

# Methods: end-stage renal disease

Did sea define the land or land the sea?  
Each drew new meaning from the waves' collision.  
Sea broke on land to full identity.

Seamus Heaney  
"LOVERS ON ARAN"

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In this appendix we present details on the USRDS database, its standardized working datasets and specialized code definitions, and our common data processing practices. We also describe the statistical methods used in this ADR. The researcher's guide to the USRDS database, available online, provides additional information about the database and standard analysis files.

### *data sources*

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

#### **REMIS/REBUS/PMMIS DATABASE**

The major source of ESRD patient information for the USRDS is the Renal Beneficiary and Utilization System (REBUS) of the Centers for Medicare and Medicaid Services (CMS, formerly HCFA), 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 who were incident after this date. This database is known as the Renal Management Information System (REMIS).

CMS updates the REMIS/REBUS/PMMIS database on a regular basis, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the Organ Procurement and Transplantation Network (OPTN) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notification forms (2746) obtained from renal providers, as well as the Standard Information Management System (SIMS) database of the ESRD networks. CMS has also established data integrity rules to ensure accurate identification of patients in the SIMS and CMS databases. Each ESRD patient is now 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 (EDB)**

The Medicare Enrollment Database is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payer (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

#### **ESRD MEDICAL EVIDENCE FORM (CMS 2728)**

The ESRD Medical Evidence (ME) form is used to register patients at the onset of ESRD, and must be submitted by dialysis or transplant providers within 45 days of initiation. The form establishes Medicare eligibility for individuals previously not Medicare beneficiaries, reclassifies previously eligible beneficiaries as ESRD patients, and provides demographic and diagnostic information on all new patients. The CMS, USRDS, and renal research communities rely on the form to ascertain patient demographics, primary diagnosis, comorbidities, and biochemical test results at the time of ESRD initiation. Before 1995, units were required to file the ME form only for Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients.



The third major revision of the ME form, in May, 2005, remedied several shortcomings of the 1995 form and its earlier version. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on glycosylated hemoglobin and lipid testing, on the frequency of hemodialysis sessions, and on whether patients are informed of transplant options.

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

#### **ESRD DEATH NOTIFICATION FORM (CMS 2746)**

The ESRD Death Notification form is used to report the death of ESRD patients. According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient's death, and provides the date and causes of death (primary and secondary), reasons for discontinuation of renal replacement therapy, if applicable, and evidence of hospice care prior to death. It is the primary source of death information for CMS and the USRDS, identifying more than 99 percent of deaths. The USRDS also utilizes the Social Security Administration's (SSA) Death Master File as a supplemental data source for ascertaining death in a small group of lost-to-follow-up ESRD patients; this file, however, identifies only all-cause deaths.

#### **OPTN TRANSPLANT DATABASE**

In the early 1980s CMS began collecting data on all Medicare kidney transplants. In 1988, the United Network of Organ Sharing (now OPTN) was created to provide a national system for allocating donor organs. 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 ME forms indicating transplant as the initial modality are not included in either file. To resolve conflicts among the three sources,

the USRDS adopts the following procedure:

- OPTN transplants are accepted into the database.
- CMS transplants before 1988 are accepted.
- CMS transplants from 1988 to 1993 are accepted if there is no OPTN transplant record for that patient within 30 days of the CMS transplant.

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

#### **CMS STANDARD ANALYTICAL FILES (SAFS)**

These files contain billing data from final action claims, submitted by Medicare beneficiaries with ESRD, in which all adjustments are resolved. For inpatient/outpatient institutional claims we use the following data: inpatient, 100 percent SAF; outpatient, 100 percent SAF; home health agency (HHA), 100 percent SAF; hospice, 100 percent SAF; and skilled nursing facility (SNF), 100 percent SAF. For physician/supplier claims, we use: physician/supplier, 100 percent SAF; and durable medical equipment (DME), 100 percent SAF.

CMS SAFS are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2013 ADR includes all claims up to December 31, 2011. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2012.

Inpatient transplant and outpatient dialysis claims records are used to identify new ESRD patients for whom no ME form has been filed. These patients, primarily non-Medicare patients, or beneficiaries who develop ESRD while 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 ME 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 data on incidence and prevalence.

The problem of timely identification has lessened with the revision of the ME 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.

#### **CMS 5 PERCENT STANDARD ANALYTICAL FILES (SAFS)**

These files contain billing data from final action claims submitted by Medicare beneficiaries, in which all adjustments have been resolved. The claims data are selected randomly from general Medicare claims (final action claims) using five combinations of the last two digits of the CMS Health Insurance Claims (HIC) number: 05, 20, 45, 70, and 95. Since the same two-digit numbers are used each year, one should expect to see the same beneficiaries in these annual datasets. These claims are categorized into the inpatient (IP), outpatient (OP), home health agency (HHA), hospice (HS), skilled nursing facility (SNF), physician/supplier (PB), and durable medical equipment (DME) SAFS.

The files are updated each quarter through June of the next year, when 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 2013 ADR includes all claims up to December 31, 2011.

#### **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 ME form, the USRDS could establish the first ESRD service date, but could not generate a more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can now address issues in the non-Medicare ESRD population such as the large and growing number of lost-to-follow-up patients, and look as well at patients for whom there previously were no data on initial modality or death. This data integration is detailed in the section on data management and preparation.

#### **CMS DIALYSIS FACILITY COMPARE DATA**

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

#### **ESRD CLINICAL PERFORMANCE MEASURES PROJECT**

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

In anticipation of the national release of the CROWNWEB system and its supporting performance measures reports, CMS concluded its CPM project in 2009, making 2008 its final survey year. CMS is currently working with ESRD communities to develop new CPM measures on the CROWNWEB system.

#### **MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)**

The Medicare Current Beneficiary Survey is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. The MCBS contains information on the health status, health care use and expenditures, drug prescriptions, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. Data are made available by CMS in two datasets: Access to Care (1992-2010), and Cost and Use (1992-2009), with the 2010 and 2009 files, respectively, the latest updates for the 2013 ADR.

In the fall of 1991, the MCBS began to be conducted three times per calendar year (winter, summer, and fall), and in 1994 a sample rotation scheme was introduced. Survey participants are kept in the sample for four years, with approximately one-third rolling off, and with new participants added each fall to keep the overall sample size at approximately 12,000 each calendar year.

#### **CMS PRESCRIPTION DRUG EVENT (PDE) FILE**

In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. The PDE record contains 37 data elements; the USRDS receives PDE records with 30 data elements and excluding a few non-critical fields. Each

drug is identified by a National Drug Index (NDC) code; the record also contains prescription dosing information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (TROOP) amounts, plan paid amounts, and low-income cost-sharing subsidy amounts.

Due to delays in the availability of the data, only the 2006 and 2007 PDE files were available for the 2010 ADR; 2008 PDE data were included in the 2011 ADR. Starting with the 2012 ADR, however, PDE data had caught up with ESRD claims, so 2009 and 2010 PDE data were both included in that ADR. The USRDS 2013 ADR includes 2011 PDE data.

#### **TRUVEN HEALTH MARKETSCAN DATA**

The Truven Health (formerly Thomson Reuters) MarketScan Commercial Claims and Encounters Database includes specific health services records for employees and their dependents in a selection of large employers, health plans, and government and public organizations. The database includes nine files: Annual Enrollment Summary Table, Enrollment Detail Table, Inpatient Admissions Table, Inpatient Services Table, Outpatient Services Table, Outpatient Pharmaceutical Claims Table, Facility (Inpatient and Outpatient) Header Table, Aggregated Populations Table, and the Red Book (prescription drug information by National Drug Code). The strength of this database lies in the quality of its cost information, where claims data include actual paid dollars and net payments by the insurer.

The database links billing and encounter data to detailed patient demographic and enrollment information across sites and types of providers, and over time from 1999 to 2011, and includes commercial health data from approximately 100 payers; about 80 percent of those covered are self-insured. Each year the database contains health data for about 10.5 million people. For details about the data, please visit [www.USRDS.org](http://www.USRDS.org).

#### **CLINFORMATICS DATAMART DATA**

The Clinformatics DataMart (formerly Ingenix i3) database is a commercial, non-capitated health plan database covering employees from multiple employers within a single insurer. In addition to the usual service encounter and drug data, it also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. To protect the discount structure of its business, the billing data of this single insurer discloses only charged dollars without actual paid amounts or the portion paid by the insurer.

The database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2011, and contains health data for about 14 million people annually. For details about what is contained in the data, please visit our website at [www.USRDS.org](http://www.USRDS.org).

#### **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 1999–2010 were nationally representative cross-sectional surveys and used a complex, stratified, multi-stage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

#### ANNUAL FACILITY SURVEY (AFS)

Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS's Annual Facility Survey (CMS 2744), which all Medicare-certified dialysis units must complete at the end of each year. The AFS reports counts of patients being treated at the end of the year, new ESRD patients starting treatment during the year, and patients dying during the year. Both Medicare and non-Medicare end-of-year patients are counted. While AFS files do not carry patient-specific demographic and diagnosis data, they provide independent patient counts used to complement the CMS patient-specific records. Starting with the 2005 AFS, CMS stopped posting data from these surveys on the web. And beginning with the 2007 ADR, the USRDS has extracted the relevant facility survey data directly from the SIMS database.

#### CDC SURVEILLANCE

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

#### UNITED STATES CENSUS

In rate calculations throughout this year's ADR we use data from the 2000 and 2010 U.S. Census, and also incorporate CDC population estimates by race. Our methods are described on later in this appendix.

#### *data management & preparation*

Our main computer system is based on a VMS cluster running Alpha EV6 processors. We currently maintain three nodes in the cluster: three 4-CPU (i.e. Alpha EV6 processor) servers, each at 1.25 GHz with 16-GB RAM memory. Through the HP Advanced Server System, we map VMS directories to network shares accessible to Windows clients as mapped network drives. The Alpha EV6s are connected to 100 terabytes of RAID-5 (Redundant Array of Independent Disks, level 5) disk farms, which are managed by three interconnecting high-speed disk controllers via Fibre Channel. All data in disk farms are independently accessible through Alpha server nodes.

We use SAS database management system and development tools as our core database technology platform; this differs from the Oracle RDBMS system used by the previous contractor only in

physical data allocation and management. All information in the earlier system was integrated into the new database, and its continuity and completeness are maintained.

#### DATA LOADING AND CLEANING

The USRDS receives data files in IBM 3490 and 3490E cartridges/CD-ROMS with EBCDIC, ASCII, or SAS formats. Due to increased awareness of and concerns over data security and patient privacy protection, in 2008 CMS began delivering most of the USRDS requested data via a dedicated and secured T1 line connection. CMS has also instituted data encryption procedures on all out-bound data regardless of file format and transportation medium. Once loaded and decrypted, files are converted into SAS datasets for processing, and a series of data verification steps is completed to ensure data quality and integrity before updating the USRDS database.

#### DATABASE UPDATES

For this ADR, patient demographic and diagnosis data are updated through October, 2012, and Medicare inpatient/outpatient and physician/supplier claims through December 31, 2011.

#### ESRD PATIENT DETERMINATION

A person is identified as having ESRD when a physician certifies the disease on the CMS 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 if their ME forms have not been submitted. Patients who die soon after kidney failure without receiving dialysis are sometimes missed.

The ESRD First Service Date (FSD) is the single most important data element in the USRDS database, and each patient must, at a minimum, have a valid FSD. This date is used to determine the incident year of each new patient and the first year in which the patient is counted as prevalent. The date 90 days after the FSD is used as the starting point for most survival analyses.

The FSD is derived by taking the earliest of the date of 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. However, starting with the 2007 ADR, a patient entering into the ESRD program after December 31, 1994, has his or her FSD defined solely by the regular dialysis start date or the preemptive transplant date, whichever is earliest, on the ME form. This new method of determining the FSD aligns more closely to the methods used by CMS. After careful monitoring and repeated comparative analyses of the traditional USRDS method to the new ME method, the USRDS began applying the ME method to incident patients entering into the ESRD program on or after January 1, 1995.

#### MEDICARE AND 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 payer. 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), and must wait 30–33 months before becoming eligible to have Medicare as their primary payer. Some of these patients, particularly new patients since 1995, have FSDs established by ME 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 be included in patient counts for incidence, prevalence, and modality. Calculations of standardized mortality ratios, standardized hospitalization ratios, and standardized transplantation ratios, 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 or the OPTN transplant data, or to determine comorbidity or inpatient/outpatient and physician/supplier services. Because such data are limited, event rates that include these patients must be assessed with caution.

We continue to include ‘zz’ patients in the mortality rate calculations of the ADR. The USRDS, in working with CMS, has been able to resolve most of the ‘zz’ patients since the release of the ESRD Patient Database, REMIS, in the fall of 2003. According to our most recent assessment — performed during production of the 2007 ADR — we have determined that at least 99 percent of ‘zz’ patients have been resolved due to significant advancements in the REMIS/REBUS database system.

#### DEATH DATE DETERMINATION

After the ESRD First Service Date, the date of death is the most critical piece of information in the ESRD database. Death dates are obtained from several sources, including the CMS Medicare Enrollment Database, CMS forms 2746 (ESRD Death Notification form) and 2728 (ESRD Medical Evidence form), the OPTN transplant follow-up form, the ESRD Network SIMS database, and the Social Security Death Master File. Because multiple sources report death information for the same patient, one patient may have several reported dates. The USRDS therefore uses an algorithm to determine the date of death. EDB information is given first priority, and, in the absence of an EDB death date, other sources are evaluated in the following order: form 2746, form 2728, SIMS data, the transplant follow-up form, and, if no other death date is available, the Death Master file.

#### LOST-TO-FOLLOW-UP METHODOLOGY

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

Gaps frequently exist in the billing data upon which modality periods are based. The USRDS assumes that a modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to maintain it unless a transplant failure or death notification is encountered in the data. In the absence of a death notification, dialysis claims, or other confirmation of a continuing modality, a dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim. After this period the patient is declared lost-to-follow-up until the occurrence of a dialysis claim or transplant event.

Because Medicare may be the secondary payer for up to the first 30–33 months of ESRD, delaying the submission of Medicare dialysis claims, lost-to-follow-up categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data 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-follow-up patients in the prevalent population.

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

- The patient may have recovered renal function (RRF) and no longer have ESRD. For a valid patient classification, this event must occur within 180 days of the FSD, and the RRF period must persist for at least 90 days.
- The patient may have left the country.
- The patient may receive dialysis covered by a payer 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, AND REMIS DATABASES

We have worked 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. 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.

Treatment histories compiled by the USRDS rely on Medicare dialysis billing records, which contain no information on dialysis therapy or modality changes in non-Medicare patients. Beginning with the 2003 ADR, we incorporate treatment-specific information from the ESRD Networks’ SIMS event database to improve the tracking of these patients in the USRDS database, and of patients who are considered lost-to-follow-up. Efforts to integrate the USRDS, SIMS, and REMIS databases continue to pay dividends in reducing the number of lost-to-follow-up patients.

We continue to take a conservative approach to incorporating SIMS Event History data into the USRDS treatment history; as we

learn more about the data, we may expand this approach. We currently make the following updates on an annual basis:

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

Since 2007 we have included the RRF event in the modality sequence, reducing lost-to-follow-up episodes for prevalent patients. This event is now established in our database only if it occurs within the first 180 days of the FSD and lasts for at least 90 days, a definition more conservative than that in the SIMS event database.

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

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

#### **90-DAY RULE: OUTCOMES ANALYSES**

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

#### **SERUM ALBUMIN DATA**

The ME form reports albumin level along with the test’s lower limit, which indicates the testing method: bromocresol purple or bromocresol green, with lower limits of 3.2 and 3.5 g/dl, respectively.

In producing the 2004 ADR we found that, in 1995–2003, 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. Further analyses, however, showed that these patients are a representative cohort sample, with similar demographic distributions by age, gender, race, and

cause of ESRD to those of the overall ESRD population. For all figures in the 2005 and later ADRs which present serum albumin data from the ME form, we therefore include 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 USRDS and the CMS ESRD group have worked extensively on methods of categorizing patients by ESRD modality. While the ME 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 in 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 designating modality. Patients younger than 65 and in employer group health plans (EGHPs) 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 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 thus not recognized as being hemodialysis or peritoneal dialysis patients. Because these patients tend to have higher death and hospitalization rates, interpretations of modality-specific outcome data including them should be viewed with caution. These patients are included in the “all ESRD” category, which provides a more complete view of mortality and hospitalization with the least biasing of the data.

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

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

#### **PAYERS**

Information on payers is obtained from the CMS Medicare Enrollment Database. We also examine Medicare outpatient claims to identify patients for whom the EDB does not indicate Medicare as primary payer (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 payer sequence file to provide payer history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payers.

The construction of this file is similar to that of the treatment history file. Payer status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payer data are used to categorize a patient as MPP,

MSP with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payers. With this approach, the USRDS is now able to apply payer 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 ME 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 ME 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 ME form
- ♦ missing cause: no ICD-9-CM code listed

#### RACE AND ETHNICITY

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

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

Because of the small number of ESRD patients of some races, as well as the construction of the U.S. census data, we concentrate on white, African American, Native American (including Alaskan Native), and Asian (including Pacific Islander) populations. Data on patients of other races will be presented as their numbers increase.

#### EGHP COHORT

As mentioned, EGHP data in this year’s ADR are derived from the Truven Health MarketScan and Clinformatics DataMart 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 analytical demands, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

#### ESRD COHORT IN THE EGHP POPULATION

As the Truven Health MarketScan and Clinformatics DataMart databases provide no identifiable data elements, we cannot link them directly to the USRDS ESRD registry. To identify ESRD

patients we thus use a process similar to that of the registry. Transplant patients are identified by evidence of a transplant procedure or 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 service claims in at least 70 percent of treatment months. Treatment months are defined from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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

#### *precis*

In Figure p.1 we identify chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in patients from the 5 percent Medicare sample; these methods are also used to determine diabetic status and CHF in the ESRD population. 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 a qualifying ICD-9-CM diagnosis code of diabetes on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims. ICD-9-CM codes are as follows: CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.X1, 403.X0 (after October 1, 2006), 404.X2, 404.X3, 404.X0 and 404.X1 (after October 1, 2006), 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; congestive heart failure, 398.91, 402.X1, 404.X3, 422.XX, 425.XX 428.XX, and V42.1; diabetes, 250.XX, 357.2, 362.0X, and 366.41.

Costs for the “cost year” are determined for the entire calendar year for patients who have fee-for-service coverage and Medicare as primary payer. Because this analysis combines the ESRD cohort with the 5 percent Medicare sample, ESRD patients in the 5 percent sample are excluded.

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

Total transplant counts shown in Table p.a include all transplants performed in 2011, as reported by the OPTN. Transplants of unknown donor type are excluded from by-donor counts. New wait list counts include all patients added to the list for a kidney-alone or kidney-pancreas transplant in 2011; patients added at multiple centers are counted once. The total N on the wait list includes all patients listed for a kidney-alone or kidney-pancreas transplant as of December 31, 2011, regardless of when they first listed. If patients are added to the list in early 2010 and removed from the list before the end of the year, it is possible for a group to have more new patients than existing patients. Median time on the list is shown for patients on the list on December 31, 2011.

Data for Table p.2 are from the CMS Annual Facility Survey.

#### *healthy people 2020*

**OBJECTIVE CKD-3** Data for this objective include all patients in the 5 percent Medicare sample who are age 65 and older and who have hospitalized acute kidney injury (AKI) events in the given year



(1992–2011). Hospitalized AKI is defined by ICD-9-CM diagnosis code 584 in inpatient claims, and renal evaluation is identified by a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. CPT codes for urinary microalbumin measurement are identified from HEDIS 2008 specifications (HEDIS 2008, an NCQA program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

**OBJECTIVE CKD-D-12** The cohort includes general Medicare patients diagnosed with diabetes in each year, continuously enrolled in Medicare Parts A and B during the whole year, and age 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Methods of defining diabetes are described in the appendix of the CKD volume.

**OBJECTIVE CKD-4.1** The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the appendix of the CKD volume. Serum creatinine is identified through CPT codes 80047–80050, 80053–80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715–83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3, above.

**OBJECTIVE CKD-4.2** Methods and codes used to determine rates of glycosylated hemoglobin (A1c) testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify A1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients. Methods of defining diabetes are described in the appendix of the CKD volume.

**OBJECTIVE CKD-5** The cohort includes general Medicare patients diagnosed with both diabetes and chronic kidney disease in each year, continuously enrolled in Medicare Parts A and B during the entire year, and age 65 or older at the beginning of the year. Additionally, for 2006, patients are enrolled in Medicare Part D for at least six months; in 2007–2011, patients are enrolled in Medicare Part D during the entire year. Use of angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin II receptor blockers (ARBs) is defined by at least one prescription fill from either drug class during the year.

**OBJECTIVE CKD-8** Incident rates are calculated using the methods described for Chapter One. Overall rates are adjusted by age, gender, and race; rates by age are adjusted for gender and race;

rates by gender are adjusted for age and race; and rates by race and ethnicity are adjusted by age and gender.

**OBJECTIVE CKD-9.1** Rates of kidney failure due to diabetes are also calculated using the methods described for Chapter One, and adjustments are the same as those described for Objective CKD-8, above.

**OBJECTIVE CKD-9.2** This table uses data from the National Health Interview Survey (NHIS); all ages are included. Three-year data are used to estimate the prevalence of diabetes in the middle year, and the size of the population with diabetes is based on U.S. census data. The incident rate per million of ESRD caused by diabetes is calculated as the number of incident ESRD patients with a primary diagnosis of diabetes divided by the size of the population with diabetes in that group.

**OBJECTIVES CKD-10 & CKD-11.3** These tables use data from the newest version of the ME form. The cohorts include incident hemodialysis patients, with CKD-11.3 limited to those age 18 and older at initiation and with a known vascular access at that time. CKD-10 includes only patients for whom it is known whether they saw a nephrologist prior to initiation.

**OBJECTIVES CKD-11.1 & CKD-11.2** use data from the CMS ESRD Clinical Performance Measures (CPM) project. Included patients are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and access type represents the access used during the last quarter of the year, according to the CPM data.

**OBJECTIVE CKD-12** The cohort here includes patients younger than 70 in 2000–2010. Percentages are calculated as the number of patients placed on the deceased donor organ wait list or receiving a deceased donor transplant within one year of initiation, divided by the number of patients without a living donor available (i.e., patients receiving a living donor transplant are excluded), and are estimated using the Kaplan-Meier method.

**OBJECTIVE CKD-13.1** Data include patients from 1998–2008 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first of death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

**OBJECTIVE CKD-13.2** The cohort includes patients from 2001–2011 who are younger than 70 at the initiation of ESRD. Preemptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated in the usual way:  $100 \times (N/D)$ , where N = the number of preemptive transplants in the year and D = the number of ESRD patients in the year.

**OBJECTIVES CKD-14.1 & CKD-14.3** Cohorts for these tables include period prevalent dialysis patients in each calendar year, 2001–2011, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients). We exclude patients with unknown age or gender and those with an age calculated to be less than zero, as well as patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. Age is calculated on January 1, and race is defined from the ME form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis

patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

**OBJECTIVE CKD-14.2** Cohorts here include incident dialysis patients in each calendar year, 2001–2011. In addition to applying the same exclusion criteria described for Objectives 14.1 and 14.3, we further exclude patients with recovered kidney function. Age is calculated on the first ESRD service date. Patients are followed from the first service date until death, transplant, or 90 days after ESRD. Rates are estimated as the number of patients who die from any cause per 1,000 patient years at risk.

**OBJECTIVES CKD-14.4–5** Patient cohorts here include period prevalent transplant patients, 2001–2011, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment (incident patients). Exclusion criteria are the same as those described for Objectives 14.1 and 14.3. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.4) and who die from cardiovascular disease (Objective 14.5) in each year, per 1,000 patient years at risk.

## *incidence, prevalence, & modalities* chapter one

### INCIDENCE & PREVALENCE

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

Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS are not included in the database. We therefore qualify the terms incidence and prevalence as incidence and prevalence of reported ESRD. Some ESRD registries use the term "acceptance into ESRD therapy." We believe, however, that "incidence of reported ESRD therapy" is more precise, because "acceptance" implies that remaining patients are rejected, when they may simply not be identified as ESRD cases or may not be reported to CMS. Beginning with the 1992 ADR, lost-to-follow-up patients are not included in the point prevalent counts; they are, however, reported in Table B.1 of the Reference Tables.

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, gender, and race; rates by age are adjusted for gender and race; rates by race or ethnicity are adjusted for age and gender; and rates by primary diagnosis are adjusted for age, gender, and race. Census data rate calculations are now based on intercensal estimates; for details, see the section on census populations later in this appendix.

Figures 1.17 and 1.19 show patient distribution by modality and payer among ESRD incident and point prevalent populations,

respectively. Medicare HMO refers to patients with Medicare Advantage or Medicare+Choice plans. The detailed discussion of payer categories can be found in the database definitions section at the beginning of this appendix.

Figures 1.18 and 1.20 report home dialysis patient distribution by therapy type among incident and point prevalent populations, respectively.

### PATIENT CARE AND LABORATORY VALUES

Table 1.f includes data on pre-ESRD nephrologist care of incident ESRD patients with ME forms.

Figure 1.21 includes incident hemodialysis patients during July–December, 2011. Vascular access data based on the ME form include only those patients with a valid ME form at initiation. For the other measures, eligible patients are those with at least one outpatient dialysis claim within 14 days after each time point (day 1 or day 90) and (when applicable) age 65 or older at initiation. For these measures, vascular access is determined from the first outpatient dialysis claim after each time point, using the HCPCS modifier codes: v5, catheter; v6, arteriovenous graft; v7, arteriovenous fistula.

Figure 1.22 includes 2011 incident hemodialysis patients with ME forms. Access type is identified from the ME form, and data exclude patients with unknown access type.

Data for Figures 1.23–24 and Table 1.g are also obtained from the ME form.

### REFERENCE SECTION A

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31 point prevalence (Section B). Section B also presents annual period prevalent counts and counts of lost-to-follow-up patients. Because the U.S. population figures (shown in Reference Section M) used in the ADR include only residents of the 50 states and the District of Columbia, tables also focus on patients from these areas. Exceptions are Tables A.1, A.6, A.8, and A.10, all of which present data specific to patients in Puerto Rico and the Territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Rates in Table A.9 are calculated using the model-based method (described in the Statistical Methods section later in this appendix), and adjusted for age, gender, and race, with the 2010 national population as reference.

### REFERENCE SECTION B

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

### REFERENCE SECTION C

Data in these tables are based on information collected with the 1995 and 2005 ME forms. Table C.1 contains data on biochemical markers from 2003–2011. A new ME form was introduced in 2005 that included hemoglobin A1c, total cholesterol, LDL, and HDL. Data prior to 2005 on mean values reported for these markers may be unreliable due to low numbers of patients. BUN was dropped from the new 2005 form.

## TREATMENT MODALITIES

Modality figures 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-follow-up or having recovered renal function (RRF). The RRF event, introduced in the 2007 ADR, is defined as an event that occurs within the first 180 days of ESRD initiation and lasts for at least 90 days. By definition, patients classified as having RRF post-initiation are included in the incident counts. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined 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
- peritoneal dialysis: analyses typically consist of CAPD and CCPD only, unless stated otherwise
- 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 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 deceased 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)

In Tables 1.d–e, rates by age are adjusted for gender and race, rates by gender are adjusted for age and race, rates by race and ethnicity are adjusted for age and gender, and rates by primary diagnosis are adjusted for age, gender, and race.

## REFERENCE SECTION D

Reference Section D is divided into four parts. 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 day 90 and at two years after first service for all incident Medicare patients beginning renal replacement therapy from 2007 to 2009. 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.

The fourth section, Tables D.17–24, presents counts of incident and prevalent patients alive at the end of selected years (i.e. 2003, 2007, 2011), by demographic characteristics, payer category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients, and as of December 31 for point prevalent patients. The payer categories are:

- Medicare FFS (i.e. Medicare as primary payer)
- Medicare/Medicaid (i.e. dually eligible),
- MSP (i.e. Medicare as secondary payer): EGHP and non-EGHP
- HMO (i.e. Medicare Advantage or Medicare+Choice plans)
- other and unknown payers

The detailed discussion of payer categories can be found in the database definitions section at the beginning of this appendix.

## *clinical indicators, preventive health* chapter two

In Figure 2.1, the URR for prevalent hemodialysis patients in 2011 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. For the Kt/V measurement, 2008 ESRD CPM data are used to calculate a mean Kt/V value for each patient from the 1–3 values present for each, and the percent of patients with a mean Kt/V over a certain threshold is determined. Information on new hemodialysis patients with an AV fistula as the first access is determined from the ME form. Data on diabetic care are obtained from Figures 2.14, 2.15, and 2.17, while data for influenza vaccinations are from Table 2.a.

## ANEMIA TREATMENT

Figure 2.2 presents the monthly distribution of patients by mean hemoglobin group, with each month containing all hemodialysis patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by three. Figure 2.3 shows the mean hemoglobin, by month, for prevalent hemodialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. A patient's time at risk includes only those days in which he or she is not in an inpatient hospital setting.

Figures 2.4–6 include data from all incident hemodialysis patients with an EPO claim in the first 30 days of ESRD therapy and with 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 2011, 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 ME form, and their starting hemoglobin is determined from this value. In Figure 2.4, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 2.5, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only.

Figures 2.8–12 are the same as those used in Figures 2.2–6, but for peritoneal dialysis patients.

#### PREVENTIVE CARE

Figures 2.14–17 present data on diabetic preventive care. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; who have a missing date of birth; who do not survive the entire reporting period; who have ESRD for fewer than 90 days prior to the start of the reporting interval; or who are lost to follow-up during the study period.

Age is generally calculated at the end of the study period. Methods and codes used to determine rates of glycosylated hemoglobin (A1C) testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify A1C testing (claims made within 30 days of the last claim for each patient are excluded, and at least two A1C claims must be counted). Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715–83721, 84478, 83700, 83701, and 83704. Patients are defined as having diabetes either through medical claims (one inpatient/outpatient, two physician/supplier, two outpatient, or one physician/supplier and one outpatient), or through a listing of diabetes on the ME form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define diabetes are 250, 357.2, 362.0x, and 366.41. Comprehensive diabetic care includes at least four A1C tests, at least two lipid tests, and at least one eye exam. A1C and lipid tests are at least 30 days apart.

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

Table 2.a shows rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality, age, race/ethnicity, and time period. The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to September 1 of each year and alive on December 31. For pneumococcal pneumonia vaccinations, the cohort includes all ESRD patients initiating therapy at least 90 days before January 1 of the graphed time period and alive on December 31. And the cohort for hepatitis B vaccinations includes patients initiating therapy at least 90 days before January 1 of each year and alive on December 31. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, 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 have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Influenza vaccinations are tracked between September 1 and December 31 of each year, pneumococcal pneumonia vaccinations are tracked during the time periods reported, and hepatitis B vaccinations are tracked in each year. All ages are calculated at the end of the graphed time period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations through CPT codes 90670, 90669 and 90732, and HCPCS codes J6065, S0195, and G0009; and hepatitis B vaccinations through CPT codes 90636, 90740, 90743–90748, 90731, 90723, and G0010. Hepatitis B vaccinations are at least 30 days apart.

#### VASCULAR ACCESS

Data for Figures 2.18–20 are obtained from the ME form.

### *hospitalization* chapter three

Methods used to examine hospitalization in prevalent patients generally echo those used for the tables in Reference Section G (described below). Inclusion and exclusion criteria are generally the same, as are the methods for counting hospital admissions and days, and defining the follow-up time at risk. One difference is the exclusion in Section G of patients of races that are unknown or other than white, black/African American, Native American, or Asian; these patients are included in the Chapter Three figures. Included patients have Medicare as primary payer, with Parts A and B coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk divided by patient years at risk. The period at risk begins at the latest of January 1 or day 91 of ESRD, and censoring occurs at death, end of Medicare Parts A and B coverage, or December 31, in addition to other censoring criteria which vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions. Additionally, rehospitalization rates include the percentage of live hospital discharges that are followed by a subsequent hospital admission within 30 days.



Hospitalization data exclude inpatient stays for the purpose of rehabilitation therapy. Inpatient rehabilitation claims are identified by provider numbers; numbers for inpatient rehabilitation facilities include values 3025–3099 in the third through sixth positions or “R” or “T” in the third position.

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

Methods in Figures 3.1–2 follow those for Reference Section G. Figure 3.1 shows the percent change in admission rates since 1993 for period prevalent ESRD patients. Included patients have Medicare as primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or gender information. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2010. New dialysis access codes for peritoneal dialysis patients appeared in late 1998; dialysis access values are therefore shown for peritoneal dialysis patients as a change since 1999 rather than 1993. For peritoneal dialysis patients, dialysis access hospitalizations are those defined as “pure” inpatient vascular/dialysis access events, as described for Tables G.11–15. For hemodialysis patients, vascular access hospitalizations include “pure” inpatient vascular access events, and vascular access for hemodialysis patients excludes codes specific to peritoneal dialysis catheters (996.56, 996.68, and v56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infectious admissions. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 423–438, and 440–459, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598.0, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Figure 3.2 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, gender, race, and primary diagnosis, with the 2010 ESRD cohort used as the reference.

Figure 3.3 shows adjusted infectious and cardiovascular hospital day rates among prevalent ESRD patients. Again, rates are adjusted for age, gender, race, and primary diagnosis, with ESRD patients in 2010 used as the reference cohort. Principal ICD-9-CM codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1.

Table 3.a presents unadjusted and adjusted admission rates among adult (age 20 and older) period prevalent hemodialysis

patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 3.1, while codes for vascular access infection are 996.62 and 999.31. Rates are adjusted for age, gender, race, and primary ESRD diagnosis; values presented by one factor are adjusted for the other three. For adjusted rates, hemodialysis patients in 2010 are used as the reference cohort. Values by age, gender, race, and primary diagnosis are shown for 2010–2011 prevalent hemodialysis patients.

Figures 3.4–7 show adjusted infectious admission rates among period prevalent ESRD patients. These figures illustrate two different methods of classifying infection by diagnosis code type. The traditional method defines cause-specific admissions based on principal ICD-9-CM diagnoses, and these rates are interpreted as admissions for the reason of the stated condition. The other method uses both principal and secondary inpatient ICD-9-CM diagnoses recorded for hospital stays. In contrast, these rates are interpreted as admissions with the condition, and by definition, are more inclusive than those restricted to principal diagnoses. ICD-9-CM codes for infectious hospitalizations are listed in the discussion of Figure 3.1, and those for vascular access infection are listed for Table 3.a. Other infectious groups are as follows: bacteremia/sepsis, 038.0–038.9 and 790.7; peritonitis (peritoneal dialysis patients only), 567; and pneumonia, 480–486 and 487.0. Rates are adjusted for age, gender, race, and primary ESRD diagnosis. The reference cohort includes ESRD patients in 2010.

Figure 3.8 illustrates infectious hospital admission rates among period prevalent home hemodialysis and center hemodialysis patients. Rates are presented for admissions *with* infection and admissions *for* infection, by diagnosis code type as described for Figures 3.4–7 and using the ICD-9-CM codes for infection listed for Figure 3.1. Similar to Figures 3.4–7, analyses are intent-to-treat regarding dialysis modality, and patients are followed from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Parts A and B coverage, or December 31. Rates in Figure 3.8, however, are unadjusted.

Figures 3.9–13 display adjusted cardiovascular admission rates, using methods parallel to those used for 3.4–7. ICD-9-CM codes for cardiovascular admissions are listed for Figure 3.1, and other groups are as follows: AMI: 410.X0 and 410.X1; CHF: 398.91, 402.X1, 404.X1, 404.X3, 425, and 428; CVA/TIA: 430–437; and dysrhythmia: 426–427.

Figures 3.14–20 show rates of rehospitalization and/or death among prevalent hemodialysis patients of all ages (age 66 and older in Figure 3.20), 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude rehabilitation claims and transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For hemodialysis patients in Figures 3.14–19, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For ESRD patients in Figure 3.20, the same exclusions apply except as related to transplant; discharges from transplant patients are excluded if they occur after two years and 11 months following the

most recent transplant to ensure that complete claims are available during the 30-day post-discharge period.

Figures 3.14–16 and 3.18–19 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Figures 3.14–15 include all-cause index hospitalizations, while in 3.16 categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1; vascular access infection codes are 996.62 and 999.31. Figures 3.18–19 include the codes for discharges from cardiovascular hospitalizations listed for Figure 3.1, and Figure 3.19 includes the codes for AMI, CHF, and dysrhythmia listed for Figures 3.9–13, in addition to stroke: 430–434.

Figure 3.17 indicates the percentage of hospital discharges followed by a 30-day rehospitalization by cause-specific groups for both the index hospitalization and the rehospitalization. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

Figure 3.20 shows overall percentages of discharges with 30-day rehospitalization and/or death in the general Medicare, CKD, and ESRD populations. Data include point prevalent Medicare patients on December 31, 2010 who are age 66 and older. For general Medicare patients with and without CKD, CKD is defined during 2010, and patients remain without ESRD, with continuous enrollment in Medicare Parts A and B, and without HMO coverage. Live hospital discharges from January 1 to December 1, 2011 are included.

#### REFERENCE SECTION G

Hospitalization reference tables present adjusted total admission and hospital day rates, by year, 1993–2011. 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 payer. Hospitalization data are obtained from institutional inpatient claims. As in Chapter Three, hospitalization data in Reference Section G also exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1–15 include dialysis and transplant patients on their modality for at least 60 days, reaching day 91 of ESRD by the end of the year, and residing in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, gender, or race; and patients of races that are unknown or other than white, African American, Native American, or Asian. Age is determined on January 1 of each year. Patients are also classified according to their primary cause of ESRD, in which the “other” category includes patients with missing data or causes other than diabetes, hypertension, or glomerulonephritis.

Patients are classified by modality at the beginning of the year:

- all dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as those on more than one modality in the past 60 days
- hemodialysis: patients on hemodialysis for at least 60 days as of the start of the period at risk
- CAPD/CCPD: patients 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 do not have Medicare coverage but do have Medicare as a secondary payer or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare Parts A and B coverage at the start of follow-up. The follow-up period is censored when a patient’s payer status changes to no longer having Medicare Parts A and B coverage or Medicare as a primary payer.

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, end of Medicare Parts A and B coverage, 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, end of Medicare Parts A and B coverage, 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, end of Medicare Parts A and B coverage, or December 31 of the year. The censoring of transplant patients at three years following the transplant is necessary because Medicare eligibility may be lost and hospitalization data may be incomplete for these patients.

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

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

As in previous ADRs, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

The methodology for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the section on statistical methods). Predicted rates for each subgroup combination of age, gender, race, primary diagnosis, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ½. Adjusted rates are then calculated using the direct adjustment method, with all 2010 ESRD patients as the reference cohort.

Tables G.11–15 show inpatient utilization in period prevalent ESRD patients. Methods — including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations — generally follow those described for the total admission rates in Tables G.1–5, but some differences do exist. While patients of races other than white, African American, Native American, or Asian are excluded from G.1–5, they are included in G.11–15, except where rates are given by race. Rates are unadjusted and reflect total admissions per 100 patient years for 2003–2005, 2006–2008, and 2009–2011 (pooled) prevalent patients. While the rates for all causes are computed similarly to the unadjusted

rates in G.1–5, the other nine cause-specific categories only include admissions for specific diseases. Vascular access and peritoneal dialysis access hospitalizations are those classified as “pure” inpatient vascular/dialysis access events. Such access events are defined as admissions with a specified ICD-9-CM principal diagnosis code, or an ICD-9-CM principal procedure code in conjunction with a certain DRG code. Codes are listed in Table b. If an admission does not qualify as vascular/dialysis access, it is classified by the principal diagnosis code into one of eight other mutually exclusive groups. Categories and ICD-9-CM codes are as follows: circulatory diseases, 390–459; digestive diseases, 520–579; genitourinary diseases, 580–629; endocrine and metabolic diseases, 240–279; respiratory diseases, 460–519; infectious diseases, 001–139; and cancer, 140–172, 174–208, 230–231, and 233–234. 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.1.1–5.1 present adjusted rates similar to those shown in G.1–5, but include more patient subgroups. Additional tables (G.1.2–5.2) display the counts of the total admissions, patient years at risk, and total patients that are used to calculate the total admission rates. Standard errors of the rates in Tables G.1–10 and G.1.1–5.1 are also available.

## cardiovascular disease chapter four

Data for Figure 4.1 are obtained from Reference Table H.12.

Table 4.a displays the relative risk of a cardiovascular diagnosis or procedure, by age, gender, race, ethnicity, and modality. The cohort includes point prevalent hemodialysis, peritoneal dialysis, and transplant patients with Medicare as primary payer on

### a CPT codes for vascular access & peritoneal dialysis access services

Complication 34101\*, 35190\*, 35321\*, 35458\*, 35460\*, 35475\*, 35476\*, 35484\*, 35875\*, 35876\*, 35900\*, 35903\*, 35910\*, 36005\*, 36145, 36534\*, 36535\*, 36550\*, 36575\*, 36580\*, 36581\*, 36584\*, 36589\*, 36593, 36596\*, 36597\*, 36815, 36831, 36832, 36833, 36834\*, 36838, 36860, 36861, 36870, 37190\*, 37201\*, 37205\*, 37206\*, 37207\*, 37208\*, 37607, 49422, 75790, 75820\*, 75860\*, 75896\*, 75960\*, 75962\*, 75978\*, 75998\*, 76937\*, 77001, 00532\*, 01784\*, 01844\*, 90939, 90940, G0159, G0392, G0393, and M0900  
Hemodialysis catheter placement 36011\*, 36488\*, 36489\*, 36490\*, 36491\*, 36533\*, 36555\*, 36556\*, 36557\*, 36558\*, 36565\*, and 36800  
Peritoneal dialysis catheter placement 49419, 49420, and 49421  
Synthetic graft placement 36830  
Fistula placement 36818, 36819, 36820, 36821, and 36825  
Other placement 36810, 36835

\*Requires accompanying renal diagnosis code for inclusion.

This list is comprehensive and includes codes that are now obsolete, but that were in use at some point during the study period.

### b DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access services

DRG codes: prior to October 1, 2007  
112 Percutaneous cardiovascular procedure 120 Other circulatory system OR procedure 315 Other kidney and urinary tract OR procedure 442 Other OR procedure for injuries with complication 443 Other OR procedure for injuries without complication 478 Other vascular procedure with complication 479 Other vascular procedure without complication  
DRG codes: after September 30, 2007  
252 Other vascular procedures with Major complicating conditions (MCC) 264 Other circulatory system O.R. procedures 673 Other kidney & urinary tract procedures with MCC 674 Other kidney & urinary tract procedures with CC 675 Other kidney & urinary tract procedures without CC/MCC 907 Other O.R. procedures for injuries with MCC 908 Other O.R. procedures for injuries with CC 909 Other O.R. procedures for injuries without CC/Medicare  
ICD-9-CM procedure codes<sup>a</sup>  
38.95 Venous catheterization for renal dialysis 39.27 Arteriovenostomy for renal dialysis 39.42 Revision of arteriovenous shunt for renal dialysis 39.43 Removal of arteriovenous shunt for renal dialysis 39.93 Placement of vessel-to-vessel cannula 39.94 Replacement of vessel-to-vessel cannula 86.07 Placement of totally implantable vascular access device  
ICD-9-CM diagnosis codes<sup>b</sup>  
996.1 Mechanical complication of vascular device, implant, graft 996.56 Mechanical complication due to peritoneal dialysis catheter 996.62 Infectious complication of vascular device, implant, graft 996.68 Infectious complication due to peritoneal dialysis catheter 996.73 Other complication due to renal dialysis device, implant, graft V56.1 Fitting and adjustment of extracorporeal dialysis catheter V56.2 Fitting and adjustment of peritoneal dialysis catheter

- a DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present).  
b The presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event.

January 1, 2009, who are continuously enrolled in Medicare Parts A and B from July 1, 2008 to December 31, 2008, and whose first ESRD service date is at least 90 days prior to January 1, 2009. We exclude patients with unknown age or gender and those with an age calculated to be less than zero or greater than 110. Follow-up is from January 1, 2009 until the earliest date of cardiovascular event, death, modality change, loss to follow-up, end of Medicare as primary payer status, recovery of renal function, or December 31, 2011. Patients with a cardiovascular event or procedure before 2009 are not excluded. The Cox model is used to evaluate potential risk factors for a cardiovascular diagnosis or procedure. Factors included in the model are age, gender, race, ethnicity, modality, and comorbidities, including atherosclerotic heart disease (ASHD), other cardiac disease, congestive heart failure (CHF), CVA/TIA, peripheral vascular disease (PVD), chronic obstructive pulmonary disease (COPD), gastrointestinal (GI) disease, liver disease, dysrhythmia, cancer and diabetes, each defined in the entry year 2008.

To define comorbidity, we use the Medical Evidence (ME) form and its listed primary cause of ESRD, along with Medicare claims during the entry period. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is considered 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:

- CHF: 398.91, 422, 425, 428, 402.XI, 404.XI, 404.X3, and V42.1
- CVA/TIA: 430–438
- PVD: 440–444, 447, 451–453, and 557
- diabetes: 250, 357.2, 362.OX, and 366.41
- ASHD: 410–414, V45.81, and V45.82
- other cardiac: 420–421, 423–424, 429, 785.0–785.3, V42.2, and V43.3
- COPD: 491–494, 496, and 510
- GI: 456.0–456.2, 530.7, 531–534, 569.84, 569.85, and 578
- liver disease: 570, 571, 572.1, 572.4, 573.1–573.3, V42.7
- dysrhythmia: 426–427, V45.0, and V53.3
- cancer: 140–172, 174–208, 230–231, 233

Cardiovascular events include CHF, CVA/TIA, peripheral arterial disease (PAD), cardiac arrest, and AMI, while treatments include percutaneous coronary interventions (PCI), coronary artery bypass graft (CABG) surgery, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy with defibrillator (CRT-D).

Cardiovascular events of AMI and CVA/TIA are identified from both Medicare claims data and the cause of death listed on the ESRD Death Notification form (2746), while CHF, PAD, and revascularization procedures (CABG and PCI) are identified from Medicare claims data only. Based on form 2746, an AMI event is defined if AMI is the primary cause of death (death code 23) or the secondary causes of death with cardiac death as the primary cause of death; a CVA/TIA event is defined if CVA/TIA is listed as either primary cause of death or secondary cause of death (death codes 36–37). Based on Medicare claims, the event dates of AMI, cardiac arrest, CHF, CVA/TIA, and PAD are defined as the date of

the first appearance of a qualifying ICD-9-CM diagnosis code in one or more Part A inpatient claims only (for AMI), 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 physician/supplier claims (for CHF, CVA/TIA, and PAD), or in one or more Part A or Part B claims (cardiac arrest). CABG surgery is identified through ICD-9-CM procedure codes in Part A inpatient claims, and PCI is identified through ICD-9-CM procedure codes in Part A inpatient and outpatient claims as well as CPT codes in Part A outpatient claims and Part B claims. PAD is also identified through ICD-9-CM procedure codes and CPT codes for amputation, using the same methods as described for PCI. Codes used to define these events include the following:

- AMI: 410, 410.X0 and 410.X1 (ICD-9-CM diagnosis codes)
- CHF: 398.91, 428, 402.XI, 404.XI and 404.X3 (ICD-9-CM diagnosis codes)
- CVA/TIA: 430–437 (ICD-9-CM diagnosis codes)
- PAD: 440–444, 447 and 557 (ICD-9-CM diagnosis codes); 84.0, 84.1, 84.91, 39.25, 39.26, and 39.29 (ICD-9-CM procedure codes); 24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, and 35671 (CPT codes)
- CABG: 36.IX (ICD-9-CM procedure code)
- PCI: 00.66, 36.01, 36.02, 36.05, 36.06, and 36.07 (ICD-9-CM procedure code); 92980–92982, 92984, 92995–92996, 60290 and 60291 (CPT codes)
- ICD/CRT-D: 37.94 and 00.51 (ICD-9-CM procedure code)
- cardiac arrest: 427.4 and 427.5 (ICD-9-CM diagnosis codes)

Figures 4.2–3 demonstrate event rates of first cardiovascular diagnoses and procedures per 1,000 patient years in 2009–2011, by age and modality, respectively. The cohort is the same as that described for Table 4.a.

Figure 4.4 illustrates, by modality, the unadjusted survival of patients with cardiovascular events or procedures. The study cohort is that described for Table 4.a, with a first cardiovascular event or procedure in 2009–2011 (index date). Patients are followed from the index date until the earliest date of death, modality change, transplant, loss to follow-up, recovery of renal function, two years after the index date, or December 31, 2011. The Kaplan-Meier method is used to estimate all-cause survival after a cardiovascular event or procedure.

Table 4.b describes rates of cardiovascular events and procedures in ESRD patients by modality. The cohorts include point prevalent hemodialysis, peritoneal dialysis, and transplant patients on January 1 of each calendar year from 1996 to 2011, whose first ESRD service date is at least 90 days prior to the beginning of the year, and who have Medicare Parts A and B coverage at the



beginning of the year. Patients with unknown age or gender, and those with an age calculated to be less than zero, are excluded. Patients having the disease or procedure of interest before January 1 of the year are not excluded. Follow-up begins on January 1 of each year and ends at the earliest of death, modality change, transplant, loss to follow-up, change of Medicare Parts A and B coverage, recovery of kidney function, or December 31 of the year. Rates are unadjusted, and are estimated as the number of patients who have a cardiovascular event or receive a procedure in each year per 1,000 patient years at risk.

The methodology and codes used to define cardiovascular events (AMI, CVA/TIA, CHF, PAD) and procedures (PCI and CABG) are the same as those introduced in Table 4.a.

Figures 4.5–6 present unadjusted event rates for a CHF diagnosis and an AMI event in point prevalent ESRD patients from 1996 to 2011. Cohort construction and rate estimation are the same as those described for Table 4.b.

Figures 4.7–9 present rates of sudden cardiac death (SCD) in prevalent dialysis patients. Figure 4.7 shows trends in SCD rates in prevalent dialysis patients from 1991 to 2011. The cohorts include period prevalent dialysis patients in each calendar year from 1991 to 2011 whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment during the year (incident patients), and who have Medicare Parts A and B coverage at the beginning of the year or on day 91 of ESRD of the year. We exclude patients with unknown age or gender, and those with an age calculated to be less than zero. Patients are followed from January 1 (for point prevalent patients) or day 91 of ESRD (for incident patients) until death, transplant, loss to follow-up, change of Medicare Parts A and B coverage, recovery of kidney function, or December 31 of the year. Rates are unadjusted, and are estimated as the number of SCD patients in each year per 1,000 patient years at risk.

Figures 4.8–9 present rates of SCD by race and modality in 2001, 2006, and 2011. In Figure 4.9, which compares rates in hemodialysis and peritoneal dialysis patients, follow-up time is also censored at a change in modality.

Two methods are used to identify SCD. The “simple method” identifies SCD based on the primary or secondary cause of death listed on form 2746, and consists of all deaths due to “cardiac arrhythmia” or “cardiac arrest, cause unknown.” The “complex method” includes three components: place of death and cause of death reported on form 2746, and diagnosis codes on Medicare claims. For deaths occurring in the hospital setting, an inpatient Medicare claim for ventricular fibrillation or cardiac arrest (ICD-9-CM diagnosis codes 427.4 or 427.5) and a primary cause of death due to cardiac disease (death codes 23 and 25–32 on form 2746) are required to classify a SCD. In the absence of claims evidence, SCD can be defined only if the primary cause of death is listed as “cardiac arrhythmia” or “cardiac arrest, cause unknown.” For deaths occurring in the outpatient setting, an outpatient Medicare claim for ventricular fibrillation or cardiac arrest and a primary cause of death due to cardiac disease or “unknown” on form 2746 are required to classify a SCD. In the absence of claims evidence, SCD is defined only if the primary cause of death is cardiac disease.

Deaths excluded from consideration are those due to hyperkalemia, septicemia, and malignant disease, and those occurring in

the setting of dialysis withdrawal or hospice care. Three sources are used to identify death occurring in the setting of dialysis withdrawal based on form 2746: 1) primary or secondary cause of death is listed as “withdrawal from dialysis/uremia;” 2) reason for discontinuation of renal replacement therapy prior to death is listed as “following HD and/or PD access failure” or “following chronic failure to thrive;” and 3) discontinuation of renal replacement therapy was after patient/family request to stop dialysis. Death in the setting of hospice care is defined if the answer to the question “Was patient receiving hospice care prior to death?” on form 2746 is “yes” or there is a hospice claim with date of death within the claim period. Both methods are used in Figure 4.7, and the “complex method” is used in Figures 4.8–9.

Figures 4.10–11 show the probability of SCD by race and modality in 2010 incident dialysis patients, using the “simple method” described above. The Kaplan-Meier method is used to estimate SCD-free survival, and cumulative probabilities of SCD are obtained by subtracting the cumulative survival probabilities from one. In Figure 4.11, follow-up time is also censored at change in modality.

Table 4.b describes pharmacological interventions for cardiovascular disease in ESRD patients. The cohort includes prevalent hemodialysis, peritoneal dialysis, and kidney transplant patients on January 1, 2011; with date of ESRD onset at least 90 days before January 1 and with Medicare as primary payer; followed until the earliest of death, change in renal replacement modality (i.e., change in dialytic modality, receipt of kidney transplant, or failure of kidney transplant), cessation of Medicare coverage (with either Part A or B), or December 31. First cardiovascular disease events in the follow-up interval are identified with the claims-based method, as described in Table 4.a. For CHF, events are identified by ICD-9-CM codes 398.91, 402.x1, 404.x1, 404.x3, 425.x, and 428.x. For AMI, events are identified by codes 410, 410.x0, and 410.x1 on inpatient claims. For CVA/TIA, events are identified by codes 430–437. And for all other diagnoses and procedures, events are identified with codes used in Table 4.a. The index date of each event is defined as the admission or service date of the first claim in the follow-up interval with a qualifying diagnosis code. Baseline cardiovascular disease is ascertained from claims during the one year preceding the index date; algorithms and codes are the same as those used in Table 4.a.

Because Table 4.c and Figures 4.12–17 describe pharmacological interventions, only a subset of cardiovascular disease events is retained for analysis. Specifically, each patient is required to be discharged within two weeks of the index date of the event (if the patient is hospitalized on the index date), to not be hospitalized at one month after the index date, and to carry continuous Medicare Part D coverage during the interval from one month before to one month after the index date. This set of requirements establishes prescription drug coverage during an interval of time around the index date of the event, and admits sufficient cumulative time outside the hospital for the patient to fill a prescription at an outpatient pharmacy. Use of a medication is defined by at least one prescription fill between one month before and one month after the index date. Drugs are identified from National Drug Codes linked to Generic Product Identifiers, using the Medi-Span Master Drug Database.

In Table 4.c, all cardiovascular disease events that satisfy inclusion criteria regarding Medicare Part D coverage and

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hospitalization are retained for analysis, regardless of baseline cardiovascular disease status, except for events with an index date between December 1 and December 31, 2011, as Part D data after December 31 were unavailable. Patients with no cardiac event include those whose entire follow-up interval is marked by no cardiovascular disease events. In Figures 4.12–17, only the subset of cardiovascular disease events not accompanied by baseline disease is retained for analysis.

In Table 4.d, we summarize patient distribution by body mass index (BMI) in Medicare dialysis patients with their CVD diagnosis or treatment in 2011. Cohort construction is identical to that of Table 4.a, and patients with a pre-existing condition are excluded. BMI is estimated from the mean of measurements on outpatient dialysis facility claims submitted between October 1 and December 31, 2010.

Figure 4.18 shows the distribution of dialysis patients on the transplant waiting list, stratified by BMI. The cohort includes point prevalent hemodialysis and peritoneal dialysis patients whose first ESRD service date is at least 90 days prior to the beginning of the year, who have Medicare Parts A and B coverage at the beginning of the year, and who are on the transplant waiting list in 2006 and in 2011.

Figure 4.19 shows adjusted relative risks of cardiovascular death in 2011, by body mass index. The cohort includes adult dialysis patients alive on January 1, 2011, with initiation of renal replacement therapy at least 90 days before January 1 and with Medicare Parts A and B coverage on January 1. Cardiovascular death is ascertained from the ESRD Death Notification Form, with primary cause of death code 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, or 37. BMI is estimated from the mean of measurements on outpatient dialysis facility claims submitted between October 1 and December 31, 2010. The Cox model of time to death is adjusted for age, gender, race, diabetes, and dialytic modality.

Figure 4.20 shows the adjusted relative risks of incident CHF in 2011. Cohort construction is identical to that of Table 4.a; patients with a pre-existing condition are excluded. BMI is defined as in Table 4.d. Patients are followed from January 1, 2011, until the earliest of a CHF event, death, change in modality, or December 31, 2011. Relative risks are derived from a Cox proportional hazards regression model, with adjustment for age, gender, race, diabetes, and dialytic modality. Figure 4.21 shows unadjusted survival in patients after a first cardiovascular diagnosis in 2010. Cohort construction is identical to that of Table 4.a., except that the cohort is constructed in 2010 (versus 2011). BMI is estimated from the mean of measurements on outpatient dialysis facility claims submitted between October 1 and December 31, 2009. Patients are followed from the first cardiovascular diagnosis or procedure in 2010 until the earliest of death or one year after the date of the cardiovascular diagnosis or procedure.

Table 4.e displays demographic and BMI distributions for Medicare ESRD patients undergoing bariatric surgery in 2002–2011. Events are defined by inpatient facility claims with (1) a specific or non-specific procedure code for bariatric surgery; (2) a diagnosis-related group (DRG) for obesity surgery, but only if the aforementioned procedure code is non-specific; (3) a diagnosis code for obesity; and (4) the absence of any diagnosis code for cancer of the digestive tract or peritoneum or inflammatory bowel disease. Codes used to identify patients are as follows:

- bariatric surgery (procedure codes, specific): 44.31, 44.38, 44.39, 44.95, 44.96, and 44.97
- bariatric surgery (procedure codes, non-specific): 43.82, 43.89, 44.5, 44.68, 44.99, 45.51, 45.90, 45.91, 45.92, 45.93, 45.94, and 45.95
- obesity surgery (DRGs): 288 (before September 30, 2007) and 619, 620, and 621 (after October 1, 2007)
- obesity (diagnosis codes): 278.00, 278.01, 278.02, v85.2, v85.3, and v85.4
- cancer of the digestive tract or peritoneum (diagnosis codes): 150–159 and 230
- inflammatory bowel disease (diagnosis codes): 555–558

In Table 4.e, BMI is measured at the time of ESRD initiation, diabetes is defined from the ME form and from Medicare claims during the one year preceding surgery, and modality is defined as the time of surgery. Figure 4.23 shows the distribution of bariatric surgery types: open gastric bypass (44.31 or 44.39), laparoscopic gastric bypass (44.38), adjustable gastric banding (44.95, 44.96, and 44.97), and other. Figure 4.24 illustrates survival following bariatric surgery; patients are followed until the earliest of death, three years after the date of surgery, or December 31, 2011. Figure 4.25 shows mean BMI, by month, during the three years following bariatric surgery, among dialysis patients who underwent bariatric surgery between 2005 and 2011. BMI is ascertained from outpatient dialysis facility claims.

Figure 4.26 presents geographic variations in BMI in 2008 and 2011 dialysis patients. Study cohorts include point prevalent dialysis patients, alive and with Medicare Parts A and B coverage on January 1 of the year, with follow-up until the earliest of death, modality change, cessation of Medicare coverage, or December 31 of the year. The BMI of each patient is estimated from the mean of all BMI measurements on outpatient facility claims submitted during follow-up.

Table 4.f looks at the use of resting echocardiograms in incident dialysis patients. Patients receiving these tests are identified through ICD-9-CM procedure codes in Part A inpatient, outpatient, or skilled nursing facility claims and by CPT codes (93303, 93304, 93306–93308, 93312–93318, 93320, 93321, and 93325) in Part A outpatient claims or Part B physician/supplier claims.

The study cohort for Table 4.f includes incident dialysis patients who reach day 91 of ESRD in 2011 and have Medicare Parts A and B coverage. We exclude patients with unknown age or gender, and those with an age calculated to be less than zero on the first ESRD service date. Patients are followed from the first ESRD service date until the earliest of death, transplant, loss to follow-up, recovery of kidney function, change of Medicare Parts A and B enrollment status, one year after first ESRD service date, or December 31, 2011. Diagnostic testing is identified during the entire follow-up period for patients age 65 or older on the first ESRD service date, but from day 91 of ESRD to the end of follow-up for patients younger than 65 years because of incomplete Medicare claims during the first 90 days of ESRD for these younger patients. Table 4.f presents the percentage of patients receiving their first echocardiograms during the first 90 days of ESRD (for patients age 65 and older) and from day 91 of ESRD to one year after ESRD, respectively.

Figure 4.27 and Table 4.g describe characteristics of hemodialysis and peritoneal dialysis patients with heart failure. The study cohort includes January 1, 2011 point prevalent dialysis patients with Medicare Parts A, B, and D coverage, who are identified with a heart failure diagnosis in 2011, who survive 2011, and who have no change of modality status in 2011 and no change of Medicare as primary payor status. Patients with unknown age or gender, and those with an age calculated to be less than zero or greater than 110, are excluded, as are patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories.

Figures 4.28–31 illustrate unadjusted survival for dialysis patients with different types of congestive heart failure type, stratified by age. The study cohort includes January 1, 2009 point prevalent dialysis patients identified with a heart failure diagnosis in 2009, surviving 2009, and with no change of modality status and or of Medicare as primary payor status in 2009. Exclusions are the same as those describe for Figure 4.27. Follow-up time is from January 1, 2010 until the earliest event of death, transplant, or December 31, 2011. The Kaplan-Meier method is used to estimate all-cause survival.

The congestive heart failure (CHF) event is defined by using ICD-9 –CM diagnosis codes 398.91, 428, 402.x1, and 404.x3. Codes 422 and 425, which are included in the definition of CHF as a comorbid condition, are not used to define CHF event. The types of heart failure are defined using the same method described for Table 4.c of Chapter Four in the CKD volume.

Table 4.h illustrates adjusted survival in dialysis patients by modality. The study cohort includes point prevalent dialysis patients in 2009 who survive 2009 and have no change of modality status or of Medicare as primary payor status in 2009. Exclusions are the same as those describe for Figure 4.27. Patients with previous CHF condition are not excluded. Follow-up time begins from January 1, 2010 until the earliest event of death, transplant, or December 31, 2011. The Cox model is used to estimate the hazard ratio for all-cause death for patients with each type heart of failure compared to patients without heart failure, adjusting for age, gender, race, ESRD duration time, diabetes, hypertension, and other comorbidities, including atherosclerotic heart disease (ASHD), CVA/TIA, peripheral vascular disease (PVD), other cardiac disease, chronic obstructive pulmonary disease (COPD), gastrointestinal (GI) disease, liver disease, dysrhythmia, and cancer. Each comorbidity is defined in the entry year 2009, using the definitions introduced for Table 4.a.

## mortality chapter five

Unless otherwise specified, patient cohorts for mortality figures include both Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories.

Figure 5.1 shows trends in mortality rates, by modality, for incident ESRD patients, 1980–2010. The population groups include all ESRD, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). The all ESRD, hemodialysis, and CAPD/CCPD cohorts are defined on the date of onset of ESRD, and patients are followed from day 1 after the onset of ESRD until December 31, 2011. All dialysis patients, including those on hemodialysis, CAPD/CCPD, or an unknown modality, are censored at

transplant, loss to follow-up, or recovery of function; first transplant populations are censored only at loss to follow-up. Adjusted first-, second-, third-, fourth-, and fifth-year mortality rates for each incident cohort are computed from the Cox model using the model-based adjustment method, described later in this appendix. Mortality rates for all patients are adjusted for age, gender, race, and primary diagnosis, and the reference population consists of 2010 incident ESRD patients.

Figure 5.2 shows all-cause mortality, by age, for 2011 prevalent ESRD, dialysis, transplant, and general Medicare patients, calculated using generalized mixed models, and adjusted for gender and race. Medicare patients from 2011 are used as the reference cohort.

Figure 5.3 displays adjusted all-cause and cause-specific mortality for incident hemodialysis patients. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year, and censored at loss to follow-up, transplant, or recovery of kidney function. Overall rates are adjusted for age, gender, race, Hispanic ethnicity, and primary diagnosis, and adjusted rates can be compared across years and causes of mortality. The reference population consists of 2010 incident hemodialysis patients.

Figure 5.4 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 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, black/African American, Native American, or Asian, are excluded. Patients are followed from January 1 or the date of first service of ESRD until death, transplantation, loss to follow-up, recovery of function, or the end of the year, and all-cause rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2010 prevalent dialysis patients, and adjusted mortalities are comparable across vintages.

Table 5.a presents expected remaining lifetimes in years for the 2009 general U.S. population and for 2011 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2011, 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. 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, Table 7 ("Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2009"), at [http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60\\_03.pdf](http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_03.pdf).

Table 5.b presents five-year survival by modality, 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. All patients are followed from day 1 until death, transplantation, loss to follow-up, recovery of function, or the end of 2011, while transplant patients are followed from the first transplant date until death or the end of 2011. All probabilities are adjusted for age, gender, Hispanic ethnicity, and race; overall probabilities are also adjusted for primary diagnosis. The reference

population consists of 2010 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Table 5.c presents unadjusted and adjusted all-cause mortality in ESRD, dialysis, transplant, and general Medicare patients with cancer, diabetes, CHF, CVA/TIA, and AMI. All cohorts are defined on January 1, and include patients age 65 and older. Follow-up for ESRD patients is from January 1 to December 31 of each year, and for transplant patients is censored at transplant patients. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement. Adjusted mortality is adjusted for age, gender, race, and comorbidities defined in the previous year. ESRD patients in 2010 are used as the reference cohort.

Figures 5.5–6 present adjusted all-cause mortality in the ESRD, dialysis, transplant, and general Medicare populations in 2011. The cohorts and adjustment method are same as those used in Table 5.c; 2011 ESRD patients are used as the reference cohort.

#### 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.

New in this year's ADR, the cohorts in Tables H.1–12 are comprised of period prevalent patients, including those alive on January 1 and those incident during a calendar year. All patients are followed from either January 1 (for those alive on January 1) or from the date of onset of ESRD (for those patients incident in a calendar year). Follow-up is censored at loss to follow-up, date of transplant (for dialysis patients), recovery of function, or December 31 of the year. Age is defined at the beginning of follow-up. In calculating adjusted mortality, we have adjusted and reported for five race groups (white, black/African American, Native American, Asian, and other), and starting in 1996, for Hispanics and non-Hispanics.

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, gender, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. The unadjusted mortality rates are calculated by dividing total patient deaths in a category — male, for example — by total follow-up time in the same category. For the adjusted rates, generalized mixed models are used to calculate the smoothed rates; these methods are described in the statistical methods section 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 individual category are adjusted for the remaining four. The reference population includes 2010 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by age, gender, race, and primary diagnosis for 2011 prevalent ESRD patients; rates are smoothed using a generalized mixed model.

The same methods are used for Tables H.3, H.4, and H.4.1 (dialysis); H.5 (dialysis patients, never on transplant waitlist); H.6 (dialysis patients on transplant waitlist); H.7 (dialysis patients, returned to dialysis from transplant); H.8 and H.8.1 (hemodialysis); H.9 and H.9.1 (CAPD/CCPD); and H.10 and H.10.1 (transplant).

#### REFERENCE SECTION I

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

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients with a first ESRD service date between January 1, 1980, and December 31, 2010 are included in the analysis. These patients are followed from day 1 until December 31, 2011. For all ESRD patients, follow-up is censored at loss to follow-up, recovery of function, or December 31, 2011. For dialysis patients, both hemodialysis and peritoneal dialysis, follow-up is censored at loss to follow-up, recovery of function, transplant, or December 31, 2011.

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. The adjusted survival probability for a cohort is based on expected survival probability for the cohort and the reference population. The calculation for expected survival probability in this year's ADR is slightly different from that of previous years. In previous ADRs, the expected survival probabilities of 90 days, one year, two years, three years, five years, and ten years was directly modeled based on follow-up from ESRD date to 90 days, one year, two years, and so on. This year, survival/conditional probabilities are modeled separately for each period: 0–90 days, 91 day to one year, one year to two years, two years to three years, three years to five years, and five years to ten years, and the expected survival probabilities for 90 days, one year, two years, and so on are calculated based on the survival/conditional survival probabilities. Another difference from previous years is that we fit one model for each cohort to obtain adjusted probabilities overall and for age, gender, race, Hispanic ethnicity, and primary cause of ESRD. The reference population consists of 2010 incident ESRD patients.

### *prescription drug coverage* chapter six

In figures and tables regarding enrollment and utilization of Medicare Part D, we analyze cohorts of Medicare enrollees in 2006–2011 based on the 100 percent ESRD population receiving hemodialysis, receiving peritoneal dialysis, or with a functioning kidney transplant, along with cohorts of Medicare enrollees in 2006–2011 based on the 5 percent sample (general Medicare enrollees). For general Medicare enrollees, we require continuous enrollment in Medicare Parts A and B during the previous calendar year; no participation in Medicare Advantage during the previous year; and Medicare enrollment in January of the index year. For hemodialysis, peritoneal dialysis, and kidney transplant cohorts, we identify all point prevalent patients alive and enrolled in Medicare on January 1 of the index year, with ESRD onset at least 90 days earlier; treatment modality is identified on January 1.

Figure 6.1 includes Part D claims for all adult dialysis patients, regardless of payer status, beginning at the latest of the first ESRD service date or January 1, 2011, and continuing until the earliest of death or December 31, 2011. In Figures 6.2–4, the type of



prescription drug coverage is defined sequentially. That is, we first classify patients as “Part D with LIS” if there exists at least one calendar month in 2011 with Part D enrollment and receipt of the low-income subsidy (LIS). In patients without one such month, we classify remaining patients as “Part D without LIS” if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as “retiree drug subsidy” if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as “other creditable coverage” if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans. And we classify all remaining patients as “no known coverage.”

For Figure 6.5 and Table 6.a we classify Part D enrollees as LIS recipients if there exists at least one calendar month in 2011 with receipt of the LIS. In Table 6.c, the proportion enrolled in Part D is the sum of those enrolled in Part D with the LIS and without the LIS.

In Figures 6.6–7 we include only those Part D enrollees who are not LIS recipients during any calendar month of the index year; Figure 6.8 includes only Part D enrollees with the LIS. In all figures, patients enrolled in Medicare Advantage Part D (MA-PD) plans are excluded.

Part D costs for ESRD patients are based on the 100 percent ESRD population, using the period prevalent, as-treated model (Model 1) described for Chapter Eleven. Some figures also include the general Medicare population (all Part D enrollees) based on the 5 percent Medicare sample.

Costs in Figures 6.9–11 and Table 6.d are presented as the total Part D net payment, estimated as the Medicare covered amount plus the low income subsidy amount (LIS). Figure 6.12 present total and PDPY costs for Part B and Part D medications.

In Figures 6.13 and Tables 6.e, we consider only those Part D enrollees who are not LIS recipients during any calendar month of 2011. Patients enrolled in employer group waiver plans or national Programs of All-inclusive Care for the Elderly (PACE) are excluded, as these types of plans do not report data concerning coverage phase progression of enrollees. Diagnoses of hypertension, cardiovascular disease, diabetes, and cancer are ascertained from the ME form.

In Figure 6.14 and 6.15, we show, by unit affiliation, the percentage of dialysis patients receiving antibiotics under Medicare Parts B and D in 2010 and 2012 — before and after implementation of the bundled ESRD Prospective Payment System (PPS).

Also looking at data from before and after implementation of the PPS, Figure 6.16 show the percentage of dialysis patients with at least one prescription (or record of administration for IV vitamin D) for bone and mineral medications, while Figure 6.17 shows PDPY net payment amounts for bone and mineral medications. Included patients are alive at January 1 of the year and are enrolled in Medicare Parts B and D.

Figure 6.18 shows the top 15 prescribed Part D drug classes (based on modified Medi-Span’s generic product identifier therapeutic classification system) by total days supply and cost.

## Transplantation

### chapter seven

Figure 7.1 presents an overview of the transplant population. The first panel juxtaposes the growing rate of ESRD with the falling

rate of transplantation in patients age 20 and older at transplant, 1988–2011. Most adult-only figures are limited to patients age 18 and older, but this figure is limited to age 20 and older because census population data are provided in five-year increments. The second panel shows, by prior transplant status, the number of patients on the OPTN kidney or kidney-pancreas wait list on December 31 of the year, and the median wait time for a deceased-donor kidney. Patients with overlapping listings at more than one center are counted once. Median wait time is plotted only when the Kaplan-Meier median is observed, and is thus missing for patients listed more recently. The third panel presents transplant counts for all patients, by donor type, obtained through a combination of OPTN and CMS data. The fourth panel shows functioning transplant counts for all patients 20, by donor type.

### WAIT LIST AND DONATION

Figure 7.2 shows the percentage of patients wait-listed or a receiving a deceased donor kidney transplant within one year of ESRD initiation, stratified by age, while Figures 7.3–4 illustrate the number and distribution of adult (age 18 and older) patients on the OPTN kidney or kidney-pancreas wait list on December 31 of the year. Because patients may list at multiple transplant centers, Figure 7.3 shows the number of unique patients by status (active/inactive) and the overall proportion of patients listed at multiple centers. Figure 7.4 reports, by blood type, proportions of adult patients who receive a deceased donor transplant, receive a living donor transplant, or die within three years of listing. Because these outcomes are subject to competing risks, we use cumulative incidence estimates.

In Figure 7.5 we illustrate three-year outcomes for adult patients first listed in 2008. Outcomes are classified into five groups: 1) received a deceased donor transplant, 2) received a living donor transplant, 3) died awaiting a transplant, 4) removed from the list prior to transplantation, or 5) still waiting. Calculated PRA is used where available.

Figure 7.6 shows median wait times, by state, for adults receiving a deceased donor kidney during 2011. 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.

Figure 7.7 presents adjusted one-year mortality, by state of residence, for January 1, 2011 point prevalent wait-list patients. A Poisson regression is used to estimate rates, adjusting for age, gender, white/non-white race, willingness to accept an ECD donor, and time on the list prior to 2011. Patients are followed for up to one year.

Figure 7.8 shows the likelihood of adult patients dying while awaiting transplant in the first through fifth year after listing, looking at those first listed in 1991–2010. The likelihood of dying is estimated from Cox proportional hazard models, adjusted for listing year, age, gender, race, primary diagnosis, and PRA level at listing; the 2010 period prevalent cohort is used as reference. Patients are censored at December 31, 2011. CPRA is used in place of PRA when available.

In Figure 7.9 we present the three-year cumulative incidence of transfusion among wait-listed patients by PRA level at listing. The cohort is limited to wait-list patients with primary Medicare

coverage, and transfusion data are obtained from Medicare claims. Incidence is estimated using Kaplan-Meier methods, with censoring at transplant, death, removal from the waiting list, or loss of Medicare coverage.

Figure 7.10 shows rates of organ donation per million population by age, gender, and race. A deceased donor is counted once, regardless of how many organs are transplanted. Figure 7.11 presents unadjusted donation rates per 1,000 deaths, by state. Population and death count estimates for the year from July 1, 2010 to July 1, 2011 are obtained from the U.S. Census Bureau.

#### TRANSPLANT AND OUTCOMES

Figures 7.12 and 7.14 illustrate the number of deceased and living donor transplants for both kidney and kidney-pancreas recipients, while Figures 7.13 and 7.15 present transplant rates by age, gender, race, and primary diagnosis; rates by one factor are adjusted for the remaining three (i.e., rates by age are adjusted for gender, race, and primary diagnosis). Figure 7.16 shows adjusted transplant rates per 100 dialysis patient years by state of patient residence and donor type in 2011. Rates are adjusted for age, gender, race, and primary diagnosis.

Figures 7.17–18 present one-, five-, and ten-year graft and patient outcomes for adult recipients of kidneys from deceased and living donors. Data are reported as unadjusted probabilities of each outcome, computed using Kaplan-Meier competing risk methods. All-cause graft failure includes retransplant, return to dialysis, and death. The death outcome is not censored at graft failure, and includes deaths that occur after retransplant or return to dialysis.

Figure 7.19 presents the one-year cumulative incidence of acute rejections in adult, first-time, kidney-alone transplant patients discharged from the transplant hospitalization with a functioning graft. A patient is assumed to have acute rejection if OPTN data collection forms note 1) acute rejection episodes, 2) that medications were given for acute rejection, or that 3) acute rejection was the primary or secondary cause of graft failure. Biopsy-proven status was available starting in 1991 on the OPTN Transplant Recipient Registration, which identifies early rejection; it was not, however, added to the Transplant Recipient Follow-up form until April, 2003, so incidence of biopsy-proven rejection is available for 2004 and later. Rejections that are a primary or contributing cause of graft failure are assumed to be biopsy-proven, while rejections identified by treatment status are not. Cumulative incidence is estimated using Kaplan-Meier competing risk methods.

Figure 7.20 reports the percentage of patients with evidence of delayed graft function (defined by a need for dialysis in the first week after transplantation), by donor type and ECD and DCD status, as reported to the OPTN.

Figure 7.21 presents first-year and second-year post-transplant hospital admission rates for adult Medicare patients receiving their first kidney-alone transplant in 2009. Data are collected from Medicare claims occurring within two years of discharge from the transplant hospitalization, and exclude the hospitalization itself. Admission rates are censored at graft failure, loss of Medicare coverage, or December 31, 2011. Statistical methods for computing admission rates are similar to those described for Reference Section G, but cohorts are constructed differently. Instead of

computing rates in point prevalent patients within a given year, we define the cohort based on the transplant year, and examine hospital claims up to a year post-transplant for first-year data and two years post-transplant for second-year data. Figure 7.22 illustrates the primary cause of hospitalization for cardiovascular problems and infection in the first and second years post-transplant in Medicare patients with a first kidney-alone transplant in 2007–2009.

Figure 7.23 presents data on the three-year cumulative incidence of post-transplant lymphoproliferative disorder (PTLD). The population includes first-time, kidney-only transplant recipients, 2004–2008. PTLD is identified from the OPTN Post-Transplant Malignancy form and the Transplant Recipient Follow-Up form. Cumulative incidence is computed estimated using Kaplan-Meier competing risk methods.

Figure 7.24 illustrates the three-year cumulative incidence of new onset diabetes following transplant, looking at Medicare patients transplanted during 2004–2010. To identify *de novo* post-transplant diabetes, the cohort is limited to patients with six months of Medicare primary payer coverage prior to transplantation; patients with claims for diabetes during this period are omitted. Cumulative incidence in the three years following the transplant is estimated using a Cox proportional hazards model, adjusting for recipient age, gender, race, cause of ESRD, donor type, hepatitis status, duration of dialysis, donor factors, HLA mismatch, and initial immunosuppression. Events are censored at loss of Medicare coverage.

In Figure 7.25 we show the rate of return to dialysis or retransplant, the rate of death with a functioning graft, and the rate of all-cause graft failure, which includes failure due to death. Rates are limited to adult patients, and estimated from a Poisson regression, adjusting for age, gender, and race.

Figure 7.26 displays causes of death for adult patients transplanted in 2007–2011 who subsequently die with a functioning graft. Causes of death are ascertained from OPTN transplant follow-up data, or, if unknown, from the ESRD Death Notification form.

#### FOLLOW-UP CARE

Figure 7.27 presents data on immunosuppressive medications used in adult recipients at the time of transplantation, as reported to the OPTN. All such medications are indicated on the form as maintenance immunosuppression. Mycophenolate data include mycophenolate mofetil and mycophenolate sodium, while mTOR inhibitors include sirolimus and everolimus. Data on mTOR inhibitors and steroids are also shown at one year post-transplant.

Figure 7.28 displays the percentage of patients with Medicare claims for influenza vaccinations, lipid testing, and CBC panels. The cohort is limited to adult patients with Medicare coverage, transplanted in 1991–2011, and discharged alive with graft function. To avoid counting inpatient procedures done as part of the transplant hospitalization, claims are searched from one day after the discharge date to one year post-transplant. Percentages are estimated using Kaplan-Meier methods, with censoring at graft failure, death, or loss of Medicare coverage. HCPCS codes for testing are as follows: influenza vaccination, 90724, 90657, 90658, 90659, 90660, and G0008; lipid panel, 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720, 83721, and 84478; and CBC panel, 85025, 85027, 80050, and 80055.



Figures 7.29–30 illustrate the sources of prescription drug coverage among transplant patients. Sources are defined sequentially. We first classify patients as “Part D with LIS” if there exists at least one calendar month in the given year with Part D enrollment and receipt of low-income subsidy (LIS). In patients without one such month, we classify remaining patients as “Part D without LIS” if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as “retiree drug subsidy” if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as “other creditable coverage” if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans. And we classify all remaining patients as “no known coverage.” Figure 7.31 shows the proportion of transplant recipients enrolled in the Medicare Part D program, among new transplants and live transplants. “Live recipients” are those alive with graft function in the given year, regardless of when the transplant occurred.

Figure 7.32 displays total expenditures for Part B prescription drugs (injectable drugs and immunosuppressive agents) compared to Part D net payments in the Medicare-covered transplant population.

Figures 7.33–35 address medication use in the first six months post-transplant. The cohort for these figures includes adult patients receiving a first-time, kidney-only transplant between January 1, 2009 and June 30, 2011 who remain alive with graft function and who have Medicare Part D coverage during the six months following transplant. Medication use is defined by at least one prescription fill during this six-month period. In Figure 7.34, with data on lipid-lowering agents, “other” agents include cholesterol absorption inhibitors, niacin, and omega-3 fatty acids. For Figure 7.35, which shows medications for diabetes control, diabetic status is based the primary diagnosis recorded on the ME form.

Figures 7.a–b show the top 15 Part D medications used by transplant recipients enrolled in Medicare Part D. We provide the generic names, and show the top ten medications by frequency (measured as total prescribed days supply) and cost for transplant patients in the first, second, and third years following transplant.

#### REFERENCE SECTION E

Tables E.1–5 present data on the kidney transplant wait list. The OPTN wait list began in earnest in 1987. All wait list data are limited to ESRD certified patients. Table E.1 presents counts of patients newly added to the wait list for a kidney or kidney-pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents wait times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and estimated with the Kaplan-Meier method. Patients listed at multiple centers are counted from the time of the first listing. Table E.3 presents counts of patients on the wait list at any center on December 31 of the given year, regardless of when the first listing occurred. Table E.4 includes point prevalent dialysis patients on December 31 of the given year. And Table E.5 presents the percentage of patients wait-listed or receiving a transplant within one year of ESRD initiation; patients receiving a transplant from a living donor are excluded from the measure in the first half

of the table and included in the second half. Percentages are calculated using the Kaplan-Meier methodology.

Transplant counts are presented in Tables E.6–8. All known transplant events are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.8 illustrates the distribution of transplanted patients by donor type and PRA level, determined from the OPTN Recipient Histocompatibility form, and shows as well a cross-tabulation of recipients and donors in terms of CMV antibody status, hepatitis C antibody status, and Epstein-Barr antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. “Unknown” status is applied when no applicable data fields indicate “positive” or “negative.” Cold ischemia time (in hours; Table E.8) is reported for deceased donor transplants only, and is taken from the OPTN Transplant Recipient Registration form.

Transplant rates per 100 dialysis patient years 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 follow-up in a given year are not censored at the lost-to-follow-up date, but are followed until the end of the calendar year. Dialysis time for patients returning from transplant is counted. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each year.

#### REFERENCE SECTION F

This section presents probabilities of graft survival and graft failure necessitating dialysis or retransplantation, by donor type, age, gender, race, ethnicity, primary diagnosis, and transplant number. Data are presented for outcomes at 90 days, one year, two years, three years, five years, and ten years post-transplant. In ADRs prior to 2010, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to confusion regarding terminology, we renamed this outcome in the 2010 ADR. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2011). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or retransplantation, patients are followed until graft failure (excluding death), and patient follow-up is censored at death. To produce a standard patient cohort, patients with unknown age or gender are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier methodology, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, gender, race, primary diagnosis, and first versus subsequent transplant, and standardized to 2010 patient characteristics.

## *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.

### PREVENTIVE CARE

Figures 8.5–6 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine vaccination rates are similar to those described for Chapter Two. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare inpatient/outpatient and physician/supplier coverage for the entire period.

For influenza vaccinations, 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, 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. Years 2008–2011 are grouped in both figures.

### HOSPITALIZATION

Figures 8.7–9 present adjusted admission rates in the first year among incident ESRD patients age 0–19 in 2001–2010. Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients are required to survive the first 90 days after initiation, and are followed for admissions for up to one year after day 90. Data cleaning, and counting of admissions and time at risk for admissions, generally follow methods described for Reference Section G. Censoring occurs at death, loss to follow-up, end of payer status, December 31, 2011, or one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates are adjusted for gender, race, Hispanic ethnicity, and primary diagnosis. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference cohort includes incident ESRD patients age 0–19 in 2009–2010. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 3.1.

### MORTALITY AND SURVIVAL

Figure 8.10–12 present adjusted all-cause and cause-specific mortality in the first months of ESRD, by age and modality, for 2001–2005 and 2006–2010 incident patients younger than 20. Dialysis patients are followed from the day of ESRD onset until December 31, 2011, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2011. Rates are adjusted for gender, race, Hispanic ethnicity, and primary diagnosis. Incident ESRD patients younger than 20, 2009–2010, are used as the reference cohort.

Figure 8.13 presents five-year survival for 2002–2006 incident ESRD patients age 0–19. Dialysis patients are followed from the day

of ESRD onset until December 31, 2011, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2011. Probabilities by age are adjusted for gender, race, Hispanic ethnicity, and primary diagnosis; probabilities by modality are adjusted for age, gender, race, Hispanic ethnicity, and primary diagnosis. The reference population consists of 2009–2010 incident pediatric ESRD patients.

### MEDICATION USE

Tables 8.b–c and Figure 8.17 include period prevalent ESRD patients in 2010 and 2011. The study cohort of pediatric (age younger than 20) dialysis patients includes prevalent hemodialysis and peritoneal dialysis patients on January 1, 2010, with date of ESRD onset greater than 90 days before January 1 and with Medicare Parts A, B, and D coverage; and incident hemodialysis and peritoneal dialysis patients (who survive the first 90 days of dialysis) in 2010 and 2011. Patients are followed from the later of January 1, 2010, or 90 days after the date of ESRD onset to the earliest of change in dialytic modality, kidney transplant, death, or December 31, 2011. Continuous coverage with Medicare Parts A, B, and D is required during the follow-up interval. The study cohort of pediatric transplant patients includes prevalent kidney transplant patients on January 1, 2010, with date of ESRD onset greater than 90 days before January 1 and with Medicare Parts A, B, and D coverage; and new kidney transplant recipients in 2010 and 2011. Patients are followed from the later of January 1, 2010, or date of new kidney transplant until the earliest of graft failure, death, or December 31, 2011. Continuous coverage with Medicare Parts A, B, and D is required during the follow-up interval.

Figure 8.17 describes the percentages of patients treated with injectable and oral medications during the follow-up interval. Epoetin alfa, darbepoetin alfa, intravenous (IV) iron, and IV vitamin D analogue use are ascertained from Part B claims for dialysis, whereas cinacalcet, phosphate binder, and somatropin use are identified from Part D claims. Oral drugs are identified from National Drug Codes linked with Generic Product Identifiers, using the Medi-Span Master Drug Database. Use is defined by at least one injection or prescription during the follow-up interval. In Table 8.b, methods are identical. Calcium channel blockers include only dihydropyridine agents; alpha agonists include clonidine, guanfacine, and methyldopa; and vasodilators include hydralazine and minoxidil. Table 8.c describes mean administered doses of injectable medications in pediatric dialysis patients. Doses are calculated from the quotient of the sum of all administered doses in the study cohort and the sum of all follow-up time spanned by claims for such doses.

## *special studies* chapter nine

Methods for the figures and tables in Chapter Nine are described within the chapter itself.

## *providers* chapter ten

Throughout the atlas and in Reference Section J, we define a chain-affiliated unit as one of a group of 20 or more freestanding dialysis





units owned or operated by a corporation at the end of a year. The category of small dialysis organization (SDO) includes all organizations meeting our definition of a chain but having 20 or more and fewer than 200 units. In previous years, chain affiliation was determined from the “Provider Name” field of the CMS Annual Facility Survey and the “Chain Organization Name” field of the CMS Independent Renal Facility Cost Report. Currently, however, it is determined solely from the “Chain Name” field of the CMS patient-accessible, web-based Dialysis Facility Compare database (DFC).

Data are obtained from the Facility Survey (1988–2011), the Cost Report (Form 265–94, 1994–2000), the DFC database (2001 to the present), and the CDC National Surveillance of Dialysis-Associated Diseases in the United States (1988–2002, excluding 1998, when the CDC did not conduct a survey). The CDC discontinued the National Surveillance of Dialysis-Associated Diseases after 2002. In 2010, there were 6,009 facilities in the Facility Survey.

A facility’s hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. For years prior to 2002, we determine 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 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 figure showing profit status.

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

Figure 10.1 shows the distribution of units and patients for large dialysis organizations (LDOs) and SDOs from the 2011 Facility Survey. Figure 10.2 presents the number of dialysis facilities and patients by renal network for 2006 and 2011, while Figure 10.3 compares chain affiliations for 2011.

Figures 10.4–6 employ the same cohort as Figure 2.14 in Chapter Two, here for 2010–2011, and limited to dialysis patients.

For Table 10.a and Figures 10.7, facilities are defined as opting into the new dialysis bundle if 25 percent or fewer of their 2011 EPO line item claims had a payment greater than 0. Non-bundle facilities are those in which 75 percent or more of their EPO line item claims had a payment greater than 0; facilities with 25–75 percent of EPO line item claims having a payment greater than 0 are not classified.

Figure 10.a shows the distribution of facilities opting into the new dialysis bundle. Only facilities that classified as bundle or non-bundle providers are included.

Figure 10.7 summarizes the total monthly dose of anemia treatment therapeutics (EPO, IV iron, and IV vitamin D), hemoglobin levels, and transfusions in period prevalent dialysis patients before (July 2010) and after (July 2011 and July 2012) implementation of the dialysis bundle. Patients need to have a dialysis claim within the month to be included in the denominator for the percentage

of patients with an EPO claim and the percentage with at least one transfusion. Transfusion dates are defined based on the from date of the claim.

Figure 10.8 summarizes, by provider DSA, the percentage of period prevalent dialysis patients receiving at least one transfusion.

Figures 10.9–12 compare mortality and hospitalization among dialysis provider types and chains, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both are estimated by the traditional SMR calculation method. A patient’s dialysis provider is defined on January 1, 2011. Patients are followed from January 1, 2011, to the first of death, transplant, or December 31, 2011. Patients dying of AIDS are excluded; those dying of drug overdose (street drugs) or of an accident not related to treatment are censored at the date of death. SMR calculations include all January 1, 2011, point prevalent hemodialysis patients, while SHR calculations include only hemodialysis patients with Medicare as primary payer, and use the number of hospital admissions as the endpoint. Both SMRs and SHRs are adjusted for age, gender, race, primary diagnosis, and vintage, with 2011 national point prevalent hemodialysis patients as the reference cohort for the SMR calculations, and Medicare patients used for the SHR data.

## *costs of esrd* chapter eleven

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

### **PAYER SEQUENCE**

The payer 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 payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), Medicare Advantage (HMO), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, since it is impossible to determine the complete cost of care for ESRD patients with MSP coverage, most analyses exclude patients during the periods when they have this coverage.

### **CHAPTER ELEVEN**

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total 2011 Medicare spending is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation for each patient begins at the first ESRD service date. Total 2011 Medicare spending is inflated by 2 percent to account for incomplete claims, and organ acquisition costs are estimated with the same methods used in the 1999 ADR (pages 149–150). HMO costs are estimated using the total HMO months for 2011 (obtained from the CMS managed care organization file) in conjunction with the 2011 AAPCC rate.

Non-Medicare EGHP spending 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 2011. Patient obligations are estimated as the difference between Medicare allowable and net payment amounts. Non-Medicare patient

<b>C Medicare categories of payment &amp; basis for categorizing claim</b>	
<b>Total</b>	Sum of all payments
<b>Total inpatient</b>	Sum of all payments originating from the inpatient SAF, including pass-throughs
Medical DRG	Inpatient SAF, DRG
Surgical DRG	Inpatient SAF, DRG
Transplant DRG	Inpatient SAF, DRG 302 & 512
Other DRG	Inpatient SAF, DRG not included in the above categories
Non-transplant pass-throughs	Inpatient SAF, DRG not 302 or 512, calculated from per diem and covered days
Transplant pass-throughs	Inpatient SAF, DRG 302, calculated from per diem and covered days
<b>Total outpatient</b>	Sum of all payments originating from the Outpatient SAF
Outpatient hemodialysis	Outpatient SAF, hemodialysis revenue codes
Outpatient peritoneal dialysis	Outpatient SAF, peritoneal dialysis revenue codes
Outpatient other dialysis	Outpatient SAF, dialysis revenue codes other than HD or PD
Outpatient ESA	Outpatient SAF, revenue codes and/or HCPCS code
Outpatient vitamin D hormones	Outpatient SAF, revenue and HCPCS codes
Outpatient iron	Outpatient SAF, revenue and HCPCS codes
Outpatient other injectables	Outpatient SAF, revenue and HCPCS codes
Radiology	Outpatient SAF, revenue and/or CPT codes
Pharmacy	Outpatient SAF, revenue codes
Ambulance	Outpatient SAF, revenue codes
Laboratory/pathology	Outpatient SAF, revenue and/or CPT codes
Outpatient other	Outpatient SAF, does not qualify for any other cost category
Skilled nursing facility	Skilled nursing facility SAF
Home health agency	Home health SAF
Hospice	Hospice SAF
<b>Total physician/supplier</b>	Sum of physician/supplier payments
Transplant surgery	Physician/supplier SAF, CPT codes
Inpatient surgery	Physician/supplier SAF, CPT, and place of service codes
Outpatient surgery	Physician/supplier SAF, CPT and place of service codes
E&M nephrologist inpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M nephrologist outpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M non-nephrologist inpatient	Physician/supplier SAF, CPT, place of service and specialty codes
E&M non-nephrologist outpatient	Physician/supplier SAF, CPT, place of service and specialty codes
Dialysis capitation	Physician/supplier SAF, CPT and/or type of service codes
Inpatient dialysis	Physician/supplier SAF, CPT codes
Home dialysis	Physician/supplier SAF, HCPCS and place of service codes
Vascular access	Physician/supplier SAF, CPT codes
Peritoneal access	Physician/supplier SAF, CPT codes
Physician/supplier ESA	Physician/supplier SAF, HCPCS codes
Physician/supplier iron	Physician/supplier SAF, HCPCS codes
Immunosuppressive drugs	Physician/supplier SAF, HCPCS codes
Durable medical equipment	Physician/supplier SAF, HCPCS codes
Physician/supplier radiology	Physician/supplier SAF, CPT and specialty codes
Physician/supplier lab/pathology	Physician/supplier SAF, CPT codes
Physician/supplier ambulance	Physician/supplier SAF, HCPCS and place of service codes
Other physician/supplier	Physician/supplier SAF, does not qualify for any other category
E&M: Evaluation and management	

spending is estimated as the number of patient months at risk for non-Medicare patients (determined from the USRDS payer sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2010 to 2011 are obtained from Table K.2, without the 2 percent adjustment for late claims. Calculations of per person per year (PPPY) at-risk costs are based on patients for whom Medicare is the primary payer during the study period (Table K.e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (3.0 percent) and Medical Consumer Price Index (3.6 percent).

Figure 11.9 describes PPPY costs for items billed in the outpatient SAFs for period prevalent dialysis patients with Medicare as primary payer.

Figures 11.10–11 present cost data for the Medicare Part D prescription drug benefit. Costs are estimated net pay, calculated as the sum of the plan payment amount and the low income subsidy (LIS); they do not include out-of-pocket expenditures. Figure 11.10 includes all Part D claims for ESRD patients, starting on January 1, 2011 (or the first ESRD service date if after this date), regardless of payer status; total Medicare costs for Part D (estimated from the 5 percent Medicare sample) are included for comparison. Figure 11.11 includes 2011 period prevalent ESRD patients enrolled in Part D for all of 2011. LIS status is determined from the Part D enrollment file. Per person per year (PPPY) costs are estimated net pay as well as true out-of-pocket costs, presented separately for dialysis and transplant patients. General Medicare costs are included for comparison.

Figure 11.12 presents, by unit affiliation, overall PPPY cost data for Part D-enrolled dialysis patients with and without the LIS benefit, while Figures 11.13–16 show costs for phosphate binders, calcimimetics, cardiovascular agents, and diabetes agents. Unit affiliation is determined as at the beginning of the follow up period, and PPPY costs are estimated as the sum of the Medicare covered amount and the LIS amount.

#### REFERENCE SECTION K: MEDICARE CLAIMS DATA

Cost information in this section is derived from Medicare inpatient/outpatient, physician/supplier and Part D claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. The data for 2007–2011 are comprised of approximately 48 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 409 million line items from physician/supplier claims. Claims data are obtained for all patient identification numbers in the USRDS database, and the Renal Management Information System (REMIS) is used to gather all CMS ID numbers under which patients may have claims. The claims data are then merged with patient demographic data and modality information in the USRDS database.

The economic analyses for this section focus on two amounts found in the claims data: the claim payment amount, which is the amount of the payment made from the Medicare trust fund for the services covered by the claim record; and the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and kidney acquisition costs.

## PAYMENT CATEGORIES

Medicare payments are broken into several categories, shown in Table C. 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, 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 starting with the 2001 Outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2001–2010, with adjustments as noted.

## MODEL 1: AS-TREATED ACTUARIAL MODEL

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

In Section K of the Reference Tables 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 20 years from January 1, 1991, to December 31, 2010, and ESRD patients prevalent on January 1, 1991 or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payer sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payer at any time during the study period are classified as MSP for the duration of the MSP status in the payer sequence. If the payer status changes to Medicare as primary payer, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare Advantage program are excluded until their payer status changes to Medicare (either as primary or

secondary payer). Patients classified as MSP are included in Tables K.1–4, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2010. Patients incurring no inpatient/outpatient or physician/supplier Medicare costs for the entire period are excluded, and Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself.

To express costs as dollars per year at risk, total costs during the follow-up period are divided by the length of the period. Costs per patient year at risk are calculated by patient category, and stratified by age, gender, race, modality, and diabetic status. Diabetic status is based on the primary diagnosis, as recorded on the Medical Evidence form. A patient with a non-diabetic cause of renal failure may have diabetes, but the disease is not judged to be the cause of ESRD. Patient age is recalculated for each calendar year, 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 Figure 11.8, as well as Reference Tables K.10–13. 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 receiving a kidney transplant during the calendar year.
- functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled.
- graft failure: ESRD patients who have had a transplant, but return to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are classified in the transplant category.

## EGHP PATIENTS

Figure 11.8 includes data for EGHP patients. Patients in the Truven Health MarketScan (THMS) database who are identified as having ESRD, are younger than 65, and do not have evidence of Medicare payments (either as primary or secondary payer) are included in these analyses. Medicare payments are identified in the THMS database, and patients are excluded on the basis of these payments in order to obtain a more accurate estimate of ESRD costs in the private sector. The payment amounts presented are the net payments and do not include deductibles and copayments.

## *international comparisons*

### CHAPTER TWELVE

The USRDS Coordinating Center would like to thank all of the organizations below and the staff of the dialysis and transplant facilities who help collect these data. The organizations listed here have contributed data for this year’s Annual Data Report using the data collection form at the end of this section.

- Sociedad Argentina de Nefrología (SAN) and Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI), Buenos Aires, Argentina
- the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA)
- the Austria OEDTR
- the Bangladesh Renal Registry
- the French-Speaking Belgium ESRD Registry, Bruxelles
- Nederlandstalige Belgische Vereniging voor Nefrologie (NBVN)
- Clinical Center University of Sarajevo, Bosnia, and Herzegovina
- Sociedade Brasileira de Nefrologia and Associação Brasileira de Transplante de Órgãos
- the Canadian Organ Replacement Register (CORR), Canadian Institute for Health Information.
- the Chilean Renal Registry
- the Cuenta del Alto Costo (CAC) Colombia
- the Croatian Society of Nephrology, Dialysis, and Transplantation
- the Czech Registry of Dialysis Patients (RDP)
- the Danish Society of Nephrology
- the ERA-EDTA Registry
- the Finnish Registry for Kidney Diseases
- the French Renal Epidemiology and Information Network (REIN) Registry
- the Hellenic Renal Registry, Greece
- the Hong Kong Renal Registry
- the Landspítali University Hospital, Iceland
- the Israeli Renal Registry
- the Jalisco State Dialysis and Transplant Registry, Mexico
- the Japanese Society of Dialysis Therapy
- the Korean Society of Nephrology ESRD registry
- the National Renal Registry, Malaysia
- the Netherlands Dialysis Registry
- the Norwegian National Hospital
- the National Kidney and Transplant Institute, Philippines Renal Disease Registry
- the Sociedade Portuguesa de Nefrologia
- the Romanian Renal Registry
- the Society of Dialysis, Russia
- the Scottish Renal Registry
- the Serbian RRT Registry and the Serbian renal units working group
- Singapore Renal Registry, National Disease Registries Office
- the Registro Español de Enfermos Renales and Organización Nacional de Trasplantes, Spain
- the Swedish Renal Registry
- the Taiwan Society of Nephrology
- the Thailand Renal Replacement Therapy Registry and the Nephrology Society of Thailand
- the Turkish Society of Nephrology
- the UK Renal Registry
- the Uruguayan Dialysis Registry and Uruguayan Registry of Renal Transplantation
- the U.S. Census Bureau International Database

Thank you to all who provided data for this year's ADR. We are especially grateful to staff at the ERA-EDTA Registry for their help in coordinating much of the European data presented in this chapter. Data for some countries do not represent 100 percent of the ESRD population; interpretation of changes in incident and prevalent rates must therefore be performed with caution. Notations are made in the captions for countries reporting prevalent data only for dialysis patients. Data from Belgium do not include patients younger than 20.

The citation for the data provided for Argentina is: Marinovich S, Lavorato C, Celia E, Bisigniano L, Soratti M, Hansen Krogh D, Fernandez V, Tagliafichi V, Rosa Diez G, Fayad A, Lopez A. Registro Argentino de Diálisis Crónica 2011.

To contribute data from your country's registry, send the completed International Data Collection Form to [USRDS@USRDS.org](mailto:USRDS@USRDS.org).

### *vascular access*

#### *L tables*

Tables L.1–3 include period prevalent hemodialysis patients, 1999–2011, with Medicare as primary payer. Placements are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, change in modality, change in payer status, or the end of the prevalent year. Tables L.4–6 include January 1, 2011 point prevalent hemodialysis patients. Vintage represents the amount of time between the first service date and January 1, 2011.

Tables L.7–14 include point prevalent hemodialysis patients with Medicare as primary payer who are also in the ESRD CPM report for the corresponding year. Current access is determined from the CPM data as the access used at the time of the most recent data collection, i.e., during October–December of the year prior to the prevalent year. 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 payer status, or a claim for the placement of a different hemodialysis vascular access. Patients with a placement claim after the CPM data collection but prior to the start of the prevalent year are excluded.

Tables L.14–15 include point prevalent peritoneal dialysis patients with Medicare as primary payer. 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 payer status, or a claim for hemodialysis vascular access placement.

### *census populations*

The 2000 U.S. Census, available in 2002, introduced a new race category with additional groupings. Estimates for 1990–1999 were back-calculated based on the actual 2000 census. Later data, however, include racial groups that do not coincide with those in the ESRD data. For rate calculations throughout the ADR we thus use the CDC's Bridged Race Intercensal Estimates Dataset, which estimates white, African American, Native American, and Asian populations. The data and methods for these estimates are available at <http://tinyurl.com/28kpp9j>. For state and network rates, we use Vintage 2010 Bridged-Race Postcensal Population Estimates. Both intercensal and postcensal estimate datasets are available at [http://www.cdc.gov/nchs/nvss/bridged\\_race/data\\_documentation.htm](http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm).



## Statistical methods

### METHODS FOR CALCULATING RATES

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2009, for example, is the observed incident count divided by the 2009 population size and, if the unit is per million population, multiplied by one million; the 2009 death rate for prevalent ESRD patients is the number of deaths in 2009 divided by the total follow-up time (patient years) in 2009 of the 2009 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. The count-based rate describes the proportion having the “event” and the time-based rate tells how often the “event” happens.

#### model-based rates

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

#### measurement unit for rates

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

Take, for example, a calculation of 2010 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2010. Group A consists of three patients: Patient 1 had a first hospitalization on March 31, 2010; Patient 2 was hospitalized on June 30, 2010; and Patient 3 was on dialysis through December 31, 2010, with no hospitalizations. Group B also has three patients: Patient 4 was first hospitalized on December 31, 2010; Patient 5 was hospitalized on September 30, 2010; and Patient 6 was on hemodialysis the entire year, with no hospitalizations through December 31, 2010.

Patients 1 to 6 contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 2010. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as  $[2 \text{ total events} / 1.75 \text{ total patient years at risk}] \times 1,000$  for Group A and  $[2 \text{ total events} / 2.75 \text{ patient years at risk}] \times 1,000$  for Group B). The resulting rate is lower for Group B because of the longer total follow-up time.

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

### METHODS FOR ADJUSTING RATES

Because each cohort contains a different patient mix, observed 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 rate is a weighted average of the observed category-specific rates, using as weights the proportion of each category in the reference population. Categories are defined by the adjusting variables. For example, if a rate is adjusted for race and gender and there are three race groups (white, African American, and other) and two gender groups, there are six categories: white males, white females, African American males, African American females, males of other races, and females of other races.

Suppose we try to compare state-level incident rates in 2009 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 2009 — with five race groups (white, African American, Native American, Asian/Pacific Islander, and other).

Assuming the incident rate of state A in 2009 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is  $(153 \times 75.1\%) + (250 \times 12.3\%) + (303 \times 0.9\%) + (174 \times 3.6\%) + (220 \times 8\%) = 158.73$  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.

	Incident rate of State A	National population (%)
White	153	75.1
African American	250	12.3
Native American	303	0.9
Asian/Pacific Islander	174	3.6
Other	220	8.0

This method is used to produce some adjusted incident and prevalent rates in Chapters One and Two 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 category-specific mortality rate will be unstable, likely

making the adjusted rate unstable as well. In addition, if one includes category no patients, the method is not valid for calculating an adjusted mortality rate for the group. An attractive alternative is a model-based approach, in which we find a good model to calculate category-specific estimated rates for each group and then calculate direct adjusted rates using these estimates with a given reference population. This method can also be extended to adjustments with continuous adjusting variables (Liu et al., 2006). There is, unfortunately, no straightforward way here to calculate standard errors of the adjusted rates; 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 and state-level adjusted incident and prevalent rates using the Poisson model; adjusted HSA-level incident and prevalent rates based on the Bayesian spatial hierarchical model, and some other rates, described in the text on the individual figures.

### 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. The mortality/event rate in the period of  $(0, t)$  is calculated by  $-\ln(\text{Survivor at time } t)$ . This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit if the event rate is a constant over time.

#### *survival probability with competing risks*

When competing risks exist, the estimate of the cumulative incidence function of a specific cause may be biased if the other competing risks are ignored. If we have  $K$  competing risks, the cumulative incidence function of cause  $k$ ,  $k=1, 2, \dots, K$ , at time  $t$ ,  $I_k(t)$ , is defined as the probability of failing from cause  $k$  before time  $t$  (including time  $t$ ),  $\text{Prob}(T \leq t, D=k)$ . Then

$$I_k(t) = \int_0^t \lambda_k(s)S(s)ds$$

where  $\lambda_k(s)$  is the hazard of event from cause  $k$  at time  $s$  and  $S(s)$  is the survival probability at time  $s$  (the probability of no event happening). If we have failing time  $t_1, t_2, \dots, t_m$ , the cumulative incidence function of cause  $k$  at time  $t$  is estimated by

$$I_k(t) = \sum \hat{\lambda}_k(t_j) \hat{S}(t_{j-1})$$

where  $\lambda_k(t_j) = D_{kj}/n_j$ ,  $\hat{S}(t_{j-1})$  is the Kaplan-Meier estimate of survival at time  $t_{j-1}$ ,  $D_{kj}$  is the number of patients failing from cause  $k$  at time  $t_j$ , and  $n_j$  is the number of patients at risk at prior time  $t_j$  (Putter et al.).

#### *adjusted survival probabilities*

Adjusted survival probabilities are reported in Reference Section I, with age, gender, race, Hispanic ethnicity, and primary diagnosis used as adjusting risk factors. The

model-based adjustment method is used, with survival probabilities/conditional survival probabilities predicted from the Cox regression model (Kalbfleisch JD, Prentice RL). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, Hispanic ethnicity, 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 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 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. Rates for the intersections of age, gender, race, and diagnosis are estimated using the log linear equation  $\text{Log}(\text{rate}) = (\text{fixed effects}) + (\text{random effect})$ . Fixed effects include year, age, gender, race, and primary diagnosis, and all two-way interactions among age, gender, race, and 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.

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 in Section H 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 use a generalized linear model with log link and Poisson 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 as a covariate. 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 dialysis chain-level SMR is used to compare mortality in prevalent dialysis patients — after adjusting for age, gender, race, primary diagnosis, and ESRD vintage — in each dialysis chain, using the national dialysis population in the corresponding year as the reference. An SMR of 1.05 for a chain with the national dialysis population as the reference indicates that patients in this chain have a risk of death approximately five percent higher than that of the national population of 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 follow-up 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.

**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 age  $A$ . 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  $A + X = 100$ .

**HALF-LIVES (MEDIAN TIME)**

*conditional half-life*

The conditional half-life is conditional on having survived a given period of length  $T_0$  without the event, the point at which 50 percent of patients who survived the given period remain alive. In other words, it is the median remaining lifetime conditional on surviving a given period  $T_0$ .

The conditional half-life is estimated using the Kaplan-Meier method if the median survival time falls in the duration of follow-up. Otherwise, the conditional half-life is estimated as the following:

Estimate the survival probabilities  $S(t_0)$  and  $S(t_1)$  using the Kaplan-Meier method from the data available, where  $t_0 < t_1$  and  $t_1$  is within the follow-up

$$\mu = \frac{t_1 - t_0}{(\ln[S(t_0)] - \ln[S(t_1)])}$$

the estimate of the conditional half-life =  $\mu \cdot \ln(2)$

This method can be used only when the hazard is a constant after  $t_0$  and  $t_1$  is chosen to be big enough to obtain a stable estimate of  $\ln(S(t_0)) - \ln(S(t_1))$ .

**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 stabilize data and show geographic patterns while still maintaining geographic resolution.

Much 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). Remaining maps are by state or census division. 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. Maps by state and census division are not smoothed.

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

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

*methods for smoothing and adjusting map data*

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

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



## special studies & data collection forms

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

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Products and services provided by the USRDS to support the work of the renal community are detailed in Table A. The entire ADR is available at [www.USRDS.org](http://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 tables and regional maps. Data on website use are presented in Figure 1.

### *data requests*

Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases requests can be answered through 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 — requiring more than two hours of staff time — as well as requests for Standard Analysis Files and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the NIDDK Project Officer.

### *research files*

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

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

The Core SAF set contains basic patient data, and is needed to use any of the other SAFs. Included are each patient's demographic information, payer and treatment history, limited transplant data, provider data, and data from many of the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this data set. The Transplant data set contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the Hospital data set. All Medicare billing data are available by individual year (see Table C).

### *standard analysis files*

SAF use is governed by the USRDS policy on data release for investigator-initiated research, found later in these appendices. Research proposals must be approved by a USRDS Project Officer, and institutions and researchers must sign the USRDS "Agreement for Release of Data," on the same page. File prices are listed in Table C.

Most SAFs provide patient-specific data and are considered limited datasets. All patient identifiers are removed or encrypted, but data confidentiality remains a serious concern. The USRDS Agreement for Release of Data describes restrictions on SAF use and disposition. The agreement must be signed by the appropriate institutional authority responsible for IR and privacy security, then co-signed by the investigators/analysts as well to acknowledge their responsibility for protecting the privacy of this kind of individual patient data. SAFs include an encrypted ID number to allow patient data from multiple SAFs to be merged.

## CORE DATASET

The Core Standard Analysis Files contain the most frequently used data and are needed for use of the Transplant, Hospital, or ESRD Medicare claims. Included files are as follows (also listed in Table B).

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

**RESIDENCE** A longitudinal record of residence to ZIP code.

**PAYER HISTORY** Contains a new record for each patient at each change in insurance payer.

**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 and 2005 versions of the CMS Medical Evidence form. In April 1995 a new version of the form went into use, with data on comorbidity, employment status, lab values at initiation, and Hispanic ethnicity; an expanded form was then implemented in 2005.

**TRANSPLANT** Contains basic data for all transplants reported by CMS and UNOS, including the date of graft failure (detailed transplant data are contained in a separate transplant data set).

**TRANSPLANT WAIT LIST** Beginning with 2001 data (used in the 2002 ADR), this file 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. 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 in the late 1980s to mid-1990s. 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

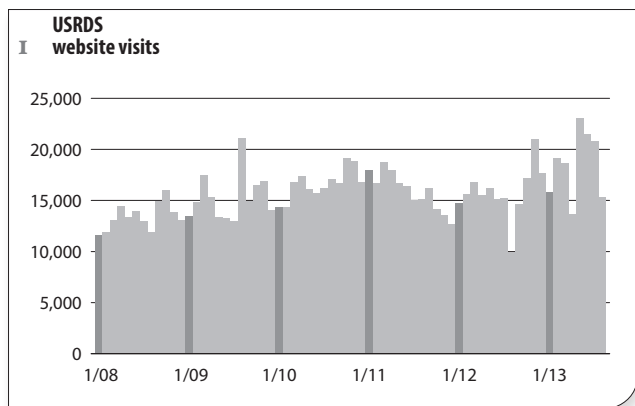
Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. Design and sampling plans are developed, samples are selected, and data collection forms and instructions are drafted, tested, 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 on a total of 16,812 participants 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 and included 4,024 participants. Case Mix Adequacy Study of Dialysis: The objectives of this USRDS Special Study were to establish the relationship between the dose of delivered dialysis therapy and mortality, determine the strength of this relationship when data are adjusted for comorbidity, assess how this relationship changes with dialysis dose, assess how this relationship is affected by dialyzer reuse, and examine the impact of different dialysis membranes on patient morbidity and mortality.

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

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

**PEDIATRIC GROWTH & DEVELOPMENT** The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relation of patient growth and sexual maturation to modality, and establish a prototype for the



## a USRDS products & services

### Reports & guides

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

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

### Researcher's Guide to the USRDS database

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

### www.usrds.org

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

### RenDER

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

### Requests for data

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

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

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

**Merged data files** Merged files can be created by the Coordinating Center for approved research projects. An hourly rate of \$119.57 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK. Contact the USRDS Coordinating Center for more information.

### Publications & presentations

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

### Contact information

**Data requests & publication orders** USRDS Coordinating Center  
914 South 8th Street, Suite S2.100  
Minneapolis, MN 55404  
612.873.6223 or 1.888.99usrds  
fax 612.873.1636  
[usrds@usrds.org](mailto:usrds@usrds.org)

**Data file contacts** Shu-Cheng Chen, MS; [schen@usrds.org](mailto:schen@usrds.org)  
Beth Forrest, BBA; [bforrest@usrds.org](mailto:bforrest@usrds.org)

## b Contents of the USRDS Core Standard Analysis CD-ROM

**File name** unit of observation & uses. This two-CD set is needed in order to use any of the other Standard Analysis Files.

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

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

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

**Payer History** one record for each period a patient is covered by one payer; each patient can have many records. The impact of insurance payers on clinical outcomes.

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

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

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

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

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

**Case Mix Severity (Special Study)** 5,255 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

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

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

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

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

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

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

**Formats.SC2** all USRDS-defined SAS formats used by SAFs. Format library used to format values of categorical variables.

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 DATASET**

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

- TX includes minimum details on 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 follow-up reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- TXFUNOS includes transplant follow-up reports collected by UNOS since 1988
- TXIFUNOS includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

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

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

CMS and UNOS transplant files overlap for 1988–1993, and some Medical Evidence (ME) forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among all 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 DATASET**

Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this data set, 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.

#### **COMPREHENSIVE DIALYSIS STUDY**

This data set contains information from the Comprehensive Dialysis Study (CDS), a USRDS special data collection study to assess rehabilitation/quality of life and nutrition issues in incident dialysis patients. The study was conducted between 2005 and 2008. All 1,677 participants answered questions on physical activity level, health-related quality of life, and work/disability status during the first six months of after the initiation of ESRD therapy. In a subset of 400 participants, dietary intake and nutritional status were also assessed.

#### **DIALYSIS MORBIDITY & MORTALITY CLAIMS**

This data set contains Medicare claims for participants in the Dialysis Morbidity and Mortality Studies. Data are followed to the currently reported claims year.

#### **CASE MIX ADEQUACY CLAIMS**

This data set contains Medicare claims for participants in the Case Mix Adequacy Special Study. Medicare payment data for these patients are followed to the currently reported claims year.

#### **MEDICARE PAYMENT DATA**

Medicare payment data are available as institutional and physician/supplier claim datasets for the ESRD population. Costs and available years can be found in Table C.

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

#### **CLINICAL PERFORMANCE MEASURES DATA COLLECTION**

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

C Prices for the USRDS Standard Analysis Files			ESRD Medicare payment data			
<b>Standard Analysis Files</b>						
Core dataset	\$1,500	Needed in order to use the other files.				
Transplant dataset	\$500	Detailed transplant data from CMS and UNOS.				
Hospital dataset	\$500	Derived from the institutional claims; contains diagnosis and surgical procedure codes for each stay but does not include the cost data from the institutional claims records.	pre-1989	\$250		
			1989	\$250		
			1990	\$250		
			1991	\$375	\$500	
CDS survey dataset	\$750	Survey information and laboratory values from the Comprehensive Dialysis Survey	1992	\$375	\$500	
			1993	\$375	\$500	
DMMS claims	\$500	Contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. Survey data are included in the Core dataset.	1994	\$375	\$625	
			1995	\$500	\$625	
			1996	\$500	\$750	
			1997	\$500	\$875	
			1998	\$500	\$875	
			1999	\$500	\$875	
Case Mix Adequacy claims	\$125	Contains all institutional and physician/supplier claims data for patients in the USRDS Case Mix Adequacy Special Study. Survey data are included in the Core dataset.	2000	\$750	\$875	
			2001	\$875	\$875	
			2002	\$875	\$1,000	
			2003	\$1,000	\$1,125	
			2004	\$1,125	\$1,125	
			2005	\$1,250	\$1,250	
			2006	\$1,250	\$1,250	\$750
			2007	\$1,750	\$1,375	\$1,000
			2008	\$1,875	\$1,500	\$1,000
			2009	\$2,000	\$1,625	\$1,250
			2010	\$2,000	\$1,750	\$1,250
			2011	\$2,000	\$1,750	\$1,250

Pre-ESRD claims available for 1993 to 2010; price ranges from \$200 to \$800 per year and claim type. Prices subject to change.

d Prices for the CKD 5 percent Medicare Sample Standard Analysis Files						
Patient cohort finder \$1,000 / Hospital file \$250						
	Institutional	Physician/ supplier		Institutional	Physician/ supplier	Part D
1992	\$375	\$375	2002	\$500	\$500	
1993	\$375	\$375	2003	\$500	\$500	
1994	\$375	\$375	2004	\$500	\$500	
1995	\$375	\$375	2005	\$625	\$625	
1996	\$375	\$500	2006	\$750	\$625	\$350
1997	\$375	\$500	2007	\$875	\$625	\$500
1998	\$375	\$500	2008	\$1,000	\$750	\$500
1999	\$500	\$500	2009	\$1,125	\$875	\$750
2000	\$500	\$500	2010	\$1,125	\$875	\$750
2001	\$500	\$500	2011	\$1,250	\$1,000	\$750

e Prices for the ESRD CPM/USRDS files	
<b>ESRD CPM Survey data</b>	
Includes 1994–2008 hemodialysis survey years and 1995–2008 peritoneal dialysis survey years	
	\$1,250
<b>ESRD CPM/SAF linked files</b>	
Core files	\$500
Hospital	\$200
Transplant	\$200
<b>ESRD CPM Medicare participant institutional &amp; physician/supplier claims</b>	
are available for the years pre-1989 through 2011; \$100–300 per year	

**f 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 files*

- 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 data fields needed in custom data file. 2) Description of data security: responsible party, computer access, etc. 3) Time frame 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 For Principal Investigator and co-authors, **required**:  
Name  
Affiliation  
Business address  
Business phone & fax  
mail address

---

**Submit to**  
Paul Eggers, PhD  
NIDDK  
6707 Democracy Blvd, Room 612  
Bethesda, MD 20892–5458  
Phone 301.594.8305  
Fax 301.480.3510  
eggersp@extra.niddk.nih.gov

information, useful in analyses of healthcare delivery in a sample of the dialysis population.

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

The USRDS Coordinating Center has made the CPM data available as SAFS. The dataset contains CPM data collected in surveys from 1994–2008. A listing of available files and the corresponding costs can be found in Table E, or you may contact the USRDS Coordinating Center for further information.

#### **CKD 5 PERCENT GENERAL MEDICARE PAYMENT DATA**

The CKD cohort datasets are built from the 5 percent general Medicare Claims SAFS, and contain a patient master file, a payer sequence file, and a set of comorbidity files. We no longer produce datasets for diabetes and CHF based on the 5 percent Medicare claims.

Separately, a 5 percent general Medicare Hospital SAF (inpatient, outpatient, skilled nursing facility, home health, hospice, Part B, and durable medical equipment) for the CKD cohort is also available. Data are derived from the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

#### **PRE-ESRD MEDICARE CLAIMS**

The pre-ESRD claims (also known as the back-casted claims) are a collection of Medicare institutional and physician/supplier billing records incurred prior to the onset of ESRD. Included in these claims are any and all claims available from Medicare for incident patients during their incident year and the two prior calendar years.

The USRDS has made the pre-ESRD data available as SAFS. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payer sequence is provided so researchers can determine Medicare enrollment for the periods prior to first ESRD service date. A listing of available files and the corresponding costs can be found in Table E.

#### **PART D DATA**

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Voluntary Prescription Drug Benefit Program (Part D). Effective January 1, 2006, Part D is an optional prescription drug benefit for individuals who are entitled to Medicare benefits under Part A or enrolled in Medicare benefits under Part B. The data from the first few months of 2006, when the benefit was very new, may be incomplete, and should be interpreted with caution.

The Part D data is obtained from CMS annually, with finder files provided by the USRDS. The Part D data are divided into

two separate files: an annual enrollment file containing monthly indicators of enrollment in Part D, and a prescription drug event file (PDE) containing details of prescriptions filled by Part D beneficiaries.

Since the Part D benefit is voluntary, not all Medicare beneficiaries are enrolled. The annual enrollment file contains 12 monthly indicators that detail whether the beneficiary is enrolled in Part D, and if so, the type of plan. There are also monthly indicators for dual eligibility (Medicare and Medicaid), the retiree drug Subsidy, and the low income subsidy (LIS).

#### **LINKAGES TO THE USRDS DATABASE**

The USRDS does provide the service of linking population cohorts to the USRDS dataset to determine ESRD status and outcomes for epidemiological research. Please contact the USRDS Coordinating Center for more information on the application process and the costs for this service.

#### **FILE MEDIA & FORMATS**

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

#### **COSTS**

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

#### **DOCUMENTATION**

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

#### *data use acknowledgement*

Publications using USRDS data should include an acknowledgment and this notice: The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the 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 (PO) at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators must provide the

PO with a detailed description of the proposed investigation (see Table D). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the "Agreement for Release of Data," later in the appendices. With your completed research proposal, please include a signed agreement for release of information.

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

The investigator and the Coordinating Center (CC) will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation. Payments by credit card or utilizing PO numbers are not accepted.

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

Any reports or articles resulting from use of USRDS data must be submitted to the PO prior to submission for publication to assure adherence to the Privacy Act. The PO must respond within

30 days. If a report or article is determined not to adhere to the Act, it shall not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO's approval indicate government endorsement of the investigator's opinions and conclusions.

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

### *caveats*

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

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

The USRDS CC will provide data in on CD or DVD. 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.



**Acute kidney injury (AKI)** Also known as acute kidney failure or acute renal failure is a sudden decline in renal function triggered by a number of acute occurrences such as shock, trauma, drug toxicity, or kidney stones.

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

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

**Albumin/creatinine ratio (ACR)** A screening test used to assess chronic conditions such as diabetes and hypertension that can put patients at risk for chronic kidney failure.

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

**Angiography** A radiographic procedure where a radio-opaque contrast material is injected into a blood vessel for the purpose of identifying its anatomy.

**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.

**Angiotensin converting enzyme (ACE) inhibitor** An antihypertensive agent that inhibits the production of angiotensin II. Can delay progression to diabetes or kidney disease.

**Angiotensin II receptor blocker (ARB)** an antihypertensive agent that inhibits 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 ingested protein.

**Body mass index (BMI)** A measure of height to weight ratio: weight (kg)/height (m<sup>2</sup>).

**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.

**Cardiac arrest** A complete cessation of cardiac activity.

**Cardiac resynchronization therapy defibrillator (CRT-D)** A device designed to arrest the fibrillation of (heart muscle) by applying electric shock across the chest, thus depolarizing the heart cells and allowing normal rhythm to return.

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

**Catastrophic coverage** The interval following the coverage gap.

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

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

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

**Cerebrovascular accident (CVA)** A general descriptor that encompasses such problems as stroke and cerebral hemorrhage.

**Cerebrovascular disease** A disease that causes narrowing or occlusion of the arteries supplying blood to the brain.

**Chain provider** A single business entity that at years end owns or operates 20 or more freestanding dialysis units. This definition applies to all chain affiliation references in the USRDS Annual Data Reports. An alternative definition from the Centers for Medicare and Medicaid Services can be found under "definitions" in

the Health Care Provider/Supplier Application Form, CMS 855.

**Chronic kidney disease (CKD)** A condition in which there is a progressive loss of kidney function which over time may lead to end-stage renal disease.

**Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI)** A method used to estimate glomerular filtration rate using a single serum creatinine. Yields a lower CKD prevalence than the Modification of Diet in Renal Disease (MDRD) Study equation.

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

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

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

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

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

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

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

**Coverage gap** The interval following the initial coverage period, but preceding catastrophic coverage.

**Creatinine** A waste product of protein metabolism found in the urine; often used to evaluate kidney

function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

**Creatinine clearance** Used as an indicator to predict the onset of uremia, which develops when creatinine clearance falls below 10 ml/minute/1.73 m<sup>2</sup>.

**Creditable coverage** Prescription drug coverage that is actuarially equivalent to the standard Part D benefit, as defined annually by CMS. Beneficiaries with creditable coverage may forgo participation in Medicare Part D without having to pay increased monthly premiums upon future enrollment. Examples of creditable coverage include the Federal Employee Health Benefits Program, TRICARE, VA Health Care Benefits, State Pharmacy Assistance Programs (SPAPs), and private insurance that is eligible for the retiree drug subsidy. Private insurance for the working aged may or may not be creditable.

**Cystatin-C equation** A method which uses the laboratory marker cystatin-C for estimating glomerular filtration rate (GFR).

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

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

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

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

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

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

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

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

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

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

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

**Fills per person** Each prescription drug purchase constitutes a fill. Fills per person are calculated from the quotient of cumulative fills in a population and the number of people in that population.

**Glomerular filtration rate (eGFR)** Estimated rate in ml/min/1.73 m<sup>2</sup> 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, blood urea nitrogen, and serum albumin. GFR is traditionally considered the best overall index to determine renal function.

**Glycosylated hemoglobin (HbA<sub>1c</sub>) test** Used to help determine how well a patient's diabetes is being controlled, this test measures the level of glucose-bound hemoglobin in the bloodstream.

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

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

**Healthy People 2010** A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people ([www.health.gov/healthypeople](http://www.health.gov/healthypeople)).

**Hemodialysis** The process of removing toxins from the blood by diffusion through a semi-permeable membrane.

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

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

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

**Implantable cardioverter defibrillator (ICD)** An implantable device designed to arrest the fibrillation of (heart muscle) by applying electric shock thus depolarizing the heart cells and allowing normal rhythm to return.

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

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

**Independent unit** A unit licensed to provide outpatient and home maintenance dialysis, and not affiliated with a chain.

**Initial coverage period** The interval following the deductible phase, but preceding the coverage gap.

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

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

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

**Low income subsidy (LIS)** For Medicare beneficiaries with limited income and/or assets, the costs of participation in Medicare Part D may be reduced by the LIS. Beneficiaries who are dually eligible for Medicare and Medicaid are automatically granted the LIS, while beneficiaries who are not dually eligible may apply for it. While the LIS may take eight different levels, with monthly premiums and copayments either eliminated or reduced, all dually eligible beneficiaries pay no monthly premiums.

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

**Medicare Advantage Part D plans (MA-PDs)** Medicare Part D plans that are offered only to participants in Medicare Part C.

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

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

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

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

**Modification of Diet in Renal Disease (MDRD) Study equation** A method used to estimate glomerular filtration (GFR) using a single serum creatinine.

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

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

**Organ Procurement and Transplantation Network (OPTN)** The unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984. A private, non-profit organization administered by the United Network for Organ Sharing, under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

**Part D Medicare coverage** A U.S. government program which subsidizes the costs of medications for Medicare beneficiaries.

**Percutaneous coronary intervention (PCI)** A therapeutic procedure to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease. Commonly known as coronary angioplasty or simply angioplasty.

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

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

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

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

**Program Medical Management and Information System for ESRD, and Renal Beneficiary and Utilization System (PMMIS/REBUS)** The major source of data for the USRDS. This CMS file incorporates data from the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.

**Prevalent ESRD patient** A patient on renal replacement therapy or with a functioning kidney transplant (regardless of the transplant date). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving

treatment for ESRD, and those whose ESRD treatments are not reported to CMS.

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

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

**Recombinant human growth hormone (rhGH)** Also called somatropin; a substance identical in its amino acid sequence to human growth hormone, and used to treat growth hormone deficiency.

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

**Renin Inhibitors** A class of drugs used to lower blood pressure by blocking the renin-angiotensin system which regulates blood volume and systemic vascular resistance.

**Retiree drug subsidy (RDS)** A program designed to encourage employers to continue to provide prescription drug coverage to retirees eligible for Medicare Part D. Under the program, employers received a tax-free rebate equal to 28 percent of covered prescription drug costs incurred by its retirees. The program is relatively simple to administer, but may ultimately be more costly than providing employees a type of Part D plan known as an "employer group waiver plan." Following passage of the Patient Protection and Affordable Care Act, the tax-free status of the subsidy is due to expire on December 31, 2012.

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

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

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

**Total days supply** Each prescription drug is disbursed with sufficient quantity to administer for a set number of

days, so long as instructions are followed (i.e., so long as adherence is perfect). The total days supplied is equal to the cumulative number of days supplied through all fills of a particular medication in a population.

**Transient ischemic attacks (TIA)** A temporary loss of neurological function caused by a brief period of inadequate blood supply in a portion of the brain supplied by the carotid or vertebral basilar arteries.

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

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

**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 Mondofacto Medical Dictionary, found at [www.mondofacto.com/dictionary](http://www.mondofacto.com/dictionary).**

## abbreviations

<b>A1c</b>	glycosylated hemoglobin	<b>CPT</b>	Current Procedure and Terminology	<b>KDOQI</b>	Kidney Disease Outcomes Quality Initiative
<b>ACEI</b>	angiotensin converting enzyme inhibitor	<b>CRT-D</b>	cardiac resynchronization therapy defibrillator	<b>LIS</b>	low income subsidy
<b>ACR</b>	albumin/creatinine ratio	<b>CVD</b>	cerebrovascular disease	<b>MCBS</b>	Medicare Current Beneficiary Survey
<b>AKI</b>	acute kidney injury	<b>DCD</b>	donation after cardiac death	<b>MDRD</b>	Modification of Diet in Renal Disease
<b>AKI-D</b>	acute kidney injury with dialysis	<b>DGF</b>	delayed graft function	<b>ME</b>	Medical Evidence form (2728)
<b>AMI</b>	acute myocardial infarction	<b>DM</b>	diabetes, diabetic	<b>MI</b>	myocardial infarction
<b>ARB</b>	angiotensin receptor blocker	<b>DPO</b>	darbepoetin alfa	<b>MPP</b>	Medicare as primary payer
<b>ASHD</b>	atherosclerotic heart disease	<b>DRG</b>	diagnosis related group	<b>MSP</b>	Medicare as secondary payer
<b>AV</b>	arteriovenous	<b>ECD</b>	expanded criteria donor	<b>NDM</b>	non-diabetic
<b>BMI</b>	body mass index	<b>EGHP</b>	employer group health plan	<b>NHANES</b>	National Health and Nutrition Examination Survey
<b>BUN</b>	blood urea nitrogen	<b>EPO</b>	erythropoietin	<b>NKF</b>	National Kidney Foundation
<b>CAPD</b>	continuous ambulatory peritoneal dialysis	<b>ESA</b>	erythropoiesis stimulating agent	<b>OOP</b>	out-of-pocket
<b>CCPD</b>	continuous cycler peritoneal dialysis	<b>ESRD</b>	end-stage renal disease	<b>OPTN</b>	Organ Procurement and Transplantation Network
<b>CCR</b>	creatinine clearance rate	<b>eGFR</b>	estimated glomerular filtration rate	<b>PACE</b>	programs of all-inclusive care for the elderly
<b>CDC</b>	Centers for Disease Control and Prevention	<b>GN</b>	glomerulonephritis	<b>PPPM</b>	per person per month
<b>CDS</b>	Comprehensive Dialysis Study	<b>HCPCS</b>	healthcare common procedure coding system	<b>PPPY</b>	per person per year
<b>CHF</b>	congestive heart failure	<b>HD</b>	hemodialysis	<b>PCI</b>	percutaneous coronary intervention
<b>CKD</b>	chronic kidney disease	<b>HEDIS</b>	Health Plan Employer Data Information Set	<b>PAD</b>	peripheral arterial disease
<b>CKD-EPI</b>	Chronic Kidney Disease Epidemiology Collaboration	<b>HMO</b>	health maintenance organization	<b>PVD</b>	peripheral vascular disease
<b>CMS</b>	Centers for Medicare & Medicaid Services	<b>HSA</b>	Health Service Area	<b>PD</b>	peritoneal dialysis
<b>COPD</b>	chronic obstructive pulmonary disease	<b>HTN</b>	hypertension	<b>PPS</b>	Prospective Payment System
<b>CPM</b>	Clinical Performance Measures Project	<b>ICD</b>	implantable cardioverter defibrillator	<b>SCD</b>	standard criteria donor
<b>CVA/TIA</b>	cerebrovascular accident/transient ischemic attack	<b>ICD-9-CM</b>	International Classification of Diseases, 9th revision, Clinical Modification	<b>SHR</b>	standardized hospitalization ratio
		<b>IPD</b>	intermittent peritoneal dialysis	<b>SMR</b>	standardized mortality ratio
		<b>ISHD</b>	ischemic heart disease	<b>UNOS</b>	United Network for Organ Sharing
				<b>WHO</b>	World Health Organization

# United States Renal Data System (USRDS) Agreement for Release of Data

Project title \_\_\_\_\_

In this agreement, "Requestor Organization" 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 Requestor with CDs, DVDs, or other media type containing the data extracted from the USRDS research database (the "Data"), which constitutes a Limited Data Set within the meaning of the HIPAA privacy regulations.
- 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 Requestor.
- C. The Requestor shall not use the Data to identify individuals on the file.
- D. The Requestor 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 Requestor shall not use the Data for purposes that are not related to biomedical research, cost-effectiveness, economic and/or other epidemiological 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 Requestor 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 Requestor shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred. However, the Requestor may release Data to a contractor for purposes of data processing or storage if (1) the Requestor specified in the research plan submitted to the USRDS Project Officer that Data would be released to the particular contractor, or the Requestor 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 Requestor 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 Requestor 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 Requestor until the date specified by the PO in the approval letter, at which time Requestor may request renewal of this data use agreement to extend the retention period to comply with legal or institutional recordkeeping requirements or to maintain the integrity of the research or research publications. If at any time during the data retention period the DUA between USRDS and CMS is canceled, the Requestor will be contacted to destroy the files in their possession. At the completion of the activities in the research plan, the file(s) and any derivative files and copies shall be destroyed. At that time the Requestor will inform the USRDS and the PO in writing that the files have been destroyed.
- J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the NIDDK and/or of CMS will, upon request, be granted access to premises where the Data are kept.

K. The following USRDS data file(s) is/are covered under this Agreement.

Name of Data file(s) requested (e.g., Core, Institutional claims, etc)

Year(s) if applicable

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

REQUESTOR SIGNATURE: \_\_\_\_\_

Authorized signatory (name, title & date)

Requestor address

Requestor telephone number

READ AND ACKNOWLEDGED:

Investigator/Analyst signature

Print Investigator/Analyst name & date

Investigator/Analyst signature

Print Investigator/Analyst name & date

Investigator/Analyst signature

Print Investigator/Analyst name & date

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

USRDS Project Officer signature & date

June 2012

# United States Renal Data System (USRDS) Merged Dataset Agreement for Release of Data

Project title \_\_\_\_\_

In this agreement, "Requestor Organization" 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 Requestor CDS, DVDS or other media type containing data extracted from the USRDS research database. Prior to receiving USRDS data, the Requestor will provide USRDS with a list of personally identifiable information (PII) so USRDS can report which of the Requestor's subjects are in the USRDS end-stage renal disease (ESRD) data.
- 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 Requestor.
- C. USRDS shall not use or disclose the Requestor's data for any purpose other than to create the data extracted from the USRDS database. In the event that the Requestor's data is used or disclosed for any purpose other than that covered by this agreement, USRDS will notify the Requestor immediately and agree to work with Requestor to address the use or disclosure. The USRDS will destroy the Requestor's data set one year after the linkage is complete unless otherwise specified by the Requestor in the research proposal.
- D. The Requestor 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 a waiver of authorization has been approved by the Requestor's IRB/Privacy Board.
- E. The Requestor shall not use the Data for purposes that are not related to biomedical research, cost-effectiveness, economic and/or other epidemiological 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 Requestor 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 Requestor shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Requestor may release data to a contractor for purposes of data processing or storage if (1) the Requestor specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor, or the Requestor 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 Requestor 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 Requestor 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 Requestor until the date specified by the PO in the approval letter, at which time Requestor may request renewal of this data use agreement to extend the retention period to comply with legal or institutional recordkeeping requirements or to maintain the integrity of the research or research publications. If at any time during the data retention period the DUA between USRDS and CMS is canceled, the Requestor will be contacted to destroy the files in their possession. At the completion of the activities in the research plan, the file(s) and any derivative files and copies shall be destroyed. At that time the Requestor will inform the USRDS and the PO in writing that the files have been destroyed.
- J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the NIDDK and/or of CMS will, upon request, be granted access to premises where the Data are kept.

K. The following USRDS data file(s) is/are covered under this Agreement.

Name of Data file(s) requested (e.g., Core, Institutional claims, etc)

Year(s) if applicable

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

REQUESTOR SIGNATURE: \_\_\_\_\_

Authorized signatory (name, title & date)

Requestor address

Requestor telephone number

READ AND ACKNOWLEDGED:

Requestor/investigator signature

Print name & date

Requestor/investigator signature

Print name & date

Requestor/investigator signature

Print name & date

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

USRDS Project Officer signature & date

June 2012



## 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 <input type="checkbox"/> Male <input type="checkbox"/> Female	8. Ethnicity <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Hispanic or Latino (Complete Item 9)	9. Country/Area of Origin or Ancestry
10. Race (Check all that apply) <input type="checkbox"/> White <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian or Other Pacific Islander* <input type="checkbox"/> American Indian/Alaska Native Print Name of Enrolled/Principal Tribe _____ *complete Item 9		11. Is patient applying for ESRD Medicare coverage? <input type="checkbox"/> Yes <input type="checkbox"/> No

12. Current Medical Coverage (Check all that apply) <input type="checkbox"/> Medicaid <input type="checkbox"/> Medicare <input type="checkbox"/> Employer Group Health Insurance <input type="checkbox"/> DVA <input type="checkbox"/> Medicare Advantage <input type="checkbox"/> Other <input type="checkbox"/> None	13. Height INCHES _____ OR CENTIMETERS _____	14. Dry Weight POUNDS _____ OR KILOGRAMS _____	15. Primary Cause of Renal Failure (Use code from back of form)
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16. Employment Status (6 mos prior and current status) <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <b>Prior</b> <input type="checkbox"/></div> <div style="text-align: center;"> <b>Current</b> <input type="checkbox"/></div> </div> <input type="checkbox"/> Unemployed <input type="checkbox"/> Employed Full Time <input type="checkbox"/> Employed Part Time <input type="checkbox"/> Homemaker <input type="checkbox"/> Retired due to Age/Preference <input type="checkbox"/> Retired (Disability) <input type="checkbox"/> Medical Leave of Absence <input type="checkbox"/> Student	17. Co-Morbid Conditions (Check all that apply currently and/or during last 10 years)*See instructions a. <input type="checkbox"/> Congestive heart failure b. <input type="checkbox"/> Atherosclerotic heart disease ASHD c. <input type="checkbox"/> Other cardiac disease d. <input type="checkbox"/> Cerebrovascular disease, CVA, TIA* e. <input type="checkbox"/> Peripheral vascular disease* f. <input type="checkbox"/> History of hypertension g. <input type="checkbox"/> Amputation h. <input type="checkbox"/> Diabetes, currently on insulin i. <input type="checkbox"/> Diabetes, on oral medications j. <input type="checkbox"/> Diabetes, without medications k. <input type="checkbox"/> Diabetic retinopathy l. <input type="checkbox"/> Chronic obstructive pulmonary disease m. <input type="checkbox"/> Tobacco use (current smoker) n. <input type="checkbox"/> Malignant neoplasm, Cancer o. <input type="checkbox"/> Toxic nephropathy p. <input type="checkbox"/> Alcohol dependence q. <input type="checkbox"/> Drug dependence* r. <input type="checkbox"/> Inability to ambulate s. <input type="checkbox"/> Inability to transfer t. <input type="checkbox"/> Needs assistance with daily activities u. <input type="checkbox"/> Institutionalized <input type="checkbox"/> 1. Assisted Living <input type="checkbox"/> 2. Nursing Home <input type="checkbox"/> 3. Other Institution v. <input type="checkbox"/> Non-renal congenital abnormality w. <input type="checkbox"/> None
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18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	If Yes, answer: <input type="checkbox"/> 6-12 months <input type="checkbox"/> >12 months
b. Was patient under care of a nephrologist?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	If Yes, answer: <input type="checkbox"/> 6-12 months <input type="checkbox"/> >12 months
c. Was patient under care of kidney dietitian?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	If Yes, answer: <input type="checkbox"/> 6-12 months <input type="checkbox"/> >12 months
d. What access was used on first outpatient dialysis: If not AVF, then: Is maturing AVF present? Is maturing graft present?	AVF <input type="checkbox"/> Graft <input type="checkbox"/> Catheter <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>	<input type="checkbox"/> Other

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

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	_____	____/____/____	d. HbA1c	_____ %	____/____/____
a.2. Serum Albumin Lower Limit	_____	____/____/____	e. Lipid Profile TC	_____	____/____/____
a.3. Lab Method Used (BCG or BCP)	_____	____/____/____	LDL	_____	____/____/____
b. Serum Creatinine (mg/dl)	_____	____/____/____	HDL	_____	____/____/____
c. Hemoglobin (g/dl)	_____	____/____/____	TG	_____	____/____/____

**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 <input type="checkbox"/> Home <input type="checkbox"/> Dialysis Facility/Center <input type="checkbox"/> SNF/Long Term Care Facility	23. Primary Type of Dialysis <input type="checkbox"/> Hemodialysis (Sessions per week ____/hours per session ____) <input type="checkbox"/> CAPD <input type="checkbox"/> CCPD <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No	27. If patient NOT informed of transplant options, please check all that apply: <input type="checkbox"/> Medically unfit <input type="checkbox"/> Patient declines information <input type="checkbox"/> Unsuitable due to age <input type="checkbox"/> Patient has not been assessed <input type="checkbox"/> Psychologically unfit <input type="checkbox"/> Other

**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) <input type="checkbox"/> Functioning <input type="checkbox"/> Non-Functioning	35. Type of Donor: <input type="checkbox"/> Deceased <input type="checkbox"/> Living Related <input type="checkbox"/> Living Unrelated	
36. If Non-Functioning, Date of Return to Regular Dialysis MM / DD / YYYY	37. Current Dialysis Treatment Site <input type="checkbox"/> Home <input type="checkbox"/> Dialysis Facility/Center <input type="checkbox"/> 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 <input type="checkbox"/> Hemodialysis    a. <input type="checkbox"/> Home    b. <input type="checkbox"/> In Center <input type="checkbox"/> CAPD <input type="checkbox"/> CCPD <input type="checkbox"/> Other	
42. This Patient is Expected to Complete (or has completed) Training and will Self-dialyze on a Regular Basis. <input type="checkbox"/> Yes <input type="checkbox"/> 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
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**E. PHYSICIAN IDENTIFICATION**

46. Attending Physician (Print)	47. Physician's Phone No. (    )	48. UPIN of Physician in Item 46
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**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
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**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 may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the *Federal Register* notice cited above. You should be aware that P.L.100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

## 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.**

### DIABETES

- 25040 Diabetes with renal manifestations Type 2
- 25041 Diabetes with renal manifestations Type 1

### GLOMERULONEPHRITIS

- 5829 Glomerulonephritis (GN)  
(histologically not examined)
- 5821 Focal glomerulosclerosis, focal sclerosing GN
- 5831 Membranous nephropathy
- 58321 Membranoproliferative GN type 1, diffuse MPGN
- 58322 Dense deposit disease, MPGN type 2
- 58381 IgA nephropathy, Berger's disease  
(proven by immunofluorescence)
- 58382 IgM nephropathy (proven by immunofluorescence)
- 5834 With lesion of rapidly progressive GN
- 5800 Post infectious GN, SBE
- 5820 Other proliferative GN

### SECONDARY GN/VASCULITIS

- 7100 Lupus erythematosus, (SLE nephritis)
- 2870 Henoch-Schonlein syndrome
- 7101 Scleroderma
- 28311 Hemolytic uremic syndrome
- 4460 Polyarteritis
- 4464 Wegener's granulomatosis
- 58392 Nephropathy due to heroin abuse and related drugs
- 44620 Other Vasculitis and its derivatives
- 44621 Goodpasture's syndrome
- 58391 Secondary GN, other

### INTERSTITIAL NEPHRITIS/PYELONEPHRITIS

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

### HYPERTENSION/LARGE VESSEL DISEASE

- 40391 Unspecified with renal failure
- 4401 Renal artery stenosis
- 59381 Renal artery occlusion
- 59383 Cholesterol emboli, renal emboli

### CYSTIC/HEREDITARY/CONGENITAL DISEASES

- 75313 Polycystic kidneys, adult type (dominant)
- 75314 Polycystic, infantile (recessive)
- 75316 Medullary cystic disease, including nephronophthisis
- 7595 Tuberous sclerosis
- 7598 Hereditary nephritis, Alport's syndrome
- 2700 Cystinosis
- 2718 Primary oxalosis
- 2727 Fabry's disease
- 7533 Congenital nephrotic syndrome
- 5839 Drash syndrome, mesangial sclerosis
- 75321 Congenital obstruction of ureteropelvic junction
- 75322 Congenital obstruction of ureterovesical junction
- 75329 Other Congenital obstructive uropathy
- 7530 Renal hypoplasia, dysplasia, oligonephronia
- 75671 Prune belly syndrome
- 75989 Other (congenital malformation syndromes)

### NEOPLASMS/TUMORS

- 1890 Renal tumor (malignant)
- 1899 Urinary tract tumor (malignant)
- 2230 Renal tumor (benign)
- 2239 Urinary tract tumor (benign)
- 23951 Renal tumor (unspecified)
- 23952 Urinary tract tumor (unspecified)
- 20280 Lymphoma of kidneys
- 20300 Multiple myeloma
- 20308 Other immuno proliferative neoplasms  
(including light chain nephropathy)
- 2773 Amyloidosis
- 99680 Complications of transplanted organ unspecified
- 99681 Complications of transplanted kidney
- 99682 Complications of transplanted liver
- 99683 Complications of transplanted heart
- 99684 Complications of transplanted lung
- 99685 Complications of transplanted bone marrow
- 99686 Complications of transplanted pancreas
- 99687 Complications of transplanted intestine
- 99689 Complications of other specified transplanted organ

### MISCELLANEOUS CONDITIONS

- 28260 Sickle cell disease/anemia
- 28269 Sickle cell trait and other sickle cell (HbS/Hb other)
- 64620 Post partum renal failure
- 042 AIDS nephropathy
- 8660 Traumatic or surgical loss of kidney(s)
- 5724 Hepatorenal syndrome
- 5836 Tubular necrosis (no recovery)
- 59389 Other renal disorders
- 7999 Etiology uncertain

## ESRD DEATH NOTIFICATION

### END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

1. Patient's Last Name	First	MI	2. Medicare Claim Number
3. Patient's Sex a. <input type="checkbox"/> Male    b. <input type="checkbox"/> Female	4. Date of Birth ____ / ____ / ____ Month    Day    Year		5. Social Security Number
6. Patient's State of Residence	7. Place of Death a. <input type="checkbox"/> Hospital    c. <input type="checkbox"/> Home    e. <input type="checkbox"/> Other b. <input type="checkbox"/> Dialysis Unit    d. <input type="checkbox"/> Nursing Home		8. Date of Death ____ / ____ / ____ Month    Day    Year
9. Modality at Time of Death a. <input type="checkbox"/> Incenter Hemodialysis    b. <input type="checkbox"/> Home Hemodialysis    c. <input type="checkbox"/> CAPD    d. <input type="checkbox"/> CCPD    e. <input type="checkbox"/> Transplant    f. <input type="checkbox"/> Other			
10. Provider Name and Address (Street)			11. Provider Number

Provider Address (City/State)

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

- a. Primary Cause    \_ \_ \_
- b. Were there secondary causes?  
 No  
 Yes, specify:    \_ \_ \_ \_ \_ \_ \_ \_ \_ \_
- c. If cause is other (98) please specify: \_\_\_\_\_

<p>13. Renal replacement therapy discontinued prior to death:    <input type="checkbox"/> Yes    <input type="checkbox"/> No</p> <p><b>If yes, check one of the following:</b></p> <p>a. <input type="checkbox"/> Following HD and/or PD access failure</p> <p>b. <input type="checkbox"/> Following transplant failure</p> <p>c. <input type="checkbox"/> Following chronic failure to thrive</p> <p>d. <input type="checkbox"/> Following acute medical complication</p> <p>e. <input type="checkbox"/> Other</p> <p>f. Date of last dialysis treatment    ____ / ____ / ____  <span style="margin-left: 100px;">Month    Day    Year</span></p>	<p>14. Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?</p> <p><input type="checkbox"/> Yes                      <input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown                <input type="checkbox"/> Not Applicable</p>
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<p>15. If deceased ever received a transplant:</p> <p>a. Date of most recent transplant    ____ / ____ / ____    <input type="checkbox"/> Unknown  <span style="margin-left: 100px;">Month    Day    Year</span></p> <p>b. Type of transplant received  <input type="checkbox"/> Living Related    <input type="checkbox"/> Living Unrelated    <input type="checkbox"/> Deceased    <input type="checkbox"/> Unknown</p> <p>c. Was graft functioning (patient not on dialysis) at time of death?  <input type="checkbox"/> Yes                      <input type="checkbox"/> No                                      <input type="checkbox"/> Unknown</p> <p>d. Did transplant patient resume chronic maintenance dialysis prior to death?  <input type="checkbox"/> Yes                                      <input type="checkbox"/> No    <input type="checkbox"/> Unknown</p>	<p>16. Was patient receiving Hospice care prior to death?</p> <p><input type="checkbox"/> Yes                                      <input type="checkbox"/> No</p> <p><input type="checkbox"/> Unknown</p>
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17. Name of Physician (Please print complete name)	18. Signature of Person Completing This Form	Date
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This report is required by law (42, U.S.C. 426; 20 CFR 405, Section 2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 U.S.C. 5520; 45 CFR Part 5a).

**ESRD DEATH NOTIFICATION FORM  
LIST OF CAUSES**

**CARDIAC**

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

**VASCULAR**

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

**INFECTION**

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

**LIVER DISEASE**

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

**GASTRO-INTESTINAL**

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

**METABOLIC**

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

**ENDOCRINE**

- 96 Adrenal insufficiency
- 97 Hypothyroidism
- 103 Hyperthyroidism

**OTHER**

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

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

<b>END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM ESRD FACILITY SURVEY (DIALYSIS UNITS ONLY)</b>	<b>FOR THE PERIOD</b>
<b>Facility Physical Address</b> _____ <i>(If different than mailing address) Suite/Room Street City State/Zip Code</i>	
<b>Number of Dialysis Stations:</b> _____ <b>Facility Telephone:</b> ( _____ )	
<b>Facility Ownership Type:</b> <input type="checkbox"/> Profit <input type="checkbox"/> Non-Profit	
<b>Facility Local/National Affiliation/Chain Information</b> _____ <i>(i.e. Gambro, etc.)</i>	
<b>Types of dialysis services offered:</b> <input type="checkbox"/> Incenter Hemodialysis <input type="checkbox"/> Peritoneal Dialysis <input type="checkbox"/> Home Hemodialysis Training	
<b>Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No	

### DIALYSIS PATIENTS AND TREATMENTS

#### DIALYSIS PATIENTS

Patients Receiving Care Beginning of Survey Period			Additions During Survey Period				Losses During Survey Period					
Incenter	Home	Total Fields 01 thru 02	Started for first time ever	Restarted	Transferred from other dialysis unit	Returned after transplantation	Deaths	Recovered kidney function	Received transplant	Transferred to other dialysis unit	Discontinued dialysis	Other (LTFU)
01	02	03	04A	05A	06A	07A	08A	09A	10A	11A	12A	13A
			04B	05B	06B	07B	08B	09B	10B	11B	12B	13B

Patients Receiving Care at End of Survey Period												Total Patients Fields 20 and 25
Incenter Dialysis		Self-Dialysis Training				Total Incenter Dialysis	Home Dialysis				Total Home Dialysis	
Hemo-Dialysis	Other	Hemo-Dialysis	CAPD	CCPD	Other	Fields 14 thru 19	Hemo-Dialysis	CAPD	CCPD	Other	Fields 21 thru 24	
14	15	16	17	18	19	20	21	22	23	24	25	26

Patient Eligibility Status End of Survey Period		
Currently enrolled in Medicare	Medicare application pending	Non-Medicare
27	28	29

Hemodialysis Patients Dialyzing More Than 4 Times Per Week		
Setting	Day	Nocturnal
Incenter		
Home		
	30A 30B	31A 31B

Vocational Rehabilitation			
Patients aged 18 through 54	Patients receiving services from Voc Rehab	Patients Employed full-time or part-time	Patients attending school full-time or part-time
32	33	34	35

#### TREATMENT AND STAFFING

Incenter Dialysis Treatments (Include Training Treatments)	
Hemodialysis	Other
36	37

Staffing				
Position	Number of Staff		Number of Open Pos.	
	Full Time	Part Time	Full Time	Part Time
a. RNs				
b. LPN/LVNs				
c. PCTs				
d. APNs				
e. Dietitians				
f. Social Workers				
	38	39	40	41

COMPLETED BY (Name)	DATE	TITLE	TELEPHONE NO.
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**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).

**END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM  
ESRD FACILITY SURVEY (TRANSPLANT CENTERS ONLY)**

FOR THE PERIOD

**KIDNEY TRANSPLANTS PERFORMED**

**PATIENTS TRANSPLANTED  
AND DONOR TYPE**

**TO BE COMPLETED BY  
KIDNEY TRANSPLANT CENTERS ONLY**

Patients who received transplant at this facility			

42

Eligibility Status of Patients Transplanted at this Facility During the Survey Period			
Currently enrolled in Medicare	Medicare application pending	Non-Medicare	
		U.S. Res.	Other

43

44

45

46

Transplant Procedures Performed at This Facility			
Living Related Donor	Living Unrelated Donor	Deceased Donor	Total Fields 47 thru 49

47

48

49

50

Patients Awaiting Transplant	
Dialysis	Nondialysis

51

52

**REMARKS/COMMENTS**

COMPLETED BY (Name)	DATE	TITLE	TELEPHONE NO.
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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).



Louis Hennebin, 1698

We have framed this ADR with maps that span more than a thousand years of history, showing how cartography and the evolving knowledge of global navigation have changed our views of the world, and drawing parallels to advancements in our understanding of kidney disease. We hope that this book enhances our readers' ability to navigate the complex terrain of this disease, just as mariners used their own analytical tools to find safe passage to distant ports of call.

*Now, bring me that horizon.*  
CAPTAIN JACK SPARROW, PIRATES OF THE CARIBBEAN





