of the first year of each study period and with diabetes in the first year. Diabetic HbA1c and lipid testing, and diabetic testing supplies, are tracked in the second year of each period. HbA1c and lipid testing claims made within 30 days of the last claim for each patient are excluded. Code A4253 (blood glucose tests or reagent strips for a home blood glucose monitor, per 50 strips) is used to determine the number of blood glucose tests per day, and patients with a missing service unit here are not included. For Figure 5.17, patients are categorized as having no tests recorded or as averaging one or fewer tests per day, 1–2 tests per day, or more than two tests per day. In Figures 5.19 and 5.21, "complete" diabetic monitoring means at least four HbA1c tests, at least two lipid tests, and at least two strips per day; in Figure 5.20, "limited" monitoring indicates at least one HbA1c test, at least one lipid test, and at least one test strip.

Figures 5.22–25 display trends in the cumulative percentage of diabetic patients who receive prescription drug therapy, while Figures 5.26–30 look at patients with both diabetes and cardiovascular disease; both analyses use EGHP patients in the Medstat MarketScan database, and are censored at the date of ESRD initiation. For non-ESRD patients in Figures 5.22–30, prescription drug use is censored in the observation period at the initiation of ESRD. For the definition of diabetes, please refer to the discussion of Chapter One. Congestive heart failure status is not used to define cardiovascular disease in the analyses. A list of included medications is available in the Chapter Five Excel spreadsheet on our website and CD-ROM.

Figures 5.31–35 include 2003 incident hemodialysis whose initiation began at least 90 days prior to June 30, 2003; who were alive, on hemodialysis, and with Medicare as primary payor for at least six months after day 90; and who had at least one valid EPO claim during each of those months. The starting hemoglobin represents the mean hemoglobin from all EPO claims during the first month after day 90. Only patients with a valid ZIP code are included. Dosages are adjusted for inpatient hospital days, and for Figures 5.32–33 the percentages are calculated as the percent change in mean dose per week from the first month after day 90. For Figure 5.35, blood transfusions are obtained from Part A and B Medicare claims.

Figures 5.36–7 include prevalent hemodialysis patients in the USRDS and CPM databases. Only patients with at least one non-missing value for iron saturation and ferritin in the CPM data are included. Patients must remain alive, on hemodialysis, and with Medicare as primary payor through June, 2003, and must have at least one valid EPO claim during each of the first six months of 2003. The mean hemoglobin represents the mean hemoglobin from claims during January, 2003. Information on IV iron is obtained from Medicare claims. For Figure 5.37, doses are adjusted for inpatient days.

Figures 5.38–41 show rates of diabetic HbA1c and lipid testing by modality, along with cumulative probabilities of the first testing in 2003. Cohorts for Figures 5.38 and 5.40 are the same as described for Figure 5.11. Cohorts for Figures 5.39 and 5.41 are 2002 point prevalent ESRD patients with Medicare Part A and B coverage at initiation, alive and remaining in the program through the end of 2002, and with diabetes diagnosed in 2002; patients who are lost-to-followup in 2002 are excluded. First HbA1c and lipid tests are tracked in 2003. The life table (or actuarial) estimation method is used to calculate cumulative probabilities. Patients are censored at death, payment status change date, end of followup, and end of 2003.

Cohorts for Figures 5.43–46 are the same as those described for Objective 14.29 in the HP2010 chapter, while the cohort for Figures 5.47–48 includes prevalent patients initiating therapy 90 days prior to January 1 and alive on December 1, 2003. Rates are calculated for patients receiving one vaccination or test in 2003. Patients without Medicare Part A and B coverage during 2003 are omitted, as are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, who do not survive until December 31, 2003, or who are lost-to-followup during 2003. Age is generally calculated at the end of the study period. Hepatitis B vaccinations are tracked in 2003, and are identified through CPT codes 90656, 90740, 90743–90744, 90748, 90731, and 90723.

Outcomes: hospitalization & mortality

CHAPTER SIX & REFERENCE SECTIONS G–I

Hospitalization

Methods used for the prevalent patient hospitalization figures in this chapter generally echo those used for the tables in Reference Section G (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the followup time at risk. One difference is the exclusion in Reference Section G of patients of races that are unknown or other than white, black, Native American, or...
Analytical methods

APPENDIX A

A young patient born in 1987 has been on dialysis since 1995. For the first 90 days, the rate of new catheter insertions per patient year for incident ESRD patients is described. The rate at month 18, for example, refers to the adjusted admission rate between months 12 and 18 following day 90 of ESRD. Dialysis patients are followed up to 60 months after day 90, but some tables restrict rates to earlier intervals due to rate instability for smaller subgroups as patients are censored. Rates for transplant patients are shown only up to 30 months after day 90, since these patients are censored three years after transplant due to potential loss of Medicare eligibility and incomplete hospitalization data. (Rates during the interval from months 30 to 36 after day 90 are not shown because it is a partial interval for most transplant patients, who are censored by month 33.) Age is determined at the beginning of each interval. Rates are adjusted with a model-based adjustment method and Poisson model.

The upper graph in Figure 6.1 is the same as Figure p.21, described in the discussion of the Précis, above. The lower two graphs in Figure 6.1 present adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, with the 2003 ESRD cohort used as the reference. Methods follow those described for Reference Section G.

Figures 6.2–3 show adjusted admission rates for incident ESRD patients during six-month intervals. Figure 6.2 includes intervals after day 90 of ESRD for patients at least 20 years old. Figure 6.3, on the other hand, shows intervals immediately after initiation of ESRD, without a 90-day period. This figure thus includes only patients at least 65 years of age, because hemodialysis patients younger than 65 may have incomplete claims in the first 90 days. Similar to Figure 6.2, Table 6.1 provides adjusted rates by intervals after day 90 for incident ESRD patients at least 20 years old. Rates for all patients are adjusted for age, gender, race, and primary diagnosis, and rates presented by one factor are adjusted for the other three.

Figures 6.4–8 present adjusted rates of total hospital admissions per patient year for incident dialysis patients age 20 and older. Because these rates are adjusted for different sets of factors (see figure captions), rate comparisons are appropriate only within a figure, not across figures. Principal ICD-9-CM diagnosis codes used here are as follows: cardiovascular disease, 276.6, 394–398.99, 403–405, 410–410, 423–438, and 440–449; and infection, 001–039, 254.0, and 540–542, 566–567.9, 569.3, 572–572.2, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 600–601.9, 604–604.9, 607.1, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.6–996.69, 997.62, 998.5, 999.3, V01–V069, V08, and V09. The “other” category includes hospitalizations that are not classified as either cardiovascular or infectious.

Figures 6.9–11 show adjusted admission rates for hospitalizations with a cardiovascular procedure. Incident adult (age 20 and older) dialysis patients are included. While the cause-specific admission rates in 6.8–6.9 include only principal diagnosis codes, the rates in Figures 6.9–11, in contrast, include any hospitalization with at least one principal or secondary ICD-9-CM procedure code for the cardiovascular procedure category. Therefore, the more inclusive rates here reflect all hospitalizations with a cardiovascular procedure, rather than only hospitalizations for the primary purpose of a cardiovascular procedure (as in Figure 6.29). The cause-specific categories are not mutually exclusive, for a hospitalization that includes more than one type of cardiovascular procedure will be counted under each category. The cardiovascular procedure category includes ICD-9-CM procedure codes listed in the discussion of Figure 6.29 (excluding vascular access procedures), but here all secondary codes are included in addition to principal codes. Other principal and secondary procedure codes are as follows: bypass, 36.1X: stent/angioplasty, 36.01, 36.02, 36.05, and 36.06; and valve procedures, 35.0X–35.2X and 35.31–35.33.

Figures 6.12–14 display adjusted vascular access insertion rates for incident adult hemodialysis patients. These are not hospital admission rates; rather, they are procedure rates that reflect vascular access insertions occurring in an inpatient setting. Vascular access insertions are obtained from CPT codes on Part B physician supplier claims, and are restricted to those occurring in the hospital (during an inpatient stay or emergency room visit). Categories include the following CPT codes: catheters, 36489, 36491, 36513, and 36800; fistulas, 36819, 36820, 36821, and 36825; and grafts, 36830. The category of all vascular access insertions includes all of the above CPT codes. Methods are also employed to exclude vascular accesses used for purposes other than dialysis. Rates for catheter and all vascular access insertions exclude patients with specific chemotherapy or parenteral nutrition claims during the year. Part A institutional, Part B physician/supplier, and durable medical equipment claims indicate chemotherapy (CPT codes 96408, 96410, and 96412) or parenteral nutrition (CPT codes B4164–B5200, B9004, B9006, and B9999). Also, catheter insertions with CPT codes 36489, 36491, and 36533 are included only if they are accompanied by an ICD-9-CM line-level diagnosis code or claim-level principal diagnosis code related to dialysis or renal failure (250, 403, 580–589, 593, 996.1, 996.62, 996.73, V45.1, or V56).

Figures 6.27–28 present adjusted rates of total hospital admissions per patient year for incident ESRD patients. The categories for cardiovascular disease, infection, and other (in Figure 6.28) are defined by the codes listed for Figures 6.6–8. Figure 6.29 shows adjusted admission rates for principal procedures and diagnoses for prevalent ESRD patients. Principal ICD-9-CM codes are as follows: for pulmonary infection, 460–466, 473–474.0, 475–477.9, 478.22–478.24, 478.29, 480–491, 494, 510–511, 513.0, and 518.6; for vascular access infection (hemodialysis patients only), 996.62; for peritonitis (peritoneal dialysis patients only), 567.2 and 567.9; for cardiovascular procedures, 35.40 (excluding hemodialysis, 39.95, and vascular access procedures, 38.95, 39.27, 39.42, 39.43, and 39.93–39.94); and for heart catheterization, 37.21, 37.22, and 37.23.

Mortality

Patient cohorts for all mortality figures here include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.
Figure 6.4 presents five-year survival by modality for 1989–1993 and 1994–1998 incident patients, with modality defined on the first ESRD service date. Transplant is defined as the first transplant in the incident year. Patients with unknown age, gender, or primary diagnosis, and those with a listed age greater than 110, are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2003, while transplant patients are followed from the first transplant date until death or the end of 2003. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. As in the 2003 and 2004 ADRs, the reference population consists of 1996 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figure 6.5 shows trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, black, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. Also consistent with the 2003 and 2004 ADRs, the reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Table 6.b shows the expected remaining lifetimes for dialysis patients, renal transplant patients, and the general U.S. population. For period prevalent ESRD patients in 2003, expected lifetimes are calculated using the adjusted death rates in Reference Tables H.4.4 and H.28.4, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.4.4 and H.28.4, and the method for calculating expected remaining lifetimes is described in the section on statistical methods at the end of this appendix. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

Figures 6.15–17 present adjusted all-cause and cause-specific mortality for each six months (up to 60) in incident dialysis patients, by age, gender, and race, respectively. Using the 90-day rule, incident patients from 1997–2001 combined are followed from day 91 until death or December 31, 2003, and censored at transplant and loss to followup. These adjusted mortality rates are computed from the Cox model using the model-based adjustment method, described later in this appendix, and are adjusted for age, gender, race, and primary cause of ESRD. The reference population for adjusted rates consists of 1996 incident ESRD patients.

For Figure 6.30, on five-year survival by modality, the population includes incident patients who are on hemodialysis or peritoneal dialysis on their first ESRD service date, and who survive and remain on dialysis for the first 90 days. Patients with unknown age, gender, or primary diagnosis, or a listed age greater than 110, are excluded. Patients are followed from day 91 until death, transplant, or the end of 2003, and survival probabilities are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1996 incident ESRD patients, and adjusted probabilities across modalities are comparable.

All-cause mortality rates by vintage and modality are shown in Figure 6.31. Populations include period prevalent patients on hemodialysis and peritoneal dialysis in a calendar year. Patients with unknown age or gender, or of race other than white, black, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplant, or the end of the year. Rates are adjusted, using generalized mixed models, for age, gender, race, and primary diagnosis. The reference population consists of 2001 prevalent dialysis patients, and rates are comparable across modalities.

Figure 6.32 presents adjusted all-cause and cause-specific mortality rates, by modality, for incident hemodialysis and peritoneal dialysis patients, 1992–1996 combined and 1997–2001 combined. Incident patients are followed from day 91 until death or December 31, 2003, and censored at transplant or loss to followup. Rates are computed from the Cox model using the model-based adjustment method, described later in this appendix, and are adjusted
Analytical methods

Standardized mortality & hospitalization ratios
As in the 2004 ADR, we use the Bayesian method to estimate standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs), and use the term BMR/BHR to identify an SMR/SHR estimated with the Bayesian method.

The study cohort for the mortality ratios in Figures 6.33–39 consists of 2002 and 2003 period prevalent dialysis patients. Criteria for including and excluding patients, for considering death as an event, and for censoring are same as those used for the tables in Reference Section H, described below. The study cohort for the hospitalization ratios includes 2002 and 2003 period prevalent dialysis patients, identified as described for Reference Section G. The total number of admissions, instead of the first hospitalization, is used for the SHRs.

Figure 6.33 compares BMRs over chains for 2002 and 2003, using the Wilcoxon rank-sum test.

Complications & pregnancy in women with ESRD
Figures 6.49–51 present data on cancer trends in adult female dialysis patients. Last year’s ADR included new cancer hospitalization rates in incident patients without cancer in the first year of dialysis. This year’s figures, in contrast, show total cancer hospitalization rates in prevalent patients, including those who had cancer prior to followup as well as those who did not. These rates therefore reflect how frequently the general population of female dialysis patients is hospitalized for breast, cervical, uterine, or ovarian cancer. The cohort includes 1993–2003 period prevalent female dialysis patients age 20 and older with Medicare as a primary payor. Within each annual cohort, patients are followed from January 1 of the year to the earliest of death, three days prior to transplant, or December 31 of the year. Hospitalizations for cancer are identified by institutional inpatient claims with principal ICD-9-CM diagnosis codes: breast, 174.x; cervical, 180.x; uterine, 179 and 182.x; and ovarian, 183.x. Note that these rates reflect hospitalizations for the primary purpose of cancer, since only principal (and not secondary) diagnosis codes for cancer are counted. A model-based adjustment method is used to calculate adjusted cancer hospitalization rates. Included female dialysis patients prevalent in 2003 are used as the reference cohort.

Figure 6.52 shows treatment distributions among adult female dialysis patients with cancer. Included patients (N=3,280) are prevalent in 1993–2003, and are alive, with Medicare as a primary payor, and without a transplant or loss to followup from January 1 to December 31 of the year. Patients with cancer (breast, cervical, uterine, or ovarian) are defined as those with at least one inpatient cancer claim during the year, using principal and secondary ICD-9-CM diagnosis codes as listed above. Institutional (inpatient, outpatient, home health, and skilled nursing) and physician/supplier sources provide chemotherapy and radiation claims during the year. Chemotherapy is identified by revenue codes 0331, 0332, and 0335; CPT/HCPCS codes 96400–96459, J9000–J9999, J8510, J8520–J8521, J8530, J8560, J8600, J8610, J8700, J8899, and Q0093–Q0085; ICD-9-CM procedure code 99.25; ICD-9-CM diagnosis code V58.1; and DRG code 410 or 492. Radiation is identified by revenue code 0333; CPT/HCPCS codes 77332–77334, 77401–77416, 77427, and 77520–77523; ICD-9-CM procedure codes 92.2 and 92.3; and DRG code 409.

Figures 6.53–60 display pregnancy and live birth rates, along with other pregnancy-associated rates and measures, for point prevalent ESRD patients, 1991–2002. For each calendar year, the dialysis cohort includes female patients age 14–45 who initiate ESRD therapy at least 90 days prior to January 1 and are alive on January 1. Dialysis patients are followed from January 1 to the earliest of transplantation, death, or December 31; during followup, patients maintain hemodialysis or peritoneal dialysis therapy. The transplant cohort includes female patients age 14–45 who receive a graft during the two years before January 1. Transplant patients are followed from January 1 to the earliest of graft failure, death, or December 31. All patients carry Medicare as primary payor and Medicare Part B supplemental insurance during followup. ESRD etiology is determined from the Medical Evidence form.

The definition of a pregnancy, as indicated by Medicare claims, has evolved from that used in the 2004 ADR. The algorithm is as follows. First, all pregnancy-associated claims from 1991 to 2003 are collected. Pregnancy-associated claims include those with ICD-9-CM diagnosis codes 630–674 and V22–V24; ICD-9-CM procedure codes 72–74; and HCPCS codes 59000–59999 and H1000–H1005. Claims are ordered chronologically for each patient and then divided into disjoint collections. The division algorithm is illustrated by example. Consider a collection of pregnancy-associated claims, followed by a new claim. This new claim is considered part of the existing collection if (1) the claim is submitted within three months of the last claim in the existing collection, or (2) the claim is submitted between three months and nine months of the last claim in the existing collection, and the existing collection does not include a claim for a terminal event. Terminal events include ectopic pregnancy, spontaneous or induced abortion, and vaginal or Caesarean delivery. These events are indicated by ICD-9-CM diagnosis codes 610–637 and 650; ICD-9-CM procedure codes 72–74; and HCPCS codes 59100–59160 and 59400–59870. If neither of the above two conditions is met, the new claim marks the beginning of a new collection of pregnancy-associated claims. A pregnancy event is defined as a collection of claims with at least one Part A inpatient, home health, hospice, or skilled nursing facility claim; at least two Part A outpatient or Part B claims; or at least one claim for a terminal event. The date of the pregnancy event is defined as the date of the first claim within the supporting collection of claims.

Figure 6.53 shows the average age at pregnancy. For the general population, average age is taken from Matthews and Hamilton.

Figure 6.54 displays comorbid conditions among pregnant patients, pooling the comorbidity burden across all pregnancy events between 1991 and 2002. For each comorbidity, prevalence is defined by at least one Part A inpatient, home health, hospice, or skilled nursing facility claim, or at least two Part A outpatient or Part B claims during followup.

Figure 6.55 illustrates average obstetrical visits in the final trimester before live birth. The identification of live births is described in further detail for Figure 6.58. An obstetrical visit during the final trimester is defined as any pregnancy-associated claim during the 91 days preceding the date of the last claim of the pregnancy event.

Figure 6.57 displays complications of pregnancy, identified by the following ICD-9-CM diagnosis codes: infection, 634.0, 635.0, 636.0, 637.0, 638.0, 639.0, 646.5, 646.6, 647, 658.4, 659.3, and 674.3; hemorrhage, 654.1, 655, 656, 657, 658.1, 659.1, 640, 641.1, 641.3, 641.8, 641.9, 656.0, and 666; pre-eclampsia, 642.4, 642.5, 642.6, and 642.7; early labor, 644.

Figure 6.58 shows rates of live births, defined by the absence of claims for ectopic pregnancy or for spontaneous or induced abortion, themselves identified by ICD-9-CM diagnosis codes 630–637, and by HCPCS codes 59100–59160 and 59812–59870.

Figure 6.59 illustrates hemoglobin levels before and after pregnancy. Of the 1,528 pregnancy events among dialysis patients from 1991 to 2002, 1,394 (91 percent) included hemoglobin measurements before and after pregnancy. All measurements are taken from Part A outpatient claims for EPO therapy. The figure includes
an estimated simple linear regression, along with a dashed line of equality between pre- and post-pregnancy hemoglobins.

Figure 6.60 displays dialysis patient survival after the start of pregnancy. All pregnancy events, 1991–2002, are pooled. Followup extends from the date of the first claim of the pregnancy event to the earliest of the date of the first claim of the next pregnancy event, transplantation, death, or two years after the first claim of the pregnancy event. A life table for one through twenty-four months following the start of pregnancy is used to estimate survival.

Morbidity in ESRD, CKD, & non-CKD patients

Figures 6.61–69 compare inpatient morbidity and mortality event rates among ESRD patients (dialysis and transplant), and non-ESRD Medicare patients (with and without CKD). These figures include adult patients age 20 and older who are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories.

For the ESRD cohorts, included patients are point prevalent on January 1, 2002, and are followed for up to two years from that date until the first event or censoring. For the morbidity figures (6.61–68), ESRD patients are censored at the earliest of death, loss to followup, end of Medicare primary payor coverage, December 31, 2003, transplant (dialysis patients only), or three years after transplant (transplant patients only). For the mortality figure (6.69), ESRD patients are censored on December 31, 2003, or on the date of transplant (dialysis patients only).

For the prevalent CKD and non-CKD cohorts, diabetes and CKD are defined during a one-year entry period in 2001. Patients have continuous Medicare Part A and B eligibility, have no HMO coverage, are without ESRD, and survive the complete one-year entry period. Followup of CKD and non-CKD patients begins on January 1, 2002, and is censored at the earliest of death, end of Medicare coverage (Figures 6.61–68), or December 31, 2003.

For Figures 6.61–68, events are defined by the first cause-specific inpatient ICD-9-CM diagnosis code during followup. Both principal and secondary ICD-9-CM diagnosis codes are used. The first inpatient claim with the cause-specific diagnosis during followup is identified, and the admission date of this claim is used as the event date. Patients who have a cause-specific hospitalization that spans the start of followup are excluded. ICD-9-CM codes are as follows: myocardial infarction, 410.x0 and 410.x1; CHF, 428.12, 428.42, 428.43, 402.x1, 404.x1. and 404.x3; stroke, 430–434; PVD, 440–444, 447, 451–453, and 557; pneumonia, 480–486 and 487.0; bacteremia/sepsis, 038.0–038.9 and 790.7; hip fracture, 820.0 and 821; and cancer, 140–172, 174–208, 230–231, and 233–234.

Adjusted rates by age are computed with the model-based adjustment method, and adjusted for gender, race, and diabetic status. The reference cohort consists of all included patients (ESRD, CKD, and non-CKD).

Withdrawal & hospice care in the Medicare ESRD population

Figures 6.70–77 and Tables 6.c–f describe the use of withdrawal and hospice in an ESRD patient cohort composed of ESRD patients who died between January 1, 2001, and December 31, 2002, who were on dialysis (including hemodialysis, peritoneal dialysis, and unspecified dialysis) immediately prior to death, and who had Medicare as primary payor coverage; this cohort contains 115,239 patients.

A secondary six-month cohort—with the additional criteria that patients be on dialysis and have Medicare as primary payor coverage for the entire six months prior to death—is used in analyses examining costs and site of death; this cohort contains 91,687 patients. Tables 6.e–f are based on this secondary cohort.

A subset of the primary cohort, patients who withdrew, contains 25,075 patients and is highlighted in Figure 6.76 and Tables 6.c–d, and in the green bar on Figure 6.70.

Withdrawal status is determined from the ESRD Death Notification form, which indicates whether a patient withdrew, and, if so, identifies a withdrawal cause as described in Figure 6.71.

Hospice status is determined from the CMS hospice claims Standard Analytical Files. A patient is classified as using hospice if a claim exists showing the patient was in hospice on the date of death, or the discharge code from hospice is "death."

Stroke

For Figures 6.78–83, "first stroke in year 2001" indicates the first stroke occurring in 2001, while "incident stroke in 2001" indicates the patient's first stroke ever. Claims data in an entry period are used to exclude any previous stroke. Unless specified, patients are not required to survive at least 90 days after ESRD initiation.

Figure 6.78 compares incident stroke rates for incident hemodialysis, peritoneal dialysis, and transplant patients, using all incident 2000 ESRD patients age 67 and older at initiation who have Medicare Parts A and B as primary payor. A two-year entry period prior to the first ESRD service date is used to exclude those with previous strokes, and mortality is determined on the first ESRD service date. Patients with unknown age, gender, or race are excluded. Incident stroke is identified during the one-year followup period after ESRD initiation for dialysis patients, and from the transplant date for transplant patients. Followup time is censored at the earliest of death, loss to followup, transplantation, modality change (hemodialysis to peritoneal dialysis, the reverse, or graft failure), and end of Medicare as primary payor status. Stroke events are defined by ICD-9-CM diagnosis codes 430–436 in any Part A institutional or Part B physician/supplier claims.

Figures 6.79–80 describe hospitalization and survival rates, by modality, of the incident 2000 ESRD cohort during the two-year followup period after an incident stroke. The study cohort is constructed in a way similar to that of Figure 6.78. Patients with an incident stroke are assigned to the case group and followed from the day of the incident stroke; patients with no stroke claims are assigned to the control group and followed from one year after their dialysis initiation or transplant date. Hospitalization is identified in the two-year followup period, censored as in Figure 6.78. Hospitalization and survival rates are computed from a Cox regression model, adjusted for age, gender, and race. The entire incident 2000 ESRD cohort with known modality is used as the reference group.

Figure 6.81 shows the incidence of recurrent strokes for incident hemodialysis, peritoneal dialysis, and transplant patients. The study cohort is similar that of Figure 6.78, but only patients with incident stroke are considered for analysis. Recurrent stroke is identified over the one-year followup period following the incident stroke date, and the period is censored as in Figure 6.78. Stroke events are defined as in Figure 6.78.

Figures 6.82–83 describe hospitalization and survival rates, by modality, of incident 2000 ESRD patients in the one-year followup period after a second stroke. The study cohort is similar that of Figure 6.81. Patients with a second stroke are assigned to the case group and followed from the date of the second stroke, while patients with no claims for a second stroke are assigned to the control group and followed for one year after their first stroke. Followup time is censored as in Figure 6.78. Hospitalization and survival rates are computed from a Cox regression model and adjusted for age, gender, and race, using the entire incident 2000 ESRD cohort with known modality as the reference group.

Figure 6.84 displays rates of first stroke occurring in 2003 among period prevalent 2003 ESRD patients, using incident 2003 ESRD patients with Medicare as primary payor and point prevalent 2003 ESRD patients with Medicare as primary payor on January 1, 2003. All patients must survive at least 90 days after ESRD initiation. Pa-
patients are followed from January 1, 2003, or their ESRD initiation date until death, loss to followup, stroke, transplantation, modality change, three years after the transplant date (for transplant patients), change in Medicare as primary payor status, and end of 2003.

Figure 6.85 shows incident stroke rates among point prevalent 2003 ESRD patients who are alive on January 1, 2003, and have had Medicare as primary payor for the prior two years. Patients younger than 18, or with unknown age, gender, or race, are omitted, as are those with previous stroke, Medicare as secondary payor, ineligibility for Medicare, or HMO enrollment in the two-year entry period. Patients are followed from January 1, 2003, up to one year. The followup criteria are those used for Figure 6.84.

Figure 6.86 presents stroke rates by diabetic and hypertensive status. A one-year entry period of 2002 is used to define patients with diabetes or hypertension, using the methodology described for Figure 1.1. Figure 6.87 shows adjusted rates of stroke by type, and the percentage that are atrial fibrillation (AF). A two-year entry period of 2001–2002, with ICD-9–CM code 427.3 and the methodology described for Figure 1.1, are used to identify the AF event. Rates are adjusted for gender, race, and dialysis vintage, using the direct adjustment method. In both figures, the entire point prevalent 2003 ESRD cohort is used as the reference group.

Dementia
Figures 6.88–94 and Table 6.g display measures describing the state of dementia, as indicated by Medicare claims, among point prevalent ESRD patients, 2001 and 2003. Each cohort is split into three subgroups: hemodialysis, peritoneal dialysis, and transplant. For the 2001 cohort, dialysis patients initiate ESRD therapy at least 90 days prior to January 1, 2000, are alive from January 1, 2000, to December 31, 2001, and were receiving hemodialysis or peritoneal dialysis on December 31, 2001. Transplant patients initiate ESRD therapy at least 90 days prior to January 1, 2000, receive a graft between January 1, 1999, and December 31, 2001, and have a functioning graft on December 31, 2001. All patients carried Medicare Part A as primary payor and Medicare Part B supplemental insurance during the entry period (i.e. calendar years 2000 and 2001). The 2003 cohort is constructed analogously.

Figures 6.88–89 display rates of prevalent dementia. Dementia is indicated by at least one instance of diagnosis code 290 or 331.0 on Part A or B claims during the entry period. Alzheimer’s disease is indicated by 331.0, and vascular dementia by 290.4.

Figures 6.90–91 display hospitalization and survival probabilities, respectively, among patients in the 2001 cohort. Followup extends from December 31, 2001, until the earliest of hospitalization (in Figure 6.90), transplantation, death, or December 31, 2003.

Figure 6.92 shows the cumulative per member costs among patients in the 2001 cohort. All dialysis and transplant patients are included, as are costs from all Medicare Part A and B claim sources.

Figures 6.93–94 illustrate rates of incident dementia. For the 2001 cohort, incident dementia is defined by the absence of claims for dementia during 1999 and 2000, along with a claim for dementia during 2001. For the 2003 cohort it is defined analogously.

Table 6.g displays the adjusted odds ratios of incident dementia. The 2001 and 2003 cohorts are pooled for each of the three subgroups. ESRD etiology (including diabetes, hypertension, and other cause) is taken from the Medical Evidence form. For the 2001 cohort, stroke is identified by the presence of ICD-9–CM diagnosis codes 430, 431, 432, 434, or 436 on any claim submitted before 2000; claims submitted during 2000 are used for the 2003 cohort.

Reference Section G
Hospitalization reference tables present adjusted total admission and hospital day rates by year from 1993 to 2003. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section at the end of this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from Part A institutional inpatient claims, with the following exceptions: Tables G.16 and G.16.1 also include REBUS hospitalization data, and supplementary tables G.14–G.10.4 and G.15–G.10.5 (on our website and CD-ROM) use only REBUS inpatient data.

Tables G.1–10 include dialysis and transplant patients on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, gender, or race; and patients of races that are unknown or other than white, black, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the “other” category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:
- all dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days
- hemodialysis: patients who have been on hemodialysis for at least 60 days as of the start of the period at risk
- CAPD/CCPD: patients who have been on CAPD/CCPD for at least 60 days as of 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 G.1–10. Dialysis patient start dates (January 1 for prevalent patients and day 91 of ESRD for incident patients) must fall between start and end dates based on Medicare paid dialysis claims, as follows:
- start date: the first day of the first month in which there are at least $675 of Medicare paid dialysis claims
- end date: the end of a three-month period in which there are less than $675 of paid claims in each month

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

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

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

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

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the 1991–2003 institutional inpatient claims, for example, 4.5 percent 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.

The total discharges reported in Table G.16, in contrast, include all hospitalizations, and no overlapping or adjacent hospitalizations are combined. These tables present total hospital discharges by 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 for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the statistical methods section). Predicted rates for each subgroup combination of age, gender, race, primary diagnosis, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ½. Adjusted rates are then calculated using the direct adjustment method, with all 2003 ESRD patients as the reference cohort. Standardized hospitalization ratios by state (Table G.a) are calculated using the Bayesian method, also described in the statistical methods section.

New to the 2005 ADR, Tables G.11-15 show inpatient utilization in period prevalent ESRD patients. Methods—including modality definitions, inclusion criteria, data cleaning, followup time definitions, and rate calculations—generally follow those previously described for the total admission rates in Tables G.1-5, but some differences do exist. While patients races other than white, black, Native American, or Asian are excluded from G.1–5, they are included in G.11–15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2001-2003 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted rates in G.1–5, the other eight cause-specific categories only include admissions for specific diseases. Vascular access hospitalizations are those classified as “pure” inpatient vascular access events. Such vascular access events are defined as admissions with a specified ICD-9-CM principal diagnosis code (996.1, 996.56, 996.62, 996.68, 996.73, V56.1, or V56.2), or an ICD-9-CM principal procedure code (38.95, 39.27, 39.42, 39.43, 39.93, 39.94, or 86.07) in conjunction with a certain DRG code (112, 120, 315, 442, 443, 478, or 479). If an admission does not qualify as vascular access, it is classified by the principal diagnosis code into one of seven other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–519; and infectious diseases, 001–139. Hospitalizations that do not fall under any of these categories are counted under all others.

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

Long-term trends in hospitalization data are also available in supplementary tables (G.1.4–10.4). Total admission rates per 1,000 patient years and hospital day rates per patient year from 1980–2003 are presented in Tables G.1.4–3.4 and G.6.4–8.4. Due to the instability of rates in earlier years, these rates are presented from 1983 in G.4.4 and G.9.4 for peritoneal dialysis patients, and from 1986 in G.5.4 and G.10.4 for transplant patients. Rather than using Part A inpatient claims data, which are unavailable for earlier years, these tables use only REBUS inpatient claims data. All one-day hospitalizations with a discharge date on the same or next day as the admission date are excluded from these tables, since, prior to 1991, the REBUS data include no hospitalizations of less than 24 hours. To enable comparison of rates across years, therefore, only hospitalizations with a length of at least two days are included. As a result, these rates are lower than those in Tables G.1.1–10.1, which use all Part A inpatient claims. Other methods (rate calculation, model-based adjustment, etc.) generally follow those discussed for Tables G.1–10. In supplemental tables G.1.4–10.4, however, we do not exclude dialysis patients failing to reach a certain level of Medicare paid dialysis bills, since this economic information is unavailable for the earlier years. Additionally, supplementary tables G.1.5–10.5 present counts of total admissions or days, patient years at risk, and total patients, which correspond with the rates presented in G.1.4–10.4.

Reference Section H

Patient cohorts for reference tables in Section H include both Medicare and non–Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Cohorts in Tables H.1–31 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day
Analytical methods

91 of ESRD treatment during the year, while 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. 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 attributed 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. 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 date, for example, are included in the all-ESRD and functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two subgroups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD, or who have been on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

Cohorts in Tables H.32–46 include incident ESRD, dialysis, hemodialysis, CAPD/CCPD, and transplant patients who survive the first 90 days. Patient selection criteria are the same for both unadjusted and adjusted mortality rates. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2002, are included in the analysis. These patients are followed from day 91 until death or December 31, 2003.

Tables H.1, H.2, and H.2.1–2.4 present mortality information for all-ESRD patients. Total patient deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, gender, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. The unadjusted mortality rates are calculated by dividing total patient deaths in a category—male, for example—by total followup time in the same category. For the adjusted rates, generalized mixed models are used to calculate the smoothed rates; these methods are described later in this appendix. After obtaining smoothed rates from the generalized mixed models, direct adjustment methods are used. Overall mortality rates are adjusted for age, gender, race, primary diagnosis, and vintage, while rates for each category (age, gender, race, primary diagnosis, and vintage) are adjusted for the remaining four categories. The reference population includes 2001 prevalent ESRD patients.

Table H.2.1 presents adjusted mortality rates by primary diagnosis. The method for calculating the adjusted rate is same as that in Table H.2, except that vintage is not included. Overall mortality rates are adjusted for age, gender, race, and primary diagnosis, while rates for diabetes, hypertension, glomerulonephritis, and other causes of ESRD are adjusted for age, gender, and race. The difference between Table H.2.1 and H.2.2 is that the mortality rate is expressed as per 1,000 patients years in H.2.1 and per 1,000 patients in H.2.2. Table H.2.3 shows total death counts, total followup years, and total patient counts. Table H.2.4 presents mortality rate by patient age, gender, race, and primary diagnosis for 2003 prevalent ESRD patients. Mortality rates in Table H.2.4 are smoothed and unadjusted using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1–4.4 (dialysis patients); Tables H.11, H.12, and H.12.1–12.4 (hemodialysis patients); Tables H.19, H.20, and H.20.1–20.4 (CAPD/CCPD patients); and Tables H.27, H.28, and H.28.1–28.4 (transplant patients).

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

In Table H.29, unadjusted mortality rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 2001–2003. The unadjusted mortality rate for a specific primary cause of death in each subgroup is obtained by dividing the total deaths from that cause by the subgroup’s total followup time, and the sum of rates for each cause in a subgroup is equal to the overall mortality rate of that subgroup.

Patient populations for Tables H.32–46 are the same as those used in Reference Section I. The population groups include all-ESRD, all dialysis, hemodialysis, CAPD/CCPD, and transplant (known deceased and living donors only). Adjusted first-, second-, and third-year mortality rates for incident cohorts—including all-ESRD, all-dialysis, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method, described later in this appendix. These rates are presented using aggregate categories for age, gender, race, and primary diagnosis, and a rate presented for one of these variables is adjusted for the remaining three. Overall mortality rates for all patients are adjusted for each of the four variables. Mortality rates for Hispanic and non-Hispanic patients, however, are unadjusted (crude) rates calculated as the number of deaths over patient-years at risk. As in the 2003 and 2004 ADRs, the reference population for adjusted rates consists of 1996 incident ESRD patients.

Reference Section I

These tables, which include only incident cohorts, present patient counts and survival probabilities. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown gender or age, or whose listed age is greater than 110, are excluded. New to this ADR are 90-day and three-year survival probabilities.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients who have a first ESRD service date between January 1, 1980, and December 31, 2002, are included in the analysis. These patients are followed until December 31, 2003, a maximum followup time of 23 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
- dialysis only: all dialysis 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 the end of followup
- hemodialysis only: all hemodialysis 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 the end of followup
- peritoneal dialysis only: all peritoneal dialysis 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 the end of followup
- 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
Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while the Cox model and the model-based adjustment method are used for adjusted probabilities.

To limit imprecision due to small cell sizes, adjusted 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 statistical methods section. As in the 2003 and 2004 ADRs, the reference population consists of 1996 incident ESRD patients.

Transplantation
CHAPTER SEVEN & REFERENCE SECTIONS E & F

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

Figure 7.1 presents transplant counts by donor type, obtained through a combination of OPTN data and data from CMS. Living-related donors include parents, children, identical twins, full siblings, and half siblings, while living distant/unrelated donors include other relatives, spouses, and other unrelated donors.

Figure 7.2 contrasts the incident rate of ESRD per million population with the transplant rate. Geographical variations in transplant rates are presented in Figures 7.3 and 7.6, in which the state is the recipient's last known state of residence, not necessarily the state where the transplant was performed.

Figures 7.7 shows the median waiting time by state for patients receiving a deceased donor kidney during 2003. Figure 7.8 contrasts median waiting times by age, gender, and race. Waiting time is calculated as the transplant date minus the date the patient was first added to either the kidney or kidney-pancreas waiting list, not necessarily the date he or she was first listed at the center where the transplant was eventually performed.

Figures 7.9–10 show the number of patients on the OPTN kidney or kidney-pancreas waiting list on December 31 of the given year. Note that in prior Annual Data Reports, patients listed on the kidney-pancreas waiting list were not included in these counts.

Organ donation rates are presented in Figures 7.11–13. In Figure 7.11, two methods are presented for the calculation of deceased donor donations, one counting a donation twice if both kidneys are eventually transplanted, the other counting each donation only once, regardless of whether both kidneys are transplanted.

Maps of donation rates are based on the location where the donation is made. Figure 7.12 presents donation rates per million population, whereas Figure 7.13 presents donations rates per million deaths in the state. Population and death count estimates are obtained from the U.S. Census Bureau.

Figures 7.14–15 present graft survival curves, trends in first-year survival, and trends in conditional half-lives for recipients of kidneys from deceased and living donors. Estimates are made from Cox proportional hazards models adjusted for transplant year, age, gender, race, and primary diagnosis, and are based on the population's average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and are estimated from the cumulative hazard between years one and two. The median (half-life) is calculated as the estimated mean multiplied by the natural log of two, and the estimated mean is calculated as the inverse of the estimated hazard between years one and two.

Figures 7.16–17 detail death-censored graft failures during 1995–2003. For these figures, return to dialysis or preemptive retransplantation is considered an event. Figure 7.16 shows geographic variations in the rate of death-censored graft failure for all prevalent transplant patients during 1995–2003. Figure 7.17 shows the number of patients returning to dialysis or receiving a preemptive retransplant by year. Additionally, the percent of patients initiating dialysis in the given year who are returning from transplant is displayed on the second axis of the first panel.

Figures 7.18–19 show graft survival times preceding death-censored graft failures for grafts failing in the given year. Figure 7.20 contrasts the rate of returning to dialysis/preemptive retransplantation with the rate of death with function, while Figure 7.21 shows the rate of return to dialysis/preemptive retransplantation by age, gender, and race. Figure 7.22 displays the percent of graft failures that are preemptively retransplanted. A patient is considered to have been preemptively retransplanted if the subsequent transplant date is within one day of the previous graft failure date. Figure 7.23 contrasts the cumulative incidence—estimated using the Kaplan-Meier methodology—of retransplant and death following a graft failure, by era of graft failure.

Figure 7.24 displays causes of death for patients who died with a functioning graft between 1995 and 2003. Causes of death are ascertained from OPTN transplant followup data or, if unknown, from the ESRD Death Notification form. Figure 7.25 shows trends in causes of death as a function of time post-transplant. Figures 7.26–33 display various risk factors for death with a functioning graft. Hazard ratios are estimated from a multivariate Cox proportional hazards model, adjusting for donor type, year, age, gender, race, Hispanic ethnicity, primary cause of renal failure, donor race, donor gender, cold ischemia time, length of prior dialysis, donor-recipient CMV, hepatitis B, and hepatitis C serologies, education level, HLA mismatches, and body mass index. A separate model is run to assess the effect of expanded criteria donors (Figure 7.27), which includes only recipients of a deceased donor kidney.

Figure 7.34 details the number of patients with a followup form on file with OPTN, by year post-transplant. Prevalent transplant patients receiving their transplants in 1988 or later are included within each year. The location of followup care presented in Figure 7.35 is taken from the OPTN followup form for prevalent transplant patients within the given year who received their transplants in 1988 or later. Figure 7.36 displays the cumulative incidence of acute rejections, taken from the OPTN followup form, as estimated using the Kaplan-Meier methodology for patients transplanted in 1995 or later. Figure 7.37 contrasts the percent of patients with delayed graft function, defined as the need for dialysis within the first post-transplant week, by donor type.

Figure 7.38 displays all-cause and cause specific hospitalization rates for the first three years post-transplant for Medicare patients transplanted between 1995 and 2003. Hospitalization events are ascertained from Medicare claims data for patients with Medicare Part A and B primary payor coverage. Patient followup is censored at graft failure, death, loss of Medicare coverage, or December 31, 2003. Rates are estimated separately for recipients of living and deceased donor kidneys, and are adjusted for age, gender, and race using a Poisson regression model.

Figure 7.39 presents the mean serum creatinine, as reported to OPTN, for patients with a functioning graft by year post-transplant. Patients transplanted between 1995 and 2003 are included.

Data on patients receiving various preventive healthcare measures are presented in Figures 7.40–48. Included transplant patients have Medicare as primary payor during the measurement period, and are alive with a functioning graft for the entire study period. General Medicare estimates are obtained from a random 5 percent sample of Medicare beneficiaries. Figures 7.40–41 present HbA1c testing results. For the transplant population, diabetic patients with functioning grafts in each post-transplant year are included.
Diabetes as the primary cause of renal failure or a comorbid condition is determined form the Medical Evidence or OPTN forms. HbA1c tests are identified from Medicare claims data by HCPCS code 83036, and must be at least 30 days apart to be counted. Two-year intervals are used for the general Medicare population, and patients who survive the entire two-year interval are included. Diabetic status is determined from claims data during year one, and HbA1c testing is determined during year two. For Figure 7.41, the percent of patients tested within one year post-transplant is estimated using the Kaplan-Meier methodology.

For lipid monitoring, in Figures 7.42–43, diabetic and non-diabetic patients are included in the analyses. Methods are the same as those used for HbA1c testing, except that the general Medicare estimates are made for one-year intervals rather than two-year intervals since no determination of diabetic status is made. Lipid monitoring is determined from HCPCS codes 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478. Tests within 30 days of a previous test are not counted.

For diabetic testing supplies, in Figures 7.44–45, methods are similar to those of Figures 7.40–41. Diabetic test strips are identified using HCPCS code A4253. As the claim indicates the number of packs of 50 test strips, the number of strips per day is calculated as the number of test packs multiplied by 50 and divided by 365.

Cancer screening measures are presented in Figures 7.46–48. For all measures, only transplant recipients between 1999–2003 with Medicare Part A and B as primary payor are included. Pap smears are identified using CPT codes 88141, 88142, 88143, 88144, 88145, 88147, 88148, 88150, 88152, 88153, 88154, 88155, 88156, 88158, 88164, 88165, 88166, and 88167, ICD-9-CM diagnosis code V762, ICD-9-CM procedure code 91.46, and revenue code 923. Females age 21–64 at three years post-transplant are included in the transplant population, and general Medicare beneficiaries age 21–64 at the end of 2003 are included. For mammograms, the population includes female transplant patients age 52–69 at two years post-transplant, and female general Medicare beneficiaries age 52–69 at the end of 2003. Mammograms are identified using CPT codes 76090, 76091, and 76092, ICD-9-CM procedure codes 87.36 and 87.37, ICD-9-CM diagnosis codes V76.11 and V76.12, and revenue codes 401 and 403. For prostate screening, the transplant population includes males age 53 and older at three years post-transplant, and the general Medicare population includes patients age 53 and older at the end of 2003. Prostate screenings are identified using CPT code 84153, revenue codes 300 and 310 (in combination with ICD-9-CM diagnosis codes 185 and 233.4), and ICD-9-CM procedure codes 91.39, 87.92, 60.11, 60.12, and 60.18. For all measures, the percent are estimated for the transplant population using the Kaplan-Meier methodology, and for the general Medicare population as the number screened over the number of patients in the prevalent population.

Figures 7.49–55 present data on immOPTNPresseptive medications used at the time of transplantation between 1995 and 2003, according to the OPTN ImmOPTNPresseption Treatment form. All immOPTNPresseptive medications (apart from induction antibodies) are indicated as maintenance immOPTNPresseption on the OPTN form.

In Figures 7.56–61 we examine two methodologies for estimating one-year graft failure ratios. CMS recently proposed requirements for the approval and re-approval of transplant centers to perform organ transplants (Federal Register, 70 (23): 6319–6382). In addition to a variety of data submission rules, CMS proposed three outcome requirements for transplant centers, all based on a comparison of observed and expected graft failures within the first year after transplantation, among all transplants performed during the 30 months prior to analysis. The requirements include: (1) that the p-value for a two-sided test that the standardized graft failure ratio (i.e. the observed graft failures, divided by the expected graft failures) equals one is not less than 0.05; (2) that observed graft failures not exceed expected graft failures by more than three; and (3) that the standardized graft failure ratio not exceed 1.5. If a transplant center were to fail to achieve all three criteria, it may not be approved to perform organ transplants. Of note, CMS has proposed the above requirements only for transplant centers with at least nine transplants during the 30 months prior to analysis.

In our analysis of the proposed CMS requirements, expected graft failures are calculated from the estimated baseline (Kaplan-Meier) survival curve and hazard ratios, as derived from a Cox proportional hazards regression model of all transplants performed in the United States during the 36 months prior to analysis. The model includes adjustors for recipient characteristics, including age, gender, race, end-stage renal disease etiology, and pre-transplantation dialysis time; and for transplantation characteristics, including calendar year of transplantation, an indication of whether the transplantation was the patient’s first, an indication of whether the transplanted organ was obtained from a living donor, and human leukocyte antigen mismatches between donor and recipient. Patients are followed from the date of transplantation until graft failure (including death) or the conclusion of one year. Both the p-value for a two-sided test that the standardized graft failure ratio equals one and the confidence interval for the standardized graft failure ratio are derived from an exact Poisson test. The exact test guarantees nominal error coverage of at least 95 percent, a useful property in the presence of small event counts.

We also propose an alternative Bayesian approach for the identification of transplant centers with high rates of graft failure. The Bayesian graft failure ratio was calculated from a model with Poisson likelihood, with the distribution parameter (i.e. the mean) equal to the sum of the logarithm of expected graft failures and a normally distributed center effect, with mean zero and precision \( \tau \). The parameter \( \tau \) is assigned an almost non-informative Gamma prior distribution. Confidence intervals are derived from the appropriate empirical percentiles of the posterior distribution of each center’s graft failure ratio.

Reference Section E

Tables E.1–4 present various measures regarding wait-listing for renal transplantation. Tables E.1–2 present counts of patients wait-listed for a kidney or kidney–pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents counts for patients that have been certified ESRD, and Table E.3 the rate of wait-listing per 100 dialysis patient-years for patients who certified with ESRD. Rates are calculated for all period prevalent dialysis patients during the given year. Dialysis patients listed prior to the start of the given year are excluded from the measure. Table E.4 presents the percent of patients wait-listed or receiving a deceased-donor transplant within one year of ESRD initiation; patients receiving a transplant from a living donor are not included in the measure. Percentages are calculated using the Kaplan-Meier methodology. This measure is modeled after Healthy People 2010 Objective 4.5.

Transplant counts are presented in Tables E.5–8. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients.

Transplant rates per 100 patient years on dialysis are shown in Table E.9. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. A patient’s dialysis days are counted from the beginning of the specified year, or day one of ESRD dialysis therapy if treatment begins mid-year, until the
first of transplant, death, or the end of the year. Patients lost-to-followup in a given year are not censored at the lost-to-followup date, but are followed until the end of the calendar year. Dialysis time for patients returning from transplant is counted. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year.

In Table E.10, treatment status two years after first transplant is shown by age at first transplant for patients transplanted between 1999 and 2001. Table E.12 presents a cross-tabulation of recipients and donors in terms of their cytomegalovirus (CMV) antibody status at the time of transplantation. A recipient/donor is considered positive if any applicable OPTN data source indicates positive, and “unknown” status is applied only in the event that none of the applicable tests are performed. Table E.13 presents similar data for Hepatitis C antibody status.

Table E.14 presents transplant counts based on cold ischemia times in hours. Cold ischemia times are taken from OPTN Transplant Recipient Registration data.

Reference Section F

This section presents probabilities of graft survival and survival with a functioning graft, by donor type, for various demographic groups and followup times. Patients are followed from the transplant date to graft failure, death, or the end of the followup period (December 31, 2003). Death in the analysis of graft survival is considered a graft failure. In the analysis of survival with a functioning graft, patients are followed until death with a functioning graft, and patient followup is censored at graft failure prior to death. Because a minimum of one year of followup is required, 2002 is the most recent year reported.

To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated 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, primary diagnosis, first vs. subsequent transplant, and standardized to 1996 patient characteristics.

Finally, Tables E.25–26 present the relative risk of graft failure, return to dialysis, and death with a functioning graft for various recipient, donor, and transplant characteristics for recipients of first deceased donor and living donor kidneys, respectively. Relative risks are estimated from Cox proportional hazards models, one for each donor type cohort and outcome. Patients transplanted between 1998 and 2003 are included. Followup is censored at December 31, 2003, for a maximum followup of six years. For graft failure, death is considered a graft failure. For return to dialysis, patients are censored at death with a functioning graft. For death with function, follow-up is censored at return to dialysis.

Pediatric ESRD

CHAPTER EIGHT

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.

Figures 8.8–11 show rates of preventive healthcare in pediatric ESRD patients. Methods and codes used to determine rates of influenza vaccinations, pneumococcal pneumonia vaccinations, and lipid testing are similar to those described for Chapter One. Hepatitis B vaccinations are identified through CPT codes 90736, 90740, 90743–90744, 90748, 90731, and 90723. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare Parts A and B coverage for the entire period.

For influenza vaccinations (Figure 8.8), the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients receiving a vaccination in the last four months of each year.

For pneumococcal pneumonia vaccinations (Figure 8.9), the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year of each two-year period; rates are calculated for patients receiving one vaccination during each period. And for hepatitis B vaccinations and lipid testing (Figures 8.10–11), the cohorts include prevalent patients initiating therapy 90 days prior to January 1 and alive on December 31 of each year; rates are calculated for patients receiving one vaccination or testing in each year.

Figure 8.12 includes incident hemodialysis patients who are in both the USRDS and the CPM databases. Demographic and vascular access information is obtained from the CPM data, and incident years 1999–2002 are combined.

In Figure 8.13 we include prevalent hemodialysis patients from the 1999–2002 combined CPM data who are also in the USRDS database, and who have Medicare as their primary payor as of January 1 of the CPM year. Events and complications are obtained from Medicare claims, as described in the methods for Figures 5.5–8. Figure 8.14 includes incident peritoneal dialysis patients who have Medicare as primary payor on day 91 after their first service date. Events and complications here are also obtained from Medicare claims, as described in the methods for Figure 5.8.

Figures 8.15–16 display the mean hemoglobin and mean weekly EPO dose for prevalent pediatric dialysis patients. Because of the small number of patients within some categories, multiple years are grouped. Doses are adjusted for inpatient days.

Figure 8.17 shows the percent of pediatric and adult patients with a carnitine lab test and receiving levocarnitine. Included prevalent dialysis patients are alive with Medicare as a primary payor during the entire year; are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have non-missing age information. Part A outpatient and Part B physician supplier claims are used to identify patients with at least one claim during the year. A HCPCS code of J955 indicates a levocarnitine claim, while a CPT code of 82379 (first used in 1999) indicates a carnitine lab test.

For Figures 8.18–20, the mean hemoglobin and mean weekly EPO dose are calculated on a quarterly basis, and each quarter includes only patients with at least one valid EPO claim during that time. Doses are adjusted for inpatient days.

Figure 8.21 includes prevalent hemodialysis patients who are alive and remain on hemodialysis for the entire prevalent year. Patients are identified as receiving iron if they have at least one IV iron claim during the year.

Data on infectious complications, in Figures 8.22–26, include incident dialysis patients with Medicare as their primary payor at incidence. Infectious hospitalizations represent inpatient stays with a principle diagnosis of infection. Figure 8.26 includes peritoneal dialysis patients only, and for Figures 8.22–24, transplant patients are first-time, kidney-only transplant recipients with Medicare as the primary payor as of the date of transplant. Figures 8.27–29 include the same patient population used in Figures 8.22–26, except that incident years 1991–2000 are combined. Bacterial infections are identified by codes 011.x–012.x, 010.x–018.x, 020.x–027.x, 030.x–036.x, 038.x–041.x, 073.x, 076.x, 080.x–083.x, 087.x, 088.x, 091.x–014.x, 137.x, and 008.0–008.5. Viral infection codes include 042.x, 045.x–051.x, 055.x–057.x, 060.x–066.x, 071.x, 072.x, 074.x, 075.x, 052.x–054.x,
Appendix A

CPT codes 33500–33523 and 33533–33536; coronary artery stenting, identify patients receiving these procedures are as follows: coronary codes in Part B physician/supplier claims. Codes used to identify (CKD). Coronary revascularization is defined according to ICD-9-CM diagnosis codes used for cardiovascular, infectious, and other hospitalizations are listed in the discussion of Figures 6.6–8. In Figure 8.37, “other” race includes those with a race that is missing, unknown, or other than black or white.

Patient cohorts for all mortality figures here include both Medicare and non-Medicare patients in the 50 states, the District of Columbia, Puerto Rico, and the Territories. The dialysis cohort includes patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplant, or the end of 2003, while transplant patients are followed from the first transplant date until death or the end of 2003. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 1996–1997 incident pediatric ESRD patients, and adjusted probabilities can be compared across modalities.

Figure 8.34 presents adjusted mortality rates for incident dialysis patients younger than 20, using cohorts from 1992–1996 combined and 1997–2001 combined. Rates are computed from the Cox model using the model-based adjustment method, described later in this appendix, and are adjusted for age, gender, race, and primary cause of ESRD. The reference population for adjusted rates consists of 1995–1996 incident ESRD patients younger than 20.

Figure 8.38 presents adjusted all-cause and cause-specific mortality by age for incident dialysis patients, 1992–1996 combined and 1997–2001 combined. These rates are also computed from the Cox model, and adjusted for age, gender, race, and primary cause of ESRD. The reference population for the pediatric cohort consists of 1995–1996 incident ESRD patients age 0–19, and for the adult cohort includes 1996 incident ESRD patients age 20 or above.

Figure 8.39 presents adjusted all-cause and cause-specific mortality by gender for incident dialysis patients, 1992–1996 combined and 1997–2001 combined; these are computed from the Cox model, and adjusted for age, gender, race, and primary diagnosis. The reference population consists of 1995–1996 incident ESRD patients younger than 20.

Cardiovascular special studies

Chapter Nine

Figures 9.1–15 describe survival related to cardiovascular comorbidity at the initiation of dialysis, the use of coronary revascularization, and survival following the procedure in dialysis and general Medicare patients with and without chronic kidney disease (CKD). Coronary revascularization is defined according to ICD-9-CM procedure codes in Part A institutional claims and/or CPT codes in Part B physician/supplier claims. Codes used to identify patients receiving these procedures are as follows: coronary artery bypass graft (CABG), ICD-9-CM procedure code 36.13, CPT codes 33510–33523 and 33533–33536; coronary artery stenting, ICD-9-CM procedure code 36.06, CPT codes 92980–92981; percutaneous transluminal coronary angioplasty (PTCA), ICD-9-CM procedure codes 36.01, 36.02, and 36.05, CPT codes 92982, 92984, and 92995–92996. Figures 9.1–5 examine these issues in the incident population. Figure 9.1 presents adjusted survival probabilities related to cardiovascular comorbidity and diabetes at initiation. The study population includes all incident dialysis patients in 1998–2000, including those with unknown dialysis modality, who survive at least 90 days after initiation, have Medicare as primary payor, and are age 20–110; those with unknown gender are excluded. Diabetic status is defined using both the primary diagnosis and comorbidity fields on the Medical Evidence form, while cardiovascular disease is defined through the comorbidity field, and includes myocardial infarction, cardiac arrest, ischemic heart disease, pericarditis, cardiac dysrhythmia, congestive heart failure, cerebrovascular disease/transient ischemic attack, and peripheral vascular disease. All patients are followed from day 90 after initiation to the earliest of death, transplantation, loss to followup, three years after initiation, or December 31, 2003. Using the model-based adjustment method (described in the statistical methods section), survival probabilities are estimated by the Cox proportional hazards model and adjusted for gender and race. The 1998–2000 cohort is used as the reference group.

Figures 9.2–3 compare demographic characteristics and comorbidities in incident hemodialysis and peritoneal dialysis patients, 1995–2003. The study population is selected using the same method described for Figure 9.1. Cardiovascular comorbidity is defined from the Medical Evidence form. Other atherosclerotic heart disease includes cardiac arrest and ischemic heart disease; other cardiac disease includes pericarditis and cardiac dysrhythmia. Figure 9.4 illustrates the long-term use and frequency distribution of revascularization procedures among 1998–2000 incident hemodialysis and peritoneal dialysis patients, and trends in first-year coronary revascularization rates during 1995–2003. Patients are followed from day 90 after initiation to the earliest of death, transplant, modality change, loss to followup, change of Medicare as primary payor status, three years after the study start, or December 31, 2003. Using the model-based adjustment method, procedure rates and cumulative procedure probabilities are estimated with the Cox proportional hazards model, and adjusted for age, gender, race, and primary cause of ESRD. Incident hemodialysis and peritoneal dialysis patients, 2001–2003, are used as the reference group.

Figure 9.5 shows, by modality and diabetic status, long-term survival following coronary revascularization in 1998–2000 incident hemodialysis and peritoneal dialysis patients, as well as trends in first-year death rates after the procedure for 1995–2003 incident patients. Yearly cohorts constructed for 1995 to 2003 include patients who receive their first procedure in the calendar year. Diabetes is defined using the same method described for Figure 9.1. All patients are followed from the procedure date to the earliest of death, transplant, modality change, loss to followup, three years after the procedure, or December 31, 2003. Using the model-based adjustment method, death rates and survival probabilities are estimated with the Cox proportional hazards model, and adjusted for age, gender, and race. The 2001–2003 incident hemodialysis and peritoneal dialysis populations are used as the reference group.

Figures 9.6–10 compare demographic characteristics, comorbidities, coronary revascularization use, and survival following the procedure in prevalent dialysis patients and in elderly general Medicare patients with and without CKD. Figures 9.6–7 describe demographic characteristics and comorbidities among the three study populations. The dialysis cohort includes point prevalent
Medicare dialysis patients, including those with unknown dialysis modality, who are age 20 or older and on dialysis for at least one year. The general Medicare cohort is derived from the 5 percent Medicare Standard Analytic Files, and includes enrollees who are age 66 or older, enrolled in Medicare Parts A and B, not enrolled in an HMO, and not diagnosed with ESRD during the year before January 1 of the prevalent year. Age is defined on the first day of each year. Data on comorbidities are obtained from Medicare Part A institutional claims and Part B physician/supplier claims during the one year prior to the prevalent year. For dialysis patients, the Medical Evidence form is also used to identify patients with cardiovascular comorbidities including myocardial infarction, congestive heart failure, other atherosclerotic heart disease (cardiac arrest and ischemic heart disease), other cardiac disease (pericarditis and cardiac dysrhythmia), cerebrovascular disease/transient ischemic attack, and peripheral vascular disease. ICD-9-CM diagnosis codes used to identify patients with cardiovascular comorbidities and CKD are as follows: AMI, 410 and 412; other ASHD, 411, 413–414, V45.81, and V45.82; CHF; 398.01, 422, 425, 428, 402.x1, 404.x1, 404.x3, and V42.1; other cardiac disease, 420–421, 423–424, 426–427, 429, 785.0–785.3, V42.2, V43.3, V45.0, and V53.3; CVA/TIA, 430–438; PVD; 440–444, 445, 451–453, and 575; and CKD, 016.0, 016.5, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 401.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4.

Figure 9.8 illustrates geographic variations in CAGB and PTCA/stenting rates for elderly dialysis patients and for general Medicare patients with and without CKD. The dialysis cohort includes period prevalent dialysis patients, 1998–2000, who have Medicare Part A and B primary payor coverage, continue on dialysis for at least one year, and are age 66 or older. The general Medicare cohort includes individuals who are enrolled in Medicare Parts A and B as of January 1, 1998, or at any time during 1998–2000, continue enrollment for at least one year without enrollment in an HMO and without diagnosis of ESRD, and are age 66 or older. Prevalent dialysis patients and general Medicare enrollees on January 1, 1998, are followed from January 1, 1999, while incident dialysis patients and new general Medicare enrollees during 1998–2000 are followed from one year after dialysis initiation or enrollment in general Medicare; followup continues until the earliest of a coronary revascularization procedure, death, the last day of Medicare coverage, three years after followup starts, or December 31, 2003. For dialysis patients, followup is also censored at transplant or loss to followup, while for the general Medicare population it is also censored at ESRD diagnosis. Age is defined on the followup start date. For the general Medicare population, CKD is defined from Medicare claims during the one year before followup starts. Rates of CAGB and PTCA/stenting are estimated as the number of procedures per 1,000 patient years at risk for each Health Service Area for dialysis patients, and for each state for general Medicare patients with and without CKD.

Figure 9.9 compares long-term coronary revascularization use and the frequency distribution of revascularization procedures in point prevalent Medicare dialysis patients and general Medicare patients with and without CKD, 2001, and shows as well the trends in first-year coronary revascularization rates during 1995–2003. Patients included in this study are age 66 or older on January 1 of each prevalent year; they are followed from that day to the earliest of death, change of Medicare as primary payor status, three years after the study start, or December 31, 2003. Followup is also censored at transplant and loss to followup for dialysis patients, and at ESRD diagnosis for the general Medicare population. Using the model-based adjustment method, procedure rates and cumulative procedure probabilities are estimated by the Cox proportional hazards model, and adjusted for age, gender, and race. The 2003 elderly general Medicare population is used as the reference group.

Similar information is presented in Figure 9.10, comparing coronary revascularization use, the frequency distribution of revascularization procedures, and trends in first-year coronary revascularization rates in prevalent hemodialysis and peritoneal dialysis patients. Patients age 20 or older are included. Statistical analysis methods are the same as those used in Figure 9.9, with followup also censored at change of modality. Procedure rates and cumulative procedure probabilities are adjusted for age, gender, race, and diabetic status. The 2003 prevalent hemodialysis and peritoneal dialysis populations are used as the reference group.

Figures 9.12–13 compare survival following a coronary revascularization procedure in prevalent hemodialysis and peritoneal dialysis patients, by age on the procedure date. Cohorts for 1995–2002 are constructed according to the year in which patients receive their first procedure, and the 2001 cohort is used to investigate differences in long-term survival between the modalities. Followup starts on the procedure date and continues until the earliest of death, modality change, transplant, loss to followup, three years after the procedure, or December 31, 2003. Using the model-based adjustment method, survival probabilities and death rates by age are estimated by the Cox proportional hazards model, and adjusted for gender, race, and diabetic status. Diabetes is defined according to the primary cause of renal failure on the Medical Evidence form and through Medicare Part A and B claims during the one year prior to the procedure. ICD-9-CM diagnosis codes used to identify patients with diabetes are 250, 357.2, 362.0, and 366.41. The 2003 point prevalent hemodialysis and peritoneal dialysis populations are used as the reference group.

Figure 9.11 compares survival after a coronary revascularization procedure in prevalent elderly dialysis patients and in general Medicare patients with and without CKD, and similar information is presented in Figures 9.14–15 by diabetic status. Patients who undergo their first procedure during 1995–2002 and are age 66 or older on the procedure date are included in the study. For the dialysis cohort, patients are on dialysis for at least one year before the procedure; for the general Medicare cohort, patients are enrolled in Medicare Parts A and B, not enrolled in an HMO, and not diagnosed with ESRD for at least one year prior to the procedure. Followup begins on the procedure date and continues until the earliest of death, three years after the procedure, or December 31, 2003. Followup is also censored at transplant and loss to followup for dialysis patients, and at ESRD diagnosis for general Medicare patients. Survival probabilities and death rates following the procedure are estimated using the same method described for Figure 9.12–13, and are adjusted for age, gender, race, and diabetic status in Figure 9.11, and for age, gender, and race in Figures 9.14–15. The 2003 general Medicare population is used as the reference group.

Figures 9.16–23 and Table 9.a include point prevalent patients who remain alive, on the same modality, and with Medicare as primary payor for the entire calendar year. Atrial fibrillation is identified through at least one Part A inpatient claim or two outpatient or Part B claims with atrial fibrillation as a diagnosis (ICD-9-CM code 427.3) on the claim. For Figures 9.17–18, an incident patient is defined as one for whom atrial fibrillation is not identified in the current prevalent year, but is identified in the following year; the cohort includes only patients who remain alive, on the same modality, and with Medicare as primary payor for the entire year following the prevalent year. In Figures 9.20–23 and Table 9.a, strokes are defined through the occurrence of a Part A inpatient claim with an ICD-9-DM diagnosis of stroke in any position (ischemic, 434.x or 436.x; hemorrhagic, 430.x or 431.x).
Analytical methods

**ESRD providers**

**CHAPTER TEN & REFERENCE SECTION J**


Throughout the atlas and in Reference Section J the USRDS defines a chain-affiliated unit as one of a group of 20 or more freestanding dialysis units owned or operated by a corporation and located in more than one state. Chain identification is determined from the "Provider Name" field of the Facility Survey, the "Chain Name" field of the Dialysis Facility Compare database, and the "Organization Name" field of the Cost Report. In 2003, the year for which data are presented in this ADR, six chains met this criterion. Some graphs compare data from 1999 and 2003; in 1999, seven chains met this criterion. Chains are ranked ordered from largest to smallest.

A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each dialysis unit by CMS.

For years prior to 2002, the USRDS determines facility profit status through the ownership type field on the CMS survey. In the 2002 CMS Survey the profit status variable was dropped, so for 2002 and after we use the profit status field of the Dialysis Facility Compare database. There are, however, a small number of facilities in the CMS survey that are not in the DFC database; these facilities have an unknown profit status, and are omitted from any graph showing profit status.

Figures 10.2–8 include providers of period prevalent hemodialysis patients with at least three months of dialysis prior to June, 2003, and a valid EPO claim during June, 2003. For Figures 10.2–3, a mean hemoglobin is calculated for each provider, and that provider is then classified into one of the three hemoglobin groups. For Figure 10.4, included patients also have a valid EPO claim in July, 2003, so that when providers are classified into a hemoglobin group for June, it is done using only patients who also have an EPO dose for July. The mean dose for each patient within each provider is calculated for July, and that patient is classified into one of the four dose groups. Figures 10.5–8 include only patients who continue to dialyze at the same provider through December of 2003, who have a valid EPO claim in each of the months from June through December, and who are from a provider with at least ten such patients. Each provider is classified into a hemoglobin group based on the mean hemoglobin in June, and the mean EPO dose for each patient is then calculated for each month from July through December, 2003. Figure 10.6 uses the mean dose in July for mapping purposes. Figures 10.7–8 classify a patient as receiving iron if he or she had at least one iron claim during June through December, 2003.

Figures 10.21–23 include period prevalent dialysis patients, 2003. Data for mean hemoglobin and EPO dose include only patients with valid EPO claims. A mean is calculated for each patient from all valid claims during the year, and doses are adjusted for inpatient days. URR and Kt/V data are obtained from the 2003 CPM data, and only include patients in both the USRDS and CPM databases.

Data for Figure 10.24 are obtained from the CDC’s 2003 National Surveillance of Dialysis-Associated Diseases in the U.S.

Figure 10.25 includes prevalent hemodialysis patients from the USRDS database who are also in the 2003 CPM database. The access represents the current access used, as indicated in the CPM data.

Figure 10.26 includes incident dialysis patients from 2003. Values for albumin, serum creatinine, and hemoglobin are obtained from the Medical Evidence form. Albumin calculations ignore whether a patient’s albumin was measured using brom cresol purple or brom cresol green.

Cohorts for Figures 10.27–29 and 10.31 are the same as those used for Objective 14.29 in Chapter HP2010. The non-chain designation here includes independent and hospital-based units. The cohort for Figure 10.30 includes all ESRD patients initiating therapy 90 days before January 1, 2002, with Medicare Part A and B coverage at initiation; the first pneumococcal vaccination is tracked in 2002 and 2003. For Figure 10.32, the cohort includes all ESRD patients initiating therapy 90 days before January 1, 2003, with Medicare Part A and B coverage at initiation. Cohorts for Figures 10.33–34 and 10.36–38 are the same used in Figure 5.11, and cohorts for Figures 10.35 and 10.38 are the same as those used in Figure 5.39.

The life table (or actuarial) estimation method is used to calculate the cumulative probability for Figures 10.30, 10.32, 10.35, and 10.38. Patients are censored at death, payment status change date, end of followup, and end of 2003. Patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories are omitted from all figures.

**Costs of ESRD**

**CHAPTER ELEVEN & REFERENCE SECTION K**

The majority of the economic analyses in this year’s ADR use the as-treated model, described in detail later in this section.

**Payor sequence**

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

**Chapter Eleven**

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total Medicare spending from 2003 is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation for each patient begins at the first ESRD service date. Total 2003 Medicare spending is inflated by 2 percent to account for incomplete claims, and organ acquisition costs are estimated with the same methods used in the 1999 ADR (pages 149–150). HMO costs are estimated using the total HMO months for 2003 (obtained from the CMS managed care organization file) in conjunction with the 2003 AAPCC rate.

Non-Medicare spending by EGHPs is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multiplying the difference by the EGHP years at risk for 2003. 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). Non-Medicare patient spending is estimated as the number of patient months at risk for non-Medicare patients (determined from the USRDS payor sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2002–2003 are obtained from Table K.2, without the 2 percent adjustment for late claims.
Calculations per patient year at risk are based on patients for whom Medicare is the primary payor during the study period (Tables K–d–e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (2.3 percent) and the Medical Consumer Price Index (4.0 percent). Calculations per patient per year at risk by modality for 1999–2003 are taken from Tables K–a–e; these data include MPP patients only, and are not adjusted for late claims.

Data on costs for vascular access services (Figures 11.38–44) are obtained from event-based analyses. Part B (physician/supplier) vascular access procedures and costs are identified through CPT codes (Table a,b). Because some of the CPT codes are not specific to an ESRD access (e.g., central venous catheter, radiological procedures), our selection process requires that certain CPT codes be accompanied by a renal-related diagnosis code for inclusion in the analysis (these codes are identified with an asterisk in Table a,b). Facility costs 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). 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 outpatient claim are considered part of a single vascular access event. Since the CPT code is not a required element on outpatient claims, not all outpatient facility costs for vascular access can be identified. Events that can be identified in the outpatient claims are labeled “pure” outpatient vascular access events.

Although vascular access procedures can be identified from claims data, it is not possible to determine with certainty the type of vascular access being used for dialysis at any given time. In order to compare overall and vascular access costs by type of vascular access, data are analyzed for the hemodialysis cohort from the CMS Clinical Performance Measures Project (CPM) for 1999 and 2003. The CPM project collects data annually on a random sample of hemodialysis and peritoneal dialysis patients, including the type of vascular access being used for dialysis at the time of data collection. The 1999 CPM data for hemodialysis patients were collected from October through December, 1998, and the 2003 CPM data were collected from October through December, 2002. For Figures 11.45–47 we classify patients by the vascular access in use at the time of the CPM data collection, and aggregate costs for the following calendar year, with followup until the earliest of death, transplant, modality change, or the end of the calendar year. This analysis is limited to patients with Medicare as primary payor.

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 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 1999–2003 are comprised of approximately 35 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 Management Information System (REMIS) 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 analyses for this section focus on two amounts found in the claims data: the claim payment amount, which is the amount of the 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.

Payment categories

Medicare payments are broken down into several categories, as shown in Table a.d. 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). In August of 2000 CMS added to the Outpatient SAF a field containing line item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line item cost is discounted by the ratio of the sum of line item payment amounts to the total paid amount for the claim. Since complete data on line item payments are available for the 2001 Outpatient SAF, the estimates for outpatients payment categories are taken directly from the claims data for calendar years 2001–2003, with adjustments as noted.

Model 1: As-treated actuarial model

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

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

The study spans the 13 years from January 1, 1991, to December 31, 2003, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payor sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor at any time during the study period are classified as MSP for the duration of the MSP status in the payor sequence. If the payor status changes to Medicare as primary payor, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare+Choice program are excluded until payor status changes to Medicare (either primary or secondary payor). Patients classified as MSP are included in Tables K.1–3, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to followup, or December 31, 2003. Patients incurring no Part A or B Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

### Medicare categories of payment

<table>
<thead>
<tr>
<th>Medicare payment categories</th>
<th>Basis for categorizing claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total sum of all payments</td>
<td>Sum of all payments originating from the inpatient SAF, including pass-throughs</td>
</tr>
<tr>
<td>Total inpatient</td>
<td>Inpatient SAF, DRG</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 and covered days</td>
</tr>
<tr>
<td>Transplant pass-throughs</td>
<td>Inpatient SAF, DRG 302, calculated from per diem and covered days</td>
</tr>
<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 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/or CPT codes</td>
</tr>
<tr>
<td>Radiology</td>
<td>Outpatient SAF, revenue 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>Total physician/supplier</td>
<td>Sum of physician/supplier payments</td>
</tr>
<tr>
<td>Transplant surgery</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Inpatient surgery</td>
<td>Physician/supplier SAF, CPT and place of service codes</td>
</tr>
<tr>
<td>Outpatient surgery</td>
<td>Physician/supplier SAF, CPT and place of service codes</td>
</tr>
<tr>
<td>E&amp;M nephrologist inpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M non-nephrologist inpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>E&amp;M non-nephrologist outpatient</td>
<td>Physician/supplier SAF, CPT, place of service and specialty codes</td>
</tr>
<tr>
<td>Dialysis capitiation</td>
<td>Physician/supplier SAF, CPT and/or type of service codes</td>
</tr>
<tr>
<td>Inpatient dialysis</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Home dialysis</td>
<td>Physician/supplier SAF, HCPCS and place of service codes</td>
</tr>
<tr>
<td>Vascular access</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Peritoneal access</td>
<td>Physician/supplier SAF, CPT codes</td>
</tr>
<tr>
<td>Physician/supplier 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>

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

**Model 2: Categorical calendar year model**

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figures 11.5–6, 11.20–25, and, in the Précis, Figures p.30 and p.32, as well as Reference Tables K.9–12. With this method, patients are classified into four mutually exclusive treatment groups:

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

**International comparisons**

**CHAPTER TWELVE**

The international data for this ADR have been collected from the following sources, using a USRDS data form: the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA); the Austria OEDTR; the Bangabandhu Sheikh Mujib Medical University of Bangladesh; the Basque Renal Registry; the French-Belgian Nephrologists Registry; Centre Hospitalier Etterbeek-Ixelles; the Ripas Hospital of Brunei; Bulgaria First Hemodialysis Center; the Canadian Organ Replacement Registry; the Division of Nephrologists, University Hospital of Canary Islands; the Catalan Renal Registry, RMRC; the Chilean Renal Registry; the Croatian Society of Nephrology; the Czech Society of Nephrology; the Danish National Registry; the ERA-EDTA Registry; the Finnish Registry for Kidney Diseases; the QuaSi-Niere in Germany; the Greek Hellenic Renal Registry; the Department of Transplantation and Surgery in Hungary; Landspitali University Hospital, Iceland; the Israeli Renal Registry; the Italian Registry of Dialysis and Transplantation; the Jalisco State Dialysis and Transplant Registry, Mexico; the Japanese Society of Dialysis Therapy; the Catholic University of Korea, Republic of South Korea; the Latvian Medical Academy; Registre Néphrologique du Grand Duché de Luxembourg; the Netherlands Dialysis Registry; the National Renal Registry of Malaysia; the Norwegian National Hospital; the Kidney Foundation of Pakistan; the Philippines Renal Disease Registry Project; the Polish Dialysis Registry; Hamad Medical Corporation in Qatar; the Society of Dialysis, Russia; the Scottish Renal Registry; Sociedad Española de Nefrología; the Swedish Renal Registry; the Taiwan Society of Nephrology; the Thailand Registration of Renal Replacement Therapy; the Turkish Society of Nephrology; the Uruguay Dialysis and Transplant Renal Registry; Valencian Renal Registry; the U. S. Census Bureau International Database; and the USRDS.

We are particularly grateful to Drs. Kitty Jager and Paul van Dijk at the ERA-EDTA Registry for their help in coordinating much of the data presented in this chapter.

To contribute data from your country’s registry, please complete the form on pages 271–272 and return it to the USRDS.

**Vascular access**

**REFERENCE SECTION L**

The vascular access events and complications in Reference Section L are identified through the same codes used in Chapter Five.

Tables L.1–3 and L.11–13 include point prevalent dialysis patients from 1999 to 2003 who have Medicare as their primary payor. insertions are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, change in modality, change in payor status, or the end of the prevalent year. For Tables L.11–13, data from 2003 is used, and vintage represents the amount of time between the first service date and January 1, 2003.

Tables L.4–9 include prevalent hemodialysis patients with Medicare as their primary payor who are also in the CPM report for the corresponding year. Their current access is determined from the CPM data as the access used at the time of the most recent data collection, i.e., during the months of October, November, and December of the year prior to the prevalent year. Complications and intervention events are obtained from claims during the time at risk during the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the insertion of a different hemodialysis vascular access. Patients who have an insertion claim after the time of the CPM data collection but prior to the start of the prevalent year are excluded.

Table L.10 includes prevalent peritoneal dialysis patients with Medicare as primary payor. Complications and intervention events are obtained from claims during the time at risk in the prevalent year, which is censored at death, change in modality, change in payor status, or a claim for the insertion of a hemodialysis vascular access.

**Census population base**

**REFERENCE SECTION M**

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

**Statistical methods**

**METHODS FOR CALCULATING RATES**

**Raw rate (observed)**

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

**Model-based rates**

Some patient groups may be very small, and their observed rates therefore unstable. A model-based method can improve the stabil-
ity of these estimates. In this ADR, for example, we have used the generalized linear mixed Poisson model to estimate prevalent patient mortality rates for Reference Section H.

Measurement unit for rates
Both raw and model-based rates are calculated per unit of population (such as per thousand patients) or per unit of followup time (such as per thousand patient years). Calculating rates per unit of followup time can 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 for two groups of patients, all receiving dialysis therapy on January 1, 1997. Group A consists of three patients: Patient 1 had a first hospitalization on March 31, 1997; Patient 2 was hospitalized on June 30, 1997; and Patient 3 was on dialysis through December 31, 1997, with no hospitalizations. Group B also has three patients: Patient 4 was first hospitalized on December 31, 1997; Patient 5 was hospitalized on September 30, 1997; and Patient 6 was on hemodialysis the entire year, with no hospitalizations through December 31, 1997.

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

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

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

Direct adjustment
There are several rate adjustment methods, but only the direct method allows rates to be compared (Pickle LW, White AA). 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 to a single standard population, i.e. the adjustment as the whole country.

Assuming the incident rate of state A in 2001 is 173 per million population, and the race-specific rates (per million population) and national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is (153 x 75.1%) + (250 x 6.3%) + (303 x 6.9%) + (174 x 3.6%) + (220 x 8%) = 158.73 per million population. This means that if state A had the same racial distribution as the entire country, its incident rate would be 158.73 instead of 173. If state B had an adjusted incident rate of 205, we could say that state B had a higher incident rate than state A if they both had the same racial distribution as the whole country.

<table>
<thead>
<tr>
<th>Incident rate of State A</th>
<th>National Population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White 153</td>
<td>75.1</td>
</tr>
<tr>
<td>Black 250</td>
<td>12.3</td>
</tr>
<tr>
<td>Native American 303</td>
<td>0.9</td>
</tr>
<tr>
<td>Asian/Pacific Islander 174</td>
<td>3.6</td>
</tr>
<tr>
<td>Other 220</td>
<td>8.0</td>
</tr>
</tbody>
</table>

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

MODEL-BASED ADJUSTMENT
Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one category has no patients, the method is not valid for calculating an adjusted mortality rate for the group. An attractive alternative is a model-based approach, in which we find a good model to calculate category-specific estimated rates for each group and then calculate direct adjusted rates using these estimates with a given reference population. There is, unfortunately, no straightforward way here to calculate standard errors of the adjusted rates for some models; the bootstrap approach works well, but is time consuming.

In this ADR we use model-based adjustments to calculate adjusted mortality rates, adjusted survival probabilities based on the Cox regression model, adjusted hospitalization rates using the Poisson model, adjusted HSA-level incident and prevalent rates based on the Bayesian spatial hierarchical model, and some other rates.

SURVIVAL PROBABILITIES & MORTALITY RATES
Unadjusted survival probabilities
In this ADR, unadjusted survival probabilities are calculated using the Kaplan-Meier method, and corresponding standard errors are calculated with Greenwood’s formula (Kalbfleish JD, Prentice RL). Survival probabilities in Reference Section I are expressed as percentages from 0 to 100.

Adjusted survival probabilities
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 probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, and primary
diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

GENERALIZED LINEAR MODELS

Generalized linear mixed model for mortality rates
We use the generalized linear mixed model with log link and Poisson sampling distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates. The generalized linear mixed model is used as well for SMR and BMR calculations, described later in this section.

The generalized linear 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 (rate) = (fixed effects) + (random effect). Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and primary 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. Age is used as a categorical variable in main effect and four-way interactions, and as a continuous variable in the two-way interactions.

For tables with mortality rates for both intersecting and marginal groups we have used a single model to calculate all rates in each 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 errors for some of these estimated rates; the bootstrap method is therefore used instead.

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

Generalized linear model for hospitalization rates
In this ADR, hospitalization reference tables present rates of total admissions and hospital days. We have used a generalized linear model with log link and Poisson sampling distribution; the model includes age, gender, race, primary diagnosis, and their two-way interactions. To stabilize the estimates, three years of data are used with different weights. Year is also included in the model. The adjustment hospitalization rates are calculated using the direct adjustment method based on the category-specific admission rate from the generalized linear mixed models.

Interval Poisson model
When the hazards of risk groups defined by a risk factor are not proportional, use of the Cox regression model is not appropriate. But when the time interval is short enough the assumption that the hazards are constant is valid, and the hazards of groups defined by the risk factor, therefore, are proportional. In Chapters Six and Nine, instead of Cox regression models, we use interval Poisson models for some analyses because the hazards of the risk factors we are interested in are not proportional. We cut the followup time to several intervals, and assume that in each all hazards are constant. The number of intervals and the length of each depend on the densities of events and the slopes of the hazards.

STANDARDIZED MORTALITY RATIOS

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

Traditional method of SMR calculation
The traditional approach used to calculate unit-specific SMRs is straightforward: produce unit-specific expected death counts and compute the “observed/expected” ratio. There are two methods of producing unit-specific expected death counts. In the indirect method, the expected death count is the weighted sum of category-specific death rates in the reference population, and the weights are the category-specific total followup times in the units. In the model-based method, a statistical model is employed to estimate the category-specific death rate for the reference population, and the indirect method is then used to produce the expected death count for each unit based on the estimates of category-specific death rates of the reference population from the model.

Bayesian method of SMR calculation
When using the traditional method of calculating unit-specific SMRs, differences in unit sizes may cause very large differences in variations of the estimated SMR, making direct comparisons unfair, especially for small units. The Bayesian hierarchical model, however, provides a good alternative for stabilizing estimated SMRs to make comparisons more appropriate. The model assumes that the observed death count follows a Poisson distribution with mean \( \mu \theta \), and that \( \theta \), the logarithm of SMR, has a normal distribution with Gamma precision, where \( \mu \) is the expected death count from a generalized linear mixed model incorporating patient age, gender, race, primary diagnosis, and ESRD vintage (Liu et al.). To distinguish the two estimation methods, we use the term BMR to designate the estimated SMR from the Bayesian model.

EXPECTED REMAINING LIFETIMES

The expected remaining lifetime for a patient group is the average of the remaining life expectancies for the patients in that group. Some patients will live longer than, and some will live less than, the average. Although the average cannot be known until all patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let \( S(A) \) denote the survival function of patients at time \( A \). Among patients alive at age \( A \), the probability of surviving \( X \) more years is \( S(X|A) = S(A+X)/S(A) \). 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 majority of disease mapping within the ADR is by Health Service Area (HSA), an approach we continue to adopt from the
Analytical methods

Atlas of United States Mortality (Centers for Disease Control and Prevention). Each HSA is a group of counties described by the CDC authors as “an area that is relatively self-contained with respect to hospital care.” The methods described here have been used for all HSA-level maps in the ADR. Because the distribution of age, gender, and race in a population can affect incident and prevalent ESRD rates, we have included maps in which data are adjusted for these variables as well as smoothed. In many figures, data ranges have been standardized to invite comparisons across years, modalities, or patient characteristics. In remaining maps, HSAs are divided into quintiles. Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. HSA-level information is mapped according to the patient’s residence (with the exception of some maps of organ donation rates in Chapter Seven). Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. Territories are not included in the maps.

Methods for smoothing & adjusting map data

To smooth map data we use a Bayesian spatial hierarchical model (Waller et al.). This method is a statistical approach that uses the log linear model (Poisson regression model) to fit the incident counts of the regions. The region effects, as random effects, follow the Conditional Autoregressive (CAR) Normal distribution, and the precision of the effects has a Gamma distribution. The model smooths the incident counts by borrowing information for each HSA from its neighbors through the relationship defined by CAR; neighbors, in our definition, are HSAs sharing a boundary. Smoothed incident rates are obtained by dividing the predicted 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 with the national population as reference.

Smoothed incident rates are obtained by dividing the predicted values from the Bayesian spatial hierarchical model, 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.

The 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.

Miscellaneous

SPECIAL STUDIES & DATA COLLECTION FORMS

The USRDS website includes complete copies of the CMS Medical Evidence form (2728) and Death Notification form (2746); the OPTN 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 ADR provide descriptions of patient cohorts and data adjustments, along with other general information regarding the figures and tables, and should be read in conjunction with the explanations provided in this appendix.

Bibliography


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

SMR/SHR reports & spreadsheets
From 1996 to 1999 the USRDS produced 2,300 unit-specific reports each year, compiling data on the patients treated in each dialysis facility, and calculating Standardized Mortality Ratios (SMRs) and Standardized Hospitalization Ratios (SHRs). These reports are now created by the Kidney Epidemiology and Cost Center (KECC) at the University of Michigan (www.med.umich.edu/kidney). Beginning with the 2003 ADR, the USRDS has also stopped producing SMR and SHR spreadsheets. All questions on these reports and spreadsheets, and on SMR/SHR/STR calculations, should be directed to the KECC.

Data requests
Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases 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.

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

Prior to 1994 all researcher files were created for specific projects. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a patient finder file to be matched with the USRDS database.

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

Standard analysis files
The use of Standard Analysis Files is governed by the USRDS policy on data release for investigator-initiated research (page 264). Research proposals must be approved by the USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data” (page 269). File prices are listed in Table b.c.

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

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

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

Residence A longitudinal record, to ZIP code level, of patient residence.

Payor History Contains a new record for each patient at each change in insurance payor.

Treatment History Modality Sequence file; contains a new record for each patient at each change in modality or dialysis provider.

Medical Evidence Contains full data from the 1995 version of the CMS Medical Evidence form, the data source for 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 (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant CD).

**Transplant Waiting List** Beginning with 2001 data (used in the 2002 ADR), this CD has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.

**Facility** Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.

**Facility Cost Reports** CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.

**Dialyzers** The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies collected information on patient dialyzers. 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 along with characteristics such as membrane type and clearance. We believe that these data, from published sources available at the time of the study, accurately represent the dialyzer characteristics, but they should be used with caution.

**Data from Special Studies** Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. 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.

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

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

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

**Case Mix Severity Study** For this USRDS Special Study, data were collected on 5,255 patients incident in 1986–87 at 328 dialysis units nationwide. Objectives were to estimate the correlation of comorbidity and other factors existing at the onset of ESRD to mortality and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis; evaluate possible associations of these factors with reported causes of death; assess the distribution of comorbidity and other factors among patients on different modalities; and compare relative mortality rates by treatment modality, adjusting for comorbid conditions and other factors.

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

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

**TRANSPLANT CD**

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

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**Graphs**

- **Data requests, by month**
- **Website visits, by month**

**b.1 · USRDS data requests & website visits**
APPENDIX B

USRDS services & data requests

- TXWAIT: contains one record for each patient in the USRDS database per wait list event
- TXHCFMA: includes transplant information collected by CMS’s PMMIS system prior to 1994
- TXUNOS: includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- TXIRUNOS: includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- TXFUHCFMA: 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
- TXFUHUNOS: includes transplant followup reports collected by UNOS since 1988
- TXIFUNOS: includes information on immunosuppressive drugs, collected by UNOS at followup visits

Tables in Section F of the reference section are produced primarily from the CMS and UNOS transplant files.

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

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

HOSPITAL CD
Hospitalization inpatient data are a subset of the data in 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 CLAIMS CD
This CD contains files from the Dialysis Morbidity and Mortality Study, with data extracted from all CMS Medicare payment data for the study patients. All data on Medicare payments for these patients are followed to the currently reported claims year.

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

MEDICARE PAYMENT DATA CDs
Medicare payment data on institutional claims are available for pre-1989 through 2003, while data on physician/supplier claims are available for 1991–2003. The 2003 claims will be available, along with other updated USRDS SAF CDs, by the end of 2005.

Institutional claims consist of all Part A claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), including outpatient dialysis claims. Physician/supplier claims are Part B, and account for 80 percent of the claims but only 20 percent of the dollars.

The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating the type of claim, the dollar amounts, the DRG code, the type of diagnosis involved (if any), and the dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

CPM/USRDS MERGED CDs
CMS’s annual Clinical Performance Measures (CPM) project assesses quality of care in the delivery of dialysis therapy, including anemia management, vascular access, and dialysis adequacy. Data are also collected on risk parameters such as albumin and blood pressure. To allow researchers to perform outcomes analyses with project data, the USRDS generates a set of merged CPM/USRDS data files. The initial dataset contains CPM data collected in surveys from 1994–2000, combined with the 2001 USRDS SAF research files; also included are institutional claims from pre-1989 to 1999 and physician/supplier claims from 1991–1999.


The 2003 CPM/USRDS merged CD is also available as part of the standard USRDS SAF research files. This dataset contains the cumulative CPM cohort (1994–2002), with appropriate updates of institutional and physician/supplier claims for CPM cohorts of prior years.

The CPM survey data are available separately for those who want only the CPM survey data, or who may already possess relevant USRDS SAF products.

For details on these files, please visit our website or email us at usrds@usrds.org.

FILE MEDIA & FORMATS
SAFs are provided on CDs as SAS files, and can be used by SAS on any i86 or Pentium PC with a CD reader. The USRDS has chosen a SAS format 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, and is almost universally available on university computer systems. The SAFs take full advantage of the program’s ability to incorporate detailed documentation into the file. Researchers needing a different format or medium must arrange for the conversion. The USRDS may be able to convert files, but there will be a substantial cost.
(b.a) USRDS products & services
products are provided without charge except as noted

Reports & guides
Annual Data Reports
Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.4415, nkudic@info.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Disease.

Annual Data Report CD
Contains the text and graphics of the ADR, data tables, PowerPoint slides, and the Researcher’s Guide.

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

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

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

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

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

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

Custom data files
Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of $72.70 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK.

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

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

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

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

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

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

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

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

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

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

Dialysis Morbidity and Mortality (DMMS; Special Study)
Wave 1: 5,670 patients; Wave 2: 4,024 patients; Wave 3: 11,142 patients
Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.

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

Case Mix Severity (Special Study) 5,215 patients
Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Pediatric Growth and Development (Special Study) 3,067 patients
Growth, development, and other issues relating to pediatric ESRD patients.

CAPD Peritonitis (Special Study) 3,385 patients
CAPD and peritonitis.

Facility one record for each facility ever in operation
Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.

Facility Cost Reports one record per facility per year (1989–1995)
Costs and staffing of dialysis facilities.

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

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

FORMATS.SC2 all USRDS-defined SAS formats used by SAFs
Format library used to format values of categorical variables.
COSTS
File prices cover reproduction and shipment of files and documentation, administrative costs of handling the sales, and costs of technical support to researchers. Prices are subject to change.

DOCUMENTATION
The Researcher’s Guide to the USRDS Database provides most of the SAF documentation. It includes a codebook of variables, copies of data collection forms used by 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; a hard copy will be sent to those who order SAFs.

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

Data release policy
Since the SAFs and custom data files contain confidential, patient-specific data, their release requires the approval process described here. Investigators may contact the USRDS Project Officer 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 b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the “Agreement for Release of Data,” page 269.
- Indicate needed USRDS SAFs. If these files cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.
- If the project is approved, return a signed copy of the USRDS “Agreement for Release of Data” to the PO. The investigator and the Coordinating Center (CC) will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation.

The NIH will review the project for technical merit and for conformity with the Privacy Act. The Project Officer 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.

<table>
<thead>
<tr>
<th>(b.c) Prices for the USRDS Standard Analysis Files</th>
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<td>checks must be made payable to the Minneapolis Medical Research Foundation</td>
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<table>
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<tr>
<th>Standard Analysis File CD-ROMs</th>
<th>CDs</th>
<th>Price</th>
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</thead>
<tbody>
<tr>
<td>Core CD</td>
<td>2</td>
<td>$600</td>
</tr>
<tr>
<td>Transplant CD</td>
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<td>$200</td>
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<td>Hospital CD</td>
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<td>DMMS claims CD set</td>
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<td>Case Mix Adequacy CD</td>
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<td>$100</td>
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<tr>
<td>CPM/USRDS merged dataset</td>
<td>variable</td>
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Price includes cost of handling the sales, and costs of technical support to researchers. Prices are subject to change. For more information, please see www.usrds.org/cpm.htm, or call 1.888.99USRDS.
All publications using released data must contain the standard acknowledgement and disclaimer presented above. Investigators are requested to send copies of all final publications resulting from this research to both the PO and the 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 SAF data, these data are considered confidential. The USRDS “Agreement for Release of Data” contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

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

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.

(b.d) Outline for research proposals using USRDS data

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

I. Research topic title and submission date.
II. Background information.
III. Study design: objectives, hypothesis(es), analytical methods.
IV. Data being requested: 1) List of Standard Analysis Files needed (if multiple years, please specify), or fields needed in custom data file. 2) Description of data security: responsible party, computer access, etc. 3) Timeframe for the project. 4) Statement that data will be returned to the USRDS or destroyed at the end of the project.
V. To address patient privacy issues, to be consistent with HIPAA policies, and to ensure that researchers are adhering to local privacy standards as well as to USRDS and CMS privacy policies, the USRDS now requires IRB approval for all research proposals. IRB approval is not required from those requesting aggregate data.
VI. Outline of estimated costs of requested data; source of funding.
VII. Agreement for Release of Data, signed by all researchers.
VIII. Investigator information.

For Principal Investigator and co-authors, supply:
- Name
- Affiliation
- Business address
- Business phone & fax
- Email address

Submit to:
Paul Eggers, PhD
NIDDK
6707 Democracy Blvd, Room 615
Bethesda, MD 20892-5458
Phone 301.594.8305
Fax 301.480.3510
egggersp@extra.niddk.nih.gov
ACE inhibitors  Antihypertensive agents that inhibit the production of angiotensin II. Can delay progression to diabetes or kidney disease.

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

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

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

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

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

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

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

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

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

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

Beta blockers Antihypertensive medications that block production of nor-epinephrine, slowing the heart rate and preventing the constriction of blood vessels.

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

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

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

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

Cancer A disease that causes abnormal cell growth.

Cardiac arrest A complete cessation of cardiac activity.

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

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

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

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

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

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

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

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

Common Working File (CWF) System The Medicare 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.

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.

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

Creatinine clearance Used as an indicator to predict the onset of uremia, which develops when creatinine clearance falls below 10 ml/minute/1.73 m².
Death Notification Form (CMS-2740) 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.

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

End-stage renal disease (ESRD) A condition in which a person’s kidney function is 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 networks Regional organizations, established by law in 1978, contracted by CMS to perform quality oversight activities to assure the appropriateness of services and protection for dialysis patients.

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

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

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

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

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

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

Health Maintenance Organization (HMO) A competitive medical plan, such as Medicare+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 2001 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 national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people (www.health.gov/healthypeople).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

National Claims History (NCH) 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 Health and Nutrition Examination Survey (NHANES) A survey conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention; uses home interviews and health tests to collect information on health and diet in the United States.
National Institutes of Health (NIH)
The federal focal point for medical research in the U.S. and one of eight health agencies of the Public Health Services, which are part of the Department of Health and Human Services.

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

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

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

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

Program Medical Management and Information System for ESRD, and Renal Beneficiary and Utilization System (PMMIS/REBUS) The major source of data for the USRS. 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 ESRD patient A patient on renal replacement therapy or with a functioning kidney transplant (regardless of the transplant date). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving treatment for ESRD, and those whose ESRD treatments are not reported to CMS.

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

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

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

Pyrogen reaction A condition in which a patient is febrile 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), which has replaced the Renal Beneﬁcial and Utilization System (REBUS). It includes an operational interface to the SIMS Central Repository.

Reuse A process through which a hemodialyzer is cleaned and disinfect ed, 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.

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 mortality rates for a subgroup of patients to national rates, with adjustments for age, gender, race, primary diagnosis, and ESRD vintage.

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

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

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

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

Urea reduction ratio (URR) A measure of measuring dialysis dose by calculating the change in BUN over the course of a dialysis treatment. URR = (pre-dialysis – post-dialysis BUN) / pre-dialysis BUN x 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 of patients awaiting an organ transplant; maintained by the United Network for Organ Sharing (UNOS).

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

Project title _________________________________________________________________________________________________

In this agreement, "Recipient" means ____________________________________________________________________________
__________________________________________________________________________

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

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

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

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

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

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

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

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

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

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

J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon
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

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<thead>
<tr>
<th>Country</th>
<th>Population of country</th>
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<tbody>
<tr>
<td></td>
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B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year

<table>
<thead>
<tr>
<th>Country</th>
<th>Incidence: Total number of incident (new) patients starting renal replacement therapy during the year</th>
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B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes

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<thead>
<tr>
<th>Country</th>
<th>Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes</th>
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C) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).

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<thead>
<tr>
<th>Country</th>
<th>Prevalence: the point prevalent count of patients at the end of the calendar year (December 31)</th>
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<tbody>
<tr>
<td></td>
<td>All patients on some form of treatment, dialysis or transplantation.</td>
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<tr>
<td></td>
<td>Patients with a functioning kidney transplant as of December 31.</td>
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</table>

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

You may return this form to us by email or fax: usrds@usrds.org, and 1.612.347.5878.
<table>
<thead>
<tr>
<th>Years</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
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**C1) Prevalence:** Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

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<th>Years</th>
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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

<table>
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<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>2002</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>2003</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>2004</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
<td>_______</td>
</tr>
</tbody>
</table>
A. COMPLETE FOR ALL ESRD PATIENTS

1. Name (Last, First, Middle Initial)

2. Health Insurance Claim Number

3. Social Security Number

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

5. Phone Number ( )

6. Date of Birth ______/_____/______

7. Sex Male Female

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

9. Race (Check one box only)

<table>
<thead>
<tr>
<th>Race</th>
<th>Mid-East/Arabian</th>
<th>Indian sub-Continent</th>
<th>Other, specify _____</th>
<th>Unknown</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pacific Islander</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. Medical Coverage (Check all that apply)

<table>
<thead>
<tr>
<th>Coverage</th>
<th>a. Medicaid</th>
<th>b. DVA</th>
<th>c. Medicare</th>
<th>d. Employer Group Health Insurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Medical Insurance</td>
<td>e.</td>
<td>f. None</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

11. Is Patient Applying for ESRD Medicare Coverage? (if YES, enter address of Social Security office)

   Yes    No

   CITY

   STATE

   ZIP

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

13. Height INCHES OR CENTIMETERS

14. Dry Weight POUNDS OR KILOGRAMS

15. Employment Status (6 mos. prior and current status)

<table>
<thead>
<tr>
<th>Prior</th>
<th>Current</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unemployed</td>
<td></td>
</tr>
<tr>
<td>Employed Full Time</td>
<td></td>
</tr>
<tr>
<td>Employed Part Time</td>
<td></td>
</tr>
<tr>
<td>Homemaker</td>
<td></td>
</tr>
<tr>
<td>Retired due to Age/Preference</td>
<td></td>
</tr>
<tr>
<td>Retired (Disability)</td>
<td></td>
</tr>
<tr>
<td>Medical Leave of Absence</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td></td>
</tr>
</tbody>
</table>

16. Co-Morbid Conditions (Check ALL that apply currently or during last 10 years) *See instructions


17. Was pre-dialysis/transplant EPO administered?

   Yes    No

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

<table>
<thead>
<tr>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Hematocrit (%)</td>
<td></td>
<td></td>
<td>e. Serum Creatinine (mg/dl)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Hemoglobin (g/dl)*</td>
<td></td>
<td></td>
<td>f. Creatinine Clearance (ml/min)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Serum Albumin (g/dl)</td>
<td></td>
<td></td>
<td>g. BUN (mg/dl)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Serum Albumin Lower Limit (g/dl)</td>
<td></td>
<td></td>
<td>h. Urea Clearance (ml/min)*</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Provider

20. Medicare Provider Number

21. Primary Dialysis Setting

<table>
<thead>
<tr>
<th>Hospital Inpatient</th>
<th>Dialysis Facility/Center</th>
<th>Home</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hemodialysis</td>
<td>IPD</td>
</tr>
<tr>
<td></td>
<td>CAPD</td>
<td>CCPD</td>
</tr>
</tbody>
</table>

22. Primary Type of Dialysis

23. Date Regular Dialysis Began ______/_____/______

24. Date Patient Started Chronic Dialysis at Current Facility ______/_____/______

25. Date Dialysis Stopped ______/_____/______

26. Date of Death ______/_____/______
### C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

27. Date of Transplant: 

28. Name of Transplant Hospital: 

29. Medicare Provider Number for Item 28: 

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

30. Enter Date: 

31. Name of Preparation Hospital: 

32. Medicare Provider Number for Item 31: 

33. Current Status of Transplant: 

<table>
<thead>
<tr>
<th>Functioning</th>
<th>Non-Functioning</th>
</tr>
</thead>
</table>

34. If Nonfunctioning, Date of Return To Regular Dialysis: 

35. Current Dialysis Treatment Site:  

<table>
<thead>
<tr>
<th>Hospital Inpatient</th>
<th>Dialysis Facility/Center</th>
<th>Home</th>
</tr>
</thead>
</table>

36. Name of Training Provider: 

37. Medicare Provider Number of Training Provider: 

38. Date Training Began: 

39. Type of Training: 

<table>
<thead>
<tr>
<th>Hemodialysis</th>
<th>IPD</th>
<th>CAPD</th>
<th>CCPD</th>
</tr>
</thead>
</table>

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

| Yes | No |

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

42. Printed Name and Signature of Physician Personally Familiar with the Patient's Training: 

43. UPIN of Physician in Item 42: 

### E. PHYSICIAN IDENTIFICATION

44. Attending Physician (Print): 

45. Physician’s Phone No.: 

46. UPIN of Physician in Item 44: 

### PHYSICIAN ATTESTATION

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

47. Attending Physician’s Signature of Attestation (Same as Item 44): 

48. Date: 

49. Remarks: 

### F. OBTAIN SIGNATURE FROM PATIENT

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

50. Signature of Patient (Signature by Mark Must Be Witnessed): 

51. Date: 

### G. PRIVACY ACT STATEMENT

The collection of this information is authorized by section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Privacy Act Issuance, 1991 Compilation, Vol. 1, pages 436–437, December 31, 1991, or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9337. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for a research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

### H. FOR ESRD NETWORK USE ONLY IN CASES REFERRED TO ESRD MEDICAL REVIEW BOARD

52. Network Confirmed as ESRD: 

| Yes | No |

53. Authorized Signature: 

54. Date: 

55. Network Number: 

---

CMS-2728-U3 (6-97)
LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

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

<table>
<thead>
<tr>
<th>ICD-9</th>
<th>LTR</th>
<th>NARRATIVE</th>
<th>ICD-9</th>
<th>LTR</th>
<th>NARRATIVE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>DIABETES</strong></td>
<td></td>
<td></td>
<td><strong>HYPERTENSION/LARGE VESSEL DISEASE</strong></td>
</tr>
<tr>
<td>25000</td>
<td>A</td>
<td>Type II, adult-onset type or unspecified type diabetes</td>
<td>4039</td>
<td>D</td>
<td>Renal disease due to hypertension</td>
</tr>
<tr>
<td>25001</td>
<td>A</td>
<td>Type I, juvenile type, ketosis prone diabetes</td>
<td>4401</td>
<td>A</td>
<td>Renal artery stenosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>GLOMERULONEPHRITIS</strong></td>
<td></td>
<td></td>
<td>(no primary renal disease)</td>
</tr>
<tr>
<td>5829</td>
<td>A</td>
<td>Glomerulonephritis (GN)</td>
<td>59381</td>
<td>B</td>
<td>Renal artery occlusion</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(histologically not examined)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5821</td>
<td>A</td>
<td>Focal glomerulosclerosis, focal sclerosing GN</td>
<td>59381</td>
<td>E</td>
<td>Cholesterol emboli, renal emboli</td>
</tr>
<tr>
<td>5831</td>
<td>A</td>
<td>Membranoproliferative GN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5832</td>
<td>A</td>
<td>Membranoproliferative GN type 1, diffuse MPGN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5832</td>
<td>C</td>
<td>Dense deposit disease, MPGN type 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>58381</td>
<td>B</td>
<td>IgA nephropathy, Berger’s disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>(proven by immunofluorescence)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>58381</td>
<td>C</td>
<td>IgM nephropathy (proven by immunofluorescence)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5804</td>
<td>B</td>
<td>Rapidly progressive GN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5834</td>
<td>C</td>
<td>Goodpasture’s Syndrome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5800</td>
<td>C</td>
<td>Post infectious GN, SBE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5820</td>
<td>A</td>
<td>Other proliferative GN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>SECONDARY GN/VASCULITIS</strong></td>
<td></td>
<td></td>
<td><strong>CYSTIC/HEREDITARY/CONGENITAL DISEASES</strong></td>
</tr>
<tr>
<td>7100</td>
<td>E</td>
<td>Lupus erythematosus, (SLE nephritis)</td>
<td>75313</td>
<td>A</td>
<td>Polycystic kidneys, adult type (dominant)</td>
</tr>
<tr>
<td>2870</td>
<td>A</td>
<td>Henoch-Schonlein syndrome</td>
<td>75314</td>
<td>A</td>
<td>Polycystic, infantile (recessive)</td>
</tr>
<tr>
<td>7101</td>
<td>B</td>
<td>Scleroderma</td>
<td>75316</td>
<td>A</td>
<td>Medullary cystic disease, including nephronophthisis</td>
</tr>
<tr>
<td>2831</td>
<td>A</td>
<td>Hemolytic uremic syndrome</td>
<td>7595</td>
<td>A</td>
<td>Tuberos. sclerosis</td>
</tr>
<tr>
<td>4460</td>
<td>C</td>
<td>Polyarteritis</td>
<td>7598</td>
<td>A</td>
<td>Hereditary nephritis, Alport’s syndrome</td>
</tr>
<tr>
<td>4464</td>
<td>B</td>
<td>Wegener’s granulomatosis</td>
<td>2700</td>
<td>A</td>
<td>Cystinosis</td>
</tr>
<tr>
<td>5839</td>
<td>C</td>
<td>Nephropathy due to heroin abuse and related drugs</td>
<td>2718</td>
<td>B</td>
<td>Primary oxalosis</td>
</tr>
<tr>
<td>4462</td>
<td>A</td>
<td>Vasculitis and its derivatives</td>
<td>2727</td>
<td>A</td>
<td>Fabry’s disease</td>
</tr>
<tr>
<td>5839</td>
<td>B</td>
<td>Secondary GN, other</td>
<td>7533</td>
<td>A</td>
<td>Congenital nephrotic syndrome</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>INTERSTITIAL NEPHRIS/PYELONEPHRITIS</strong></td>
<td></td>
<td></td>
<td><strong>NEOPLASMS/TUMORS</strong></td>
</tr>
<tr>
<td>9659</td>
<td>A</td>
<td>Analgesic abuse</td>
<td>1890</td>
<td>B</td>
<td>Renal tumor (malignant)</td>
</tr>
<tr>
<td>5830</td>
<td>B</td>
<td>Radiation nephritis</td>
<td>1899</td>
<td>A</td>
<td>Urinary tract tumor (malignant)</td>
</tr>
<tr>
<td>9849</td>
<td>A</td>
<td>Lead nephropathy</td>
<td>2230</td>
<td>A</td>
<td>Renal tumor (benign)</td>
</tr>
<tr>
<td>5909</td>
<td>A</td>
<td>Nephropathy caused by other agents</td>
<td>2239</td>
<td>A</td>
<td>Urinary tract tumor (benign)</td>
</tr>
<tr>
<td>27410</td>
<td>A</td>
<td>Gouty nephropathy</td>
<td>2395</td>
<td>A</td>
<td>Renal tumor (unspecified)</td>
</tr>
<tr>
<td>5920</td>
<td>C</td>
<td>Nephrolithiasis</td>
<td>2395</td>
<td>B</td>
<td>Urinary tract tumor (unspecified)</td>
</tr>
<tr>
<td>5996</td>
<td>A</td>
<td>Acquired obstructive uropathy</td>
<td>20280</td>
<td>A</td>
<td>Lymphoma of kidneys</td>
</tr>
<tr>
<td>5900</td>
<td>A</td>
<td>Chronic pyelonephritis, reflux nephropathy</td>
<td>2030</td>
<td>A</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>58389</td>
<td>B</td>
<td>Chronic interstitial nephritis</td>
<td>2030</td>
<td>B</td>
<td>Light chain nephropathy</td>
</tr>
<tr>
<td>58089</td>
<td>A</td>
<td>Acute interstitial nephritis</td>
<td>2773</td>
<td>A</td>
<td>Amyloidosis</td>
</tr>
<tr>
<td>5929</td>
<td>B</td>
<td>Urolithias</td>
<td></td>
<td></td>
<td><strong>MISCELLANEOUS CONDITIONS</strong></td>
</tr>
<tr>
<td>2754</td>
<td>A</td>
<td>Nephrocalcinosis</td>
<td></td>
<td></td>
<td><strong>Sickle cell disease/anemia</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NEOPLASMS/TUMORS</strong></td>
<td></td>
<td></td>
<td><strong>Sickle cell trait and other sickle cell (HbS/Hb other)</strong></td>
</tr>
<tr>
<td>28260</td>
<td>A</td>
<td>Sickel cell disease/anemia</td>
<td>64620</td>
<td>A</td>
<td>Post partum renal failure</td>
</tr>
<tr>
<td>28269</td>
<td>A</td>
<td>Sickel cell trait and other sickle cell (HbS/Hb other)</td>
<td>0429</td>
<td>A</td>
<td>AIDS nephropathy</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>NEOPLASMS/TUMORS</strong></td>
<td></td>
<td></td>
<td><strong>Traumatic or surgical loss of kidney(s)</strong></td>
</tr>
<tr>
<td>8660</td>
<td>A</td>
<td><strong>MISCELLANEOUS CONDITIONS</strong></td>
<td>5724</td>
<td>A</td>
<td>Hepatorenal syndrome</td>
</tr>
<tr>
<td>5836</td>
<td>A</td>
<td>Tubular necrosis (no recovery)</td>
<td></td>
<td></td>
<td><strong>Miscellaneous</strong></td>
</tr>
<tr>
<td>59389</td>
<td>A</td>
<td>Other renal disorders</td>
<td></td>
<td></td>
<td><strong>Sickle cell disease/anemia</strong></td>
</tr>
<tr>
<td>7999</td>
<td>A</td>
<td>Etiology uncertain</td>
<td></td>
<td></td>
<td><strong>Sickle cell trait and other sickle cell (HbS/Hb other)</strong></td>
</tr>
</tbody>
</table>
INSTRUCTIONS FOR COMPLETION OF END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

For whom should this form be completed:

This form SHOULD NOT be completed for those patients who are in acute renal failure. Acute renal failure is a condition in which kidney function can be expected to recover after a short period of dialysis; i.e., several weeks or months.

This form MUST BE completed within 45 days for ALL patients beginning any of the following:

A. For all patients who initially receive a kidney transplant instead of a course of dialysis.
B. All patients for whom a regular course of dialysis has been prescribed by a physician because they have reached that stage of renal impairment that a kidney transplant or regular course of dialysis is necessary to maintain life. The first date of a regular course of dialysis is the date this prescription is implemented whether as an inpatient of a hospital, an outpatient in a dialysis center or facility, or a home patient. This form should be completed for all patients in this category even if the patient dies within this time period.

C. For beneficiaries who have already been entitled to ESRD Medicare benefits and those benefits were terminated because their coverage stopped 3 years post transplant but now are again applying for Medicare ESRD benefits because they returned to dialysis or received another kidney transplant.

D. For beneficiaries who stopped dialysis for more than 12 months, have had their Medicare ESRD benefits terminated and now returned to dialysis or received a kidney transplant. These patients will be reapplying for Medicare benefits.

All Items except as follows: To be completed by the attending physician, head nurse, or social worker involved in this patient's treatment of renal disease.

Items 12, 16, 47-48: To be completed by the attending physician.

Item 42: To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.

Items 50 and 51: To be signed and dated by the patient.

1. Enter the patient's legal name (Last, first, middle initial). Name should appear exactly the same as it appears on patient's Social Security or Medicare card.
2. If the patient is covered by Medicare, enter his/her Health Insurance Claim Number as it appears on his/her Medicare card. This number can be verified from his/her Medicare card.
3. Enter the patient's own Social Security number. This number can be verified from his/her Social Security card.
4. Enter the patient's mailing address (number and street or post office box number, city, State, and ZIP code).
5. Enter the patient's home area code and telephone number.
7. Check the appropriate block to identify sex.
8. Check the appropriate block to identify ethnicity. Definitions of the basic ethnicity categories for Federal statistics are as follows:
   Black—A person having origins in any of the black racial groups of Africa.
   American Indian/Alaskan Native—A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.
   Asian—A person having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan and Korea.
   Pacific Islander—A person having origins in any of the peoples of the Pacific Islands. Examples of this area include the Philippine Islands, Samoa and Hawaiian Islands.
   Mid-East/Arabian—A person having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.
   Indian Sub-Continent—A person having origins in any of the peoples of the Indian Sub-continent. Examples of this area include India and Pakistan.
   Other, specify—A person not having origins in any of the above categories. Write race(s) in space provided.
   Unknown—Check this block if race is unknown.
9. Check one appropriate block to identify race. Definitions of the basic racial categories for Federal statistics are as follows:
   White—A person having origins in any of the original white peoples of Europe.

Black—A person having origins in any of the black racial groups of Africa.

American Indian/Alaskan Native—A person having origins in any of the original peoples of North America, who maintains cultural identification through tribal affiliation or community recognition.

Asian—A person having origins in any of the original peoples of the Far East and Southeast Asia. Examples of this area include China, Japan and Korea.

Pacific Islander—A person having origins in any of the peoples of the Pacific Islands. Examples of this area include the Philippine Islands, Samoa and Hawaiian Islands.

Mid-East/Arabian—A person having origins in any of the peoples of the Middle East and Northern Africa. Examples of this area include Egypt, Israel, Iran, Iraq, Saudi Arabia, Jordan, and Kuwait.

Indian Sub-Continent—A person having origins in any of the peoples of the Indian Sub-continent. Examples of this area include India and Pakistan.

Other, specify—A person not having origins in any of the above categories. Write race(s) in space provided.

Unknown—Check this block if race is unknown.

10. Check all the blocks that apply to this patient's current medical insurance status.

Medicare—Patient is currently entitled to Federal Medicare benefits.

Medicaid—Patient is currently receiving State Medicaid benefits.

DISTRIBUTION OF COPIES:

• Forward the first part (blue) of this form to the Social Security office servicing the claim.
• Forward the second (green) of this form to the ESRD Network Coordinating Council.
• Retain the last part (white) in the patient's medical records file.

According to the Paperwork Reduction Act of 1995, no persons are required to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information is 0938-0046. The time required to complete this information collection is estimated to average 25 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.
DVA—Patient is receiving medical care from a Department of Veterans Affairs facility.

Employer Group Health Insurance—Patient receives medical benefits through an employer group health plan that covers employees, former employees, or the families of employees or former employees.

Other Medical Insurance—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, nor an employer group health insurance plan. Examples of other medical insurance are Railroad Retirement and CHAMPUS beneficiaries.

None—Patient has no medical insurance plan.

11. Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare. Note: Even though a person may already be entitled to general Medicare coverage, he should re-apply for ESRD Medicare coverage. If answer is yes, enter the address of the local Social Security office (street address, city, State and zip code) where patient will be applying for benefits.

12. To be completed by the attending physician. Enter the ICD-9-CM plus letter code from back of form to indicate the primary cause of end stage renal disease. These are the only acceptable causes of end stage renal disease. Enter the patient’s most recent recorded height in inches OR centimeters at time form is being completed. If entering height in centimeters, round to the nearest centimeter. Estimate or use last known height for those unable to be measured. (Example of inches - 62. DO NOT PUT 52")

NOTE: For amputee patients, enter height prior to amputation.

14. Enter the patient’s most recent recorded dry weight in pounds OR kilograms at time form is being completed. If entering weight in kilograms, round to the nearest kilogram.

NOTE: For amputee patients, enter actual dry weight.

15. Check the first box to indicate employment status 6 months prior to renal failure and the second box to indicate current employment status. Check only one box for each time period. If patient is under 6 years of age, leave blank.

16. To be completed by the attending physician. Check all co-morbid conditions that apply.

*Ischemic heart disease* includes prior coronary artery bypass (CABG), angioplasty and diagnoses of coronary artery disease (CAD)/coronary heart disease.

*Cerebrovascular Disease* includes history of stroke/ cerebrovascular accident (CVA) and transient ischemic attack (TIA).

*Peripheral Vascular Disease* includes absent foot pulses, prior typical claudication, amputations for vascular disease, gangrene and aortic aneurysm.

*Drug dependence* means dependent on illicit drugs.

17. If EPO (erythropoietin) was administered to this patient prior to dialysis treatments or kidney transplant, check "Yes." If EPO was not administered to this patient prior to dialysis treatments or kidney transplant, check "No."

NOTE: For those patients re-entering the Medicare program after benefits were terminated, Items 18a thru 18h should contain initial laboratory values within 45 days of the most recent ESRD episode.

18.a. Enter the hematocrit value (%) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. If hematocrit value is not available, complete 18.b. hemoglobin.

18.b. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. Enter value if hematocrit is not available.

18.c. Enter the serum albumin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant.

18.d. Enter the lower limit of the normal range for serum albumin (g/dl) from the laboratory which performed the serum albumin test entered in 18.c.

18.e. Enter the serum creatinine value (mg/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. THIS FIELD MUST BE COMPLETED.

NOTE: Except for diabetic and transplant patients, it has been determined by a consensus panel that the value of this field should be greater than or equal to 8.0 for a patient to receive renal replacement therapy without further justification. If this value is less than 8.0 AND creatinine clearance is equal to or greater than 10.0 this case will be subject to ESRD Network Medical Review Board Review. In these cases, please annotate in Remarks (Item 49) additional medical evidence to support renal replacement therapy. If there is not enough room in the remarks section, you may attach an additional sheet of paper.

18.f. If value of 18.e., serum creatinine, is < 8.0 mg/dl, enter creatinine clearance value (ml/min) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or transplant. If these data are not available, creatinine clearance will be computed, therefore Items 13 and 14 must be completed.

18.g. If value of 18.e., serum creatinine, is < 8.0 mg/dl, enter BUN value (mg/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or transplant.

18.h. If value of 18.e., serum creatinine, is < 8.0 mg/dl and 18.f., creatinine clearance, is > 10.0, enter the urea clearance value (ml/min) and date test was taken. This value and date must be 45 days prior to the first dialysis treatment or transplant.

19. Enter the name of the dialysis provider where patient is currently receiving care and who is completing this form for patient.

20. Enter the 6-digit Medicare identification code of the dialysis facility in Item 19.

21. If a person is receiving a regular course of dialysis treatment, check the appropriate anticipated long term treatment setting at the time this form is being completed. If a patient is a resident of and receives their dialysis in an intermediate care facility or nursing home, check home.

22. If the patient is, or was, on regular dialysis, check the anticipated long term primary type of dialysis: Hemodialysis, IPD (Intermittent Peritoneal Dialysis), CAPD (Continuous Ambulatory Peritoneal Dialysis), CCPD (Continuous Cycle Peritoneal Dialysis), or Other. Check only one block.

NOTE: Other has been placed on this form to be used only if a new method of dialysis is developed prior to the renewal of this form by Office of Management and Budget.

23. Enter the date (month, day, year) that a "regular course of dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a “regular course of dialysis” is the “Date Regular Dialysis Begun” regardless of whether this prescription was implemented in a hospital inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription.

NOTE: For these purposes, end stage renal disease means irreversible damage to a person’s kidneys so severely affecting his/her ability to remove or adjust blood wastes that in order to maintain life he or she must have either a course of dialysis or a kidney transplant to maintain life.

If re-entering the Medicare program, enter beginning date of the current ESRD episode. Note in Remarks, Item 49, that patient is restarting dialysis.
24. Enter date patient started chronic dialysis at current provider of dialysis services. In cases where patient transferred to current dialysis provider, this date will be after the date in Item 23.

25. If a patient began a regular course of dialysis, then stopped dialysis therapy, enter the last dialysis treatment date. Examples of when this field should be completed are: (1) dialysis stopped due to transplant; (2) patient died during Medicare 3-month qualifying period (also complete item 26); (3) patient withdrew from treatment.

26. If the patient has died, enter the date of death. If date of death is completed, please also complete CMS-2746 ESRD Death Notification and attach to ESRD Network copy of CMS-2728.

27. Enter the date(s) of the patient’s kidney transplant(s). If re-entering the Medicare program, enter current transplant date.

28. Enter the name of the hospital where the patient received a kidney transplant on the date in Item 27.

29. Enter the 6-digit Medicare identification code of the hospital in Item 28 where the patient received a kidney transplant on the date entered in Item 27.

30. Enter date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation. This includes hospitalization for transplant workup in order to place the patient on a transplant waiting list.

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

32. Enter the 6-digit Medicare identification number for hospital in Item 31.

33. Check the appropriate functioning or nonfunctioning block.

34. If transplant is nonfunctioning, enter date patient returned to a regular course of dialysis. If patient did not stop dialysis post transplant, enter transplant date.

35. If applicable, check where patient is receiving dialysis treatment following transplant rejection. A nursing home or skilled nursing facility is considered as home setting.

**Self-dialysis Training Patients (Medicare Applicants Only)**

Normally, Medicare entitlement begins with the third month after the month a patient begins a regular course of dialysis treatment. This 3-month qualifying period may be waived if a patient begins a self-dialysis training program in a Medicare approved training facility and is expected to self-dialyze after the completion of the training program. Please complete items 36–43 if the patient has entered into a self-dialysis training program. Items 36–43 must be completed if the patient is applying for a Medicare waiver of the 3-month qualifying period for dialysis benefits based on participation in a self-care dialysis training program.

36. Enter the name of the provider furnishing self-care dialysis training.

37. Enter the 6-digit Medicare identification number for the training provider in Item 36.

38. Enter the date self-dialysis training began. (While it is expected that this date will be after the date patient started a regular course of dialysis, it should not be more than 30 days prior to the start of a regular course of dialysis.)

39. Check the appropriate block which describes the type of self-care dialysis training the patient began.

40. Check the appropriate block as to whether or not the physician certifies that the patient is expected to complete the training successfully and self-dialyze on a regular basis.

41. Enter date patient completed or is expected to complete self-dialysis training.

42. Enter printed name and signature of the attending physician or the physician familiar with the patient’s self-care dialysis training.

43. Unique Physician Identification Number (UPIN) of physician in Item 42. (See Item 46 for explanation of UPIN.)

44. Enter the name of the physician who is supervising the patient’s renal treatment at the time this form is completed.

45. Enter the area code and telephone number of the physician who is supervising the patient’s renal treatment at the time this form is completed.

46. Enter the physician’s UPIN assigned by CMS. A system of physician identifiers is mandated by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985. It requires a unique identifier for each physician who provides services for which Medicare payment is made. An identifier is assigned to each physician regardless of his or her practice configuration. The UPIN is established in a national Registry of Medicare Physician Identification and Eligibility Records (MPIER). Transamerica Occidental Life Insurance Company is the Registry Carrier that establishes and maintains the national registry of physicians receiving Part B Medicare payment. Its address is: UPIN Registry, Transamerica Occidental Life, P.O. Box 2575, Los Angeles, CA 90051-0575.

47. To be signed by the physician supervising the patient’s kidney treatment. Signature of physician identified in Item 44. A stamped signature is unacceptable.

48. Enter date physician signed this form.

49. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or Social Security field office.

50. The patient’s signature authorizing the release of information to the Department of Health and Human Services must be secured here. If the patient is unable to sign the form, it should be signed by a relative, a person assuming responsibility for the patient or by a survivor.

51. The date patient signed form.

---

**NOTICE**

This form is to be completed for all End Stage Renal Disease patients beginning April 1, 1995, regardless of when the patient started dialysis or received a kidney transplant. Versions of the HCFA-2728 dated prior to April 1995 will not be accepted by the Social Security Administration or the ESRD Network Coordinating Councils.
**ESRD DEATH NOTIFICATION**

**END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM**

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

### 1. PATIENT'S LAST NAME

<table>
<thead>
<tr>
<th>FIRST</th>
<th>MI</th>
<th>2. HEALTH INSURANCE CLAIM NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3. PATIENT'S SEX

<table>
<thead>
<tr>
<th>a. Male</th>
<th>b. Female</th>
</tr>
</thead>
</table>

### 4. PATIENT'S STATE OF RESIDENCE

<table>
<thead>
<tr>
<th>5. DATE OF BIRTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>MONTH DAY YEAR</td>
</tr>
</tbody>
</table>

### 6. DATE OF DEATH

<table>
<thead>
<tr>
<th>MONTH DAY YEAR</th>
</tr>
</thead>
</table>

### 7. PROVIDER NAME AND ADDRESS (CITY AND STATE)

### 8. PROVIDER NUMBER

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

<table>
<thead>
<tr>
<th>a. Hospital</th>
<th>b. Dialysis</th>
<th>c. Home</th>
<th>d. Other</th>
</tr>
</thead>
</table>

### 10. WAS AN AUTOPSY PERFORMED?

<table>
<thead>
<tr>
<th>a. Yes</th>
<th>b. No</th>
</tr>
</thead>
</table>

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

#### a. Primary Cause

#### b. Were there

<table>
<thead>
<tr>
<th>No</th>
</tr>
</thead>
</table>

#### Secondary Causes?

<table>
<thead>
<tr>
<th>Yes, Specify</th>
</tr>
</thead>
</table>

### LIST OF CAUSES

#### CARDIAC

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

#### VASCULAR

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

#### INFECTION

- 49 Septicemia, due to vascular access
- 50 Septicemia, due to peritonitis
- 51 Septicemia, due to peripheral vascular disease, gangrene
- 52 Septicemia, other
- 53 Pulmonary infection (bacterial)
- 54 Pulmonary infection (fungal)
- 55 Pulmonary infection (other)
- 56 Viral Infection, CMV
- 57 Viral Infection, Other (not 64 or 65)
- 58 Tuberculosis
- 59 A.I.D.S.
- 60 Infections, other

#### LIVER DISEASE

- 64 Hepatitis B
- 65 Other viral hepatitis
- 66 Liver-drag toxicity
- 67 Cirrhosis
- 68 Polycystic liver disease
- 69 Liver failure, cause unknown other

#### GASTRO-INTESTINAL (see also 50)

- 72 Gastro-intestinal hemorrhage
- 73 Pancreatitis
- 74 Fungal peritonitis
- 75 Perforation of peptic ulcer
- 76 Perforation of bowel (not 75)

#### OTHER

- 80 Bone marrow depression
- 81 Cachexia
- 82 Malignant disease, patient ever on immunosuppressive therapy
- 83 Malignant disease (not 82)
- 84 Dementia, incl. dialysis dementia, Alzheimer's
- 85 Seizures
- 86 Diabetic coma, hyperglycemia, hypoglycemia
- 87 Chronic obstructive lung disease (COPD)
- 88 Complications of surgery
- 89 Air embolism
- 90 Accident related to treatment
- 91 Accident unrelated to treatment
- 92 Suicide
- 93 Drug overdose (street drugs)
- 94 Drug overdose (not 92 or 93)
- 98 Other identified cause of death, please specify:

#### 99 Unknown

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

Renal replacement therapy discontinued prior to death:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If Yes, check one of the following:

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

### 13. IF DECEASED RECEIVED A TRANSPLANT

#### a. Date of most recent transplant

<table>
<thead>
<tr>
<th>MONTH DAY YEAR</th>
</tr>
</thead>
</table>

#### b. Was kidney functioning (patient not on dialysis) at time of death?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Unknown</th>
</tr>
</thead>
</table>

#### c. Did transplant patient resume chronic maintenance dialysis prior to death?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### 14. REMARKS

### 15. NAME OF PHYSICIAN

### 16. SIGNATURE OF PERSON COMPLETING THIS FORM


Form CMS-2746-U3 (8-96)
### PART ONE — DIALYSIS

#### Patients Receiving Care at End of Survey Period

<table>
<thead>
<tr>
<th>Outpatient Dialysis</th>
<th>Self-Dialysis Training</th>
<th>Total Outpatient Dialysis</th>
<th>Home Dialysis</th>
<th>Total Home Dialysis</th>
<th>Total Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemo-Dialysis IPD</td>
<td>Hemo-Dialysis IPD</td>
<td>Fields 14 thru 19</td>
<td>Hemo-Dialysis IPD</td>
<td>CAPD CCPD</td>
<td>Fields 21 thru 24</td>
</tr>
<tr>
<td>14</td>
<td>15</td>
<td>16</td>
<td>17</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>20</td>
<td>21</td>
<td>22</td>
<td>23</td>
<td>24</td>
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</tr>
<tr>
<td>26</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Patient Eligibility Status

- **Currently enrolled in Medicare**
- **Medicare application pending**
- **Non-Medicare**

<table>
<thead>
<tr>
<th>Eligibility Status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>28</td>
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</tbody>
</table>

#### Self-Dialysis Completing Training

<table>
<thead>
<tr>
<th>Hemo-Dialysis</th>
<th>IPD</th>
<th>CAPD</th>
<th>CCPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>31</td>
<td>32</td>
<td>33</td>
</tr>
</tbody>
</table>

#### Transient Patients

- **Treated during survey period**
- **Number of outpatient treatments during survey period**

<table>
<thead>
<tr>
<th>Transient Patients</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>34</td>
<td>35</td>
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</tbody>
</table>

### TREATMENT LOAD

#### Outpatient Dialysis Treatments

<table>
<thead>
<tr>
<th>Hemodialysis</th>
<th>IPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>36</td>
<td>37</td>
</tr>
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</table>

#### Dialysis Training Treatments

<table>
<thead>
<tr>
<th>Hemodialysis</th>
<th>IPD</th>
<th>CAPD</th>
<th>CCPD</th>
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</thead>
<tbody>
<tr>
<td>38</td>
<td>39</td>
<td>40</td>
<td>41</td>
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</tbody>
</table>
### Part Two — Kidney Transplants

#### Patients Transplanted and Donor Type

<table>
<thead>
<tr>
<th>Living Related Donor</th>
<th>Living Unrelated Donor</th>
<th>Cadaveric Donor</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>47</td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>50</td>
</tr>
</tbody>
</table>

#### Eligibility Status of Patients Transplanted at this Facility During the Survey Period

<table>
<thead>
<tr>
<th>Currently enrolled in Medicare</th>
<th>Medicare application pending</th>
<th>Non-Medicare</th>
<th>U.S. Res.</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Transplants Performed at This Facility

<table>
<thead>
<tr>
<th>Field 47 thru 49</th>
<th>Field 42</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>43</td>
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<tr>
<td></td>
<td>44</td>
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<tr>
<td></td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>46</td>
</tr>
</tbody>
</table>

#### Patients Awaiting Transplant

<table>
<thead>
<tr>
<th>Dialysis</th>
<th>Non-dialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Disposition of Cadaver Kidneys

<table>
<thead>
<tr>
<th>Source of Cadaver Kidneys</th>
<th>Transplanted at this facility</th>
<th>Sent to another U.S. facility</th>
<th>Sent Outside the U.S.</th>
<th>Non-Viable Kidneys</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvested at this center</td>
<td>53</td>
<td>54</td>
<td>55</td>
<td>56</td>
<td>57</td>
</tr>
<tr>
<td>Obtained from another transplant hospital</td>
<td>58</td>
<td>59</td>
<td>60</td>
<td>61</td>
<td>62</td>
</tr>
<tr>
<td>Obtained from Independent OPOs</td>
<td>63</td>
<td>64</td>
<td>65</td>
<td>66</td>
<td>67</td>
</tr>
<tr>
<td>Obtained from Non-transplant hospital</td>
<td>68</td>
<td>69</td>
<td>70</td>
<td>71</td>
<td>72</td>
</tr>
<tr>
<td>Total</td>
<td>73</td>
<td>74</td>
<td>75</td>
<td>76</td>
<td></td>
</tr>
</tbody>
</table>

#### remarks regarding information provided on this survey should be entered on the last page of the survey

This report is required by law (42 USC 426; 42, CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).
According to the Paperwork Reduction Act of 1995, no persons are required to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information is 0938-0447. This time required to complete this information collection is estimated to average 8 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-28, Baltimore, Maryland 21244-1850.