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And if the world were black or white entirely
And all the charts were plain
Instead of a mad weir of tigerish waters,
A prism of delight and pain,
We might be surer where we wished to go
Or again we might be merely
Bored but in brute reality there is no
Road that is entirely right.

*Louis MacNiece*

“Entirely”
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 Researcher’s Guide to the USRDS Database, published separately, provides additional detail about the database and Standard Analysis Files.

**Data Sources**

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

**REMIS/REBUS/PMMIS Database**

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

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

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

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) 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 (ME) forms indicating transplant as the initial modality are not included in either file. To resolve conflicts among the three sources, the USRDS has adopted the following procedure:

- 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 ME forms are accepted if there is no previously accepted record of a transplant for that patient within 30 days of the date listed on the ME form.

CMS STANDARD ANALYSIS FILES (SAFS)
These 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 at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2006 ADR includes all claims up to December 31, 2004. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2005.

STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS) DATABASE (ESRD NETWORKS)
The USRDS continues to collaborate with CMS and the ESRD networks to address data tracking issues relating to non-Medicare ESRD patients. Past ADRs have documented the lack of consistent Medicare claims data among these patients. Working solely with data from the Medical Evidence form, the USRDS could establish the first ESRD service date for them, but could not generate a more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can now address issues in the non-Medicare ESRD population such as the large and growing number of lost-to-followup patients, and look as well at patients for whom there previously were no data on initial modality or death. This data integration is detailed on page 239.

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, 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 264.

**data management & preparation**

Our main computer system is a Compaq Alpha system—one Compaq AlphaServer ES45 with four EV-6 (1 GHz) and one Compaq AlphaServer DS20 with dual EV-6 (500 MHz) processors, with a total of 12 GB of RAM memory and 10 terabytes of RAID-5 (Redun-
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. USRDS, in working with CMS, have been able to resolve most of the ‘ZZ’ patients since the release of ESRD Patient Database, REMIS, in the fall of 2003.

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. 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 it unless a transplant failure or death notification is encountered in the data. In the absence of a death notification, dialysis claims, or other confirmation of a continuing modality, a dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim. After this period the patient is declared lost-to-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 recategorization 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—17,641 in 2002 (2006 ADR), compared to 24,726 in 2002 (2004 ADR).

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 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 within 90 days of 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 albumin level along with the test’s lower limit, which indicates the testing method. There are currently two methods in use: brom cresol purple and brom cresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

While producing the 2004 ADR we uncovered severe problems in data quality related to albumin information on the ME form. We found that, from 1995 to 2003, almost 50 percent of forms contained lower limit values equal to “zero,” while another 25 percent reported values other than the expected 3.2 and 3.5 g/dl. Only 25 percent (n=173,000) of incident patients had legitimate lower limit values for determining normal serum albumin. Further analyses have shown that these patients are a representative cohort sample, with 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 payer at day 91 or, for EGHP patients, at 30–33 months after the first ESRD service date. These limitations influence our ability to determine a patient’s exact modality at any one point in time.

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

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

#### PAYORS

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

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

### PRIMARY CAUSE OF RENAL FAILURE

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

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

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

Patient ethnicity became a required field on the 1995 revised ME form; because data for 1995 are incomplete, information on Hispanic patients is presented starting in 1996. The non-Hispanic category includes all non-Hispanics and patients with unknown ethnicity.

Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we concentrate on white, 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 theUSRDS 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
For Figure p.1 we identify CKD, hypertension, and diabetes in patients from the 5 percent Medicare sample using methods described for Chapter One; these methods are also used to determine diabetic status in the ESRD population. Since hypertension is so prevalent in the ESRD population, only patients with hypertension as the primary cause of renal failure are included in the ESRD hypertension category. Costs for the “cost year” are determined for the entire calendar year for patients who have fee-for-service coverage and Medicare as primary payor. For those who survive the “cost year,” costs are computed for the next year. 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.

TRENDS IN QUALITY OF CARE
Methods used to determine vascular access infection and peritonitis rates in Figure p.10 are described in the discussion of Figure 6.5. Figure p.11 includes prevalent hemodialysis patients in the CPM database with at least one valid URR measurement. For each patient, we calculate a mean URR measurement from all measurements available, then the percentage of patients whose mean URR is in each category.

Figure p.12 includes prevalent peritoneal dialysis patients in the CPM database with at least one valid Kt/V measurement. For each patient, we calculate a mean Kt/V measurement from all those available, then the percentage of patients whose mean Kt/V is in each category.

Figure p.13 presents the distribution of patients by mean hemoglobin group on a monthly basis, in which each month contains all patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by 3. Figure p.14 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. The mean EPO dose is adjusted in the same way used in Chapter Five, with a patient’s time at risk including only those days in which he or she is not in an inpatient hospital setting. (Because inpatient claims data for 2005 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 2005 EPO doses.)

The method and cohort used for Figure p.15, on diabetic care in prevalent patients, are the same as those used for Figures 5.10, 5.13, and 5.16.

Figure p.16 displays medication persistency of incident CKD/ESRD patients during different drug treatment periods in the Medstat MarketScan database. Incident CKD/ESRD patients (2000–2004) are selected if patients have CKD or ESRD in the current year, but not in the previous year, and if their first CKD or ESRD diagnosis/service date occurs during their fee-for-service continuous enrollment period. Incident patients using a particular drug are defined as those with at least one pharmacy claim after the first CKD or ESRD diagnosis/service date, and at least three months of enrollment before the first pharmacy claim. The medication possession ratio (MPR) captures the amount of time that a patient remains on chronic drug therapy, and is used to measure adherence to drug therapy. 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 in these analyses can be found on our website and CD-ROM.

HOSPITALIZATION & MORTALITY
Figure p.17 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, 2003, and June 30, 2004. To avoid including patients without Medi-
care coverage, we exclude patients without at least one claim of any type (Part A institutional or Part B physician/supplier) in the two-year period prior to initiation. For Figures p.17–18 and p.20, principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. For Figure p.18, vascular access hospitalizations are those defined as “pure” inpatient vascular access events, as described for Tables C.11–15.

Figures p.18–20 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 G. Included patients have Medicare as a primary payor 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 section. The reference cohort includes period prevalent ESRD patients, 2004, and vintage 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.21 presents adjusted first- through fifth-year mortality rates, by modality, for incident ESRD patients. Patients are followed from day 91 until death or December 31, 2004. Dialysis patients are also censored at transplant. Rates are computed from the Cox model using the model-based adjustment method, 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.22 shows trends in mortality rates by modality and vintage, and includes period prevalent patients on hemodialysis, 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.

Figure p.23 illustrates five-year survival by first modality. Populations for the 1990–1994 and 1995–1999 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, transplant, or the end of 2004, while transplant patients are followed from the first transplant date until death or the end of 2004. 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.

ESRD EXPENDITURES
Methods used for Figures p.24–29 are described in the text for Chapter Eleven and in the figure captions.

CKD EXPENDITURES
In Figures p.30–38, CKD, hypertension, and diabetes are determined using methods from Chapter One. The population for the 5 percent Medicare data (p.30–33) is limited to those with fee-for-service coverage and Medicare as primary payor. The EGHP cohort (Figures p.34–38) is described in the “EGHP cohort” section, above, and limited to patients age 50–64. 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.

Figure p.36 illustrates the mean costs of incident CKD/ESRD patients in the Medstat MarketScan database during their first 12 months of drug therapy. Only inpatient and outpatient costs are considered, and these are adjusted quarterly to year 2000 based on the CMS Market Basket (see http://www.cms.hhs.gov/medicare-programraterestats/04_marketbasket.asp). Patients are grouped by MPR. For comorbidity definitions, study populations, and drug libraries, please refer to the discussion of Figure p.16.

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, 1991–2004. Cause-specific cardiovascular mortality is defined using CMS codes 27, 31, and 32 (congestive heart failure), 26 (atherosclerotic heart disease), 02 and 23 (myocardial infarction), and 01, 04, 25, 28–30, and 36–37 (other cardiovascular disease). Age is calculated for point prevalent patients as of January 1, and for incident patients as of the first ESRD service date. We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.4: For Figures hp.9–10, the calculation of insertion rates follows methods used in Chapter Five. For Table hp.c (CPM year 2004) and Figures hp.8 and hp.25 (CPM years 1999–2004), data are obtained from the CMS Clinical Performance Measures (CPM) Project. Patients included in these two figures and the table are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and the access type represents the access used at the time 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
chronic kidney disease

CHAPTER ONE

prevalence of CKD

Figure 1.1 illustrates the size of the chronic kidney disease (CKD) population in 2004 and the proportion of patients with diabetes and/or hypertension (HTN), and includes general Medicare patients, EGHP patients age 50–64, and EGHP patients older than 65. The general Medicare cohorts are derived from the 5 percent Medicare Denominator files, 2004, 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, 2004, and include patients 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 HTN in each calendar year. Codes used to identify patients are as follows: HTN, 362.11, 401.x–405.x, 437.21; 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, 753.3, and 794.4; and diabetes, 250, 357.2, 362.0x, and 366.41.

Figure 1.2 illustrates geographic variations in prevalent CKD rates for the general Medicare population (age younger than 65, and age 65 and older) and for the EGHP population (age 50–64, and age 65 and older). Study cohorts are constructed with the method used for Figure 1.1, with the additional requirement that patients be continuously enrolled in Medicare during 2003–2004, and we exclude patients who reside in Puerto Rico or the U.S. territories from the general Medicare cohorts. The prevalent rate of CKD is estimated as the number of patients with CKD per 1,000 population in each Health Service Area (for the Medicare population) or in each state (for the EGHP population). Figures 1.4–5 illustrate the interactions of CKD with diabetes and hypertension in the general Medicare and EGHP populations. The study cohorts are defined using the same methods as in Figure 1.1.

Figure 1.6 displays the size of the CKD population by age and race. Study cohorts are constructed following the method used for Figure 1.1, with the additional requirement that patients be continuously enrolled in Medicare during two consecutive calendar years.

assessment of at-risk populations; preventive care

Figures 1.7–11 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, 2003, alive and age 66 or older on December 31, 2003, and with no CKD diagnosed during 2003. 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. Patients who do not reside in the 50 states are excluded from the maps. The EGHP cohort includes patients enrolled for all of 2003 in a fee-for-service-plan, age 50 or above, and with no CKD diagnosed during 2003. Patients diagnosed with ESRD before or during the year are excluded. For both cohorts, diabetes and hypertension are defined in 2003. Methodologies and codes used to define CKD and the comorbidities are described above.

Assessments of CKD include serum creatinine, microalbuminuria or proteinuria, calcium and phosphorus testing, and parathyroid hormone testing; the battery of tests in Figure 1.11 includes all of these except the PTH tests. The first testing of each assessment is tracked in 2004. Patients are censored at the end of the plan, at the end of 2004, and, for the general Medicare population, at death. Tests are identified through the following CPT codes: serum creatinine, 80069 and 82565; microalbuminuria or proteinuria etc.
Appendix A

Analytical Methods

(described in the HP2010 methods), 82042, 82043, and 82044; calcium and phosphorous, 80069, 80073, 82310, 82315, 82320, 82325, 82330, and 84100; and parathyroid hormone, 83970.

Figures 1.12–16 display the cumulative probabilities of CKD assessments in all EGHP populations by industry and union status. The codes and methods for those figures are the same used for Figures 1.7–11, but only a cohort of primary subscribers of a fee-for-service plan are included. Industry units include 1) oil and gas extraction, mining; 2) manufacturing, durable goods; 3) manufacturing, nondurable goods; 4) transportation, communications, utilities; 5) retail trade; 6) finance, insurance, real estate; 7) services.

Figures 1.17–18 illustrate the cumulative probabilities of bone and mineral metabolism testing in the general Medicare and EGHP populations with CKD, while Figures 1.19–24 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 from HEDIS 2002 specifications, described in the 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 1.17–22, the prevalent Medicare cohort includes patients entering Medicare before January 1, 2003, and alive and remaining in the program through December 31. For Figure 1.23, patients are alive and in the program through August 31, 2004. And for Figure 1.24, patients must enter Medicare before January 1, 2002, and remain alive and in the program though December 31, 2002. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during 2003 (for 1.18, during 2002) are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients who do not reside in the 50 states are excluded from the maps. The EGHP cohort includes patients enrolled during the study period in a fee-for-service plan and age 50 or above. Patients diagnosed with ESRD before or during 2003 (for 1.18, during 2002) are excluded. For Figures 1.19–21, patients are diagnosed with CKD and diabetes in 2003. For Figures 1.17–18 and 1.12–1.13, patients are diagnosed with CKD in 2003, and for Figure 1.24, patients are diagnosed with CKD in 2002.

The testing analyzed in Figures 1.17–22 is also illustrated in Figures 1.25–32, for the EGHP population, by industry and union status, using a subset of the primary subscribers of a fee-for-service plan.

The Kaplan-Meier estimation method is used to calculate cumulative probabilities. The first testing of each preventive healthcare measure is tracked in 2004. Patients are censored at the end of the plan, at the end of 2004, 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 80061, 80065, 83715–83721, and 84478; HbA1c testing, CPT code 83036 (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, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations, CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009.

Hospitalization rates

Figures 1.33 and 1.35–38 show adjusted all-cause and cause-specific hospitalization admission rates, by the presence of diabetes and hypertension, for general Medicare (1993–2004) and EGHP (2000–2004) patients with and without CKD. The prevalent Medicare cohort includes patients age 66 or older who are continuously enrolled in Medicare Parts A and B, have no HMO or Medicare as secondary payor coverage, are alive during the one-year entry period, and who reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. The prevalent EGHP cohort is comprised of patients age 50 or older with fee-for-service coverage during the two consecutive calendar years and alive on the last day of the one-year 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 a maximum of one year, from January 1 until the earliest of death, end of Medicare Parts A and B 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 hypertension. 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, admission rates are adjusted for gender and race, using the direct adjustment method (described in the section on statistical methods), with the 2004 general Medicare care cohort used as the reference group. Rates for EGHP patients are adjusted for gender, using the 2004 EGHP cohort as reference.

Figure 1.34 displays geographic variations in unadjusted all-cause admission rates for general Medicare CKD and non-CKD patients in 2004. Patient exclusion criteria are the same as those used in Figure 1.33. Followup begins on January 1, 2004, and continues until death, the last day of Medicare coverage, or December 31, 2004.

Acute kidney failure

Figures 1.39–45 present data on acute kidney failure (AKF). Figure 1.39 shows the cumulative probability of hospitalization for AKF, by diabetic and hypertensive status, for general Medicare populations with and without CKD in 1993 and 2002. The study cohort consists of patients continuously enrolled in Medicare Parts A and B during the one-year entry period, with no HMO or Medicare as secondary payor coverage; residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and alive on the last day of the one-year entry period. Patients diagnosed with ESRD before or during the entry period are omitted from the study. Patients are followed up to three years from January 1 of the year (1993 or 2002) until the earliest of AKF hospitalization, ESRD, death, end of Medicare Parts A and B coverage, or December 31, 2004. The longest followup time is three years.

A one-year entry period is used to define patients with CKD, diabetes, or hypertension. 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 AKF is identified through this code, appearing on Medicare inpatient claims, by three methods, 1) as any diagnosis code (A-AKF), 2) as a principle diagnosis code (P-AKF), and 3) as a secondary diagnosis code (S-AKF). The three sets of graphs are thus generated through different methods to identify AKF hospitalizations. Patients with hospitalizations for AKF overlapping the start date of the followup period are excluded from the analysis. We use the Kaplan-Meier method to investigate the cumulative unadjusted probability of hospitalization for AKF at years one, two, and three of the followup period.

Figures 1.40–43 display the pattern of ESRD development and death in Medicare patients with AKF hospitalization. Study periods of January 1, 1993, to December 31, 1995, and January 1, 1999, to December 31, 2001, are used to identify patients with an AKF hospitalization any time during these time frames. The followup
period extends after the first AKF hospitalization discharge until the earliest of death, ESRD diagnosis, or December 31, 2004. Patients who do not survive the first AKF hospitalization or who develop ESRD before or during that hospitalization are excluded. A one-year entry period before the first AKF hospitalization discharge date is used to define CKD, diabetes, and hypertension status. Patients who are not continuously enrolled in Medicare Parts A and B, who have HMO or Medicare as secondary payor coverage during the entry period, or who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, are omitted.

The methodology used to define patients with CKD, diabetes, or hypertension is the same as that described for Figure 1.39, and hospitalization for AKF is identified through the 584 ICD-9-CM diagnosis code (A-AKF) on inpatient claims. Rates for ESRD development or death in each three-month interval are estimated by the Poisson model, adjusted for baseline age, race, and gender; the 2004 cohort is used as the reference group.

Figure 1.44 shows the pattern of developing ESRD one year after AKF hospitalization for general Medicare CKD/non-CKD patients, 1995–2003. Patients with an AKF hospitalization are identified for each calendar year. The followup period starts after the first AKF hospitalization discharge during each year until the earliest of death, ESRD diagnosis, or one year after followup begins. A one-year entry period before the AKF hospitalization discharge date is used to define CKD. The patient exclusion criteria and the methodology to define CKD and the AKF hospitalization are the same as those used in Figures 1.40–43. The percentage is adjusted for age, race, and gender; the 2004 cohort is used as the reference group.

Figure 1.45 shows the percent of incident ESRD patients hospitalized for AKF in the two years prior to dialysis initiation. The study cohort consists of incident ESRD patients age 67 or older at dialysis initiation, with Medicare Parts A and B as primary payor during the two-year study period prior to initiation. AKF hospitalizations are identified through the all 584 ICD-9-CM diagnosis code (A-AKF) on inpatient claims.

adherence to prescription drug therapy
Figures 1.46–51 illustrate medication adherence in incident CKD patients, using data from the Medstat MarketScan Database. For comorbidity definitions, methods used to define the study population, and drug libraries, please refer to the discussion of Figure p.16.

incidence & prevalence
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 in Table B.1 of the Reference Tables.

ICD-9-CM codes for the diagnoses in Tables 2.a–b can be found on page 283, in the Medical Evidence (2728) form.

Figure 2.40 presents hospitalization data for incident ESRD patients. Included Medicare patients have a first ESRD service date of January 1, 2003, to June 30, 2004, and are at least 67 years old at initiation. To ensure Medicare eligibility, we exclude patients with no Medicare claims (Part A or Part B) in the two years prior to initiation. Figure 2.40 shows admission rates in the two years before and six months after initiation. Patients who die during the six months after initiation are censored. Unadjusted admissions per patient year are computed by age, race, and incident year.

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, 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.6, B.8, and B.10, these tables focus on patients residing in the 50 states and the District of Columbia. Age is calculated as of December 31.

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 from each version so that detail is not lost through trying to convert one set of codes to the other.

Figures 3.2–5 include incident patients, 1984–2003, who are age 20 and older, survive at least one year plus 90 days after initiating dialysis, and have Medicare Parts A and B coverage. Data on diabetes as the cause of renal failure are obtained from the Medical Evidence form. The period from 90 days after initiation to one year plus 90 days is searched for inpatient claims with diagnosis codes for cardiovascular causes and hypertension. The first three diagnosis codes are searched across all years.

Figures 3.6–11 illustrate adherence to prescription drug therapy in incident ESRD patients, using data from the Medstat Mar-
kettScan database. For comorbidity definitions, a description of the incident ESRD study population, and drug libraries, please refer to the discussion of Figure p.16.

Table 3.a displays the odds ratios of having a hemoglobin less than 10 g/dl at ESRD initiation. Odds ratios are estimated from separate but identical logistic models for white, black, Native American, Asian, and Hispanic patients who submitted a Medical Evidence Form between January 1, 2000, and December 31, 2004. Patients with missing measurements of blood urea nitrogen, hematocrit, or serum creatinine are excluded.

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 point 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 1997–1999 incident ESRD dialysis cohort with the built-in 60-day stable modality rule. All incident dialysis patients are followed from ESRD initiation to a maximum of five years. Cumulative probabilities are adjusted for age, gender, and race, censoring at change in dialysis modality, transplantation, death, and the end of the followup 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 2000 to 2002. The 90-day rule is used to exclude patients who die during the first 90 days of ESRD, and age is computed as of the first ESRD service date.

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

clinical care & preventive health
CHAPTER FIVE
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 5.27–47 are obtained from EPO claims data, while in Figures 5.3, 5.2–8, and 5.47, 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 on Kt/V and vascular access in Figure 5.1 come from the CPM Project, while data on albumin are obtained from the Medical Evidence form.

In Figure 5.1, for both Kt/V measurements, 2004 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 2004, 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, 2004 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500 or greater than 80,000 units, or with a hematocrit value less than 10 or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hematocrit values divided by three. Data on albumin are obtained for incident hemodialysis patients in 2004 who have a valid value on their Medical Evidence form; those with a lower limit equal to zero are omitted.

vascular access
Figures 5.2–7 include incident hemodialysis patients who are in both the USRDS and CPM databases, and whose day 91 begins prior to October 1 of the incident year. The access represents the access being used on day 90 according to the CPM data. Claims are then searched during the one-year period after day 90 for events and complications. 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.

diabetic care

Figures 5.9–20 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. Patients who reside in the District of Columbia, Puerto Rico, and the Territories are also omitted from the maps. Age is generally calculated at the end of the study period.

Methods and codes used to determine rates of diabetic glycated hemoglobin (HbA1c) testing, lipid testing, and the prescription of diabetic test 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 5.9, 5.12, 5.15, and 5.18 compare rates of diabetic preventive care in 1994 and 2004, while Figures 5.11, 5.14, 5.17, and 5.20 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 1993 or 2003, alive on December 31 of 1994 or 2004, and with diabetes defined in 1993 or 2003. Rates include patients receiving at least four HbA1c tests, at least two lipid tests, a prescription for at least two strips per day, or all of the above during 1994 or 2004. Figures 5.11, 5.14, 5.17, and 5.20 show diabetic preventive care in 2003 only; patients with unknown urban or rural status are excluded.

For Figures 5.10, 5.13, 5.16, and 5.19, 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 5.16, 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 5.18 and 5.20, “comprehensive” diabetic monitoring means at least four HbA1c tests, at least two lipid tests, and a prescription for at least two strips per day; in Figure 5.19, “limited” monitoring indicates at least one HbA1c test, at least one lipid test, and at least one test strip.

adherence to prescription drug therapy

Figures 5.21–26 illustrate adherence to prescription drug therapy in incident dialysis patients, using data from the Medstat MarketScan database. Incident dialysis patients from 2000–2004 are on dialysis in the current year, but not in the previous year, and the first dialysis service date occurs during each patient’s fee-for-service continuous enrollment period. Medication use is identified through at least one pharmacy claim after first dialysis service date, and at least three months of enrollment before the first pharmacy claim. For comorbidity definitions and drug libraries, please refer to the discussion of Figure P.16.

anemia treatment

Figures 5.27–28 are described in the discussion of Figures P.13–14. Figures 5.29–31 include data from all incident hemodialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. EPO claims with a dose per administration of less than 500 units or more than 80,000 units are omitted, as are those with an average dose per day (calculated as the total EPO units on the claim divided by the number of days spanned by the claim) of less than 100 units or greater than 10,000 units. For 2004, patients are incident prior to June 1, to allow them to have six months of EPO and/or iron claims after their incident date. For graphs by starting hemoglobin, patients are included only if they have a hematocrit listed on the Medical Evidence form, and their starting hemoglobin is determined from this value. In Figure 5.29, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 5.30, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only. And for Figure 5.31, each patient is classified for each month as receiving iron if he or she has an iron claim in that month or in one of the previous months (but after initiating ESRD therapy). The percent of patients receiving iron then represents a cumulative percent of patients receiving iron after starting ESRD therapy.

Figures 5.32–35 include prevalent hemodialysis patients with at least one EPO claim during their prevalent year and a hematocrit on that claim of 10–50. Mean hemoglobin and weekly EPO dose are calculated using the same methods described above. Diabetics are those patients whose primary cause of renal failure is diabetes.

anemia management

Erythropoietin (EPO) and darbepoetin (DPO) dose information and hemoglobin values (calculated from hematocrit values) in Figures 5.36–43 are obtained from outpatient EPO claims data. The provider analysis in Figure 5.39 is based on the CMS provider number included on the EPO or DPO claims.

EPO resistance

Figures 5.44–47 show mean hemoglobin and EPO dose per week by the rate of infectious hospitalizations. They include 2004 period prevalent hemodialysis patients with at least one valid EPO claim during 2004. Infections represent the number of inpatient hospital stays per patient year at risk with an infection as the principal diagnosis. Catheter insertions represent the number of insertion claims per patient year at risk from HCPCs codes on Part A and B claims during 2004. The mean EPO dose has been adjusted for days spent in an inpatient hospital setting, and excludes patients whose adjusted dose is 100,000 units per week or more. Patients with less than 0.3 patient years at risk during 2004 are excluded. Figures 5.45–47 include only patients age 20 years or older as of January 1, 2004.

preventive care

Figures 5.48–51 show rates of diabetic HbA1c and lipid testing by modality, along with cumulative probabilities of the fourth HbA1c test and the second lipid test in 2004. Cohorts for Figures 5.48 and 5.50 are the same as those described for Figure 5.10. Cohorts for Figures 5.49 and 5.51 are 2003 point prevalent ESRD patients with Medicare Part A and B coverage at initiation, alive and remaining in the program through the end of 2003, and with diabetes diagnosed in 2003; patients who are lost-to-followup in 2003 are excluded. The fourth HbA1c test and second lipid test are tracked in 2004. 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 2004.

Figures 5.52–57 show rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality and time period. Cohorts for Figures 5.52–55 are the same as those described for Objective 14.29 in the HP2010 chapter, while the cohort for Figures 5.56–57 includes prevalent patients initiating therapy 90 days prior to January 1 and alive on December 1, 2004. Rates are calculated for patients receiving one vaccination or test in 2004. Patients without Medicare Part A and B coverage during 2004 are omitted, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, who do not survive until December 31, 2004, or who are lost-to-followup during 2004. Patients who reside in the District of Columbia, Puerto Rico, and the Territories are also omitted for the maps. Age is generally calculated at the end of the study period. Hepatitis B vaccinations are tracked in 2004, and are identified through CPT codes 90636, 90740, 90743–90744, 90748, 90731, and 90723.

**morbidity & 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 Asian; these patients are included in the Chapter Six figures, except where data are presented by race.

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

Figure 6.2 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, with the 2004 ESRD cohort used as the reference. Methods for the rates in Figures 6.2–3 follow those described for Reference Section G. Figure 6.3 presents unadjusted rates for period prevalent ESRD patients in 2004 by HSA and state. (Rates for peritoneal dialysis and transplant patients are presented by state rather than by HSA due to few patients and events in many HSAs.) Maps by HSA are smoothed using the Bayesian method.

The methods used in Figure 6.4 are similar to those described for Figure p.18 in the discussion of the Précis, with admissions for pneumonia, bacteremia/sepsisemia, and cellulitis in Figure 6.4 replacing the categories of all-cause, infection, and cardiovascular disease in p.18. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: pneumonia, 480–486 and 487.0; bacteremia/sepsisemia, 038.0–038.9 and 790.7; and cellulitis, 682. Vascular access hospitalizations are “pure” inpatient vascular access events, as described for Tables G.11–15 later in this appendix.

Figure 6.5 shows adjusted admission rates for principal diagnoses for prevalent ESRD patients. Principal ICD-9-CM codes for pneumonia, bacteremia/sepsisemia, and cellulitis are listed above for Figure 6.4. Other principal ICD-9-CM codes are as follows: for vascular access infection (hemodialysis patients only), 996.62; and for peritonitis (peritoneal dialysis patients only), 567.

Figure 6.6 presents the percent change in adjusted hospital admission rates for period prevalent dialysis patients, 1995–2004.

Values presented for all patients are adjusted for age, gender, race, and primary diagnosis, while rates presented by one of these factors are adjusted for the remaining three. As noted in the caption, these adjustments for different factors mean that rates across the individual graphs are not directly comparable. We use the model-based adjustment method here, with 2004 dialysis patients as the reference cohort. Vascular access hospitalizations are “pure” inpatient vascular access events, as described later for Tables G.11–15. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 423–438, and 440–449, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.3, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 610.1, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7, 790.8, 996.60–996.69, 997.62, 998.6, and 999.3.

Tables 6.a–c present adjusted hospital admission rates by vintage for adult (age 20 and older) period prevalent ESRD patients in 1994 and 2004. Patient vintage is calculated as the time from the first ESRD service date to the first of the year for prevalent patients, or as less than one year for incident patients. Rates in the “all” row are adjusted for age, gender, race, and primary ESRD diagnosis, while rates presented by one factor are adjusted for the other three.

Figures 6.7–9 show rates by age, adjusted for gender, race, and primary diagnosis using the model-based adjustment method. These figures include period prevalent dialysis patients age 20 and older, with the 2004 dialysis cohort as the reference. Figure 6.7 presents adjusted rates of cause-specific hospital admissions per patient year. The categories for cardiovascular disease and infection are defined by the codes listed for Figure 6.6; the infection codes for Figure 6.7, however, exclude those due to internal device. The principal ICD-9-CM diagnosis codes used for infection due to internal device (related to a vascular access device or peritoneal dialysis catheter) are 996.62 and 999.68.

Figure 6.8 shows adjusted event rates for inpatient coronary revascularization. Patients are followed until the first coronary revascularization event, and are censored at the earliest of death, three days prior to transplant, or the end of the calendar year. Events are identified from Part A inpatient claims and Part B physician/supplier claims occurring within a hospital stay. The following ICD-9-CM procedure and CPT codes are used to identify events: angioplasty, procedure codes 36.01, 36.02, and 36.05, and bypass, procedure code 36.06 and CPT codes 92980–92981; and bypass, procedure codes 36.10 and CPT codes 33510–33532, 33533–33536.

Figure 6.9 displays adjusted vascular access insertion rates for period prevalent adult hemodialysis patients. These are not hospital admission rates, but procedure rates for vascular access insertions 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, 36488–36491, 36533, 36555–36558, 36565, 36800, and 76937; fistulas, 36819–36821 and 36825; and grafts, 36830. The category for all vascular access insertions includes all of the above CPT codes. Methods are also used to exclude vascular access used for purposes other than dialysis. Rates for catheter and all vascular access insertions exclude patients with specific chemotherapy or parental 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...
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.

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

Figure 6.1 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. 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; rates for the ESRD population as a whole are adjusted for modality as well. Because the reference population consists of 2001 period prevalent ESRD patients, adjusted rates across modalities can be compared.

Figure 6.12 shows all-cause mortality by age for 2004 prevalent ESRD, dialysis, transplant, and general Medicare patients. General Medicare patients are non-ESRD patients with at least one month of Medicare eligibility in 2004; they are followed from the first day of the first month with Medicare eligibility until death or December 31, 2004. ESRD patients are followed from January 1 until December 31, 2004. All-cause mortality rates by age are calculated using generalized mixed models, and are adjusted for gender and race. Medicare patients from 2004 are used as the reference cohort.

Figure 6.13 presents unadjusted all-cause mortality, by HSA, for 2004 prevalent ESRD, dialysis, transplant, and general Medicare patients. The populations are those used in Figure 6.12, except that general Medicare patients are age 65 and older.

Table 6.d shows expected remaining lifetimes for dialysis patients, renal transplant patients, and the general U.S. population. For period prevalent ESRD patients in 2004, expected lifetimes are calculated using the death rates from the mixed model with 16 age groups, assuming constant survival and mortality within each age group. Patient inclusion and exclusion criteria are those used in Tables H.4.4 and H.28.4, and the method for calculating expected remaining lifetimes is described in the section on statistical methods at the end of this appendix. Data for the general population are obtained from the CDC’s National Vital Statistics Reports.

Figure 6.14 illustrates trends in mortality rates by patient vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, 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. Consistent with the 2003 and 2004 ADRs, the reference population consists of 2001 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figures 6.15 and 6.17 show all-cause mortality and survival rates for general Medicare and ESRD patients with cardiovascular disease, malignancy, and septicemia. Figure 6.15 presents annual mortality rates for the 2004 general Medicare and ESRD populations, while Figure 6.17 shows one- and five-year survival rates for 1992–2000 general Medicare, dialysis, and transplant patients. Using Medicare claims in a calendar year, diseases are identified through the appearance of ICD-9–CM codes at least once in Part A inpatient claims or at least twice in outpatient or Part B claims. The ICD-9–CM codes are 390.xx–398.xx, 402.xx, 404.xx, and 410.xx–429.xx for heart disease; 140.xx–208.xx for malignancy, and 038 for septicemia. Mortality rates in Figure 6.15 are calculated using generalized mixed models, and are adjusted for gender and race. Survival rates in Figure 6.17 are calculated using Cox regressions, and are adjusted for age, gender, and race. In both figures, 2004 general Medicare patients are used as the reference cohort.
Figure 6.16 presents five-year survival by modality for 1990–1994 and 1995–1999 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 2004, while transplant patients are followed from the first transplant date until death or the end of 2004. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. As in the 2003–2005 ADRs, the reference population consists of 1996 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Figures 6.18 present adjusted all-cause and cause-specific mortality in incident dialysis patients, by age. Using the 90-day rule, incident patients from 1997–2002 combined are followed from day 91 until death or December 31, 2004, 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 the adjusted rates consists of 1996 incident ESRD patients.


stroke

For Figures 6.24–32, “prevalent CVA/TIA” indicates the first CVA/TIA event occurring in the followup period, while “incident CVA/TIA” indicates the patient’s first CVA/TIA event ever. Unless otherwise specified, hemodialysis patients are not required to survive at least 90 days after ESRD initiation.

Figure 6.24 displays incident CVA/TIA rates for incident hemodialysis patients, incident CKD patients, and non-CKD patients in 2001. Patients with first claims in 2001 are defined as incident CKD. The followup period begins at the first ESRD service date for hemodialysis patients, at the CKD diagnosis date for CKD patients, and at January 1, 2002, for non-CKD patients. Patients age 67 or older at initiation are enrolled and required to have Medicare Parts A and B coverage. A two-year entry period before initiation is used to identify those with previous CVA/TIA. Patients with unknown age, gender, or race are excluded. Incident CVA/TIA is identified during the one-year followup period after initiation. Followup of hemodialysis patients is censored at the earliest of death, loss to followup, transplantation, modality change (hemodialysis to peritoneal dialysis, the reverse, or graft failure), end of Medicare Parts A and B coverage, or December 31, 2004. Followup of CKD patients is censored at the earliest of death, loss to follow-up, ESRD date, end of Medicare Parts A and B coverage, or December 31, 2004. And followup of non-CKD patients is censored at the earliest of death, loss to followup, first diagnosis of CKD, ESRD date, end of Medicare Parts A and B coverage, or December 31, 2004.

CVA/TIA events are defined using the methodology described for Chapter One (one Part A inpatient or two Part B outpatient claims). The following ICD-9-CM codes are used to identify patients: CVA, 430–432, 434, and 436; TIA, 435.

Figures 6.25–28 describe hospitalization and survival rates for the 2001 incident cohort during the two-year followup period. Patients with incident CVA/TIA are followed from the first CVA/TIA diagnosis date; patients with no CVA/TIA claims are followed from one year after initiation. Hospitalization is identified in the two-year followup period; patients are censored as described above. Hospitalization and survival rates are computed from a Cox regression model, adjusted for age, gender, and race. The reference group is hemodialysis patients incident in 2001, age 67 or older.

Figures 6.29–32 display rates of prevalent and incident CVA/TIA occurring in 2004 among point prevalent hemodialysis patients, CKD patients, and non-CKD patients with Medicare Parts A and B coverage. Prevalent CKD patients are defined using 2003 claims. Patients are followed from January 1, 2004, and censored as described above. A two-year entry period from January 1, 2002, to December 31, 2003, is used to exclude patients with previous CVA/TIA.

peripheral neuropathy

For Figures 6.33–42, “prevalent peripheral neuropathy” indicates the first peripheral neuropathy event occurring in the followup period, while “incident peripheral neuropathy” indicates the patient’s first peripheral neuropathy event ever. Unless otherwise specified, hemodialysis patients are not required to survive at least 90 days after ESRD initiation. Peripheral neuropathy events are defined using the methodology described for Chapter One (one Part A inpatient or two Part B outpatient claims). The following ICD-9-CM codes are used to identify patients: 536.9, 536.4, 250.6, 337.1, and 337.2.

Figures 6.33–38 describe hospitalization and survival rates of the 2001 incident cohort during the two-year followup period. Incident peripheral neuropathy patients are followed from the first diagnosis date; patients with no peripheral neuropathy claims are followed from one year after initiation. Hospitalization is identified in the two-year followup period; patients are censored as described above. Hospitalization and survival rates are computed from a Cox regression model, adjusted for age, gender, and race. The reference group is hemodialysis patients incident in 2001, age 67 or older.

Figure 6.39 displays incident peripheral neuropathy rates for incident hemodialysis patients, incident CKD patients, and non-CKD patients in 2001. Patients with first claims in 2001 are defined as incident CKD. The followup period (initiation) begins at the first ESRD service date for hemodialysis patients, at the CKD diagnosis date for CKD patients, and at January 1, 2002, for non-CKD patients. Patients age 67 years or older at initiation are enrolled and required to have Medicare Parts A and B coverage. A two-year entry period before initiation is used to identify patients with previous peripheral neuropathy or diabetes. Patients with unknown age, gender, or race are excluded. Incident peripheral neuropathy is identified during the one-year followup period after initiation. Followup of hemodialysis patients is censored at the earliest of death, loss to followup, transplantation, modality change (hemodialysis to peritoneal dialysis, the reverse, or graft failure), end of Medicare Parts A and B coverage, or December 31, 2004. Followup of CKD patients is censored at the earliest of death, loss to follow-up, ESRD date, end of Medicare Parts A and B coverage, or December 31, 2004. And followup of non-CKD patients is censored at the earliest of death, loss to followup, first diagnosis of CKD, ESRD date, end of Medicare Parts A and B coverage, or December 31, 2004.

Figure 6.40 displays rates of prevalent peripheral neuropathy occurring in 2002 among point prevalent hemodialysis patients, CKD patients, and non-CKD patients with Medicare Parts A and B coverage. Prevalent CKD patients are defined using 2001 claims. Patients are followed from January 1, 2002, and censored as described above. A two-year entry period from January 1, 2000, to December 31, 2002, is used to identify patients with diabetes.

Figures 6.41–42 present hospitalization and survival rates of the 2002 prevalent cohort during a two-year followup period. Prevalent peripheral neuropathy patients are followed from the
first diagnosis date in the prevalent year; patients with no peripheral neuropathy claims are followed for one year after January 1, 2002. Hospitalization is identified in the followup period; patients are censored as described above. Rates are computed from a Cox regression model, adjusted for age, gender, and race. The reference group is hemodialysis patients incident in 2001, age 67 or older.

**dementia**

Figures 6.43–48 and Table 6.e use Medicare claims to illustrate the state of dementia among point prevalent patients at least 67 years old in 1999 and 2004. Each cohort is split into three subgroups: hemodialysis, chronic kidney disease, and non-CKD. For the 1999 cohort, hemodialysis patients become incident ESRD patients no later than December 31, 1998, receive hemodialysis therapy on December 31, 1998, and carry Medicare as primary payor (MPP) from January 1, 1997, to December 31, 1998. CKD and non-CKD patients re alive on December 31, 1998, and carry MPP from January 1, 1997 to December 31, 1998. CKD is identified by the submission of at least one inpatient or two outpatient claims with an applicable diagnosis code between January 1, 1997, and December 31, 1998. The 2004 cohort is constructed analogously. For all measures, age is calculated at the beginning of the cohort year.

Figures 6.43–44 illustrate prevalent rates. Dementia is defined by the submission of at least one inpatient or two outpatient claims with a diagnosis code of 290.x or 331.0 during the two calendar years preceding the cohort year. In 6.43, Alzheimer’s is defined by diagnosis code 331.0, vascular dementia is defined by 290.4, and other dementia is defined by all relevant codes, excluding 331.0 and 290.4.

Figures 6.45–46 illustrate first hospitalization and mortality life table estimates during the cohort year. For hospitalization analyses, patients are followed from the beginning of the cohort year until the earliest of hospitalization, ESRD initiation (for CKD and non-CKD patients), death, or the end of the cohort year. For mortality analyses, patients are followed until the earliest of death, ESRD initiation (for CKD and non-CKD patients), or the end of the cohort year.

Figures 6.47–48 illustrate incident rates. Incident dementia is defined by the submission of at least one inpatient or two outpatient claims with a diagnosis code of 290.x or 331.0 during the cohort year (but prior to ESRD initiation, in the case of CKD and non-CKD patients), along with the absence of relevant codes during the two years preceding the cohort year. Only patients without prevalent dementia are included in the calculation of incident rates.

Table 6.e displays hazard ratios of incident dementia. A proportional hazards model is used to correlate the time to incident dementia—measured from the beginning of the cohort year until the earliest of the submission of the first inpatient claim or second outpatient claim with a diagnosis code of 290.x or 331.0—with age, gender, race, recent anemia, prevalent diabetes, recent hypertension, and history of stroke. Anemia and hypertension are assessed during the three months preceding the cohort year, while diabetes and stroke are assessed during the two years preceding that year. For hemodialysis patients, anemia is defined by the submission of any outpatient claim for EPO, with hematocrit less than 33 percent.

**reference section**

Hospitalization reference tables present adjusted total admission and hospital day rates by year from 1993 to 2004. 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.1.4–G.10.4 and G.1.5–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 transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

Time at risk is calculated differently for hospital days and total admissions. Since a hospitalized patient remains at risk for additional hospital days, rates for hospital days include hospital days in the time at risk. Since a currently hospitalized patient is not,
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 1980–2004 are presented in G.1.4–3.4 and G.6.4–8.4. Due to the instability of rates in earlier years, these rates are presented from 1985 in G.4.4 and G.8.4 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 data. Other methods (rate calculation, model-based adjustment, etc.) generally follow those discussed for Tables G.1–10. In supplemental tables G.1.4–10.4, however, we do not exclude dialysis patients failing to reach a certain level of Medicare paid dialysis bills, since this economic information is unavailable for the earlier years. Additionally, supplementary tables G.1.5–10.5 present counts of total admissions or days, patient years at risk, and total patients, which correspond with the rates presented in G.1.4–10.4.

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

Cohorts in Tables H.1–31 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year, while prevalent cohorts include patients 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 contributed only if day 91 of ESRD is January 1 and the patient
survives to the end of the year. Patients considered lost-to-followup at the beginning of the year are excluded. 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, 2003, are included in the analysis. For incident ESRD and transplant cohorts, these patients are followed from day 1 until death or December 31, 2004; for incident dialysis, hemodialysis, and CAPD/CCPD cohorts, patients are followed from day 1 until death, transplant, or December 31, 2004.

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 2004 prevalent ESRD patients. Mortality rates in Table H.2.4 are smoothed and unadjusted using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1–4.4 (dialysis); Tables H.11, H.12, and H.12.1–12.4 (hemodialysis); Tables H.19, H.20, and H.20.1–20.4 (CAPD/CCPD); and Tables H.27, H.28, and H.28.1–4 (transplant). Tables H.5–10 (dialysis), H.13–18 (hemodialysis), and H.21–26 (CAPD/CCPD) include total patient deaths and annual unadjusted and adjusted mortality rates for patients who have never been on the transplant waitlist, for those who have been listed, and for those who have returned to the modality after a transplant.

In Table H.29, unadjusted mortality rates are reported by primary cause of death for patients prevalent at the beginning of, or incident during, 2002–2004. 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. Two new categories of primary cause of death due to congestive heart failure and withdrawal from dialysis have been added, based on the new ESRD Death Notification form introduced in October, 2004.

Patient populations for Tables H.32–46 are the same as those used in Reference Section I. The population groups include all-ESRD, all dialysis, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, and third-year mortality rates for incident cohorts—including all-ESRD, all-dialysis, hemodialysis, CAPD/CCPD, and first transplant patients—are computed from the Cox model using the model-based adjustment method, described later in this appendix. These rates are presented using aggregate categories for age, gender, race, and primary diagnosis, and a rate presented for one of these variables is adjusted for the remaining three. Overall mortality rates for all patients are adjusted for each of the four variables. Mortality rates for Hispanic and non-Hispanic patients, however, are unadjusted (crude) rates calculated as the number of deaths over patient-years at risk. As in the 2003–2005 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, 2003, are included in the analysis. These patients are followed until December 31, 2004, a maximum followup time of 24 years and a minimum of one year.

Results are reported for the following groups:
- all-ESRD: all ESRD patients beginning renal replacement therapy in a calendar year and surviving beyond day 90; patients are censored only at the end of 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 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 use aggregate categories for age, gender, race, and pri-
Appendix A presents donation rates per million population, while Figure 7.16 are based on the location where the donation is made. Figure 7.15 both kidneys are eventually transplanted. Maps of donation rates 1995–2004. Rates are calculated as the number of each type of trans by state, in 2004. These rates are estimated from a Poisson regres censored patients at death or December 31, 2004. Figure 7.9 pres wait list, or still waiting. Patients listed at multiple centers counted more than once. Figure 7.6 contrasts median wait times by age, race, blood type, and PRA. Wait time is calculated as the transplant date minus the date the patient is added to the kidney or kidney-pancreas wait list, not necessarily the date he or she is first listed at the center where the transplant is performed. Year indicates the year the transplant is received, not the year the patient is listed. The discussion of Figures 7.44–45, below, explains wait times by year of listing. Figure 7.8 presents the percentage of incident ESRD patients in a given year who are wait-listed or transplanted within one year of their ESRD certification date. Unlike data presented in the Healthy People 2010 chapter (Objective 4.5), this figure includes patients who receive a living donor transplant, and patients age 70 and older. Percentages are estimated using the Kaplan-Meier methodology, censoring patients at death or December 31, 2004. Figure 7.9 presents similar data by state for patients incident in 2003. State-level rates are computed using a Cox proportional hazard model, and are adjusted for age, gender, race, and primary cause of renal failure. Figure 7.10 illustrates outcomes for patients first listed during 1999. Patients are classified at five years post-listing as having received a transplant, having died awaiting their transplant, having been removed from the list prior to transplantation, or still waiting.

transplant & donation rates

Figure 7.11 presents transplant rates per 100 dialysis patient years, by state, in 2004. These rates are estimated from a Poisson regression, adjusting for age, gender, race, and primary cause of renal failure, then standardized to the age, gender, race, and primary cause of renal disease makeup of the national population of dialysis patients incident in 2004. The state is the recipient’s last known state of residence, not necessarily the state where the transplant was performed. Transplant rates in Figure 7.12, by age, gender, race, and primary diagnosis, show trends from 1995 through 2004. Rates presented by one variable are adjusted for the remaining three; all rates are standardized to the 2004 dialysis population.

Figure 7.13 presents trends in transplant rates by donor type, 1995–2004. Rates are calculated as the number of each type of transplant divided by the total dialysis patient time during the year. Organ donation rates are presented in Figures 7.14–16. In Figure 7.14, a deceased donor is counted only once, regardless of whether both kidneys are eventually transplanted. Maps of donation rates are based on the location where the donation is made. Figure 7.15 presents donation rates per million population, while Figure 7.16 presents rates per hundred deaths in the state. Population and death count estimates are obtained from the U.S. Census Bureau.

graft survival

Figures 7.17–18 present graft survival curves, first- and five-year survival, and conditional and non-conditional half-lives for recipients of kidneys from deceased and living donors. Unadjusted cumulative incidence curves are estimated using the Kaplan-Meier method. Other estimates are made from Cox proportional hazards models, adjusted for transplant year, age, gender, race, and primary diagnosis, and based on the population’s average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and estimated from the cumulative hazard between years one and two. 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. Half-lives (unconditional) are not conditional on first-year survival and are estimated using a piecewise exponential function. The estimated hazard of graft failure within year one along with an estimated hazard during year two are used in the calculation of half-life. Conditional half-lives are interpreted as the estimated median survival of grafts surviving the first year, while half-lives are interpreted as the estimated median survival of all grafts. Figure 7.19 presents statistics on graft failures that necessitate long-term dialysis or retransplantation; graft failures due to death are excluded from these counts. Subsequent treatment is determined from a combination of Medicare claims and OPTN data. The percentage of patients retransplanted within one year of graft failure is presented in Figure 7.20. Preemptive retransplantations are included. Age is determined on the day of graft failure, and percent- ages are calculated using the Kaplan–Meier methodology.

Figure 7.21–22 describe the length of time a transplant survives prior to failure. The median time of kidney function is displayed along with first and third quartiles of the distribution. The year is the year of graft failure, and failures due to death are excluded. Figure 7.23 contrasts the rate of return to dialysis/preemptive retransplantation with the rate of death with a functioning graft, while Figure 7.24 shows the rate of return to dialysis/preemptive retransplantation by age, gender, and race. Rates are estimated from a Poisson regression model, adjusting for age, gender, and race, as in Figure 7.11. A patient is considered to have been preemptively retransplanted if the subsequent transplant date is within one day of the previous graft failure date.

immunosuppression

Figures 7.25–31 present data on immunosuppressive medications used at the time of transplantation, 1995–2004, as reported on the OPTN Immunosuppression Treatment form. All such medications (apart from induction antibodies) are indicated as maintenance immunosuppression on the form. Figure 7.26 shows the percent of transplant centers using a particular calcineurin inhibitor regimen. For this figure, all patients transplanted at a center during 2003–2004 are included, and centers are classified as using exclusively cyclosporine A/cyclosporine microemulsion, exclusively tacrolimus, both, or neither. Figure 7.28 contrasts the percent of patients using rapamycin with the percent of transplant centers prescribing rapamycin to any of their patients transplanted during 2003–2004.

post-transplant complications

Figures 7.32–33 look at patients with evidence of delayed graft function (defined by a need for dialysis in the first week after transplantation), as reported to the OPTN. In Figure 7.33, odds ratios for selected factors associated with delayed graft function are estimated from
two logistic regression models. The living donor model is adjusted for year of transplant, first versus subsequent transplant, age, gender, race, ethnicity, diabetes versus other primary diagnosis, hepatitis C status, education, employment status, Medicare as primary payor, prior dialysis time, donor age, donor gender and race, number of HLA mismatches, body surface area matching, matching CMV status, body mass index, PRA, and drug regimen. The deceased donor model is adjusted for all of the above, as well as cold ischemia time and the following donor characteristics: traumatic death, high creatinine, death by CVA, and history of hypertension.

Figures 7.34–36 present statistics on post-transplant complications. Figure 7.34 details the cumulative incidence of acute rejections at one-year post-transplant as reported to the OPTN through the Kidney Transplant Recipient Follow-up form. Percents are estimated using the Kaplan–Meier methodology. For Figures 7.35–36, Medicare claims data are searched for ICD-9-CM code 996.81, defined as “complications of transplanted organ: kidney.” Only patients transplanted between 1999 and 2003 and with Medicare Parts A and B primary coverage are included, and complications during the first seven post-transplant days are censored. The Kaplan–Meier methodology is used to present cumulative incidence curves, and a Cox proportional hazards analysis is used to determine the relative risk of having a Medicare claim indicating a complication. The Cox model is adjusted for transplant year, age, gender, race, ethnicity, donor status (deceased versus living), primary diagnosis, prior dialysis time, number of HLA mismatches, body mass index, PRA, drug regimen, induction antibodies, donor age, donor race, donor gender, and donor hepatitis C status.

Figures 7.37–38 detail the occurrence of and factors associated with kidney biopsies post-transplant. Only patients transplanted between 1999 and 2003 and with Medicare Part A and Part B primary insurance coverage are included in this analysis, and biopsies during the first seven post-transplant days are censored. Biopsies are identified in Medicare claims data, using CPT codes 50200, 50205, 10022, 50555, and 50574. The Kaplan–Meier methodology is used to present cumulative incidence curves, and a Cox proportional hazards analysis is used to determine the relative risk of having a Medicare claim indicating a biopsy. The Cox model is adjusted for transplant year, age, gender, race, ethnicity, donor status, primary cause of renal failure, prior dialysis time, number of HLA mismatches, body mass index, PRA, drug regimen, donor age, donor gender, donor race, and donor hepatitis B and C status.

expanded criteria donor kidneys

Figures 7.39–43 and Table 7.a present statistics on the expanded criteria donor (ECD) program, started by OPTN in 2003 to allow patients to indicate their willingness to accept a kidney from a “marginal” donor. Figure 7.39 shows the percent of patients—new and prevalent listings—willing to accept an ECD kidney; prevalent listings include all patients on the list during the year regardless of when they initially list. Figure 7.40 breaks down these percentages by age, gender, and race. Figure 7.41 shows the percent of transplants using a kidney from what would qualify as an ECD through factors listed on the OPTN Deceased Donor Registration form, and includes only first-time, kidney-only recipients of a deceased donor kidney. Geographic variations in the percent of patients willing to accept an ECD kidney, by state and by OPTN region, are illustrated in Figures 7.42–43.

Table 7.a details characteristics of patients who are and are not listed as willing to accept an ECD kidney. Only new listings are included. Odds are calculated as the number of patients listed for an ECD kidney divided by the number not listed: odds less than one indicate that more patients in the category are not listed for an ECD kidney than are listed, and vice versa for odds greater than one. Adjusted odds ratios are also presented as estimated from a logistic regression model. Adjustment is made for age, gender, race, ethnicity, OPTN region, diabetes versus other primary cause of renal failure, PRA, and blood type.

projected wait times

Figures 7.44–45 present median wait times for patients listed in the given year, along with projected median wait times. Median wait times are estimated for each year using the Kaplan–Meier methodology. Years for which the median is observed are plotted, while for cases in which a subgroup has fewer than 15 patients the median is not plotted and is left as unknown. For more recent years in which the median has not yet been observed—in other words, more than 50 percent of the patients listed in that year have yet to be transplanted—the median time is estimated using a linear regression model. The regression analysis considers all years for which the median is observed, excluding cells with fewer than 15 patients, as described above. A regression line is estimated using the year of transplantation as an independent variable. To improve the fit of this line, a quadratic term for the year of transplantation is included in the model. Predicted medians are then estimated from the resulting regression line.

Projections are plotted in Figures 7.44–45 along with 95 percent confidence bands surrounding the predicted medians. These bands are calculated as simultaneous confidence curves appropriate for the entire regression function over its entire range (Draper and Smith, p. 83). Median wait times and projected wait times are presented for pediatric and adult patients separately, with further break-downs by race, blood type, PRA, and OPTN region. Due to the small sample of pediatric patients in Region 6, no projections are made for this group.

reference section E

Tables E.1–4 present various measures regarding the wait list for renal transplantation. Tables E.1–2 present counts of patients waiting 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 as having ESRD, and Table E.3 the percent of prevalent dialysis patients on the kidney wait list. In Table E.3, point prevalent dialysis patients on December 31 of the given year are included. 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 2000 and 2002.

Table E.11 shows patients transplanted, by PRA level. Levels are determined from the OPTN Recipient Histocompatibility form.
Appendix A Analytical Methods

Table E.12 presents a cross-tabulation of recipients and donors in terms of cytomegalovirus antibody status at the time of transplantation. A recipient/donor is considered positive if any applicable OPTN data source indicates positive, and “unknown” status is applied only in the event that no applicable test is performed. Table E.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 form.

Reference Section F
This section presents probabilities of graft survival and graft failure necessitating dialysis or retransplantation, by donor type, for various groups and followup times. In previous ADRs, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to some confusion regarding terminology, we have decided to rename this outcome. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the followup period (December 31, 2003).

In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or retransplantation, patients are followed until graft failure (excluding death), and patient followup is censored at death. To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier methodology, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, primary diagnosis, and first versus subsequent transplant, and standardized to 1996 patient characteristics.

Tables F.25–26 present the relative risk of graft failure, return to dialysis (including preemptive retransplantation), and death with a functioning graft for first-time recipients of deceased donor and living donor kidneys, respectively. Relative risks are estimated from Cox proportional hazards models, one for each donor type cohort and outcome. Patients transplanted between 1999 and 2004 are included. Followup is censored at December 31, 2004, for a maximum followup of six years. For the graft failure outcome, death is considered a graft failure; for return to dialysis, patients are censored at death with a functioning graft; and for death with function, followup is censored at return to dialysis.

Vascular Access & Modality
Figure 8.13 includes incident hemodialysis patients from the 2000–2004 CPM data. Year represents the incident year, and access the access reported as being used at the time of data collection during that year. Figures 8.14–15 include incident hemodialysis patients in both the USRDS and CPM datasets. Patients are age 0–19 at dialysis initiation, and have Medicare as primary payor on January 1 of the following year. CPM data are used to determine the access used at the time of data collection in the incident year. Patients are followed from January 1 of the year following incidence, and Medicare claims are used to identify access infections and sepsis. Included events occur between January 1 and the censoring date, which is the earliest of death, modality change, change in payor status, insertion of a different vascular access, or December 31 for Figure 8.13. Time at risk is calculated as the number of days between January 1 and the censoring date. Figure 8.15 also includes incident peritoneal dialysis patients from the USRDS database who are age 0–19 and have Medicare as primary payor on day 91 after incidence. Medicare claims during the one-year period after day 91 are used to identify the first occurrence of either sepsis or an infection of the peritoneal dialysis catheter, censored by death, modality change, change in payor status, or insertion of a hemodialysis access. For Figure 8.15, the event-free probability represents the survival probability from an unadjusted Kaplan-Meier curve, using patients from 1998–2003 combined. Figure 8.17 includes all patients transplanted between January 1, 1995, and December 31, 2004, and age 0–19 at dialysis initiation. Some patients may have been age 20 or older at the time of transplant. Time is the number of months from dialysis initiation to transplant. Percents are estimated using the Kaplan-Meier methodology, stratified by race and transplant era, 1995–1999 or 2000–2004.

Clinical Indicators
Figures 8.18–19 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.

Figures 8.20–21 include prevalent hemodialysis and peritoneal dialysis patients who are alive and remain on the modality for the entire prevalent year. Patients are identified as receiving vitamin D or iron if they have at least one claim for it during the year.

For Figures 8.22–24, 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.

Infectious Complications
Data on infectious complications (Figures 8.25–32) include incident dialysis patients with Medicare as primary payor at ESRD initiation. Infectious hospitalizations represent inpatient stays with a principal diagnosis of infection. Figure 8.29 includes peritoneal dialysis patients only, and for Figures 8.25–27 and 8.30–32, transplant patients

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

Figures 8.9–12 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine rates of influenza and pneumococcal pneumonia vaccinations and lipid testing are similar to those described for Chapter One. Hepatitis B vaccinations are identified through CPT codes 90636, 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 8.9), the cohort includes patients starting ESRD therapy at least 90 days prior to September 1 and alive on December 31 of each year; rates are calculated for patients vaccinated in the last four months of each year. For pneumococcal pneumonia vaccinations (Figure 8.10), the cohort includes prevalent patients initiating therapy at least 90 days prior to January 1 of the first year of each two-year period and alive on December 31 of the second year; rates are calculated for patients receiving one vaccination in each period. And for hepatitis B vaccinations and lipid testing (Figures 8.11–12), 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 test each year. Years 2001–2004 are grouped in Figures 8.9 and 8.11–12, and 2001–2002 and 2003–2004 are grouped in Figure 8.10.
are first-time, kidney-only transplant recipients with Medicare as primary payor as of the transplant date. Figures 8.30–32 include the same patient population as Figures 8.25–29, with incident years 1991–2001 combined. Bacterial infections are identified by codes 001.x–004.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–104.x, 137.x, and 008.0–008.5; viral infections by 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, 008.6, 008.8, 078.2–078.7, 070.0–070.3, 070.6, 070.9, 070.41–070.44, 070.51–070.54, 079.51–079.53, and 079.81; parasitic infections by 066.x, 007.x, 084.x–086.x, 120.x–130.x, and 136.2–136.5; and fungal infections by 114.x–117.x, 112.x, 112.4, 112.5, 112.81, 112.83–112.85, 112.89, and 112.9.

**hospitalization & mortality**

Methods used for the hospitalization data in Figures 8.33–35 and 8.38–8.40 generally follow those described for Chapter Six, with adjusted rates computed using the model-based adjustment method. Included period prevalent dialysis patients have Medicare as primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, and those with missing age or gender information, are excluded. The reference cohort includes period prevalent ESRD patients, age 0–19, in 2001. For Figures 8.38–40, principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.6. In Figure 8.40, “other” race includes those with a race that is missing, unknown, or other than black or white.

Figure 8.36 presents five-year survival by modality for 1990–1994 and 1995–1999 incident patients age 0–19. Patients with unknown age, gender, or primary diagnosis are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplant, or the end of 2004; transplant patients are followed from the first transplant date until death or the end of 2004. 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 8.37 presents adjusted mortality rates for prevalent ESRD, dialysis, and transplant patients younger than 20, for cohorts from 1991–2004. Rates are computed from the generalized mixed model and adjusted for age, gender, and race. The reference population for adjusted rates consists of 2001 ESRD patients younger than 20.

Figure 8.41 presents adjusted all-cause and cause-specific mortality by age for prevalent dialysis patients, 1991–2004. These rates are also computed from the generalized mixed model. Rates for all patients age 0–19 and 20 and older are adjusted for age, gender, and race; rates for patients age 0–9 and 10–19 are adjusted for gender and race. The reference population for the pediatric cohort consists of 2001 ESRD patients age 0–19, and for the adult cohort includes 2001 ESRD patients age 20 or above. Figure 8.42 presents adjusted all-cause and cause-specific mortality by gender for prevalent dialysis patients from 1991 to 2004; these are computed from the generalized mixed model, and adjusted for age and race. The reference population consists of 2001 ESRD patients younger than 20.

**cardiovascular special studies**

**CHAPTER NINE**

**patient cohorts**

Figures 9.1–39 describe demographic characteristics, diabetic status, and probabilities of AMI, CHD, and cardiac arrest for incident and prevalent elderly Medicare patients with CKD and for ESRD patients. Figures 9.40–55 show adjusted cardiovascular event rates and event-free probabilities in incident and prevalent hemodialysis and peritoneal dialysis patients.

**Incident cohort:** The study cohort of elderly Medicare patients with incident CKD includes Medicare enrollees with no Medicare CKD claims for at least one year before the first CKD claim in 2000–2002, enrolled in Medicare Parts A and B for at least one year before the first CKD claim, and age 66 and older at the date of CKD diagnosis. The dialysis cohort includes incident ESRD patients receiving hemodialysis, peritoneal dialysis, or an undefined dialysis modality at day 90 of ESRD onset, 2000–2002, and enrolled in Medicare Parts A and B at day 90 of ESRD onset. The incident transplant cohort includes first renal transplant recipients in 2000–2002, regardless of the year of first ESRD service, with Medicare as primary payor.

**Prevalent cohort:** The study cohort of prevalent CKD patients includes Medicare enrollees age 66 and older who are enrolled in Medicare Parts A and B for at least one year. The cohort of prevalent dialysis patient includes January 1, 2002, point prevalent Medicare dialysis patients with Medicare as primary payor and who are receiving hemodialysis, peritoneal dialysis, or an undefined type of dialysis at day 90 after ESRD initiation, while the cohort of prevalent transplant patients includes January 1, 2002, point prevalent transplant patients with Medicare as the primary payor. We exclude those patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories. For the Medicare CKD study cohort, we also exclude those diagnosed with ESRD or enrolled in an HMO any time before the first claim for CKD (for incident CKD) or January 1, 2001 (for prevalent CKD).

Different sources of information are used to identify comorbidity for the different study cohorts. For incident CKD patients, we use Medicare claims in the one year before CKD diagnosis, while for incident dialysis and transplant patients we use the Medical Evidence form and its listed primary cause of ESRD; transplant patient comorbidity is also determined from the Medicare claims during the year before the first transplant date. For prevalent CKD patients, we use Medicare claims in 2001, while for prevalent dialysis and transplant patients we use Medicare claims along with the Medical Evidence form and its listed primary cause of ESRD.

According to a previously validated methodology 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. With this methodology, we identify patients with comorbid conditions, using the following ICD-9-CM diagnosis codes: AMI, 410 and 412; CHF, 398.91, 422, 425, 428, 402.x1, 404.x1, 404.x3, and V42.1; PVD, 440–444, 447, 451–453, and 557; and diabetes, 250, 357.2, 362.0x, and 366.41. PVD is also defined from Medicare claims for amputation. Amputation and coronary revascularization are identified through ICD-9-CM procedure codes in Part A claims and/or Current Procedural Terminology (CPT) codes in Part B claims:

- **amputation:** 84.0x, excluding 84.01–84.02, and 84.1x, excluding 84.11 (ICD-9-CM procedure codes); 23900, 23920, 24900, 24920, 25900, 25905, 25920, 25927, 27925, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, and 28805 (CPT codes)
- **coronary revascularization:** 36.01, 36.02, 36.05, 36.06, and 36.1x (ICD-9-CM procedure codes); 92980–92982, 92984, 92995, and 92996 (CPT codes)

Cardiovascular events of AMI, CHF, CVA/TIA, cardiac arrest, and PVD are identified from both non-fatal and fatal events. The event date for a non-fatal event is defined as the date of the first
appearance of an ICD-9-CM diagnosis code in one or more Part A inpatient claims only (for AMI and cardiac arrest), or in one or more Part A inpatient, skilled nursing facility, or home health agency claims or two or more Part A outpatient and/or Part B claims (for CHF, CVA/TIA, and PVD). PVD is also identified through ICD-9-CM procedure codes for amputation in Part A claims and CPT codes for amputation in Part B claims. For fatal events, the date of death due to the event is obtained from the Death Notification form. The codes of cause-specific death are: AMI, 23; CHF, 27, 31, and 32; cardiac arrest, 28 and 29; CVA/TIA, 36; and PVD, 51. For coronary revascularization, the date is defined through ICD-9-CM procedure codes in Part A claims and/or CPT codes in Part B claims.

For events of CHF, PVD and coronary revascularization, we use the same diagnosis codes and/or procedure codes used in determining comorbid conditions, while for AMI, cardiac arrest, and CVA/TIA, we use the following: AMI, 410, 410.Xo, and 410.Xi; cardiac arrest, 427.4 and 427.5; and CVA/TIA, 430.x–437.x.

AMI, CHF, & cardiac arrest

Figures 9.2–3 contrast the distribution of demographic characteristics and diabetic status of all patients and those with AMI, CHF, and cardiac arrest in a three-year followup, looking at incident and prevalent cohorts of elderly Medicare CKD patients, hemodialysis patients, peritoneal dialysis patients, and transplant patients.

Figures 9.1 and 9.4–39 illustrate overall probabilities of having an AMI, CHF, or cardiac arrest, as well as probabilities by age, gender, race, and comorbidity. For each endpoint in Figure 9.1, we use the Kaplan-Meier method to estimate the event probability for incident and prevalent cohorts of CKD, dialysis, and transplant patients. Incident CKD patients are followed from the date of CKD diagnosis to the earliest of event, death, ESRD diagnosis, change of Medicare Parts A and B enrollment, or September 30, 2004. Incident dialysis patients are followed from day 90 of dialysis initiation to the earliest of death, transplant, loss-to-followup, end of Medicare as primary payor status, three years after day 90, or December 31, 2004. And patients in the first transplant cohort are followed from the first transplant date to the earliest of death, transplant failure, end of Medicare as primary payor status, three years after transplant, or December 31, 2004.

For the prevalent CKD cohort, patients are followed from January 1, 2002 to the earliest of event, death, ESRD diagnosis, change of Medicare Parts A and B enrollment, or December 31, 2004. Patients in the prevalent dialysis cohort are followed from January 1, 2002 to the earliest of death, transplant, loss-to-followup, end of Medicare as primary payor status, or December 31, 2004.

For each endpoint in Figures 9.4–39 we use the Kaplan-Meier method to estimate the overall event probability, and a separate Cox proportional hazards model—stratified on the subgroups—to estimate event-free probabilities for each subgroup. The covariates included in the Cox model depend on the choice of subgroup: gender, race, and diabetic status are included in the model for comparing event probabilities by age; age, race, and diabetic status for comparing by gender; age, gender, and diabetic status for comparing by race; age, gender, and race for comparing by diabetic status; and age, gender, race, and diabetic status for comparing by comorbidity. Using the model-based adjustment method (described below in the section on statistical methods), and with the CKD and ESRD (hemodialysis, peritoneal dialysis, and transplant) populations as reference cohorts, respectively, these event-free probabilities are further adjusted for the same covariates included in the Cox model. The adjusted event probabilities are obtained by subtracting the adjusted event-free probabilities from one. Patient followup time is the same as that described for Figure 9.1. Dialysis patients are also censored at the date of modality change.

cardiovascular event rates in HD & PD patients

Figures 9.40–55 present adjusted cardiovascular event rates and event-free probabilities in incident and prevalent hemodialysis and peritoneal dialysis patients. For each endpoint, we use a separate Cox proportional hazards model, stratified on dialysis modality, to estimate event-free probabilities and calculate the predicted cardiovascular event rates, with age, gender, race, and diabetic status as covariates. Using the model-based adjustment method (described in the section on statistical methods), and with the entire study cohort as the reference population, these rates and probabilities are further adjusted for the same four covariates.

Patients are followed up to three years from day 90 after dialysis initiation (for incident patients) or from January 1, 2001 (for prevalent patients), to track occurrences of cardiovascular events or all-cause death. For cardiovascular events, a patient’s followup time is censored at the earliest of death, transplant, modality change, loss-to-followup, end of Medicare as primary payor status, or December 31, 2004. For all-cause death, followup time is censored at these same events, with the exclusion of death and the end of Medicare as primary payor status. For incident patients, adjusted event rates are presented as monthly rates during the first six months after day 90, and as mean monthly event rates during each following six-month interval. For prevalent patients, adjusted event rates are presented as mean monthly event rates during each six-month interval.

implantable cardioverter defibrillators

Figure 9.56 reports all sudden cardiac death (SCD), outpatient SCD, and all-cause death for period prevalent dialysis patients, unadjusted and adjusted, from 1991 to 2004. Followup begins on January 1 of the year for point prevalent patients, and 90 days after ESRD initiation for incident patients, and lasts until the earliest of death, transplant, end of Medicare as primary payor status, or December 31 of the year. Using the model-based adjustment method (described in the section on statistical methods), the mortality rates are directly adjusted for age, gender, race, primary diagnosis, and diagnosis vintage; the 2004 cohort is used as the reference group.

Patients whose SCD occurs outside of the hospital (i.e., in a skilled nursing facility, at home, or in a hospice) are identified through ICD-9-CM codes 427.4 and 427.5 on Part A or B Medicare claims, as well as through an indication of any cardiac death as primary or secondary cause on the Death Notification form; in the absence of claims evidence, patients are identified through a primary cause of death of cardiac disease. Patients whose SCD occurs in the hospital are identified through inpatient claims, using the same ICD-9-CM codes, and through a primary cause of death of cardiac disease. In the absence of inpatient claims indicating cardiac arrest, they are identified through a primary cause of death due to cardiac arrest or cardiac arrhythmia. For both the outpatient side and inpatient side, patients with sepsis, malignancy or hyperkalemia as a secondary cause of death are excluded.

Figure 9.57 shows the cumulative probability of SCD and all-cause death for period prevalent dialysis patients, 2002. The methodology used to identify SCD patients is the same used in Figure 9.56. Patients who withdraw from dialysis therapy prior to death are excluded. Point prevalent patients are followed from January 1, 2002, and incident patients from 90 days after ESRD initiation. Followup is a maximum of two years or until the earliest date of death, transplant, loss-to-followup, or change of Medicare as primary payor coverage. The cumulative probability is estimated for each following three-month interval, using the Kaplan-Meier method. Using the same methodology, Figure 9.58 displays geographic variations in unadjusted SCD rates for period prevalent dialysis patients in 2002.

Figures 9.59–61 describe the incidence of cardiac arrest and subsequent survival in general Medicare patients. Patients are classified
as having cardiac arrest as of the first occurrence of claims (Part A or B) with ICD-9-CM diagnosis code 427.4 (ventricular fibrillation and flutter) or 427.5 (cardiac arrest) during the followup period.

Figure 9.59 shows geographic variations in unadjusted incident rates of cardiac arrest. The study cohort is derived from the 5 percent Medicare Standard Analytic Files, 2002–2003. We include patients enrolled in both Parts A and B on January 1, 2002, or any time during 2002; age 65 or older on January 1, 2002, or at the time of Medicare enrollment in 2002; and without a diagnosis code for ESRD prior to followup. Each patient is followed from January 1, 2002, or the date of Medicare enrollment in 2002 to the earliest of cardiac arrest, death, diagnosis of ESRD, change of Medicare Parts A and B enrollment, or December 31, 2003. Event rates are estimated as the number of events per 1,000 patient years at risk.

Figure 9.60 presents adjusted probabilities of cardiac arrest. The cohort includes patients continuously enrolled in Medicare Parts A and B in 2000, age 65 or older on January 1, 2000, and without a diagnosis code for ESRD prior to followup. Each patient is followed from January 1, 2001, to the earliest of cardiac arrest, death, diagnosis of ESRD, change of Medicare Parts A and B enrollment, or December 31, 2003. CKD is identified from Medicare claims data in 2000 using the same methodology described earlier. We use a Cox proportional hazards model to estimate event-free probability. Using the model-based adjustment method (described in the section on statistical methods), and with the entire study cohort as the reference population, event-free probabilities are further adjusted for age, gender, and race. The event probability is obtained by subtracting the event-free probabilities from 1.0.

Figure 9.61 illustrates adjusted survival probabilities after cardiac arrest. The study cohort includes Medicare enrollees with a first cardiac arrest claim during 2000–2003, age 66 and older on the date of cardiac arrest, and continuously enrolled in Medicare Parts A and B for at least one year before cardiac arrest. Patients CKD status is identified from Medicare claims during one year before cardiac arrest. Each patient is followed from the date of the first cardiac arrest to the earliest of death, diagnosis of ESRD, three years after cardiac arrest, or December 31, 2003. Survival probability is estimated using the same method described for Figure 9.60.

Figure 9.62 describes the use of implantable cardioverter defibrillators (ICDs) in period prevalent dialysis patients with Medicare as primary payor, 1991–2003. Patients receiving an ICD are identified by ICD-9-CM procedure code 37.94 from Medicare Part A inpatient and outpatient claims. Figures 9.63–66 describe the demographic distribution, comorbidity, and survival of patients receiving an ICD during 1996–2003. The study cohort includes period prevalent dialysis patients with Medicare as primary payor, 1996–2003, who received their first ICD treatment after January 1, 1996 (for point prevalent dialysis patients), or day 90 of ESRD (for dialysis patients incident during 1996–2003), and who are on dialysis and age 20 and older at the time of treatment. The ICD is defined as primary prevention if there are claims with ICD-9-CM diagnosis codes 427.1 (paroxysmal ventricular tachycardia), 427.4, and 427.5 during the hospitalization for ICD. Otherwise, the ICD is defined as secondary prevention. Major comorbid conditions are defined from the Medical Evidence form at the initiation of ESRD treatment and from Medicare claims during one year before ICD treatment. Patients are followed from the date of the first ICD treatment to the earliest of death, transplant, loss-to-followup, change of Medicare as primary payor, date of the second ICD, three years after the first ICD, and December 31, 2004. Unadjusted survival probabilities are estimated using the life-table method for primary prevention and secondary prevention, respectively.

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 free-standing dialysis units which have been owned or operated by a corporation for one year or longer and which are 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 “Chain Organization Name” field of the Cost Report. In 2004, the year for which data are presented in this ADR, six chains met this criterion. Some graphs compare data from 2000 and 2004; in 2000, six chains met this criterion. Chains are rank ordered from largest to smallest.

cardiovascular procedure use in dialysis patients

Figures 9.67–73 describe the cumulative percent of incident hemodialysis and peritoneal dialysis patients, age 20 and older, receiving diagnostic tests or treatment for cardiac disease in the three years beginning on day 90 after dialysis initiation for the 1995, 1998, and 2001 cohorts, and in the one year beginning on day 90 after dialysis initiation for the 2003 cohort. For pediatric dialysis patients, the cumulative percentages of patients receiving echocardiograms, lipid testing, and electrocardiograms (ECGs) are presented for the combined 1995–2001 cohorts.

Patients are followed from day 90 after dialysis initiation to the earliest of death, transplant, modality change, loss-to-followup, end of Medicare as primary payor status, three years after dialysis initiation, or December 31, 2004. The cumulative percent of patients receiving diagnostic tests or treatment is calculated as the cumulative number of patients receiving diagnostic tests or treatment divided by the total number of patients at the beginning of followup.

A stress test is defined as any of the following: stress echocardiogram, stress nuclear test, and/or stress ECG. Echocardiograms, lipid testing, and ECGs are defined through CPT codes in Part B claims, while stress tests and coronary angiography and/or catheterizations are defined through ICD-9-CM procedure codes in Part A claims and/or CPT codes in Part B claims. Coronary revascularization is defined with the method used earlier. Codes used to identify patients receiving these tests are as follows:

- stress tests: 94.41–94.44 (ICD-9-CM procedure codes); 78459, 78460, 78461, 78464, 78465, 78469, 78472, 78473, 78478, 78480, 78481, 78483, 78490, 93015–93018, and 93350 (CPT codes)
- echocardiograms: 93303, 93304, 93307, 93308, 93312, 93314, 93315, 93317, 93318, 93320, 93321, and 93325 (CPT codes)
- coronary angiography and/or catheterization: 37.22–37.23 and 88.53–88.57 (ICD-9-CM procedure codes); 93508, 93510, 93511, 93524, 93526, 93527, 93529, 93531–93533, 93539, 93540, 93543, 93545, and 93555 (CPT codes)
- lipid testing: 88061, 82465, 84478, and 83715–83721 (CPT codes)
- ECG: 93000, 93005, 93010, 93012, 93014, 93224–93227, 93230–93233, 93235–93237, 93268, 93270–93272, and 93278 (CPT codes)
A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each dialysis unit by CMS. For years prior to 2002, we determine facility profit status through the ownership type field on the CMS survey. In the 2002 CMS Survey the profit status variable was dropped, so for that and subsequent years we use the profit status field of the Dialysis Facility Compare (DFC) database. There are, however, a small number of facilities in the CMS survey that are not in the DFC database; these facilities have an unknown profit status, and are omitted from any graph showing profit status.

**provider compliance with guidelines**

Figures 10.13–16 provide information on anemia management practices of different providers. These analyses employ the concept of “managed months,” defined as an appropriate response to hemoglobin levels exceeding the K/DOQI upper limit of the target range (12 g/dl). The manufacturer recommends a dose reduction of 25 percent when hemoglobin is rising and approaching this limit. Dose and hemoglobin data used here contain only monthly detail, and since dose adjustments can occur randomly during a given month, we use a monthly dose reduction of 12.5 percent to measure anemia management. To characterize this management, we flag as anemia management opportunity each EPO claim in which the reported hemoglobin exceeds 12 g/dl, then look for a dose reduction of at least 12.5 percent on the EPO claim for the following month. If the reduction is found, the anemia management opportunity is classified as “managed.” The opportunities are aggregated on the dialysis unit level for the entire year; units with fewer than ten opportunities in the year are excluded. We then calculate the percent of units falling in each decile of “managed months” (0–10 percent of opportunities managed, 10–20 percent of opportunities managed, and so on) for each standard provider grouping. Figures 10.13–15 show results for hemoglobin levels of 12.0–<12.5, 12.5–<13, and 13 and above. Figure 10.16 illustrates the mean managed months after a reported hemoglobin ≤212 g/dl for all units within each provider group.

Figures 10.17–20 use the methods described for Figure 5.1. Figure 10.21 includes period prevalent dialysis patients in 2004 who had at least one valid EPO claim during 2004. For each patient, a mean hemoglobin is calculated from all EPO claims during the year, and patients are classified into categories using that mean.

Figure 10.22 includes incident dialysis patients from 2004. Values for albumin are obtained from the Medical Evidence form. Albumin calculations ignore whether a patient’s albumin is measured using brom cresol purple or brom cresol green.

Figures 10.23–29 illustrate differences by provider in preventive care for dialysis patients. Cohorts for Figures 10.23–24 are the same as those used for Figures 5.11 and 5.14, but are limited to dialysis patients. The cohort in Figure 10.25 is the same as that used for Objective 14.29 in Chapter HP2010, limited to dialysis patients. In Figures 10.26–29 the cohorts include 2000 or 2003 point prevalent dialysis patients with the 90-day rule, age 18–75 on December 31 of the year and alive through the end of the next year, with Medicare Parts A and B primary payor coverage at initiation, and with diabetes listed as the primary cause of ESRD or a comorbid condition on the Medical Evidence form, or with diabetes diagnosed in 2000 or 2003. Diabetic care testing is tracked in 2001 or 2004. HbA1c and lipid tests are at least 30 days apart. As described in the methods for Chapter Five, comprehensive diabetic monitoring includes at least four HbA1c tests per year, at least two lipid tests per year, and a prescription for at least two strips per day.

Figures 10.30–34 show the probabilities of receiving preventive care, by provider, in dialysis patients age 65 and older. Cohorts for Figures 10.30–31 are the same as those used for Figures 5.49 and 5.51, limited to dialysis patients age 65 and older; the fourth HbA1c test and the second lipid test are tracked in 2004. The cohort for Figure 10.32 includes September 1, 2004, point prevalent patients age 65 and older at the beginning of 2004, with the 90-day rule, and with Medicare Part A and B primary payor coverage at initiation. Influenza vaccinations are tracked between September 1 and December 31, 2004. In Figure 10.33, the cohort includes all dialysis patients initiating therapy 90 days before January 1, 2003, with Medicare Part A and B primary payor coverage at initiation, and age 65 and older at the beginning of 2003; the first pneumococcal vaccination is tracked in 2003 and 2004. For Figure 10.34, the cohort includes all dialysis patients initiating therapy 90 days before January 1, 2004, with Medicare Part A and B primary payor coverage at initiation, and age 65 and older at the beginning of 2004. The first hepatitis B vaccination is tracked in 2004.

The life table (or actuarial) estimation method is used to calculate the cumulative probability. Patients are censored at death, payment status change date, end of follow up, and end of 2004. Patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories are omitted from all figures.

**Bayesian hospitalization & mortality ratios**

We use the Bayesian method to estimate standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs), and the term BMR/BHR to identify an SMR/SHR estimated with the Bayesian method.

The study cohort for the mortality ratios in Figures 10.35, 10.37, and 10.39 consists of 2002 and 2004 period prevalent dialysis patients; the cohort in Figures 10.36, 10.38, and 10.40 is limited to 2004. Criteria for including and excluding patients, for considering death as an event, and for censoring are the same as those used for the tables in Reference Section H. The study cohort for the hospitalization ratios includes period prevalent dialysis patients (from 2002 and 2004 in Figures 10.35, 10.37, and 10.39, and from 2004 in Figures 10.36, 10.38, and 10.40), as described for Reference Section G. The total number of admissions, instead of the first hospitalization, is used for the SHRs.

**costs of CKD & 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 in 2004 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 2004 Medicare spending is inflated by 2 percent to account for incomplete claims, and organ acquisi-
tion 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 2004 (obtained from the CMS managed care organization file) in conjunction with the 2004 AAPC rate.

Non-Medicare spending by EGHPs is estimated by separately computing the per year at-risk costs for EGHP and non-EGHP patients, then multiplying the difference by the EGHP years at risk for 2004. New this year, patient obligations are estimated as the difference between Medicare allowable and Medicare net payment amounts. Non-Medicare patient spending is estimated as the number of patient years at risk for non-Medicare patients (determined from the USRDS payor sequence) multiplied by the per patient per year costs for all ESRD patients identified and included in the financial analysis of the Medstat database.

Changes in Medicare spending from 2003–2004 are obtained from Table K.2, without the 2 percent adjustment for late claims. Calculations of per patient per year at risk costs are based on patients for whom Medicare is the primary payor during the study period (Table K.e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (2.7 percent) and the Medical Consumer Price Index (4.4 percent).

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 vascular access procedures are often performed when a patient is hospitalized for another reason, costs for inpatient facilities are included in the analysis only if the cause of hospitalization can be reasonably attributed to vascular access, using Diagnosis Related Grouping (DRG) and ICD-9-CM principal procedure codes, or ICD-9-CM principal diagnosis codes (Table a.c). Such hospitalizations are labeled “pure” inpatient vascular access events.

For outpatient facility costs, 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 through 2004. The CPM project collects data annually on a random sample of hemodialysis and peritoneal dialysis patients, including the type of vascular access being used for hemodialysis at the time of data collection. The CPM data for hemodialysis patients are collected from October through December of the year prior to the cohort year (e.g., CPM data were collected from October through December, 2003 for the 2004 cohort). 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 2000–2004 are comprised of approximately 36 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 280 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 (REMS) 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 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 outpatient payment categories are taken directly from the claims data for calendar years 2001–2004, with adjustments as noted.

### Table a.d

<table>
<thead>
<tr>
<th>Medicare payment categories</th>
<th>Basis for categorizing claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>Sum of all payments</td>
</tr>
<tr>
<td>Total inpatient</td>
<td>Sum of all payments originating from the inpatient SAF, including pass-throughs</td>
</tr>
<tr>
<td>Medical DRG</td>
<td>Inpatient SAF, DRG</td>
</tr>
<tr>
<td>Surgical DRG</td>
<td>Inpatient SAF, DRG</td>
</tr>
<tr>
<td>Transplant DRG</td>
<td>Inpatient SAF, DRG 302</td>
</tr>
<tr>
<td>Other DRG</td>
<td>Inpatient SAF, DRG not included in the above categories and covered days</td>
</tr>
<tr>
<td>Non-transplant pass-throughs</td>
<td>Inpatient SAF, DRG 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 codes and/or HCPCS code</td>
</tr>
<tr>
<td>Outpatient Calcitex</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient iron</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Outpatient other injectables</td>
<td>Outpatient SAF, revenue and HCPCS codes</td>
</tr>
<tr>
<td>Radiology</td>
<td>Outpatient SAF, revenue and CPT codes</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Ambulance</td>
<td>Outpatient SAF, revenue codes</td>
</tr>
<tr>
<td>Laboratory/pathology</td>
<td>Outpatient SAF, revenue and/or CPT codes</td>
</tr>
<tr>
<td>Outpatient other</td>
<td>Outpatient SAF, does not qualify for any other cost category</td>
</tr>
<tr>
<td>Skilled nursing facility</td>
<td>Skilled nursing facility SAF</td>
</tr>
<tr>
<td>Home health agency</td>
<td>Home health SAF</td>
</tr>
<tr>
<td>Hospice</td>
<td>Hospice SAF</td>
</tr>
<tr>
<td>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 and/or type of service codes</td>
</tr>
<tr>
<td>Dialysis capitation</td>
<td>Physician/supplier SAF, CPT 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>

### Model 1: as-treated actuarial model

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

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

The study spans the 14 years from January 1, 1991, to December 31, 2004, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial 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 dura-
tion 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 as primary or secondary payor). Patients clas-
sified 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, 2004. Patients
incurred 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.

In order to express the costs as dollars per year at risk, total costs
during the followup period are divided by the length of the period.
Costs per year at risk are calculated by patient category, and strati-
ﬁed by age, gender, race, modality, and diabetic status. Diabetic sta-
tus 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 11.5–8, 11.20–25, and, in
the Précis, Figures p.27 and p.29 and Table p.b, 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 cal-
endar year; patients with a graft failure and a transplant in
the same calendar year are classiﬁed in the transplant category.

EGHP patients
Several ﬁgures in the Précis and Chapter 11 include data for EGHP
patients. Patients in the Medstat database who are identiﬁed as hav-
ing ESRD (as described above), are under 65 years of age, and do
not have evidence of Medicare payments (either as primary or sec-
ondary payor) are included in these analyses. Medicare payments
are identiﬁed in the Medstat database, and patients are excluded on
the basis of these payments, in order to obtain a more accurate
estimate of ESRD costs in the private sector. The payment amounts
presented are the sum of all payments from all payors.

International comparisons
CHAPTER TWELVE
The international data for this ADR have been collected from the
following sources, using the data form shown at the end of this sec-
tion: Registro Andaluz de Enfermos Renales; the Australian and New
Zealand Dialysis and Transplant Registry (ANZDATA); the Aust-
ria OEDTR; the Basque Country Renal Registry; the French-Bel-
gian Nephrologists Registry; Centre Hospitalier Etterbeek-Ixelles,
Belgium; the Canadian Organ Replacement Registry; Sociedad
Andaluza de Nefrologia; Registro de Diálisis y Trasplante de Cas-
tilla y León; the Catalan Renal Registry, RMRC; the Chilean Renal
Registry; the Croatian Society of Nephrology, Dialysis, and Trans-
plantation; the Czech Society of Nephrology; the Danish Society
of Nephrology; the ERA-EDTA Registry; the Finnish Registry for
Kidney Diseases; the QuaSi-Niere in Germany; the Hellenic Renal
Registry, Greece; 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 Japa-
nese Society of Dialysis Therapy; the Catholic University of Korea,
Republic of South Korea; 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 Reg-
istry Project; the Polish Dialysis Registry; the Society of Dialysis,
Russia; the Scottish Renal Registry; Sociedad Española de Nefro-
logía; the Swedish Renal Registry; the Taiwan Society of Nephrol-
gy; the Thailan Registration of Renal Replacement Therapy; the
Turkish Society of Nephrology; the Uruguayan Registry of Dialysis;
Registro Enfermos Renales de la Comunidad Valenciana; the U. S.
Census Bureau International Database; and the USRDS.

Thank you to all who provided data for this year’s Annual Data
Report. We are especially grateful to Drs. Kitty Jager and Paul van
Dijk at the ERA-EDTA Registry for their help in coordinating
much of the European data presented in this chapter.

To contribute data from your country’s registry, please com-
plete the form on pages 279–280 and return it to the USRDS.

New to this year’s ADR, Figures 12.12–13 illustrate the size of the
chronic kidney disease populations in Taiwan and the U.S, along
with the proportion of patients with diabetes and/or hypertension.
For the Taiwan data, we use the 1 percent Taiwan National Health
Insurance (NHI) claims data, with a data structure similar to that
of the Medicare claims; both use ICD-9-CM diagnosis codes.
According to previously validated methods for using Medicare
claims, as described in the methods for Chapter One, we use spe-
ciﬁc diagnosis codes to identify patients with CKD, diabetes, and
hypertension. A dialysis code is used to identify ESRD patients in
the Taiwan NHI data. Costs for the “cost year” are determined for
the entire calendar year for patients with the diseases of interest.

Vascular access
REFERENCE SECTION L
Tables L.1–3 and L.11–13 include point prevalent dialysis patients
from 1999 to 2004 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. Followup
time is censored at death, change in modality, change in payor sta-
tus, or the end of the prevalent year. For Tables L.11–13, data from
2004 is used, and vintage represents the amount of time between
the ﬁrst service date and January 1, 2004.

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, Novem-
ber, and December of the year prior to the prevalent year. Compli-
cations 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 populations**

**REFERENCE SECTION M**

The 2000 U.S. census, available in 2002, introduced a new race category with additional racial groupings. Census estimates for 1990–1999 were back-calculated based on the actual 2000 census. For 2000–2004, however, the actual data include racial groups that do not coincide with those in the ESRD data. For 2000–2004 rate calculations throughout the ADR, we 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**

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 stability 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. 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 66.7 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). Here the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the adjusted rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. The categories are defined by the adjusting variables. For example, if a rate is adjusted for race and gender and there are three race groups (white, black, and other) and two gender groups (male and female), there are six categories: white males, white females, black males, black females, males of other races, and females of other races.

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

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

<table>
<thead>
<tr>
<th>Race Category</th>
<th>Incidence Rate</th>
<th>National Population (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>153</td>
<td>75.1</td>
</tr>
<tr>
<td>Black</td>
<td>250</td>
<td>12.3</td>
</tr>
<tr>
<td>Native American</td>
<td>303</td>
<td>0.9</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>174</td>
<td>3.6</td>
</tr>
<tr>
<td>Other</td>
<td>220</td>
<td>8.0</td>
</tr>
</tbody>
</table>

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

**model-based adjustment**

Under some circumstances there are disadvantages to the direct adjustment method. 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 (Kalbfleisch 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 adjusted hospitalization rates are calculated using the direct adjustment method based on the category-specific admission rate from the generalized linear models.

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 μ and that θ, the logarithm of SMR, has a normal distribution with Gamma precision, where μ 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 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 HSA-level information). Because of area size and limitations in the mapping software, data for Puerto Rico and the U.S. Territories are not included in the maps.

**methods for smoothing & adjusting map data**

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

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

**miscellaneous**

**SPECIAL STUDIES & DATA COLLECTION FORMS**

The USRDS website includes complete copies of the CMS Medical Evidence (2728) and Death Notification forms (2746); the OPTN Transplant Candidate Registration form, Kidney Transplant Recipient Registration form and Kidney Transplant Recipient Followup form; and forms used for data collection in USRDS Special Studies.

**CAPTIONS**

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

**bibliography**


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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.

**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. For more information on merged data requests, please contact the Coordinating Center.

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 followup data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD. All Medicare billing data are available either in a full set or by individual year (see Table C.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 272). Research proposals must be approved by the USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data” (page 277). 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 C.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** 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 and early 1997.

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

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

**Case Mix Severity Study** For this USRDS Special Study, data were collected on 5,255 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; and assess the distribution of comorbidi-
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.

- TX: includes minimum details about all transplants from all sources
- TXWAIT: contains one record for each patient in the USRDS database per wait list event
- TXHCFA: 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
- TXFUHCFA: includes transplant followup reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- TXFUUNOS: includes transplant followup reports collected by UNOS since 1988
- TXIFUNOS: includes information on immunosuppressive drugs, collected by UNOS at followup visits

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

In July 1994, CMS and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its 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 files overlap for 1988–1993, and some Medical Evidence (ME) forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all pre-1988 CMS transplants accepted next. CMS transplants from 1988–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the CMS transplant (it is common for dates between sources to differ by one day). Finally, transplants indicated on the ME form are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

Hospital 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-1994 through 2004, while data on physician/supplier claims are available for 1991–2003. The 2004 claims will be available, along with other updated USRDS SAF CDs, by the end of 2006.

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 dialysis involved (if any), and the dates of service, and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

CPM/USRDS Merged CD
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.

### Contents of the USRDS Core Standard Analysis CD-ROMs

<table>
<thead>
<tr>
<th>File name, unit of observation, &amp; uses; this two-CD set is needed in order to use any of the other Standard Analysis Files.</th>
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<tbody>
<tr>
<td><strong>Patient</strong></td>
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<td><strong>Incidence, prevalence, patient survival.</strong></td>
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<td><strong>Residence</strong></td>
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<tr>
<td><strong>Regional analyses.</strong></td>
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<tr>
<td><strong>Treatment History</strong></td>
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<td><strong>Modality distribution and treatment patterns.</strong></td>
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<tr>
<td><strong>Payor History</strong></td>
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<td><strong>The impact of insurance payors on clinical outcomes.</strong></td>
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<tr>
<td><strong>Medical Evidence</strong></td>
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</tr>
<tr>
<td><strong>Transplant</strong></td>
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<tr>
<td><strong>Transplant and transplant outcome analyses.</strong></td>
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<tr>
<td><strong>Transplant Wait List</strong></td>
</tr>
<tr>
<td><strong>Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to wait list.</strong></td>
</tr>
<tr>
<td><strong>Dialysis Morbidity and Mortality (DMMS; Special Study)</strong></td>
</tr>
<tr>
<td><strong>Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.</strong></td>
</tr>
<tr>
<td><strong>Case Mix Adequacy (Special Study)</strong></td>
</tr>
<tr>
<td><strong>Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.</strong></td>
</tr>
<tr>
<td><strong>Case Mix Severity (Special Study)</strong></td>
</tr>
<tr>
<td><strong>Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.</strong></td>
</tr>
<tr>
<td><strong>Pediatric Growth and Development (Special Study)</strong></td>
</tr>
<tr>
<td><strong>Growth, development, and other issues relating to pediatric ESRD patients.</strong></td>
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<tr>
<td><strong>CAPD Peritonitis (Special Study)</strong></td>
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<tr>
<td><strong>CAPD and peritonitis.</strong></td>
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<tr>
<td><strong>Facility</strong></td>
</tr>
<tr>
<td><strong>Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.</strong></td>
</tr>
<tr>
<td><strong>Facility Cost Reports</strong></td>
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<tr>
<td><strong>Costs and staffing of dialysis facilities.</strong></td>
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<td><strong>Dialyzers</strong></td>
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<tr>
<td><strong>Relation of dialyzer characteristics to patient outcomes.</strong></td>
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<tr>
<td><strong>CLMCODES</strong></td>
</tr>
<tr>
<td><strong>Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.</strong></td>
</tr>
<tr>
<td><strong>FORMATS.SC2</strong></td>
</tr>
<tr>
<td><strong>Format library used to format values of categorical variables.</strong></td>
</tr>
</tbody>
</table>

### USRDS products & services

| Reports & guides | Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.4415, nkdci-info.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Disease. |
|Annual Data Reports | |
| 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/renderc_home.asp following a short registration; a tutorial is also available on this site to help new users. |
| Requests for data | 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: two-hour | 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. |
| Data requests: more than two hours | 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.2), and users must sign a Data Release Agreement with the NIDDK. |
| Standard Analysis Files | Custom data 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. |
| Custom data files | 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. |
| Publications & presentations | 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 |
| Contact information | Data requests & publication orders | | | |
This year, the 2004 CPM/USRDS merged CD is also available as
part of the standard USRDS SAF research files. This dataset contains
the cumulative CPM cohort (1994–2003), 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 rel-
vant 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 and DVDs as SAS files, and can be used
by SAS on any 486 or Pentium PC with a CD/DVD reader. The SAS
format is widely used, easily transported, and largely self-docu-
menting. 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 docu-
mentation into the file.

Researchers needing another format or medium must arrange
for the conversion. The USRDS may release data in some specific
file formats on a case-by-case basis and at an additional cost.

COSTS
File prices cover reproduction of files, documentation, administra-
tive 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, cop-
ies of data collection forms used by CMS, UNOS, and the USRDS
Special Studies; a chapter on techniques for using the SAFs in SAS
is also provided. The guide may be downloaded from the USRDS
website, and a copy on CD-ROM will be sent to researchers with
the purchase of the SAFs

data use acknowledgement
Publications using USRDS data should include an acknowledg-
ment 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 adher-
ence are found in the “Agreement for Release of Data,” page
277. With your completed research proposal, please include
a signed agreement for release of information from each
investigator and analyst who will use the data files.

- Indicate needed USRDS SAFs by name (i.e. Core, Trans-
plant etc). If these files cannot meet requirements of the
proposed research, investigators must specify precisely
which data elements are needed, and budget for a substan-
tially 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 techni-
cal 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 Minne-
apolis Medical Research Foundation.

The NIH will review the project for technical merit and for con-
formity 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 POs’ approval indicate government endorsement of the inves-
tigator’s opinions and conclusions.

All publications using released data must contain the standard
acknowledgement and disclaimer presented above. Investigators
are requested to send copies of all final publications resulting from
this research to both the PO and the 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, how-
ever, 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 col-
lected, edited, and entered into the database.
Outline for research proposals using USRDS data

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

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 insure 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 20892-5438
Phone 301.594.8305
Fax 301.480.3510
eggersp@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 norepinephrine, 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 Children’s Health insurance programs.

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 cooperative-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 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.

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ysis in which dialyse is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity 4–5 times each day.

Continuous cyclor-assisted peritoneal dialysis (CCPD) I A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automat-ed cyclor machine.

Creatinine I A waste product of pro-tein metabolism found in the urine; of-ten used to evaluate kidney function. Abnormally high creatinine levels in-dicate kidney failure or renal insuffi-ciency.

Creatinine clearance I Used as an in-dicator to predict the onset of uremia, which develops when creatinine clear-one falls below 10 ml/minute/1.73 m².

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

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

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

Diagnosis Related Groups (DRGs) I Used by Medicare to determine pay-ment for inpatient hospital stays; based on diagnosis, age, gender, and compli-cations.

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

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

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

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

Erythropoietin (EPO) I A hormone se-creted chiefly by the adult kidney; act-ing on bone marrow to stimulate red cell production. Also produced in a formu-lated version to treat anemia.

ESRD Facility Survey I 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.A, and encompasses the full calendar year. Geographic data are in-cluded to the level of facility ZIP code. Each record contains facility informa-tion 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 I Regional organiza-tions, established by law in 1978, con-tracted by CMS to perform quality oversight activities to assure the appro-priateness of services and protection for dialysis patients.

Expanded criteria donors (ECDS) I Older kidney donors or donors whose health issues in the past would have prevented their acceptance into the don-or program.

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

Freestanding facility I A unit licensed to provide outpatient and home main-tenance dialysis; sometimes referred to as an independent unit.

Glomerular filtration rate (eGFR) I 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, se-rum blood urea nitrogen, and serum albumin. GFR is traditionally consid-ered the best overall index to determine renal function.

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

Health Care Financing Administration (HCFA) I 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) I 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 & Infor-mation Set (HEDIS) I Established by the National Committee for Quality Assurance, HEDIS 2002 is a set of stan-dardized performance measures cre-ated to aid consumers in comparing managed healthcare plans.

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

Healthy People 2010 I A national agen-da for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people (www.health.gov/ healthypeople).

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

Hepatitis I An inflammation of the liv-er that may be caused by a viral infec-tion, poisons, or the use of alcohol or other drugs. Forms include Hepatitis A, usually transmitted by contaminat-ed food or water; Hepatitis B, more se-rious than Hepatitis A and transmitted through blood and body fluids; Hepa-titis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an indi-vidual is already infected with the Hepa-titis B virus.

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

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

High-flux hemodialysis I Dialysis ther-apy using hemodialyzers with synthet-ic membranes and large surface areas that, combined with high blood and dialysate flow rates, allow enhanced solute clearance and fluid removal. De-livery systems with ultrafiltration con-trol are required for this therapy.

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

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

Hospital center unit I A dialysis unit located in or attached to a hospital and licensed to furnish inpatient and outpa-tient dialysis plus diagnostic, therapeu-tic, and rehabilitative services.

Incident ESRD patient I 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 be-for-e starting ESRD treatment, and those whose treatments are not report-ed to CMS.

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

Ischemic heart disease (ISHD) I A dis-ease of the heart evidenced by a low-ered oxygen supply to the heart tissue, caused by occlusion or narrowing of the arteries supplying the heart muscle.

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

Kt/V I An indicator of the dialysis dose per treatment, calculated by multiply-ing the urea clearance (K) by the treat-ment duration (t) and dividing by the urea distribution (V). The urea distri-bution volume is approximately equal to the volume of total body water.

Medical Evidence form (CMS-2278) I A form which provides source data about ESRD patients, including in-formation on demographics, prima-ry cause of renal disease, comorbidity, biochemical data, dialysis treatment, transplant, dialysis training, employ-ment status, initial insurance coverage, and first ESRD service date.

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

Medicare Current Beneficiary Survey (MCBS) I 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 expendi-tures, health insurance coverage, and socioeconomic and demographic char-acteristics of Medicare beneficiaries.

Medicare risk patient I A patient en-rolled in a Managed Care Organiza-tion under contract with CMS and for whom healthcare costs are paid by CMS on a per capita basis.

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

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

Modality I A method of treatment. Treatment for end-stage renal disease (ESRD) is comprised of three modaliti-ies: hemodialytic, peritoneal dialysis, and transplantation.
Glossary

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 (CWFP) 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.

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.

Pyrexia || A substance which is bactericidal in nature and capable of producing low-grade fevers.

Pyrexia 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 dialyze fluid. The fever disappears after the dialysis is complete, distinguishing the reaction from an actual infection.

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

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

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

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

Standard Analysis Files (SAFs) || CMS files containing final action Medicare Part A claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and 5 percent Sample Beneficiary.

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

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

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

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

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

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

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

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

The VISION project || CMS's Vital Information System to Improve Outcomes in Nephrology (VISION) will provide customized data entry and reporting for the nearly 4,000 U.S. dialysis facilities, and will capture and securely communicate ESRD patient records 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

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

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

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

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

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

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

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

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

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

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

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

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

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### A) Population of country

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

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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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### C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

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

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

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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
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<td>2003</td>
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<td>2005</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
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<td>2005</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
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<td>2003</td>
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<td>2004</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
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<td>2003</td>
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<td>2005</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Year</th>
<th>0–19</th>
<th>20–44</th>
<th>45–64</th>
<th>65–74</th>
<th>75+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
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<td>2003</td>
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<td>2004</td>
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<td>2005</td>
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</tr>
</tbody>
</table>
END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS  
Check one:  Initial     Re-entitlement  Supplemental

1. Name (Last, First, Middle Initial)

2. Medicare Claim Number

3. Social Security Number

4. Date of Birth  MM  DD  YYYY

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

6. Phone Number  ( )

7. Sex

   ☐ Male  ☐ Female

8. Ethnicity

   ☐ Not Hispanic or Latino  ☐ Hispanic or Latino (Complete Item 9)

9. Country/Area of Origin or Ancestry

10. Race (Check all that apply)

    ☐ White  ☐ Asian  ☐ Native Hawaiian or Other Pacific Islander*

    ☐ Black or African American  ☐ Native American Indian/Alaska Native

    ☐ Other  ☐ Full Name of Enrolled/Principal Tribe *complete Item 9

11. Is patient applying for ESRD Medicare coverage?

    ☐ Yes  ☐ No

12. Current Medical Coverage (Check all that apply)

    ☐ Medicaid  ☐ Medicare  ☐ Employer Group Health Insurance

    ☐ DVA  ☐ Medicare Advantage ☐ Other  ☐ None

13. Height

    INCHES _____ OR CENTIMETERS _______

14. Dry Weight

    POUNDS _____ OR KILOGRAMS _______

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

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

    Prior  Current

    ☐ Unemployed  ☐ Unemployed

    ☐ Employed Full Time  ☐ Employed Full Time

    ☐ Employed Part Time  ☐ Employed Part Time

    ☐ Homemaker  ☐ Homemaker

    ☐ Retired due to Age/Preference  ☐ Retired due to Age/Preference

    ☐ Retired (Disability)  ☐ Retired (Disability)

    ☐ Medical Leave of Absence  ☐ Medical Leave of Absence

    ☐ Student  ☐ Student

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

    a. Congestive heart failure  ☐ Yes  ☐ No  ☐ Unknown

    b. Atherosclerotic heart disease ASHD  ☐ Yes  ☐ No  ☐ Unknown

    c. Other cardiac disease  ☐ Yes  ☐ No  ☐ Unknown

    d. Cerebrovascular disease, CVA, TIA*  ☐ Yes  ☐ No  ☐ Unknown

    e. Peripheral vascular disease*  ☐ Yes  ☐ No  ☐ Unknown

    f. History of hypertension  ☐ Yes  ☐ No  ☐ Unknown

    g. Amputation  ☐ Yes  ☐ No  ☐ Unknown

    h. Diabetes, currently on insulin  ☐ Yes  ☐ No  ☐ Unknown

    i. Diabetes, on oral medications  ☐ Yes  ☐ No  ☐ Unknown

    j. Diabetes, without medications  ☐ Yes  ☐ No  ☐ Unknown

    k. Diabetic retinopathy  ☐ Yes  ☐ No  ☐ Unknown

    l. Chronic obstructive pulmonary disease  ☐ Yes  ☐ No  ☐ Unknown

    m. Tobacco use (current smoker)  ☐ Yes  ☐ No  ☐ Unknown

    n. Malignant neoplasm, Cancer  ☐ Yes  ☐ No  ☐ Unknown

    o. Toxic nephropathy  ☐ Yes  ☐ No  ☐ Unknown

    p. Alcohol dependence  ☐ Yes  ☐ No  ☐ Unknown

    q. Drug dependence*  ☐ Yes  ☐ No  ☐ Unknown

    r. Inability to ambulate  ☐ Yes  ☐ No  ☐ Unknown

    s. Inability to transfer  ☐ Yes  ☐ No  ☐ Unknown

    t. Needs assistance with daily activities  ☐ Yes  ☐ No  ☐ Unknown

    u. Institutionalized  ☐ Yes  ☐ No  ☐ Unknown

    v. Non-renal congenital abnormality  ☐ Yes  ☐ No  ☐ Unknown

    w. None  ☐ Yes  ☐ No  ☐ Unknown

18. Prior to ESRD therapy:

    a. Did patient receive exogenous erythropoietin or equivalent?  ☐ Yes  ☐ No  ☐ Unknown

    b. Was patient under care of a nephrologist?  ☐ Yes  ☐ No  ☐ Unknown

    c. Was patient under care of kidney dietitian?  ☐ Yes  ☐ No  ☐ Unknown

    d. What access was used on first outpatient dialysis:  ☐ AVF  ☐ Graft  ☐ Catheter

       If not AVF, then:  Is maturing AVF present?  ☐ Yes  ☐ No  ☐ Unknown

       Is maturing graft present?  ☐ Yes  ☐ No  ☐ Unknown

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

<table>
<thead>
<tr>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
<th>LABORATORY TEST</th>
<th>VALUE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.1. Serum Albumin (g/dl)</td>
<td></td>
<td></td>
<td>d. HbA1c</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>a.2. Serum Albumin Lower Limit</td>
<td></td>
<td></td>
<td>e. Lipid Profile</td>
<td>TC</td>
<td></td>
</tr>
<tr>
<td>a.3. Lab Method Used (BCG or BCP)</td>
<td></td>
<td>LDL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Serum Creatinine (mg/dl)</td>
<td></td>
<td>HDL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Hemoglobin (g/dl)</td>
<td></td>
<td>TG</td>
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</tr>
</tbody>
</table>

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility

21. Medicare Provider Number (for item 20)

22. Primary Dialysis Setting

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

23. Primary Type of Dialysis

    ☐ Hemodialysis (Sessions per week_____/hours per session_____)  ☐ CAPD  ☐ CCPD  ☐ Other

24. Date Regular Chronic Dialysis Began  MM  DD  YYYY

25. Date Patient Started Chronic Dialysis at Current Facility  MM  DD  YYYY

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

27. If patient NOT informed of transplant options, please check all that apply:

    ☐ Medically unfit  ☐ Patient declines information

    ☐ Unsuitable due to age  ☐ Patient has not been assessed

    ☐ Psychologically unfit  ☐ Other

---

FORM CMS-2728-U3 (06/04)  EF(03/2005)  A copy of the previous version of the Medical Evidence form, used between May, 1995 & April, 2005, is included on the USRDS website, at www.usrds.org.
C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

28. Date of Transplant
   MM DD YYYY

29. Name of Transplant Hospital

30. Medicare Provider Number for Item 29

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

31. Enter Date
   MM DD YYYY

32. Name of Preparation Hospital

33. Medicare Provider number for Item 32

34. Current Status of Transplant (If functioning, skip items 36 and 37)
   □ Functioning
   □ Non-Functioning

35. Type of Donor:
   □ Deceased
   □ Living Related
   □ Living Unrelated

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

37. Current Dialysis Treatment Site
   □ Home
   □ Dialysis Facility/Center
   □ SNF/Long Term Care Facility

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

38. Name of Training Provider

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

40. Date Training Began
   MM DD YYYY

41. Type of Training
   □ Hemodialysis
   □ CAPD
   □ CCPD
   □ Other

42. This Patient is Expected to Complete (or has completed) Training and will Self-dialyze on a Regular Basis.
   □ Yes
   □ No

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

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

44. Printed Name and Signature of Physician personally familiar with the patient’s training
   a.) Printed Name
   b.) Signature
   c.) Date MM DD YYYY

45. UPIN of Physician in Item 44

E. PHYSICIAN IDENTIFICATION

46. Attending Physician (Print)

47. Physician’s Phone No.

48. UPIN of Physician in Item 46

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.

49. Attending Physician’s Signature of Attestation (Same as Item 46)

50. Date
   MM DD YYYY

51. Physician Recertification Signature

52. Date
   MM DD YYYY

53. 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.

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

55. Date
   MM DD YYYY

G. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, “End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS),” published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS can be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual, an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the Federal Register notice cited above. You should be aware that P.L. 100-503, the Computer Matching and Privacy Protection Act of 1986, permits the government to verify information by way of computer matches.

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

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

<table>
<thead>
<tr>
<th>DIABETES</th>
<th>CYSTIC/HEREDITARY/CONGENITAL DISEASES</th>
</tr>
</thead>
<tbody>
<tr>
<td>25040  Diabetes with renal manifestations Type 2</td>
<td>75313 Polycystic kidneys, adult type (dominant)</td>
</tr>
<tr>
<td>25041  Diabetes with renal manifestations Type 1</td>
<td>75314 Polycystic, infantile (recessive)</td>
</tr>
<tr>
<td>GLOMERULONEPHRITIS</td>
<td>75316 Medullary cystic disease, including nephronophthisis</td>
</tr>
<tr>
<td>5829  Glomerulonephritis (GN)</td>
<td>7595 Tuberous sclerosis</td>
</tr>
<tr>
<td>(histologically not examined)</td>
<td>7598 Hereditary nephritis, Alport’s syndrome</td>
</tr>
<tr>
<td>5821  Focal glomerulosclerosis, focal sclerosing GN</td>
<td>2700 Cystinosis</td>
</tr>
<tr>
<td>5831  Membranous nephropathy</td>
<td>2718 Primary oxalosis</td>
</tr>
<tr>
<td>58321 Membranoproliferative GN type 1, diffuse MPGN</td>
<td>2727 Fabry’s disease</td>
</tr>
<tr>
<td>58322 Dense deposit disease, MPGN type 2</td>
<td>7533 Congenital nephrotic syndrome</td>
</tr>
<tr>
<td>58381 IgA nephropathy, Berger’s disease (proven by immunofluorescence)</td>
<td>5839 Drash syndrome, mesangial sclerosis</td>
</tr>
<tr>
<td>58382 IgM nephropathy (proven by immunofluorescence)</td>
<td>75321 Congenital obstruction of ureteropelvic junction</td>
</tr>
<tr>
<td>58384 With lesion of rapidly progressive GN</td>
<td>75322 Congenital obstruction of ureterovesical junction</td>
</tr>
<tr>
<td>5800  Post infectious GN, SBE</td>
<td>75329 Other Congenital obstructive uropathy</td>
</tr>
<tr>
<td>5820  Other proliferative GN</td>
<td>75330 Renal hypoplasia, dysplasia, oligonephronia</td>
</tr>
<tr>
<td>SECONDARY GN/VASCULITIS</td>
<td>75671 Prune belly syndrome</td>
</tr>
<tr>
<td>7100  Lupus erythematosus, (SLE nephritis)</td>
<td>75989 Other (congenital malformation syndromes)</td>
</tr>
<tr>
<td>2870  Henoch-Schonlein syndrome</td>
<td></td>
</tr>
<tr>
<td>7101  Scleroderma</td>
<td></td>
</tr>
<tr>
<td>28311 Hemolytic uremic syndrome</td>
<td></td>
</tr>
<tr>
<td>4460  Polyarteritis</td>
<td></td>
</tr>
<tr>
<td>4464  Wegener’s granulomatosis</td>
<td></td>
</tr>
<tr>
<td>58392 Nephropathy due to heroin abuse and related drugs</td>
<td>1190 Renal tumor (malignant)</td>
</tr>
<tr>
<td>44620 Other Vasculitis and its derivatives</td>
<td>1199 Urinary tract tumor (malignant)</td>
</tr>
<tr>
<td>44621 Goodpasture’s syndrome</td>
<td>2230 Renal tumor (benign)</td>
</tr>
<tr>
<td>58391 Secondary GN, other</td>
<td>2239 Urinary tract tumor (benign)</td>
</tr>
<tr>
<td>INTERSTITIAL NEPHRITIS/PYELONEPHRITIS</td>
<td>23951 Renal tumor (unspecified)</td>
</tr>
<tr>
<td>9659  Analgesic abuse</td>
<td>23952 Urinary tract tumor (unspecified)</td>
</tr>
<tr>
<td>5830  Radiation nephritis</td>
<td>20280 Lymphoma of kidneys</td>
</tr>
<tr>
<td>9849  Lead nephropathy</td>
<td>20300 Multiple myeloma</td>
</tr>
<tr>
<td>5909  Nephropathy caused by other agents</td>
<td>20308 Other immuno proliferative neoplasms</td>
</tr>
<tr>
<td>27410 Gouty nephropathy</td>
<td>(including light chain nephropathy)</td>
</tr>
<tr>
<td>5920  Nephrolithias</td>
<td>2773 Amyloidosis</td>
</tr>
<tr>
<td>5996  Acquired obstructive uropathy</td>
<td>99680 Complications of transplanted organ unspecified</td>
</tr>
<tr>
<td>5900  Chronic pyelonephritis, reflux nephropathy</td>
<td>99681 Complications of transplanted kidney</td>
</tr>
<tr>
<td>58389 Chronic interstitial nephritis</td>
<td>99682 Complications of transplanted liver</td>
</tr>
<tr>
<td>58089 Acute interstitial nephritis</td>
<td>99683 Complications of transplanted heart</td>
</tr>
<tr>
<td>5929  Urolithias</td>
<td>99684 Complications of transplanted lung</td>
</tr>
<tr>
<td>27549 Other disorders of calcium metabolism</td>
<td>99685 Complications of transplanted bone marrow</td>
</tr>
<tr>
<td>HYPERTENSION/LARGE VESSEL DISEASE</td>
<td>99686 Complications of transplanted pancreas</td>
</tr>
<tr>
<td>40391 unspecified with renal failure</td>
<td>99687 Complications of transplanted intestine</td>
</tr>
<tr>
<td>4401  Renal artery stenosis</td>
<td>99689 Complications of other specified transplanted organ</td>
</tr>
<tr>
<td>59381 Renal artery occlusion</td>
<td></td>
</tr>
<tr>
<td>59383 Cholesterol emboli, renal emboli</td>
<td>28260 Sickle cell disease/anemia</td>
</tr>
<tr>
<td></td>
<td>28269 Sickle cell trait and other sickle cell (HbS/Hb other)</td>
</tr>
<tr>
<td></td>
<td>64620 Post partum renal failure</td>
</tr>
<tr>
<td></td>
<td>042 AIDS nephropathy</td>
</tr>
<tr>
<td></td>
<td>8660 Traumatic or surgical loss of kidney(s)</td>
</tr>
<tr>
<td></td>
<td>5724 Hepatorenal syndrome</td>
</tr>
<tr>
<td></td>
<td>5836 Tubular necrosis (no recovery)</td>
</tr>
<tr>
<td></td>
<td>59389 Other renal disorders</td>
</tr>
<tr>
<td></td>
<td>7999 Etiology uncertain</td>
</tr>
</tbody>
</table>
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:

Check the appropriate block that identifies the reason for submission of this form.

**Initial**

For all patients who initially receive a kidney transplant instead of a course of dialysis.

For 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. The form should be completed for all patients in this category even if the patient dies within this time period.

**Re-entitlement**

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.

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 ESRD benefits.

**Supplemental**

Patient has received a transplant or trained for self-care dialysis within the first 3 months of the first date of dialysis and initial form was submitted.

---

**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 15, 17-18, 26-27, 49-50:** To be completed by the attending physician.

**Items 44:** To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.

**Items 54 and 55:** 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 Medicare claim number as it appears on 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 patient’s date of birth (2-digit Month, Day, and 4-digit Year). Example 07/25/1950.
5. Enter the patient's mailing address (number and street or post office box number, city, state, and ZIP code.)
6. 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 ethnicity categories for Federal statistics are as follows:

   **Not Hispanic or Latino**—A person of culture or origin not described below, regardless of race.

   **Hispanic or Latino**—A person of Cuban, Puerto Rican, or Mexican culture or origin regardless of race. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.
9. Country/Area of origin or ancestry—Complete if information is available or if directed to do so in question 8.
10. Check the appropriate block(s) to identify race. Definitions of the racial categories for Federal statistics are as follows:

   **White**—A person having origins in any of the original white peoples of Europe, the Middle East or North Africa.

   **Black or African American**—A person having origins in any of the black racial groups of Africa. This includes native-born Black Americans, Africans, Haitians and residents of non-Spanish speaking Caribbean Islands of African descent.

   **American Indian/Alaska Native**—A person having origins in any of the original peoples of North America and South America (including Central America) and who maintains tribal affiliation or community attachment. Print the name of the enrolled or principal tribe to which the patient claims to be a member.

   **Asian**—A person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

   **Native Hawaiian or Other Pacific Islander**—A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.
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/she should reapply for ESRD Medicare coverage.

12. Check all the blocks that apply to this patient’s current medical insurance status.
- **Medicaid**—Patient is currently receiving State Medicaid benefits.
- **Medicare**—Patient is currently entitled to Federal Medicare benefits.
- **Employer Group Health Insurance**—Patient receives medical benefits through an employee health plan that covers employees, former employees, or the families of employees or former employees.
- **DVA**—Patient is receiving medical care from a Department of Veterans Affairs facility.
- **Medicare Advantage**—Patient is receiving medical benefits under a Medicare Advantage organization.
- **Other Medical Insurance**—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, HMO/M+C organization, 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.

13. 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 5’2”) 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. To be completed by the attending physician. Enter the ICD-9-CM 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.

16. 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.

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

18. Prior to ESRD therapy, check the appropriate box to indicate whether the patient received Exogenous erythropoetin (EPO) or equivalent, was under the care of a nephrologist and/or was under the care of a kidney dietitian. Provide vascular access information as to the type of access used (Arterio-Venous Fistula (AVF), graft, catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present?

**NOTE:** For those patients re-entering the Medicare program after benefits were terminated, items 19a thru 19c should contain initial laboratory values within 45 days prior to the most recent ESRD episode. Lipid profiles and HbA1c should be within 1 year of the most recent ESRD episode. Some tests may not be required for patients under 21 years of age.

19a1. 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 kidney transplant.

19a2. Enter the lower limit of the normal range for serum albumin from the laboratory which performed the serum albumin test entered in 19a1.

19a3. Enter the serum albumin lab method used (BCG or BCP).

19b. Enter the serum creatinine value (mg/dl) and date test was taken. **THIS FIELD MUST BE COMPLETED.** Value must be within 45 days prior to first dialysis treatment or kidney transplant.

19c. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or kidney transplant.

19d. Enter the HbA1c value and the date the test was taken. The date must be within 1 year prior to the first dialysis treatment or kidney transplant.

19e. Enter the Lipid Profile values and date test was taken. These values: TC—Total Cholesterol; LDL—LDL Cholesterol; HDL—HDL Cholesterol; TG—Triglycerides, and date must be within 1 year prior to the first dialysis treatment or kidney transplant.

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

21. Enter the 6-digit Medicare identification code of the dialysis facility in item 20.

22. If the 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.

23. If the patient is, or was, on regular dialysis, check the **anticipated long-term primary type of dialysis:** Hemodialysis, (enter the number of sessions prescribed per week and the hours that were prescribed for each session), CAPD (Continuous Ambulatory Peritoneal Dialysis) and CCPD (Continuous Cycling Peritoneal Dialysis), or Other. **Check only one block.** NOTE: Other has been placed on this form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by Office of Management and Budget.

24. Enter the date (month, day, year) that a “regular course of chronic 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 Chronic Dialysis Began” 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 53, that patient is restarting dialysis.

25. Enter date patient started chronic dialysis at current facility of dialysis services. In cases where patient transferred to current dialysis facility, this date will be after the date in Item 24.

26. Enter whether the patient has been informed of their options for receiving a kidney transplant.
27. If the patient has not been informed of their options (answered “no” to Item 26), then enter all reasons why a kidney transplant was not an option for this patient at this time.

28. Enter the date(s) of the patient’s kidney transplant(s). If reentering the Medicare program, enter current transplant date.

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

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

31. 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.

32. 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.

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

34. Check the appropriate functioning or non-functioning block.

35. Enter the type of kidney transplant organ donor, Deceased, Living Related or Living Unrelated, that was provided to the patient.

36. 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.

37. 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 38-43 if the patient has entered into a self-dialysis training program. Items 38-43 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.

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

39. Enter the 6-digit Medicare identification number for the training provider in Item 38.

40. Enter the date self-dialysis training began.

41. Check the appropriate block which describes the type of self-care dialysis training the patient began. If the patient trained for hemodialysis, enter whether the training was to perform dialysis in the home setting or in the facility (in center). If the patient trained for IPD (Intermittent Peritoneal Dialysis), report as Other.

42. 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.

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

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

45. Enter the Unique Physician Identification Number (UPIN) of physician in Item 44. (See Item 48 for explanation of UPIN.)

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

47. 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.

48. 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.

49. To be signed by the physician supervising the patient’s kidney treatment. Signature of physician identified in Item 46. A stamped signature is unacceptable.

50. Enter date physician signed this form.

51. To be signed by the physician who is currently following the patient. If the patient had decided initially not to file an application for Medicare, the physician will be re-certifying that the patient is end stage renal, based on the same medical evidence, by signing the copy of the CMS-2728 that was originally submitted and returned to the provider. If you do not have a copy of the original CMS-2728 on file, complete a new form.

52. The date physician re-certified and signed the form.

53. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or social security field office.

54. 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.

55. The date patient signed form.

NOTICE

This form is to be completed for all End Stage Renal Disease patients beginning June 01, 2005 regardless of when the patient started dialysis or received a kidney transplant. Prior blank versions of this form should be destroyed. Old versions of the CMS-2728 will not be accepted by the Social Security Administration or the ESRD Network Organizations after May 31, 2005.
ESRD DEATH NOTIFICATION
END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

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

1. PATIENT'S LAST NAME
   FIRST
   MI
   2. HEALTH INSURANCE CLAIM NUMBER

3. PATIENT'S SEX
   a. □ Male  b. □ Female

4. PATIENT'S STATE OF RESIDENCE

5. DATE OF BIRTH
   MONTH
   DAY
   YEAR

6. DATE OF DEATH
   MONTH
   DAY
   YEAR

7. PROVIDER NAME AND ADDRESS (CITY AND STATE)

8. PROVIDER NUMBER

9. PLACE OF DEATH (Check one)
   a. □ Hospital  b. □ Dialysis  c. □ Home  d. □ Other

10. WAS AN AUTOPSY PERFORMED?
   a. □ Yes  b. □ No

11. CAUSES OF DEATH (Enter code form List of Causes below.)
   a. Primary Cause
   b. Secondary Causes?
   Yes, Specify

   (1)
   (2)
   (3)
   (4)

LIST OF CAUSES

CARDIAC
23 Myocardial infarction, acute
24 Hyperkalemia
25 Pernic平tis, 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 Codes 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-drug 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: □ Yes  □ No
   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
   MONTH
   DAY
   YEAR
   b. Was kidney functioning (patient not on dialysis) at time of death?
      □ Yes  □ No  □ Unknown
   c. Did transplant patient resume chronic maintenance dialysis prior to death?
      □ Yes  □ No

14. REMARKS

15. NAME OF PHYSICIAN

16. SIGNATURE OF PERSON COMPLETING THIS FORM
   DATE


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

### DIALYSIS PATIENTS

<table>
<thead>
<tr>
<th>Patients Receiving Care</th>
<th>Additions During Survey Period</th>
<th>Losses During Survey Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Started for first time ever</td>
<td>Deaths</td>
</tr>
<tr>
<td></td>
<td>Restarted</td>
<td>Recovered kidney function</td>
</tr>
<tr>
<td></td>
<td>Transferred from other dialysis unit</td>
<td>Received transplant</td>
</tr>
<tr>
<td></td>
<td>Returned after transplantation</td>
<td>Transferred to other dialysis unit</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Discontinued dialysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other (LTFU)</td>
</tr>
</tbody>
</table>

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

### Patient Eligibility Status

<table>
<thead>
<tr>
<th>Currently enrolled in Medicare</th>
<th>Medicare application pending</th>
<th>Non-Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>28</td>
<td>29</td>
</tr>
</tbody>
</table>

### Hemodialysis Patients Dialyzing More Than 4 Times Per Week

<table>
<thead>
<tr>
<th>Setting</th>
<th>Day</th>
<th>Nocturnal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incenter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>30A</td>
<td>30B</td>
<td>31A</td>
</tr>
</tbody>
</table>

### Vocational Rehabilitation

<table>
<thead>
<tr>
<th>Patients aged 18 through 54</th>
<th>Patients receiving services from Voc Rehab</th>
<th>Patients Employed full-time or part-time</th>
</tr>
</thead>
<tbody>
<tr>
<td>30A</td>
<td>31A</td>
<td>32</td>
</tr>
</tbody>
</table>

### TREATMENT AND STAFFING

<table>
<thead>
<tr>
<th>Incenter Dialysis Treatments (Include Training Treatments)</th>
<th>Staffing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodialysis</td>
<td>Position</td>
</tr>
<tr>
<td>Other</td>
<td>Number of Staff</td>
</tr>
<tr>
<td></td>
<td>Full Time</td>
</tr>
<tr>
<td></td>
<td>a. RNs</td>
</tr>
<tr>
<td></td>
<td>b. LPN/LVN</td>
</tr>
<tr>
<td></td>
<td>c. PCTs</td>
</tr>
<tr>
<td></td>
<td>d. APNs</td>
</tr>
<tr>
<td></td>
<td>e. Dietitians</td>
</tr>
<tr>
<td></td>
<td>f. Social Workers</td>
</tr>
</tbody>
</table>

COMPLETED BY (Name)  DATE  TITLE  TELEPHONE NO.

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

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

Form CMS-2744A (02/04)
# Kidney Transplants Performed

## Patients Transplanted and Donor Type

<table>
<thead>
<tr>
<th>Patients who received transplant at this facility</th>
<th>Eligibility Status of Patients Transplanted at this Facility During the Survey Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>42</td>
<td>Currenty enrolled in Medicare</td>
</tr>
<tr>
<td></td>
<td>Medicare application pending</td>
</tr>
</tbody>
</table>

## Transplant Procedures Performed at This Facility

<table>
<thead>
<tr>
<th>Living Related Donor</th>
<th>Living Unrelated Donor</th>
<th>Deceased Donor</th>
<th>Total Fields 47 thru 49</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>48</td>
<td>49</td>
<td>50</td>
</tr>
</tbody>
</table>

## Patients Awaiting Transplant

<table>
<thead>
<tr>
<th>Dialysis</th>
<th>Nondialysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>51</td>
<td>52</td>
</tr>
</tbody>
</table>

## Remarks/Comments

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).
REPORTING RESPONSIBILITY

The ESRD Facility Survey is designed to capture only a limited amount of information concerning each Federally approved renal facility's operation. It is not intended to yield information on the full range of ancillary services or activities, e.g., referrals, graft outcome, etc. These concerns are more appropriately and validly addressed by the network in supplemental requests or through other segments of the Program Management and Medical Information System.

Every facility/center approved by Medicare to provide services to ESRD patients must furnish the information requested in the ESRD Facility Survey (42 U.S.C. 426; 20 CFR 405, Section 2133). It is also the facility’s center’s responsibility to provide patient and treatment counts to their local ESRD Network upon termination of operations. Facilities certified as only providing inpatient services are not requested to complete a survey.

For purposes of this document, the word “facility” will be used interchangeably when referring to renal dialysis facilities, renal dialysis centers, or renal transplant centers, as applicable.

Survey Period

The Survey Facility is completed annually. The survey period is January 1 through December 31. This Facility Survey is to be completed for the period January 1, 2005 through December 31, 2005. Unless specified otherwise, all data entered on the Facility Survey is to cover the entire survey period. The form should be completed and forwarded to the local ESRD Network.

GENERAL INSTRUCTIONS

Please complete the following information which will be used to update the CMS Dialysis Facility Compare website. This information should reflect your facility status as of December 31:

Facility Physical Address
Complete this information if your physical address is different from your mailing address.

Number of Dialysis Stations
Provide the number of approved dialysis stations in your facility as of December 31.

Facility Telephone
Provide your facility telephone number including area code.

Facility Ownership Type
Check the appropriate block for profit or non-profit type of ownership.

Facility Local/National Affiliation/Chain Information
Provide information if your facility is owned or managed by a national corporation, e.g., Gambro, Fresenius, etc.

Types of dialysis services offered
Provide information on the types of dialysis services your facility is approved to provide as of December 31. These are the types of services that are listed on the Dialysis Facility Compare website; Incenter Hemodialysis, Peritoneal Dialysis and/or Home Hemodialysis Training.

Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?
Provide information as to whether your facility offers dialysis shifts that begin on or after 5:00 p.m. as of December 31.

DIALYSIS PATIENTS, TREATMENTS AND STAFFING (FOR COMPLETION BY DIALYSIS UNITS ONLY)

Patient Load

All patient and treatment counts requested are to include only the diagnosed chronic ESRD population; no reversible failure (Acute) patients or treatments may be counted.

All diagnosed chronic ESRD patients treated at the facility should be counted and reported as (1) regular, continuing caseload (field 03); (2) added to the regular caseload (fields 04A through 07B); or (3) lost from the regular caseload (fields 08A through 13B).

Inclusion of patients in counts should not depend on entitlement determination; newly diagnosed chronic unit admissions should be included, both for peritoneal or hemodialytic therapy and transplantation.

NOTE: Any provider who has signed an agreement with a dialysis supplier to provide support services to Method II home patients should count those patients as part of their regular dialysis population on the ESRD Facility Survey Form. Please keep this in mind when completing fields for home dialysis patients.

Patients Receiving Care Beginning of Survey Period

Field 01: Incenter. Enter the number of patients dialyzing in your facility at the beginning of the survey period. This number should reflect your “permanent” patient population; i.e., those patients for whom your facility had ongoing medical responsibility for the routine care of the patient until he/she was formally transferred elsewhere. Include those of your routine patients who were hospitalized or were in transient status away from your facility at the beginning of the survey period.

Field 02: Home. Enter the number of patients followed by your facility; that is, for whom your facility had the major medical responsibility, (e.g., the facility which provides incenter backup dialysis, performs necessary medical follow-ups, provides the patient with home dialysis supplies, or has a written agreement to provide support services to Method II patients). Enter the number of patients who were dialyzing at home (hemodialysis, continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis or other dialysis, e.g., intermittent peritoneal dialysis) at the beginning of the survey period.

Field 03: Total. Enter the sum of fields 01 and 02. This should equal the number of patients on your facility’s register at the beginning of the survey period.

Additions During the Survey Period

NOTE: This section requires counts for additional incenter and home dialysis patients accepted during the survey period.

Newly Diagnosed Patients

Field 04A: Incenter-Started for the First Time Ever. Enter the number of newly diagnosed ESRD patients who were admitted to your facility as chronic maintenance dialysis patients for the first time ever during the survey period. This is a count of patients who have begun their initial course of incenter maintenance dialysis therapy during the survey period and for whom your facility will have major medical responsibility. Do not include patients who transferred to your facility from another dialysis facility; that data is to be reported in field 06A.

Field 04B: Home-Started for the First Time Ever. Enter the number of newly diagnosed ESRD patients who, after being stabilized on dialysis, successfully completed a course of self-dialysis training and began home dialysis (their initial course of home dialysis after training) during the survey period. If they are still in training at the end of the survey period, report them in field 04A.

Restarted Dialysis

Field 05A: Incenter-Restarted. Enter the number of patients who restarted incenter dialysis during the survey period. This is a count of persons who had temporarily recovered kidney function, had discontinued dialysis, or had been lost to follow-up but restarted routine incenter dialysis during the survey period.

Field 05B: Home—Restarted. Enter the number of patients who restarted home dialysis during the survey period. This is a count of patients who had temporarily recovered kidney function, had discontinued dialysis, or had been lost to follow-up but restarted regular home dialysis during the survey period.
**Transferred From Another Facility**
NOTE: Include those patients who received their first outpatient dialysis (or transplant) at a Non-Medicare facility including a prison or a facility in another country. Do not count patients who have transferred in for transient treatments (less than 30 days).

Field 06A: Incenter - Transferred from Other Dialysis Unit. Enter the number of patients admitted to your facility who were formally transferred from another dialysis facility during the survey period and who are continuing a regular course of dialysis at your facility. A formal transfer is the transfer of a patient, including his/her medical records, to another facility that will permanently become the primary care provider.

Field 06B: Home-Transferred from Other Dialysis Unit. Enter the number of home patients who were formally transferred by another facility during the survey period to your unit for ongoing medical supervision and responsibility. A formal transfer is the transfer of a patient, including his/her medical records, to another facility that will permanently become the primary care provider.

**Returned After Transplantation**
NOTE: Do not include dialysis patients who are post transplant and are waiting for their graft to function. Include only those patients for whom a physician has written a prescription for a regular course of dialysis (at least 3 times per week).

Field 07A: Incenter - Returned After Transplantation. Enter the number of patients who returned to incenter dialysis during the survey period after a transplant failure. (Do not include patients in this field who are on temporary backup dialysis due to an Acute failure episode or patients receiving dialysis post transplant while waiting for their graft to function.)

Field 07B: Home-Returned After Transplantation. Enter the number of patients who returned to home dialysis during the survey period after a transplant failure. (Do not include patients in this field who are on temporary backup dialysis due to an Acute failure episode or patients receiving dialysis post transplant while waiting for their graft to function.)

**Losses During the Survey Period**
NOTE: These fields describe losses to your facility of both incenter and home patients that occurred during the survey period. For purposes of this survey, “incenter” includes patients who routinely dialyzed incenter at the time of loss to the reporting facility, and “home” includes patients who routinely dialyzed at home at the time of loss to the reporting facility.

**Deaths**
NOTE: If a patient death occurs within 30 days of stopping dialysis, then submit a CMS-2746, Death Notification Form, and count the patient as a death.

Field 08A: Incenter-Deaths. Enter the number of incenter dialysis patients who died during the survey period. These deaths must be shown in 08A if patient was on incenter dialysis at time of death.

Field 08B: Home-Deaths. Enter the number of home dialysis patients who died during the survey period. These deaths must be shown in 08B if patient was on home dialysis at time of death.

**Recovered Kidney Function**
Field 09A: Incenter -Recovered Kidney Function. Enter the number of patients who recovered function of their native kidneys and ceased chronic incenter dialysis during the survey period.

Field 09B: Home-Recovered Kidney Function. Enter the number of patients who recovered function of their native kidneys and ceased chronic home dialysis during the survey period.

**Transplanted**
NOTE: Any patient receiving a kidney transplant must be listed in this category, even if the graft never functioned.

Field 10A: Incenter -Received Transplant. Enter the number of patients who received a kidney transplant during the survey period.

Field 10B: Home-Received Transplant. Enter the number of patients who received a kidney transplant during the survey period.

**Transferred Out**
NOTE: Include patients who left the facility to dialyze elsewhere (at Medicare approved or non-Medicare approved facility) for more than 30 days. Include patients who have been involuntarily discharged regardless of where patients received services after discharge. Do not count patients who were dialyzing at your facility as a short-term transient patient.

Field 11A: Incenter -Transferred to Other Dialysis Unit. Enter the number of incenter dialysis patients who permanently transferred to another dialysis facility for their ongoing dialysis during the survey period; that is, those patients whose ongoing, routine medical supervision became the responsibility of another dialysis facility.

Field 11B: Home-Transferred to Other Dialysis Unit. Enter the number of home patients who had been followed by your facility but who are now permanently followed by another home dialysis program.

**Discontinued Dialysis**
NOTE: These fields should contain counts of patients whose last known activity was that they discontinued dialysis. This would pertain mostly to patients who were lost to the facility at the end of the survey period, were not lost to follow-up and had not yet expired by December 31 (a Death Notification Form has not yet been submitted on the patient). You must follow the patient for 30 days after his/her last dialysis session. If a patient death occurs within 30 days of stopping dialysis, then submit a CMS-2746, Death Notification Form, and count the patient as a death.

Field 12A: Incenter -Discontinued Dialysis. Enter the number of chronic patients who permanently discontinued dialysis (excluding those reported in fields 08A, 09A, 10A, 11A and 13A) who had been dialyzing incenter during the survey period.

Field 12B: Home-Discontinued Dialysis. Enter the number of chronic patients who permanently discontinued dialysis (excluding those reported in fields 08B, 09B, 10B, 11B and 13B) who had been dialyzing at home during the survey period.

**Lost to Follow-Up**
NOTE: Do not use this event when a patient has voluntarily discontinued dialysis (report in Fields 12A or 12B) or has transferred out to another facility (report in Field 11A or 11B). Patients should be included only after every effort has been made to locate the patient.

Field 13A: Incenter – Other - Lost to Follow-Up (LTFU). Enter the number of patients, who had been dialyzing incenter, who left your dialysis program during the survey period, and whose current status is unknown to your facility (lost to follow-up) Do not include those patients reported in fields 08A, 09A, 10A, 11A, or 12A.

Field 13B: Home- Other - Lost to Follow-Up (LTFU). Enter the number of patients, followed by your facility, who had been dialyzing at home, who were removed from your facility's rolls during the survey period, and whose current status is unknown (lost to follow-up). Do not include those patients reported in fields 08B, 09B, 10B, 11B, or 12B.

**Patients Receiving Care at the End of the Survey Period**
NOTE: DO NOT COUNT A PATIENT IN MORE THAN ONE FIELD. Patients receiving care at the beginning of the survey period plus the additions during the survey period minus the losses during the survey period should equal the patients receiving care (remaining) at the end of the survey period. Please ensure that field 03 plus field 04A through 07B, minus fields 08A through 13B, equals field 26.

**Incenter Dialysis**
NOTE: Patients who are dialyzing incenter, but are performing all dialysis procedures without the assistance of staff, are to be counted incenter self-dialyzing either in fields 14 or 15. (Since this is not a large patient population, not all facilities will have patients that fall into this category.) Treatments for these patients should be counted as outpatient treatments in fields 36 or 37.
Field 14: Hemodialysis. Enter the number of patients who, at the end of the survey period, were receiving staff-assisted hemodialysis or performing incenter self-hemodialysis.

Field 15: Other Dialysis. Enter the number of patients who, at the end of the survey period, were receiving dialysis, other than hemodialysis. For example, those patients who are on staff-assisted intermittent peritoneal dialysis or performing incenter self-peritoneal dialysis would be counted in this field.

**Self-Dialysis Training**

Field 16: Hemodialysis. Enter the number of patients who are in a self hemodialysis training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to perform their own self-dialysis incenter or at home.

Field 17: Continuous Ambulatory Peritoneal Dialysis (CAPD). Enter the number of patients who are in a CAPD training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to independently perform CAPD.

Field 18: Continuous Cycling Peritoneal Dialysis (CCPD). Enter the number of patients who are in a CCPD training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to independently perform CCPD.

Field 19: Other Dialysis. Enter the number of patients who are in a self-dialysis training program, e.g., a self intermittent peritoneal dialysis (IPD) training program as of the end of the survey period. Patients are to be reported in this category only if the training is designed to enable them to perform their own self-dialysis incenter or at home.

Field 20: Total Incenter. Enter the total number of patients who are incenter status as of the end of the survey period (the sum of fields 14 through 19).

**Home Dialysis**

NOTE: Patients who are dialyzing at home with the assistance of staff provided by a dialysis supplier or facility should be counted as home patients (fields 21 through 24).

Field 21: Hemodialysis. Enter the number of patients who were hemodialyzing at home as of the end of the survey period.

Field 22: Continuous Ambulatory Peritoneal Dialysis (CAPD). Enter the number of patients who are on CAPD as of the end of the survey period.

Field 23: Continuous Cycling Peritoneal Dialysis (CCPD). Enter the number of patients who are on CCPD as of the end of the survey period.

Field 24: Other Dialysis. Enter the number of patients who are on another type of home dialysis e.g., intermittent peritoneal dialysis (IPD) as of the end of the survey period.

Field 25: Total Home. Enter the total number of patients who are in home status as of the end of the survey period (the sum of fields 21 through 24).

**Total**

Field 26: Total. Enter the total number of patients on your facility's register at the end of the survey period (the sum of fields 20 and 25).

**Patient Eligibility Status-End of Survey Period**

NOTE: Counts should reflect entitlement only, not based on how reimbursement is made for dialysis services provided by your facility. For example, a VA (Department of Veterans Affairs) patient whose reimbursement is made by the VA, but is a Medicare entitled patient, should be counted in Field 27. Please ensure that the sum of fields 27, 28, and 29 equals field 26, the total number of patients at the facility at the end of the survey period.

Field 27: Currently Enrolled in Medicare. Enter the number of patients at the end of the survey period who were enrolled in Medicare. This count should include patients who are Medicare Secondary Payer beneficiaries or patients enrolled in Medicare HMO/Medicare+Choice.

Field 28: Medicare Application Pending. Enter the number of patients at the end of the survey period who had Medicare applications pending.

Field 29: Non-Medicare. Enter the number of patients at the end of the survey period who were not enrolled in Medicare and who did not have Medicare applications pending.

**Patients Dialyzing More Than 4 Times Per Week**

Note: Report only those patients on hemodialysis as of December 31 and dialyzing more than 4 times per week. Nocturnal dialysis is defined as hemodialysis that takes place while the patient is sleeping for approximately 8 hours.

Field 30A: Incenter/Day. Enter the number of hemodialysis patients who are dialyzing incenter, and during the day, for more than 4 times per week.

Field 30B: Home/Day. Enter the number of hemodialysis patients who are dialyzing at home, and during the day, for more than 4 times per week.

Field 31A: Incenter/Nocturnal. Enter the number of hemodialysis patients who are dialyzing incenter and nocturnal for more than 4 times per week.

Field 31B: Home/Nocturnal. Enter the number of hemodialysis patients who are dialyzing at home and nocturnal for more than 4 times per week.

**Vocational Rehabilitation**

NOTE: Enter the following information on each of the patients reported based on their activities at any time during the calendar year (January 1 through December 31). Information being provided is for patients, who as of December 31, are living and have attained the ages of 18 through 54. You can count patients as both attending school and employed either full-time or part-time.

Field 32: Patients Aged 18 through 54. Enter the number of dialysis patients who, as of December 31, were ages 18 through 54, and who were dialyzing at your facility.

Field 33: Patients Receiving Services from Voc Rehab. For the dialysis patients counted in Field 32, enter the number who are receiving Vocational Rehabilitation Services (public or private). Include any patients for whom any of the following applies:

- Talked with VR personnel AND agreed to be evaluated for services by completing an application, having medical records requested, or being assigned a counselor.
- Received evaluation services by participating in testing (for example: interest inventories, skills testing, aptitude testing, work readiness inventories) or by attending an evaluation/testing center.
- Received vocational counseling, training at a community facility private or public educational/training center or school.
- Received assistance with job seeking skills, with job placement, or with retaining or modifying a job through a VR counselor job placement specialist, private or public agencies.

Field 34: Patients Employed Full-Time or Part-Time. Enter the number of patients who are employed either full-time or part-time. Include any patient, aged 18 through 54, who received taxable wages from an employer or who was self-employed and paid taxes on earnings. Count only those patients who were receiving taxable earnings.

Fields 35: Patients Attending School Full-Time or Part-Time. Enter the number of patients who are attending school either full-time or part-time. Include any patient, aged 18 through 54, who was enrolled in any formal education or training program (for example: college, technical school, GED program, community facility training).

**TREATMENT AND STAFFING**

NOTE: The following section (fields 36 and 37) should reflect all outpatient treatments given to ESRD patients including self-care training treatments and those provided to transients during the survey year. Please be certain to report treatments to correspond with patients counted at the end of the survey period in a particular modality. If a situation occurs where a patient is reported at the end of the survey period but no treatments were provided, please explain why no treatments were provided in the Remarks section of the survey form. **DO NOT INCLUDE ACUTE TREATMENTS.**
Field 36: Outpatient Treatments. Enter the number of staff-assisted treatments, training hemodialysis treatments and treatments performed by self-dialyzing patients, incenter, during the survey period.

Field 37: Other Treatments. Enter the number of all other types of treatments provided incenter. For all types of peritoneal dialysis training, report the number of days for which exchanges were provided. Do not report the number of exchanges and do not report days where no dialysis treatments or exchanges were furnished. For example, report the number of staff-assisted and training intermittent peritoneal (IPD) treatments, CAPD and CCPD training days and all other number of treatments performed by self-dialyzing patients or training patients, incenter, during the survey period.

**Staffing**

Enter the number of Full Time and Part Time staff positions at your facility as of December 31. Also provide the number of Full Time and Part Time staff positions that are open and not filled as of December 31.

The following definitions are provided as guidelines in completing this section:

- **Full Time Position** is defined as a position with at least 32 hours employment per week.
- **Part time Position** is defined as a position with less than 32 hours per week and includes per diem staff.

**RN:** Staff holding a Registered Nurse degree.

**LPN/LVN:** Licensed Practical Nurse, Licensed Vocational Nurse: Staff holding either of those degrees.

**PCT:** Patient Care Technician. Include staff providing direct patient care.

**APN:** Advanced Practice Nurse. 10

The Advanced Practice Nurse (APN) is a Certified Registered Nurse (RN) with advanced certification as a nurse practitioner (NP) or a Clinical Nurse Specialist (CNS) who has met advanced educational and clinical practice requirements. Do not report Certified Nephrology Nurses (CNNs) in this category. Do not double count a registered nurse in this category.

**Dietitian:** Renal Dietitians. Staff with renal dietitian credentials.

**Social Worker:** Staff with LCSW, MSW, BSW or other professional social work degrees.

**Field 38:** Enter the number of Full Time staff as of December 31: a) Registered Nurses, b) Licensed Practical Nurses/Licensed Vocational Nurses, c) Patient Care Technicians, d) Advanced Practice Nurses, e) Dietitians, and f) Social Workers.

**Field 39:** Enter the number of Part Time staff as of December 31: a) Registered Nurses, b) Licensed Practical Nurses/Licensed Vocational Nurses, c) Patient Care Technicians, d) Advanced Practice Nurses, e) Dietitians, and f) Social Workers.

**Field 40:** Enter the number of Full Time staff positions that are open as of December 31: a) Registered Nurses, b) Licensed Practical Nurses/Licensed Vocational Nurses, c) Patient Care Technicians, d) Advanced Practice Nurses, e) Dietitians, and f) Social Workers.

**Field 41:** Enter the number of Part Time staff positions that are open as of December 31: a) Registered Nurses, b) Licensed Practical Nurses/Licensed Vocational Nurses, c) Patient Care Technicians, d) Advanced Practice Nurses, e) Dietitians, and f) Social Workers.

**Signatures**

Part One of the Facility Survey requires signatures, as follows:

Completed by: Enter the date completed and the name, title, and telephone number of the person who completed the Facility Survey for your facility.

This person should be the individual who the ESRD network or CMS can contact to discuss any information provided in the Facility Survey.

**KIDNEY TRANSPLANTS PERFORMED**  
**(FOR COMPLETION BY KIDNEY TRANSPLANT CENTERS ONLY)**

**NOTE:** Every kidney transplant must be reported in this category, even if the transplant never functioned.

**PATIENTS/TRANSPLANTS**

**Field 42:** Patients Who Received Transplant at This Facility. Enter the number of patients who received a kidney transplant at your facility during the survey period. If a patient received more than one transplant at your center during the survey period, the patient is to be counted only once. Total of fields 43 + 44 + 45 + 46.

**Patient Eligibility Status of Patients Transplanted During Survey Period**

**NOTE:** Fields 43 through 46 refer to those patients actually transplanted during the survey period. Ensure that the total of fields 43 through 46 equals the count in field 42. Fields 45 and 46 (Non-Medicare U.S. Residents and Other) makes reference to foreign nationals. A foreign national is any person who is not a U.S. citizen, and includes permanent resident aliens.

Field 43: Currently Enrolled in Medicare. Enter the number of patients transplanted during the survey period who were enrolled in Medicare.

Field 44: Medicare Application Pending. Enter the number of patients transplanted during the survey period that had Medicare applications pending.

Field 45: Non-Medicare, U.S. Residents. Enter the number of patients transplanted during the survey period who were not enrolled in Medicare and did not have Medicare applications pending who were either U.S. citizens or a foreign national U.S. resident.

Field 46: Non-Medicare, Other. Enter the number of patients transplanted during the survey period who were not enrolled in Medicare, did not have Medicare applications pending, and were neither a U.S. citizen nor a U.S. resident (e.g., foreign national).

**Transplants Performed at This Facility**

**Field 47:** Transplants Performed at This Facility-Living Related Donor. Enter the number of living related donor kidney transplants performed at your center during the survey period.

**Field 48:** Transplants Performed at This Facility-Living Unrelated Donor. Enter the number of living unrelated donor kidney transplants performed at your center during the survey period.

**Field 49:** Transplants Performed at This Facility-Deceased Donor. Enter the number of deceased donor kidney transplants performed at your center during the survey period.

**Field 50:** Transplants Performed at This Facility-Total. Enter the sum of fields 47 + 48 + 49.

**Patients Waiting Transplant**

**Field 51:** Patients Awaiting Transplant-Dialysis. Enter the number of current dialysis patients actively awaiting a kidney transplant at your center as of the last day of the survey period. These patients must (a) be medically able, (b) have given consent, and (c) be on an active transplant list. This count is limited to individuals awaiting transplant at the reporting center.

**Field 52:** Patients Awaiting Transplant-Non-Dialysis. Following the criteria described above, enter the number of non-dialysis patients who are awaiting transplant as of the last day of the survey period. This is to include patients scheduled for transplant who have not yet initiated a regular course of dialysis.

**Signatures**

Part Two of the Facility Survey requires signatures as follows:

Completed by: Enter the date completed and the name, title, and telephone number of the person who completed the Facility Survey for your facility.
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