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The very source and fount of day
Is dash'd with wandering isles of night.

Alfred, Lord Tennyson, "In Memoriam"

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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 payor histories, hospitalization events, deaths, physician/supplier services, and providers.

REMIS/REBUS/PMMIS DATABASE

The major source of **ESRD** patient information for the **USRDS** is the 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**

CMS MEDICARE ENROLLMENT DATABASE

The Medicare Enrollment Database (**EDB**) is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payor (**MSP**) and 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, released in May, 2005, was intended to remedy several shortcomings found in 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 2010 ADR includes all claims up to December 31, 2008. Patient-specific demographic and diagnosis information, however, includes data as recent as October, 2009.

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 information on incidence and prevalence.

The problem of timely identification has lessened since 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 2010 ADR includes all claims up to December 31, 2008.

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



ESRD NETWORKS

NETWORK 1

Connecticut, Maine,
Massachusetts, New Hampshire,
Rhode Island, Vermont

ESRD Network of New England, Inc.
30 Hazel Terrace
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phone 203.387.9332
fax 203.389.9902

NETWORK 2

New York

CKD Network for New York
1979 Marcus Avenue, Suite 105
Lake Success, NY 11042-1002
phone 516.209.5578
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NETWORK 3

New Jersey, Puerto Rico,
Virgin Islands

Cranbury Gates Office Park
109 S. Main Street, Suite 21
Cranbury, NJ 08512-3174
phone 609.490.0310
fax 609.490.0835

NETWORK 4

Delaware, Pennsylvania

ESRD Network 4, Inc.
40 24th Street, Suite 410
Pittsburgh, PA 15222
phone 412.325.2250
fax 412.325.1811

NETWORK 5

Virginia, West Virginia,
Maryland, District of Columbia

Mid-Atlantic Renal Coalition
1527 Huguenot Road
Midlothian, VA 23113
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fax 804.794.3793

NETWORK 6

Georgia, North Carolina,
South Carolina

Southeastern Kidney Council, Inc.
1000 St. Albans Drive, Suite 270
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phone 919.855.0882
fax 919.855.0753

NETWORK 7

Florida

FMQAI: The Florida ESRD Network
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Tampa, FL 33609
phone 813.383.1530
fax 813.354.1514

NETWORK 8

Alabama, Mississippi, Tennessee

1755 Lelia Drive, Suite 400
Jackson, MS 39216
phone 601.936.9260
fax 601.932.4446

NETWORK 9/10

Illinois, Indiana, Kentucky, Ohio

The Renal Network, Inc.
911 East 86th Street, Suite 202
Indianapolis, IN 46240
phone 317.255.8265
fax 317.255.8291

NETWORK 11

Minnesota, Michigan, North Dakota,
South Dakota, Wisconsin

Renal Network of the Upper Midwest, Inc.
1360 Energy Park Drive, Suite 200
St. Paul, MN 55108
phone 651.644.9877
fax 651.644.9853

NETWORK 12

Iowa, Kansas, Missouri, Nebraska

ESRD Network #12
7306 NW Tiffany Springs Pkwy
Suite 230
Kansas City, MO 64153
phone 816.880.9990
fax 816.880.9088

NETWORK 13

Arkansas, Louisiana, Oklahoma

ESRD Network Organization #13
4200 Perimeter Center Drive, Suite 102
Oklahoma City, OK 73112-2314
phone 405.942.6000
fax 405.942.6884

NETWORK 14

Texas

ESRD Network of Texas, Inc.
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Dallas, TX 75244
phone 972.503.3215
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NETWORK 15

Arizona, Colorado, Nevada,
New Mexico, Utah, Wyoming

Intermountain ESRD Network, Inc.
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Lakewood, CO 80228
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NETWORK 16

Alaska, Idaho, Montana,
Oregon, Washington

Northwest Renal Network
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Seattle, WA 98116
phone 206.923.0714
fax 206.923.0716

NETWORK 17

American Samoa, Guam,
Mariana Islands, Hawaii,
Northern California

Western Pacific Renal Network, LLC
505 San Marin Drive, Bldg A, Suite 300
Novato, CA 94945
phone 415.897.2400
fax 415.897.2422

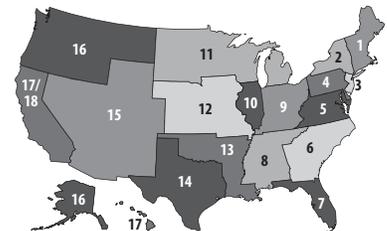
NETWORK 18

Southern California

Southern California Renal
Disease Council, Inc.
6255 Sunset Boulevard, Suite 2211
Los Angeles, CA 90028
phone 323.962.2020
fax 323.962.2891

Network 1 Connecticut, Maine, Massachusetts,
New Hampshire, Rhode Island, Vermont
Network 2 New York
Network 3 New Jersey, Puerto Rico, Virgin
Islands
Network 4 Delaware, Pennsylvania
Network 5 Maryland, Virginia, Washington
D.C., West Virginia
Network 6 Georgia, North Carolina, South
Carolina
Network 7 Florida
Network 8 Alabama, Mississippi, Tennessee
Network 9 Indiana, Kentucky, Ohio

Network 10 Illinois
Network 11 Michigan, Minnesota, North
Dakota, South Dakota, Wisconsin
Network 12 Iowa, Kansas, Missouri, Nebraska
Network 13 Arkansas, Louisiana, Oklahoma
Network 14 Texas
Network 15 Arizona, Colorado, Nevada, New
Mexico, Utah, Wyoming
Network 16 Alaska, Idaho, Montana, Oregon,
Washington
Network 17 American Samoa, Northern
California, Guam, Hawaii
Network 18 Southern California



with CMS, is now making these ESRD CPM data available to the general research community.

MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)

The Medicare Current Beneficiary Survey 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 (1992–2007), and Cost and Use (1992–2006), with the 2007 and 2006 files, respectively, the latest updates for the 2010 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. The USRDS will, however, include both 2008 and 2009 PDE data in its 2011 ADR.

THOMSON REUTERS MARKETSCAN DATA

The 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 MarketScan 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 2008, and includes commercial health data from approximately 100 payors. 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 MarketScan data, please visit www.usrds.org.

INGENIX I3 DATA

The Ingenix i3 database is a commercial and non-capitated health plan database covering employees from multiple employers within

a single insurer. In addition to the usual service encounter and drug data, similar to that of the MarketScan database, this database also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. In order 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 Ingenix i3 database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2008, and contains health data for approximately 14 million people annually. For details about what is contained in the Ingenix i3 data, please visit our website at www.usrds.org.

NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)

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

ANNUAL FACILITY SURVEY (AFS)

Independent ESRD patient counts are available not only from the CMS ESRD database, but also from CMS's Annual Facility Survey (CMS 2744), which all Medicare-certified dialysis units must complete at the end of each year. The AFS reports counts of patients being 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 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 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 30 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 & CLEANING

Data files come to the USRDS in IBM 3490 and 3490e cartridges/CD-ROMS with EBCDIC, ASCII, or SAS formats. Due to increased awareness of and 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, 2009, and Medicare inpatient/outpatient and physician/supplier claims through December 31, 2008.

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 trans-

plant 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 & NON-MEDICARE ('ZZ') PATIENTS

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

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by employer group health plans (EGHPS), and must wait 30–33 months before becoming eligible to have Medicare as their primary payor. Some of these patients, particularly new patients since 1995, have FSDs established by ME forms, but have no dialysis claims or hospitalization events in the CMS claims database. In the REBUS/PMMS 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. We are collaborating with CMS and other interested researchers to establish a consistent approach to managing the data for these patients. 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 the 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 payor for up to the first 30–33 months of ESRD, delaying the submission of Medicare dialysis claims, lost-to-follow-up categorization cannot begin until the end of the third year after the start of ESRD service. This “first three-year rule” is particularly important for non-Medicare patients, who may be followed for up to three years with limited event or mortality data. These patients would contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data 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 payor other than Medicare, or have received a transplant not paid for by Medicare or reported to OPTN.
- ◆ The patient may be enrolled in a Medicare HMO, so that Medicare dialysis claims are not generated even though the patient is eligible for Medicare coverage.
- ◆ The patient's death may not have been reported to the Social Security Administration or to CMS.

INTEGRATION OF THE USRDS, SIMS, & REMIS DATABASES

We 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 the 2007 ADR 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: bromcresol purple or bromcresol 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 payor at day 91 or, for EGHP patients, at 30–33 months after the first ESRD service date. These limitations influence our ability to determine a patient’s exact modality at any one point in time.

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

As mentioned earlier, a new modality/event — recovered renal function — 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.

PAYORS

Information on payors 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 payor (MPP), but who have at least three consecutive months of dialysis treatment covered by Medicare; these patients are also designated as having MPP coverage. From these two data sources we construct a payor sequence file to provide payor history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payors.

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

PRIMARY CAUSE OF RENAL FAILURE

Information on the primary cause of renal failure is obtained directly from the 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 & 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 MarketScan and Ingenix I3 databases. To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the 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 MarketScan and I3 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 kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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

PRÉCIS

For Figure p.1 we identify chronic kidney disease (CKD), congestive heart failure (CHF), and diabetes in patients from the 5 percent Medicare sample using methods described for Chapter Eleven; these methods are also used to determine diabetic status and CHF in the ESRD population. Costs for the “cost year” are determined for the entire calendar year for patients who have fee-for-service cover-

age and Medicare as primary payor. 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 2008, as reported by the OPTN. Transplants of unknown donor type are excluded from by-donor counts. New waiting list counts include all patients added to the waiting list for a kidney-alone or a kidney-pancreas transplant in 2008; patients added at multiple centers are counted once. The total N on the waiting list includes all patients listed for a kidney-alone or kidney-pancreas transplant as of December 31, 2008, regardless of when they first listed. If patients are added to the list in early 2008 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, 2008.

Rates in Figures p.4–5 and p.7–8 are adjusted for age, gender, and race.

Figure p.6 shows point prevalent wait list counts for those listed for a kidney-alone transplant, and displays the median time to transplant, as well as the 25th and 75th percentiles for time to transplant, among patients transplanted during the given year. Time to transplant is computed using Kaplan-Meier methodology.

QUALITY OF CARE

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

HOSPITALIZATION & MORTALITY

Figure p.16 shows the percent change since 1993 in admission rates for period prevalent ESRD patients. Included patients have Medicare as a primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or gender information. Methods generally follow those described for the prevalent patient cohorts in Chapter Six and Reference Section G. Rates are adjusted for age, gender, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2005. Principal ICD-9-CM diagnosis codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.2. 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).

Figure p.17 illustrates trends in mortality rates by vintage for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the

beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause mortality rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2005 prevalent dialysis patients, and adjusted mortalities across vintages are comparable.

Figure p.18 presents adjusted first-, second–third, and fourth–fifth-year mortality rates, by modality, for incident dialysis and first transplant patients. Patients are followed from day 91 until death or December 31, 2008. Dialysis patients are also censored at transplant. Rates are computed from the Cox model using the model-based adjustment method, described later in this appendix, and adjusted for age, gender, race, and primary cause of ESRD. The reference population consists of 2005 incident ESRD patients, and these rates are comparable across modalities.

Figure p.19 presents one-year survival for 2007 incident hemodialysis, peritoneal dialysis, and propensity-matched hemodialysis patients using the Kaplan-Meier method.

ESRD EXPENDITURES

Methods used for Figures p.20–28 are described in the text for Chapter Eleven and in the figure captions.

HEALTHY PEOPLE 2010

Targets in this chapter come directly or are estimated from published HP2010 objectives on CKD, diabetes, and immunizations.

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

Objective 4.2 The cohort includes period prevalent ESRD patients, 1991–2008. Cause-specific cardiovascular mortality is defined using CMS codes 27, 31, and 32 (congestive heart failure); 26 (atherosclerotic heart disease); 02 and 23 (myocardial infarction); and 01, 04, 25, 28–30, and 36–37 (other cardiovascular disease). Age is calculated for point prevalent patients as of January 1, and for incident patients as of the first ESRD service date. We exclude patients with unknown age, gender, or race, and those with an age calculated to be less than zero. Rates are estimated as the number of patients who die from cardiovascular disease in each year per 1,000 patient years at risk.

Objective 4.3 Figure hp.8 and Table hp.c use data from the newest version of the ME form. The cohort for Figures hp.9–10 includes incident ESRD patients, age 67 and older at initiation. Albumin and lipid tests are identified from Medicare claims during the two-year period prior to ESRD.

Objective 4.4 For Figures hp.12–13, the calculation of placement rates follows methods used in Chapter Five. Data from the CMS ESRD Clinical Performance Measures Project are used for Table hp.d (ESRD CPM year 2008) and Figures hp.11 and hp.32 (ESRD CPM years 1999–2008); included patients are those whose date of dialysis initiation, according to the CPM data, occurs in the same year as the data collection, and the access type represents the access used during the



last quarter of the year. To obtain consistent information on race and ethnicity, patients included in the CPM dataset are matched to those in the ESRD database using UID numbers.

Objective 4.5 The cohort for Figures hp.14–15 and hp.33 and for Table hp.e includes patients younger than 70 in 1991–2007. 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. Note that this method differs from those used in previous ADRS, which showed the percentage of point prevalent dialysis patients on the wait list as of December 31 of the given year.

Objective 4.6 The cohort here includes patients from 1991–2005 who are younger than 70 at ESRD certification. Patients are followed for three years, from ESRD certification until the first of death, transplant, or censoring at three years post-transplant. Percentages are calculated using the Kaplan-Meier methodology.

Objective 4.7 Incident rates of ESRD due to diabetes are calculated using the methods described for Chapter Two. Rates in Figure hp.18 are adjusted for age, gender, and race, those in Figure hp.19 are adjusted for gender and race, and those in Figure hp.20 are adjusted for age and gender. In Table hp.g, 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 for age and gender.

Objective 4.8 Methods and codes used to determine rates of glycosylated hemoglobin (A1c) testing and eye examinations are taken from HEDIS 2008 specifications (HEDIS 2008, an NCQA program, is used to monitor the performance of managed health care plans). CPT codes 83036 and 83037 are used to identify diabetic glycosylated hemoglobin testing (A1c; 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, 83715–83721, 84478, 83700, 83701, and 83704. The general Medicare population includes patients diagnosed with CKD and diabetes in each year, continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the whole year, and age 65 or older at the beginning of the year. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD and diabetes are described in the CKD volume.

Figure hp.36 illustrates diabetic preventive care among pre-ESRD patients, by network. The cohort includes 2008 incident ESRD patients age 67 or older at initiation, with diabetes one year prior to the start of ESRD, and with Medicare inpatient/outpatient and physician/supplier coverage during that year. Eye examinations are tracked in the two years prior to ESRD, while lipid and A1c testing are tracked in the one year prior.

Figures hp.21–22 and Table hp.h also show ACEI/ARB use for diabetic CKD patients in the Medicare population, using Cost and Use

data from the Medicare Current Beneficiary Survey (MCBS). To ensure that we obtain information on all therapy received by each person during each study year, included patients are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the entire year, survive until the end of the year, have a completed survey, are not enrolled in an HMO, and do not have ESRD; they also reside in the 50 states or the District of Columbia and are community-dwelling respondents. Comorbidities, including CKD and diabetes, are defined from the claims, using the same method used with the 5 percent data. Drug use information is obtained from the MCBS Cost and Use data file “Prescribed Medicine Events,” and SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data.

Objective 5.11 The cohort for Figures hp.23–25 and Table hp.i is similar to that used for Objective 4.8, but includes all diabetic patients instead of diabetic CKD patients. CPT codes for urinary microalbumin measurement are also identified from HEDIS 2008 specifications, and include 82042, 82043, 82044, and 84156. Testing is tracked during each year. Figure hp.37 illustrates urinary microalbumin measurements in the pre-ESRD population by ESRD network; the cohort is the same as that used in Figure hp.36.

Objective 14.29 The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to September 1 of each year and alive on December 31. For pneumococcal 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. Patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories are excluded, as are those who have a missing date of birth, who have ESRD for fewer than 90 days prior to the start of the reporting interval, or who are lost-to-follow-up during the study period. Influenza vaccinations are tracked between September 1 and December 31 of each year, while pneumococcal pneumonia vaccinations are tracked during the time periods graphed. Patients in both analyses have Medicare inpatient/outpatient and physician/supplier coverage during the study periods. All ages are calculated at the end of the graphed time period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008; pneumococcal vaccinations are identified through CPT codes 90669 and 90732, and HCPCS codes J6065 and G0009.

EMERGING ISSUES

CHAPTER ONE

MORTALITY & HOSPITALIZATION

Figures 1.1–14 and 1.22–24 present cause-specific infectious admission rates among dialysis patients. Patients included in Figures 1.1–12 and 1.22–24 have Medicare as a primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. The maps in Figures 1.13–14 include only residents of the 50 states and the District of Columbia. As in the hospitalization analyses (Chapter Six), patients with missing data for age or gender, or with AIDS as a primary or secondary cause of death, are excluded.

Principal ICD-9-CM diagnosis codes are used to define categories of cause-specific infectious admissions. Vascular access infections in Figures 1.1, 1.6, 1.11, and 1.14, and 1.23 are identified by ICD-9-CM diagnosis codes listed later in this appendix for Figure 6.4. Admissions for all-cause infection in Figures 1.2–5, 1.10, 1.13, and 1.22 are identified by the principal ICD-9-CM diagnosis codes listed in the discussion of Figure 6.2. Codes for pneumonia and bacteremia/septicemia in Figures 1.7–8, 1.12, and 1.24 are listed for Figure 6.4. Codes for urinary tract infection in Figure 1.9 include

590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1–2, 608.0, 608.4, 616.1, 616.3–4, and 616.8.

In Figures 1.1–9, cohorts include incident hemodialysis patients age 20 and older, 1991–2007. 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 to patients age 20–64. Patients are required to survive the first 90 days after hemodialysis initiation, and are followed for admissions after day 90. For patients age 65 and older, however, modality is determined on the first ESRD service date, and to avoid counting the admission at initiation, follow-up begins the day after initiation. Data cleaning and counting of admissions and time at risk for admissions generally follow that described for Reference Section G; here, however, incident patients are followed during intervals in the first year of hemodialysis rather than in prevalent years. Censoring occurs at death, three days prior to transplant, end of payor status, one year after initiation, or December 31, 2008, and also at loss to follow-up for those younger than 65. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. For Figures 1.1–9, the reference cohort includes incident hemodialysis patients in 2005 who are alive at day 90 after initiation. Figures 1.6–9 are presented by interval after initiation and adjusted for age, gender, race, and primary diagnosis. Figures 1.1–5 are presented by interval and a demographic factor and adjusted for the other three respective factors.

Figures 1.10–12 show admission rates for all-cause infection, vascular access infection, and bacteremia/septicemia in the first year of hemodialysis, and include patients incident in 2006–2007. These figures are restricted to patients age 65 and older so that admissions data are available in the first three months after initiation. Included patients have a Medical Evidence form indicating access type used on the first outpatient dialysis. The category “catheter/maturing internal access” includes patients with a catheter in addition to a maturing arteriovenous fistula or maturing graft, while “catheter only” includes those with a catheter and without a maturing internal access. Follow-up begins the day after initiation, and patients are censored at death, three days prior to transplant, end of payor status, one year after initiation, or December 31, 2008. Rates are presented by initial access type and race and adjusted for age, gender, and primary diagnosis. A model-based adjustment method is used, with incident patients in 2005, age 65 and older, as the reference cohort. Figures 1.13–14 display state-level infectious admission rates among 2006–2007 incident hemodialysis patients age 65 and older. Methods generally follow those described for 1.10–12, except that these state-level rates are unadjusted and restricted to the first six months after hemodialysis initiation.

Figures 1.22–24 include prevalent hemodialysis patients age 20 and older in both the CPM and USRDS ESRD Medicare data. Included patients reached day 90 following initiation on or before October 1, 2007. Follow-up begins on January 1, 2008, and censoring occurs at death, three days prior to transplant, modality change, end of payor status, placement of a different type of access, or December 31, 2008. Vascular access is defined as the most recent type used according to the CPM data. Dialysis vintage is computed as the time from the first ESRD service date to January 1, 2008. Rates are presented by race, vintage, and access type, and adjusted for age, gender, and primary diagnosis. The model-based adjustment method is used, and includes prevalent patients in the current and previous two years, weighted by 1, ½, and ¼, respectively. The reference cohort includes 2005 prevalent hemodialysis patients in both the CPM and USRDS databases.

OUTPATIENT ANTIBIOTIC USE

Figures 1.15–33 (excluding 1.22–24) use outpatient claims to identify the use of IV antibiotics and the evidence of bacterial cultures in the hemodialysis population. CPT codes used to identify IV antibiotics include J3370 (vancomycin); J0690 (cefazolin); J0713, J0692, and J0696 (broad spectrum cephalosporins); J1580, J3260, J0278, and J1840 (aminoglycosides); and J1956 (levofloxacin), as well as an extensive list of other codes which account for less than 3 percent of IV antibiotics used. Part D data is used to identify prescriptions for antibiotics. HCPCS codes for bacterial cultures include 87040–87077, 87081, and 87086–87088, where 87040 represents a blood culture.

Figures 1.15–19 include incident hemodialysis patients initiating during 2007 and surviving on hemodialysis at least six months. Figures 1.20–21 include January 1, 2007 point prevalent patients who survive and remain on hemodialysis at least 30 days, and who are also in the 2008 CPM data. Access represents the “current access” as of the CPM data collection period (October through December, 2007). Kaplan-Meier methods are used to calculate cumulative probabilities.

Figures 1.25–27 include incident hemodialysis patients initiating during 2006 or the first five months of 2007 and surviving on hemodialysis for at least six months.

Figures 1.28–33 include incident hemodialysis patients initiating in 2006 or 2007 and dying before the end of 2007. IV and antibiotic claims prior to death are identified as described above. Vascular access for patients in Figures 1.30–33 represents the access at initiation as obtained from the ME form.

INCIDENCE & PREVALENCE

CHAPTER TWO; A & B TABLES

INCIDENCE & PREVALENCE

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

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

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.

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, race, and gender, with the 2005 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.

PATIENT CHARACTERISTICS

CHAPTER THREE; C TABLES

Data used in this chapter are obtained from the ME form.

Figure 3.1 includes 2008 incident hemodialysis patients with ME forms. Access type and primary cause are identified from the ME form, and data exclude patients with unknown access type.

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

Figures 3.14–18 and Table 3.c focus on transplant as a post-dialysis modality, and are limited to patients with a revised edition ME form. Figure 3.14 details whether patients initiating dialysis in 2008 were informed of their transplant options. Figure 3.15 shows the proportion of new dialysis patients placed on the waiting list or receiving a transplant within a year of initiation; the denominator includes 2007 incident dialysis patients age 18–69. In Figure 3.16, with the same cohort, we use the Kaplan-Meier method to estimate the probability of being placed on the waiting list or receiving a transplant within a year of initiating dialysis. Follow-up is censored at death. Figure 3.17 shows geographic differences in the proportion of white and African American patients placed on the waiting list or transplanted within a year of initiating dialysis, among 2006–2007 incident dialysis patients age 18–69. Table 3.c is limited to 2007 incident dialysis patients age 18–69, and Figure 3.18 to 2008 incident dialysis patients not informed of their transplant options.

TREATMENT MODALITIES

CHAPTER FOUR; D TABLES

Chapter Four and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-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)

Data on modality and provider characteristics are presented in Figures 4.3 and 4.6. For a description of the provider data used in these figures, please see the discussion of Chapter Ten. All provider-related figures include only dialysis patients. Figures 4.4 and 4.7 show modality and payor information, while Table c and Figures 4.9–11 provide a closer look at the demographic and geographic variations of home hemodialysis patients. New in the 2010 ADR, Tables 4.d–e and Figures 4.12–13 provide information on Part D enrollment, by modality. Enrollment is defined through continuous coverage, during each year of interest, by a standard Part D plan, a managed care organization Part D plan, or an employer-sponsored Part D plan. Due to the delay in obtaining 2008 Part D event data, only 2006–2007 data are shown in this chapter. We plan to present both 2008 and 2009 data in the 2011 ADR.

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 2004 to 2006. 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. 2000, 2004, 2008), by demographic characteristics, payor 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 definitions of payor categories can be found under “database definitions” at the beginning of this appendix.

CLINICAL CARE & PREVENTIVE HEALTH

CHAPTER FIVE

In Figure 5.1, for both kt/v measurements, 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. For prevalent hemodialysis patients in 2008, each patient’s URR is obtained from the G-modifier attached to CPT code 90999, with a revenue code of 821 or 825. Each measurement is categorized into one of five ranges, and the median URR is calculated; for patients whose median lies between two ranges, we assign a weight of 0.5 to each. Information on new hemodialysis patients with an arteriovenous fistula as the first access is calculated as described for Figure hp.11. Hemoglobin levels are calculated for EPO-treated, 2008 prevalent hemodialysis patients, using available EPO claims during the year. EPO claims with a dose per administration of less than 500 or greater than 80,000 units, or with a hematocrit value less than 10 percent or greater than 50, are omitted. For each patient a yearly mean hemoglobin is calculated as the mean of all hematocrit values divided by three. Data on albumin are obtained for incident hemodialysis patients in 2008 who have a valid result on their ME form; those with a lower limit equal to zero are omitted. Data for influenza, pneumococcal pneumonia, and hepatitis B vaccinations are from Figures 5.14–16.

ANEMIA TREATMENT

Figure 5.2 presents the monthly distribution of patients by mean hemoglobin group, with each month containing all patients with at least one valid EPO claim during the month. The hemoglobin is calculated as the reported hematocrit value divided by three. Figure 5.3 shows the mean hemoglobin, by month, for prevalent dialysis patients with EPO claims, along with the monthly EPO dose per week for patients with 20 or fewer administrations per month. A patient’s time at risk including only those days in which he or she is not in an inpatient hospital setting.

Figures 5.4–8 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. EPO claims with a dose per administration of less than 500 units or more than 80,000 units are omitted, as are those with an average dose per day (calculated as the total EPO units on the claim divided by the number of days spanned by the claim) of less than 100 units or greater than 10,000 units. For 2008, 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

5.4, a mean hemoglobin is calculated for each patient from claims during the month, and the average of these values is then calculated for each month. For Figure 5.5, the mean EPO dose per week is adjusted by only including days during a month in which a patient is not in an inpatient hospital setting, so that the mean EPO dose represents outpatient dosing only. Access type is defined using the ME form. Figure 5.9 includes the same type of patients as in Figures 5.4–8, except that patients are required to have at least one EPO claim during each of the following twelve months; probabilities are calculated using the Kaplan-Meier method.

PREVENTIVE CARE

Figures 5.10–13 present data on diabetic preventive care. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted from these analyses, 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 diabetic glycosylated hemoglobin (A1c) testing, lipid testing, and eye examinations are described in the methods for the HP2010 chapter, Objective 4.8. Patients are defined as having diabetes either through medical claims (one inpatient/outpatient, two physician/supplier, two outpatient, or one physician/supplier and one outpatient), or through a listing of diabetes on the 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 lipids 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.

Figures 5.14–16 show rates of influenza, pneumococcal pneumonia, and hepatitis B vaccinations for prevalent ESRD patients by modality, age, race/ethnicity, and time period. Cohorts and methods for Figures 5.14–15 are the same as those described for Objective 14.29 in the HP2010 chapter, while the cohort for Figure 5.16 includes ESRD 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 entire year 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; or who are lost-to-follow-up during the year. Age is generally calculated at the end of the study period. Hepatitis B vaccinations are tracked in each year and identified through CPT codes 90636, 90740, 90743–90744, 90748, 90731, 90723, and G0010.

Figures 5.17–23 include prevalent hemodialysis patients who are in both the USRDS and ESRD CPM databases, and whose day 91 begins prior to October 1 of the prevalent year. The access represents the current access being used, according to the CPM data. Claims are searched during the following calendar year for events and complications. Figure 5.23 includes incident peritoneal dialysis patients from the USRDS database. For Figures 5.20–23, complication rates are calculated as the number of events (from Medicare claims)



divided by the time at risk, which is censored at death, change in modality, change in payment status, or the placement of a different type of access. Vascular access codes are listed in the methods for Chapter Eleven.

MEDICARE PART D USE

Figure 5.24 shows Part D enrollment among dialysis, transplant, CKD, and non-CKD Medicare enrollees in 2007. Each cohort includes patients alive on January 1, 2007, and alive and with Medicare inpatient/outpatient and physician/supplier coverage during all of 2007. For the dialysis and transplant cohorts, modality assignment is identified on January 1, 2007, and is uninterrupted during all of 2007. For the CKD and non-CKD cohorts, patients are age 66 or older on January 1, 2007. CKD status is identified from Medicare claims during 2006. Part D enrollment is defined through continuous coverage during 2007 by a standard Part D plan, a managed care organization Part D plan, or an employer-sponsored Part D plan. Figure 5.25 shows Part D enrollment in these cohorts, with stratification by age and race.

Using the same cohorts, Figures 5.26–28 summarize use of the Part D benefit among patients continuously enrolled in Part D during 2007. Low income subsidy (LIS) is defined by any degree of subsidization during all of 2007.

Cumulative medication use in Figure 5.28 is estimated by taking all Part D claims in 2007, linking National Drug Codes on claims to generic names in the 2007 edition of Red Book, and counting the number of unique generic names. Part D claims for products in the Red Book therapeutic classes of “device and non-drug items,” “diabetes mellitus supplies,” and “diagnostic agents” are excluded.

Figures 5.29–40 illustrate, by age and race, prescription drug use in patients continuously enrolled in Part D during 2007. Cohorts are the same as those used in Figure 5.24. Drug use is defined by at least one applicable prescription fill during 2007. For Figures 5.31–32, other lipid lowering agents include cholesterol absorption inhibitors, niacin, and omega-3 fatty acids.

MORBIDITY & MORTALITY

CHAPTER SIX; G, H, & I TABLES

HOSPITALIZATION

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 Reference Section G of patients of races that are unknown or other than white, African American, Native American, or Asian; these patients are included in the Chapter Six figures.

New to this year's ADR, 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 3rd through 6th positions or “R” or “T” in the 3rd 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. This method is described further in the discussion of Section G, and in the statistical methods section later in this appendix.

Methods for rates in Figures 6.2–3 follow those described for Reference Section G. In Figure 6.2, methods include those described for Figure p.16 in the Précis. 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, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 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 6.3 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 2005 ESRD cohort used as the reference.

Figure 6.4 shows adjusted admission rates for principal diagnoses among prevalent ESRD patients. Again, rates are adjusted for age, gender, race, and primary diagnosis, with ESRD patients in 2005 used as the reference cohort. Principal ICD-9-CM codes are as follows: pneumonia, 480–486 and 487.0; bacteremia/septicemia, 038.0–038.9 and 790.7; cellulitis, 682; vascular access infection (hemodialysis patients only), 996.62; and peritonitis (peritoneal dialysis patients only), 567.

Table 6.a presents adjusted admission rates and relative risks of admission among adult (age 20 and older) period prevalent hemodialysis patients. Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infectious admissions, and are listed in the discussion of Figure 6.2. Vascular access admissions are defined as “pure” inpatient vascular access events, as described for vascular/dialysis access events in Tables G.11–15; vascular access, however, excludes the codes specific to peritoneal dialysis catheters (996.56, 996.68, and V56.2). Rates and relative risks are adjusted for age, gender, race, and primary ESRD diagnosis, while values presented by one factor are adjusted for the other three. Adjusted relative risks are calculated with a Poisson model, with reference groups as listed. For adjusted rates, hemodialysis patients in 2005 are used as the reference cohort. Values by age, gender, race, and primary diagnosis are shown for 2007–2008 prevalent hemodialysis patients.

Figure 6.8 presents unadjusted rates of hospital admissions in 2007 hemodialysis, peritoneal dialysis, and matched hemodialysis patients, using Medicare claims.

Figures 6.11–13 show rates by age, adjusted for gender, race, and primary diagnosis, using the model-based adjustment method. They include period prevalent dialysis (Figures 6.11–12) and hemodialysis (Figure 6.13) patients age 20 and older, with the 2005 dialysis cohort as the reference. Figure 6.11 presents adjusted rates of cause-specific hospital admissions per patient year. The categories for cardiovascular disease and infection are defined by the codes listed for Figure 6.2; the infection codes for Figure 6.11 exclude those due to an internal device. The principal ICD-9-CM diagnosis codes used for infection due to internal device (related to a vascular access device or peritoneal dialysis catheter) are 996.62 and 996.68. At the end of 1998 a new ICD-9-CM code was added for infections due to internal devices in peritoneal dialysis patients; data prior to this date are omitted.

Figure 6.12 shows adjusted event rates for inpatient coronary revascularization. Patients are followed until the first coronary revascularization event, and are censored at the earliest of death, three days prior to transplant, or the end of the calendar year. Events are identified from inpatient and physician/supplier claims occurring

within a hospital stay. The following ICD-9-CM procedure and CPT codes are used to identify events: angioplasty, procedure codes 00.66, 36.01, 36.02, and 36.05, and CPT codes 92982, 92984, 92995, and 92996; coronary stents, procedure code 36.06 and CPT codes 92980–92981; and bypass, procedure codes 36.1x and CPT codes 33510–33523, 33533–33536. Rates for coronary stents are shown starting in 1997, due to the release of CPT codes.

Figure 6.13 displays adjusted vascular access placement rates for period prevalent adult hemodialysis patients. These are not hospital admission rates, but procedure rates for vascular access placements in an inpatient setting. Vascular access placements are obtained from CPT codes on physician/supplier claims, and are restricted to those occurring in the hospital (during an inpatient stay or emergency room visit). Categories include catheters, fistulas, and grafts; the CPT codes used to define them are found in Table a.a later in this appendix. The category for all vascular access placements includes the CPT codes for all of the above categories. Methods are also used to exclude vascular access used for purposes other than dialysis. Catheter placement codes that are not specific for dialysis are included only if they are accompanied by an ICD-9-CM renal diagnosis code. Also, rates for catheter and all vascular access placements exclude patients with specific chemotherapy or parenteral nutrition claims during the year. Inpatient/outpatient institutional, physician/supplier, and durable medical equipment claims indicate chemotherapy (CPT codes 96408, 96410, and 96412) or parenteral nutrition (CPT codes B4164–B5200, B9004, B9006, and B9999).

MORTALITY

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

Figure 6.1 shows trends in mortality rates, by modality, for incident ESRD patients, 1980–2007. The population groups include all-ESRD, hemodialysis, CAPD/CCPD, and first transplant (known deceased and living donors only). Adjusted first-, second-, third-, fourth-, and fifth-year mortality rates for incident cohorts — including all-ESRD, hemodialysis, CAPD/CCPD, and first transplant patients — are computed from the Cox model using the model-based adjustment method, described later in this appendix. Mortality rates for all patients are adjusted for age, gender, race, and primary diagnosis. The reference population for adjusted rates consists of 2005 incident ESRD patients.

Figure 6.5 shows all-cause mortality, by age, for 2008 prevalent ESRD, dialysis, transplant, and general Medicare patients, calculated using generalized mixed models, and adjusted for gender and race. Medicare patients from 2008 are used as the reference cohort.

Figure 6.6 illustrates trends in mortality rates, by patient vintage, for period prevalent dialysis patients alive on renal replacement therapy on January 1, with a first service date at least 90 days prior to the beginning of the year, and reaching day 91 of ESRD treatment during the year. Patients with unknown age or gender, or of a race other than white, African American, Native American, or Asian, are excluded. Patients are followed from January 1 until death, transplantation, or the end of the year, and all-cause rates are adjusted for age, gender, race, and primary diagnosis using generalized mixed models. The reference population consists of 2005 prevalent dialysis patients, and adjusted mortalities are comparable across vintages.

Figure 6.7 presents five-year survival, by modality, for 1994–1998 and 1999–2003 incident patients, with modality defined on the first ESRD service date. Transplant is defined as the first transplant in the incident year. Patients with unknown age, gender, or primary

diagnosis, and those with a listed age greater than 110, are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Dialysis patients are followed from day 91 until death, transplantation, or the end of 2008, while transplant patients are followed from the first transplant date until death or the end of 2008. All probabilities are adjusted for age, gender, and race; overall probabilities are also adjusted for primary diagnosis. The reference population consists of 2005 incident ESRD patients, and adjusted probabilities are comparable across modalities.

Table 6.b and Figures 6.9–10 present one-year survival for 2007 incident hemodialysis, peritoneal dialysis, and propensity-matched hemodialysis patients using the Kaplan-Meier method. Comorbidities are determined from the ME form. Log-rank tests are used to compare survival in Figure 6.10.

Figure 6.14 displays adjusted all-cause and cause-specific mortality in incident dialysis patients, 1991–2007, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with unknown age, gender, or primary diagnosis are excluded, as are those with a listed age greater than 110. Patients are followed from the first service date up to one year, and censored at transplant or recovery of kidney function. Overall rates are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 2005 incident dialysis patients, and adjusted rates can be compared across years and causes of mortality.

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

REFERENCE SECTION G

Hospitalization reference tables present adjusted total admission and hospital day rates, by year, 1993–2008. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. (This method is further discussed later in this section and in the statistical methods section at the end of this appendix.)

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payor. Hospitalization data are obtained from institutional inpatient claims. As in Chapter Six, hospitalization data in Reference Section G also now 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 payor 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 payor status changes to a patient no longer having Medicare Parts A and B coverage or Medicare as a primary payor.

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 hospitalizations in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When bridge hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

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

As in previous ADRS, all overlapping and only certain adjacent hospitalizations are combined, due to the fact that many adjacent claims may actually be legitimate separate hospitalizations. Specifically, hospitalizations with an admission on the same day or the day after a previous discharge are combined only when there is a discharge transfer code or indication of an interim claim. In the 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 statistical methods section). Predicted rates for each subgroup combination of age, gender, race, primary diagnosis, and year are obtained using a model with the Poisson assumption. For prevalent patient cohorts, this model uses data from the current and previous two years, with respective weights of 1, ¼, and ⅙. Adjusted rates are then calculated using the direct adjustment method, with all 2005 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 previously 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 2000–2002, 2003–2005, and 2006–2008 (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 later in this appendix in Table a.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.

REFERENCE SECTION H

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

Cohorts in Tables H.1–12 include both incident and prevalent patients. Incident cohorts are limited to patients who reach day 91 of ESRD treatment during the year, while prevalent cohorts include patients alive on renal replacement therapy on January 1 and whose first service date is at least 90 days prior to the beginning of the year. Because calculations include only one year of follow-up, a prevalent patient surviving to the end of the year contributes one year at risk, while a prevalent patient dying during the year contributes less than one year. Since the calculation for incident patients begins on day 91 of ESRD, most patients contribute less than one year at risk; a full year is contributed only if day 91 of ESRD is January 1 and the patient survives to the end of the year. Patients considered lost-to-follow-up at the beginning of the year are excluded. The period at risk is not censored at the start of a lost-to-follow-up period, however; if a

patient enters the lost-to-follow-up category during a calendar year, he or she remains in the death rate computation until the end of that year. Patient cohort populations often overlap. Patients with a functioning transplant on the start date, for example, are included in the all-ESRD and functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two subgroups — hemodialysis or CAPD/CCPD — if he or she has been on that modality for at least the previous 60 days. Dialysis patients not on hemodialysis or CAPD/CCPD, or on that modality for fewer than 60 days, are included only in the all-ESRD and all-dialysis categories.

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 2005 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by patient age, gender, race, and primary diagnosis for 2008 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 who have a first ESRD service date between January 1, 1980, and December 31, 2007, are included in the analysis. These patients are followed until December 31, 2008, with a maximum follow-up time of 24 years and a minimum of one year.

Results are reported for the following groups:

- ◆ all ESRD: all ESRD patients beginning renal replacement therapy in a calendar year and surviving beyond day 90; patients are censored only at the end of follow-up
- ◆ dialysis only: all dialysis patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up
- ◆ hemodialysis only: all hemodialysis patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up
- ◆ peritoneal dialysis only: all peritoneal dialysis patients starting renal replacement therapy in a calendar year, sur-

viving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or the end of follow-up

- ◆ transplant: patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored at the end of the year

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

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

TRANSPLANTATION

CHAPTER SEVEN; E & F TABLES

Figure 7.1 presents an overview of the transplant population. Panel 1 juxtaposes the growing rate of ESRD with the falling rate of transplantation in patients age 20 and older at transplant, 1988–2008. 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. Panel 2 summarizes the wait list, showing, by prior transplant status, the number of patients age 20 and older 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. Panel 3 presents transplant counts for patients 20 and older, by donor type, obtained through a combination of OPTN and CMS data.

TRANSPLANT WAIT LIST

Figures 7.2 and 7.4 show 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 7.2 shows the number of unique patients and the proportion of patients listed at multiple centers, by status (active/inactive). Distributions by age, race, blood type, and panel reactive antibody (PRA), shown in Figure 7.4, are based on first listings only. Age is determined as of December 31 of the given year. PRA is the maximum recorded value.

In 2003, OPTN started the expanded criteria donor (ECD) program, to allow patients to indicate their willingness to accept a kidney from a “marginal” donor. Figure 7.3 shows state-level differences in the proportion of wait-listed patients willing to accept an ECD kidney, and is limited to patients first listed for a kidney-alone transplant in 2007–2008. In this figure, “state” refers to the location of the transplant center at which a patient is listed.

Figure 7.5 presents observed and projected median wait times in patients age 18 and older at transplant and listed for a first-time, kidney-only transplant. Median wait times are estimated for each year using the Kaplan-Meier methodology. Years for which the median is observed are plotted, while for cases in which a subgroup has fewer than 15 patients the median is not plotted and is left as unknown. For more recent years in which the median has not yet been observed — i.e., more than 50 percent of the patients listed in that year have yet to be transplanted — the median time is estimat-



ed using a linear regression model, and plotted with a dotted line. The regression analysis considers all years for which the median is observed, excluding cells with fewer than 15 patients, as described above. A regression line is estimated using the year of transplantation as an independent variable. To improve the fit of this line, a quadratic term for the year of transplantation is included in the model. Predicted medians are then estimated from the resulting regression line.

Figure 7.6 shows median wait times, by state, for adults receiving a deceased donor kidney during 2008. 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 shows projected median wait times, by state, for adult patients listed for a deceased donor kidney transplant in 2008. Projections are estimated using the same methods as in Figure 7.5. In both maps, state is that of the patient's listing, not of his or her primary residence.

Figure 7.8 illustrates changes over time in the percent of listed patients who receive a living donor transplant within one year of listing. Patients include all first time listings from 1991–2007, including pediatric patients. Kaplan-Meier methods are used to estimate proportions, and data are censored at removal from the list, deceased donor transplant, or death. Figure 7.9 reports proportions of patients who receive a deceased donor transplant within three years of listing, by age and blood type. Pediatric patients are those age 0–17 at listing, while adults are 18 and older at listing; data by blood type are limited to adults. Kaplan-Meier methods are used to estimate proportions, with censoring at removal from the list, living donor transplantation, or death.

Figure 7.10 illustrates three-year outcomes for adult patients first listed in 2005, and five-year outcomes for those first listed in 2003. Patient 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.

Figure 7.11 shows adjusted one-year mortality, by state of residence, for January 1, 2008 point prevalent wait-list patients. A Poisson regression is used to estimate rates, adjusted for age, gender, white/non-white race, willingness to accept an ECD donor, and time on the list prior to 2007. Patients are followed for up to one year.

Figure 7.12 shows the likelihood of adult patients dying while awaiting transplant in the first through fifth year after listing, looking at those first listed in 1991–2007. 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 2005 period prevalent cohort is used as reference. Patients are censored at removal from the list and end of follow-up.

DONATION & TRANSPLANTATION

Figure 7.13 shows rate 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 7.14 presents unadjusted donation rates per 1,000 deaths, by state. Population and death count estimates for the year from July 1, 2007, to July 1, 2008, are obtained from the U.S. Census Bureau. Figure 7.15 presents living donor transplant counts by donor relation, with data on living donor relations obtained from the OPTN.

Figure 7.16 shows the growth in the percentage of adult transplants using kidneys from ECDs and non-heart beating donors (DCDs), 1991–2008. Factors defining ECD status are listed on the

OPTN Deceased Donor Registration form, and patients here include only first-time, kidney-only recipients of a deceased donor kidney. ECDs are age 60 or older, or age 50–59 with two or more of the following: death attributed to CVA, history of hypertension, or creatinine greater than 1.5 mg/dl. DCD status became available from the OPTN in 1993.

Figure 7.17 displays the relationship between a deceased donor kidney's ECD/SCD (standard criteria donor) status and the Kidney Donor Risk Index (KDRI) score for all first-time kidney-only transplants in 2008. The KDRI was published in 2009 by Rao, et al. as a means to more finely grade the quality of deceased donor kidneys, and is based on donor factors such as age, weight, race, and health history, and on transplant factors such as cold ischemia time and the number of HLA mismatches. Analysis here is limited to transplants in adult recipients with ABO-compatible donors and no history of any prior organ transplant. Percentages of transplants by ECD/SCD status are plotted within deciles of the KDRI in 2008.

Transplant rates in Figure 7.18, by age, gender, race, and primary diagnosis, show trends in adult transplants per 100 ESRD patient years, 1991–2008. Rates presented by one variable are adjusted for the remaining three using a Poisson regression model. Figures 7.19–20 use an identical method, but are limited to deceased and living donor transplants, respectively.

Figure 7.21 shows transplant rates per 100 dialysis patient years, by state, in 2008. Rates are estimated from a Poisson regression, adjusting for age, gender, race, and primary cause of renal failure, then standardized to the age, gender, race, and primary cause of renal disease makeup of the national population of dialysis patients incident in 2008. The state is the recipient's last known state of residence, not necessarily the state where the transplant was performed.

TRANSPLANT DISCHARGE & FOLLOW-UP

Figure 7.22 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 7.23 shows median length of stay for transplant hospitalizations by donor type, ECD and DCD status, and delayed graft function. For both figures, each year's cohort includes all adult patients whose grafts were functioning upon discharge. DCD status was unavailable until 1993, and not reported prior to that year. And Figure 7.24 shows the percentage of adult transplants with primary non-function, defined as kidney failure within seven days of transplantation.

Figure 7.25 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. 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 methods, censored at death or graft failure.

Figure 7.26–27 illustrate the distribution of eGFR by donor type, at discharge and at 12 months post-transplant. Figure 7.26 includes adult patients discharged with a functioning graft within 15 days of transplantation, while Figure 7.27 includes patients alive with graft

function 12 months post-transplant. GFR is estimated using the CKD-EPI equation.

IMMUNOSUPPRESSION

Figure 7.28 presents data on immunosuppressive medications used in adult recipients at the time of transplantation, as reported on the OPTN Immunosuppression Treatment form. All such medications are indicated on the form as maintenance immunosuppression. The mycophenolate data includes mycophenolate mofetil and mycophenolate sodium, and the mTOR inhibitors include sirolimus and everolimus. Data on mTOR inhibitors and steroids are also shown at one year post-transplant. Figure 7.29 highlights changes in the use of induction antibodies over the last decade, with data shown for first-time, kidney-alone transplants in 1998, 2003, and 2008.

Figures 7.30–33 address data related to KDIGO guidelines for post-transplant monitoring and prophylaxis. Figure 7.30 shows antibiotic use in the first three months post-transplant, Figure 7.32 illustrates use of cardiovascular medications in the first six months post-transplant, and Figure 7.33 presents data on the use of medications for the control of diabetes and hyperlipidemia during this same period. The cohort for these figures includes adult patients transplanted between January 1 and June 30, 2007, who remain alive with function six months post-transplant, and who have Medicare Parts A, B, and D coverage during this period. Medication use is defined by at least one prescription fill during the six months post-transplant. In Figure 7.33, other lipid lowering agents include bile acid sequestrants, cholesterol absorption inhibitors, fibrates, niacin, and omega-3 fatty acids; other anti-diabetes agents include alpha-glucosidase inhibitors, biguanides, dipeptidyl peptidase-4 inhibitors, incretin mimetics, meglitinides, and amylin analogs.

Figure 7.31 displays the percent 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 1991–2007, 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.

TRANSPLANT OUTCOMES

Figures 7.34–35 present five- and ten-year graft survival, as well as conditional half-lives, for adult recipients of kidneys from deceased and living donors. All estimates are made from Cox proportional hazards models, adjusted for transplant year, age, gender, race, and primary diagnosis, and based on the population's average survival curves, rather than on curves of the average patient in the population. Estimates of conditional half-lives are conditional on first-year graft survival, and estimated from the cumulative hazard between years one and two. Conditional half-lives are interpreted as the estimated median survival of grafts surviving the first year, while half-lives are interpreted as the estimated median survival of all grafts.

Figure 7.36 presents first-year and second-year post-transplant hospital admission rates for adult Medicare patients receiving their first kidney-alone transplant in 2006. 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, 2008. 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 7.37 illustrates the primary cause of hospitalization for cardiovascular problems and infection in the first and second years post-transplant in Medicare patients with their first kidney-alone transplant in 2004–2006.

Figure 7.38 presents data on the three-year incidence of post-transplant lymphoproliferative disorder (PTLD). The patient population includes first-time, kidney-only transplant recipients, 2001–2005. PTLD is identified from the OPTN Post-Transplant Malignancy form and the Transplant Recipient Follow-Up form. Figure 7.39 shows three-year cumulative incidence of malignancies other than PTLD, using data from OPTN data sources and Medicare claims. The cumulative incidence curve based on OPTN data uses the same population and methods as Figure 7.38, while the curve based on Medicare claims is limited to patients with Medicare primary coverage. PTLD and cancer indicated as cause of graft failure or death are included, under the assumption that they occurred prior to the graft failure or death they precipitated. Three-year incidence is estimated from a Cox proportional hazards model, adjusting for age, gender, race, Hispanic ethnicity, primary cause of renal failure, year of transplantation, donor type, hepatitis B and C serology, education level, employment status, time on dialysis, donor age, donor gender, donor race, HLA mismatches, recipient-donor body surface area matching, body mass index, panel reactive antibodies, cytomegalovirus matching, baseline maintenance immunosuppression (cyclosporin, neoral, tacrolimus, rapamycin, azathioprine, mycophenolate mofetil), and anti-lymphocyte receptor antibody use (IL-2, other), and estimated from the population average curve rather than the curve of the average patient. Events are censored at graft failure and death.

Figure 7.40 presents the three-year cumulative incidence of new onset diabetes following transplant, looking at Medicare patients transplanted during 2001–2005. To identify de novo post-transplant diabetes, the cohort is limited to patients with six months of Medicare primary payor 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, as above. Events are censored at graft failure, death, or loss of Medicare coverage.

Figure 7.41 shows the three-year cumulative incidence of post-transplant infection with BK virus. The study population, data sources, and analytic methods are similar to those used for 7.38. Pediatric patients are those 0–17 years old at the time of transplant, while adults are patients 18 and older at transplant.

Figure 7.42 shows the average eGFR by year post-transplant and by donor type among adult patients receiving a kidney-alone first transplant in 2002–2003. Annual serum creatinine levels from discharge to five years post-transplant come from the OPTN Transplant Recipient Follow-up form through year-end 2008, and eGFR is estimated using the CKD-EPI equation. We assume an eGFR of 0 for patients who remain alive and resume dialysis.

In Figure 7.43, we show the relationship between one-year eGFR and five-year graft failure. The cohort includes first-time, adult, kidney-alone transplant patients, 1999–2003, alive with function one year post-transplant. Patients are followed until graft failure, death, or five years post-transplant; the outcome is all-cause graft



failure. Using a Cox proportional hazard model, we estimate the hazard ratio for graft failure by one-year eGFR group, adjusting for transplant year, age, gender, race, donor time, pre-transplant time on dialysis, recipient body mass index, primary cause of ESRD, number of HLA mismatches, PRA at transplant, primary payor, donor age, donor/recipient CMV matching status, and delayed graft function. GFR is estimated using the CKD-EPI equation.

In Figure 7.44 we present the rate of return to dialysis/preemptive retransplantation, the rate of death with a functioning graft, and the rate of any graft failure, which includes failure due to death. Rates are limited to adult patients, and estimated from a Poisson regression, adjusting for age, gender, and race.

Figure 7.45 displays causes of death for adult patients transplanted in 2004–2008 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.

Figures 7.46–51 examine the transfusion status of transplant and waiting list patients and its relationship to waiting time, PRA levels, and outcomes. Figure 7.46 includes all first-time, kidney-only transplant patients, 1991–2008, and displays the proportion of patients with history of any pre-transplant transfusion. Transfusion data come from the OPTN Transplant Recipient Registration, and indicate whether or not a transfusion occurred at some time prior to transplant; the timing and number of transfusions is not recorded. Figure 7.47 uses the subset of patients who received deceased donor transplants, and reports the median months from listing to transplant by pre-transplant transfusion status. Patients with no reported no transfusion history or an unknown history are classified as “not transfused.”

Figure 7.48 presents 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 come 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 7.49 shows the distribution of listed patients by PRA and number of years after listing for adults listed between 1998 and 2003. The PRA level is the last known PRA value at each post-listing year. The denominator for each post-listing year includes all patients who remain listed at that time. A patient who receives a transplant 18 months after listing, for example, will contribute to denominators at listing and at year one, but not years two through five.

Figure 7.50 shows the effect of pre-transplant transfusion on PRA elevations at transplant. The cohort includes first-time, kidney-only transplant recipients age 18 and older, transplanted in 2004–2008. Logistic regression models are used to predict the probability of PRA above six different cut points, adjusting for age, race, time on dialysis, primary cause of ESRD, blood type, education, employment, BMI, and comorbid conditions. Separate models are run for men, nulliparous women, and parous women, and odds ratios are plotted for positive versus negative transfusion history, along with 95 percent confidence intervals. Figure 7.51 shows the relationship between pre-transplant transfusion and rates of death and transplant. The patient population includes patients age 18 and older with Medicare primary coverage, listed for a kidney transplant in 2001–2005. Hazard ratios come from a Cox proportional hazard model, where transfusion is a time-dependent covariate, and transfusion information comes from Medicare claims. Other adjusters include year of listing, age, gender, race, ethnicity, cause of ESRD, blood type, BMI, pre-transplant time on dialysis, education, dialysis type, and comorbid conditions as noted on the ME form.

REFERENCE SECTION E

Tables E.1–5 present measures regarding the wait list for renal transplantation. Wait list data prior to 1988 are not shown; the OPTN wait list began in earnest in 1987. Table E.1 presents counts of patients newly added to the wait list for a kidney or kidney-pancreas transplant on December 31 of the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents wait times, defined as the median time in days from first listing to transplant among patients listed for a kidney-alone transplant, and estimated with the Kaplan-Meier method. Table E.3 presents counts of patients on the wait list 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. 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. This measure is modeled after Healthy People 2010 Objective 4.5.

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) 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 previous ADRS, “graft failure necessitating dialysis or retransplantation” was referred to as “death-censored graft failure.” Due to confusion regarding terminology, we have renamed this outcome. This section now seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a patient will return to dialysis or require retransplantation at various times post-transplant. Patients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2008). In the analysis of graft survival, death is considered a graft

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

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

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 8.11–12 show rates of preventive healthcare in pediatric ESRD patients by modality and race. Methods and codes used to determine vaccination rates are similar to those described for Chapter Five. All patients are age 0–19 at the beginning of each study period; reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories; and have Medicare inpatient/outpatient and physician/supplier coverage for the entire period.

For influenza vaccinations, 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 2005–2008 are grouped in Figures 8.11, and 2005–2006 and 2007–2008 are grouped in Figure 8.12.

HOSPITALIZATION & SURVIVAL

Figures 8.8–10 and 8.13–15 show admission rates among pediatric ESRD patients. Patients have Medicare as their primary payor and are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with AIDS as a primary or secondary cause of death, and those with missing age or gender information, are excluded.

Figures 8.8–10 include period prevalent ESRD patients age 0–19 during pooled years 2005–2008. Age is determined on January 1 of each year. Cohorts and admission rate calculations follow those described for Reference Section G. Rates in Figures 8.8–10 are unadjusted. Principal ICD-9-CM codes for bacteremia/septicemia and pneumonia are listed under the discussion of Figure 6.4; those for respiratory infection exclude pneumonia and are as follows: 460–466, 472–474.0X, 475–476.1, 478.21–478.24, 487.1–487.8, 488–490, 491.1, 494, 510–511, 513.0, 518.6, and 519.01.

Figures 8.13–15 present adjusted admission rates in the first year of dialysis among incident dialysis patients age 0–19 in 2000–2007. 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 dialysis initiation, and are followed for admis-

sions for up to one year. Data cleaning and counting of admissions and time at risk for admissions generally follow that described for Reference Section G; here, however, incident patients are followed during intervals following day 90 rather than during prevalent years. Censoring occurs at death, loss to follow-up, three days prior to transplant, end of payor status, December 31, 2008, or after one year. Rates by age are adjusted for gender, race, and primary diagnosis, and those by race are adjusted for age, gender, and primary diagnosis. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference cohort includes incident dialysis patients age 0–19 in 2004–2005. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 6.2.

Figure 8.16–18 present adjusted all-cause and cause-specific mortality in the first months of dialysis, by age, for incident dialysis patients younger than 20. Patients are followed from the day of ESRD onset until December 31, 2008, and censored at loss to follow-up or transplantation. Rates are adjusted for gender, race, and primary diagnosis of ESRD. Incident dialysis patients younger than 20, 2004–2005, are used as the reference cohort.

Figure 8.19 presents five-year survival for 1994–1998 and 1999–2003 incident dialysis patients, age 0–19. Patients with unknown age, gender, or primary diagnosis are excluded, as are dialysis patients who die or receive a transplant in the first 90 days. Patients are followed from day 91 until death, transplant, or the end of 2008. Probabilities by age are adjusted for gender, race, and primary diagnosis; probabilities by race are adjusted for age, gender, and primary diagnosis; overall probabilities are adjusted for age, gender, race, and primary diagnosis. The reference population consists of 2004–2005 incident pediatric ESRD patients.

SPECIAL STUDIES

CHAPTER NINE

CARDIOVASCULAR SPECIAL STUDIES

Figures 9.2–3 describe the use of implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy with defibrillator (CRT-D) in ESRD patients. Annual study cohorts include period prevalent Medicare hemodialysis, peritoneal dialysis, and transplant patients followed from either January 1 (for point prevalent patients) or ESRD day 90 (for incident patients) until the earliest of death, end of Medicare as primary payor status, modality change, or December 31 of the year. Device implantation is identified from an inpatient or outpatient facility claim with ICD-9-CM procedure codes 37.94 (ICD) or 00.51 (CRT-D, for claims after January 1, 2002).

Figures 9.4–5 describe the demographics and comorbidity of patients age 20 or older who received their first ICD or CRT-D between 1999 and 2008. Comorbid conditions are defined from the ME form and from Medicare claims submitted during the one year prior to device implantation. Figure 9.6 shows all-cause survival after ICD or CRT-D implantation, with stratification by indication (primary or secondary prevention), in patients age 20 or older who received their first ICD or CRT-D between 1999 and 2008. Secondary prevention is indicated by ICD-9-CM diagnosis codes 427.1 (paroxysmal ventricular tachycardia), 427.4, or 427.5 during the hospitalization for device implantation. The absence of such diagnoses indicates primary prevention. Patients are followed from the date of first device implantation to the earliest of death, modality change, date of second device implantation, three years after implantation, or December 31, 2008.

Table 9.a describes prescription drug therapy in Medicare dialysis patients with their first diagnosis for cardiovascular disease



(CVD) or receiving their first treatment for CVD in 2007. Index events for CVD include acute myocardial infarction (AMI), atrial fibrillation (AF), cerebrovascular accident/transient ischemic attack (CVA/TIA), congestive heart failure (CHF), and peripheral arterial disease (PAD), while index events for CVD treatment include percutaneous coronary interventions (PCI), coronary artery bypass graft surgery (CABG), and use of an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy with defibrillator (CRT-D).

For each of the eight index events, a study cohort is identified from the 2007 Medicare ESRD database. Patients have the index event during 2007, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage during the one year preceding the date of the index event, and are not enrolled in an HMO during that year. The one-year period preceding the date of the index event is the baseline period. Patients with a pre-existing condition of the index event are also identified during the baseline period, but are not excluded in the analysis for Table 9.a.

Using the method employed to identify patients with CKD, we identify those with pre-existing AMI, AF, CVA/TIA, or CHF during the baseline period. ICD/CRT-D is defined through ICD-9-CM procedure codes in inpatient/outpatient facility claims, and PCI and CABG are identified through both ICD-9-CM procedure codes (in inpatient/outpatient claims) and CPT codes (in physician/supplier claims). PAD is defined through either diagnosis codes or procedure codes; if by diagnosis codes, we use the standard method; if by procedure codes, we employ the method used for PCI and CABG. AMI, AF, CVA/TIA, CHF, PAD, first PCI and CABG surgery, and the first implantation of ICD/CRT-D are defined on the date of the first appearance of a diagnosis or procedure code in the 2007 claims.

With the exception of AMI, the data sources and methods used to define each event are the same as those used in defining the pre-existing condition at baseline. The AMI event is defined as the first appearance of the diagnosis code on an inpatient claim.

The same codes are used to define AF, PAD, PCI, CABG, and ICD/CRT-D as pre-existing conditions at baseline and as an event in 2007, while different codes are used for CHF, CVA/TIA and AMI:

- ♦ AF: 427.3 (ICD-9-CM diagnosis code)
- ♦ AMI, 410 and 412 for condition at baseline; 410, 410.X0, and 410.X1 for event (ICD-9-CM diagnosis codes)
- ♦ CHF: 398.91, 422.XX, 425.X, 428.XX, 402.X1, 404.X1, 404.X3, and V42.1 for condition at baseline (ICD-9-CM diagnosis codes); 398.91, 425.X, 428.XX, 402.X1, 404.X1, and 404.X3 for event (ICD-9-CM diagnosis codes)
- ♦ CVA/TIA: 430–438 for condition at baseline; 430–437 for event (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 surgery: 36.1X (ICD-9-CM procedure codes); 33510–33523 and 33533–33536 (CPT codes)

- ♦ PCI: 00.66, 36.01, 36.02, 36.05, and 36.06 (ICD-9-CM procedure codes); 92980–92982, 92984, and 92995–92996 (CPT codes)
- ♦ ICD: 37.94 (ICD-9-CM procedure code)
- ♦ CRT-D: 00.51 (ICD-9-CM procedure code)

Table 9.a and Figures 9.7–10 include Medicare enrollees with a CVD event between January 1, 2007, and November 30, 2007, discharged within two weeks of the date of the index event (if hospitalized at the time of the event), remaining outside the hospital at one month after the date of the index event, and carrying continuous Medicare Part D coverage during the interval from one month before to one month after the date of the index event; use of a particular drug is defined by at least one filling of a prescription for the drug during this interval. Drugs are identified from National Drug Codes included on Part D claims, and linked with the 2007 edition of Red Book. In Figure 9.7, other drugs include digoxin, eplerenone, and spironolactone. In Figure 9.9, patients are followed from one month after the date of the index event until the earlier of death or one year after the date of the index event. In Figure 9.10, patients are followed from one month after the date of the index event until the earliest of hospitalization, death, or one year after the date of the index event. Patients with a pre-existing condition of the index event are excluded in Figures 9.9–10.

Figure 9.11 presents rates of rehospitalization and rehospitalization or death in Medicare dialysis patients with their first CVD diagnosis or treatment in 2007. Patients with a pre-existing condition of the index event are excluded.

In Table 9.b we summarize patient distribution by body mass index (BMI) in Medicare dialysis patients with their first CVD diagnosis or treatment in 2008. Cohort construction is identical to that of Table 9.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, 2007.

Figure 9.12 shows the adjusted relative risks of incident CHF in 2008. Cohort construction is identical to that of Table 9.a; patients with a pre-existing condition are excluded. BMI is defined as in Table 9.b. Patients are followed from January 1, 2008, until the earliest of a CHF event, death, change in modality, or December 31, 2008. Relative risks are derived from a Cox proportional hazards model, with adjustment for age, gender, race, diabetes, and dialytic modality. Figure 9.13 shows unadjusted survival in the cohort, by BMI, following the date of the CHF event. Patients are followed from the CHF event until the earliest of death or one year after the date of the CHF event. And Figure 9.14 presents adjusted relative risks of death in the cohort, following the date of the CHF event. Follow-up is identical to that described for Figure 9.13. Relative risks are derived from a Cox proportional hazards model, with adjustment for age, gender, race, diabetes, and dialytic modality.

Table 9.c displays demographic and BMI distributions for Medicare ESRD patients undergoing bariatric surgery in 1999–2008. Events are defined by inpatient facility claims with (1) a procedure code for bariatric surgery, (2) a diagnosis-related group (DRG) for obesity surgery or a diagnosis code for obesity, and (3) the absence of any ICD-9-CM 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): 43.5, 43.6, 43.7, 43.89, 44.31, 44.38, 44.39, 44.68, 44.69, 44.95, 44.96, 44.97, 45.50, 45.51, 45.62, 45.90, and 45.91.

- ♦ obesity surgery (DRGs): 288 (before September 30, 2008) and 619, 620, and 621 (after October 1, 2008)
- ♦ obesity (DRGs): 278.x and V85.4
- ♦ cancer of the digestive tract or peritoneum (DRGs): 150–159
- ♦ inflammatory bowel disease (DRGs): 555–558.

Events are retained if the patient has Medicare as primary payor at the time of surgery.

In Table 9.c, 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 at the time of surgery. Figure 9.16 shows the distribution of bariatric surgery types: adjustable band (procedure codes 44.95, 44.96, 44.97), gastric bypass (44.31, 44.38, 44.39), gastroplasty (44.68, 44.69), and malabsorptive (43.5, 43.6, 43.7, 43.89, 45.50, 45.51, 45.62, 45.90, and 45.91). Figure 9.17 illustrates survival following bariatric surgery; patients are followed until the earliest of death, three years after the time of surgery, or December 31, 2008. Figure 9.18 shows mean BMI, by month, during the two years following bariatric surgery, looking at dialysis patients undergoing bariatric surgery between 2005 and 2008. BMI is ascertained from outpatient dialysis facility claims.

Figure 9.19 presents geographic variations in BMI in 2005 and 2008 dialysis patients. Study cohorts include point prevalent dialysis patients, alive and with Medicare inpatient/outpatient and physician/supplier 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 dialysis facility claims submitted during follow-up.

REHABILITATION & QUALITY OF LIFE SPECIAL STUDIES

Data summarized in this section include 319,564 incident dialysis patients for whom the 2005 version of the ME form was completed between January 1, 2005, and September 30, 2008. The study population is derived from the 379,035 patients in the PATIENTS 2009 SAF for whom the ME form was completed. Patients are excluded if their first ESRD service date does not match the date of first regular dialysis, if their dialysis start date is prior to January 1, 2005 or more than 62 days from the date of signature on the ME form, if they are wait-listed or transplanted prior to dialysis initiation, or if their age information is missing.

Figures 9.20–24 use data from Question 26 on the ME form, while Figures 9.25–30 use data from Question 27. The ME form is also the source of all demographic information.

Medical insurance coverage categories correspond to those in Question 12 on the ME form, as follows:

- ♦ Private: employer group health insurance
- ♦ Medicare: Medicare, Medicare Advantage
- ♦ Other: DVA, other
- ♦ Medicaid: Medicaid
- ♦ None: none

Figures 9.31–32 present Kaplan-Meier estimates of wait-listed patients, by whether or not they are informed of transplant options, and by selected reasons for not being informed. In the Kaplan-Meier estimation, death and kidney transplantation prior to wait-list are treated as censoring.

NUTRITION SPECIAL STUDIES

Methods for these figures are described in the text accompanying the chapter.

PROVIDERS

CHAPTER TEN; TABLES

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 which are owned or operated by a corporation at the end of a year. The affiliation category of “small dialysis organization,” or SDO, includes all organizations meeting our definition of a chain but having 20 or more and fewer than 100 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). If there is a major reorganization of chains, such as the purchase of Gambro by DaVita, the USRDS will insure that these transactions are represented in the ADR.

Data are obtained from the Facility Survey (1988–2007), 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 2008, there were 5,501 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 dialysis unit by CMS. For years prior to 2002, we determine facility profit status through the ownership type field on the CMS survey. In the 2002 CMS survey the profit status variable was dropped, so for that and subsequent years we use the profit status field of the DFC database. There are, however, a small number of facilities in the CMS survey that are not in the DFC database; these facilities have an unknown profit status, and are omitted from any graph showing profit status.

For provider-specific analyses, unless otherwise 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 10.5 includes period prevalent dialysis patients in 2003 and 2008. Data for mean hemoglobin include only patients with valid EPO claims. A mean is calculated for each patient from all valid claims during the year, and chain affiliation is defined at the final patient claim of the year.

Figure 10.6 illustrates IV iron use, by dialysis unit affiliation and product type. The cohort consists of patients initiating ESRD therapy at least 90 days prior to the start of 2008, and receiving dialysis on December 31, 2007. All patients survive, continue dialysis, and carry Medicare as primary payor during all of 2008. Iron use is indicated by inpatient/outpatient claims with HCPCS codes J1750, J1755–J1756, J1760, J1770, J1780, and J2915–J2916. For iron use, chain affiliation is defined at the beginning of follow-up.

Figures 10.7–8 include data from all incident dialysis patients with an EPO claim in the first 30 days of ESRD therapy, and at least one EPO claim during each of the following six months. Figure 10.9 includes point prevalent dialysis patients in 2003 and 2008, with a first service date 90 days prior to January 1 of each year and alive through the end of the year. Rates represent patients with one or



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

Figures 10.10–12 include incident hemodialysis patients in 2008, and show the cumulative probability of testing in the first three months of dialysis, by unit affiliation. Tests are identified from outpatient and physician/supplier claims during the year, using the following HCPCS codes: serum ferritin, 82728; transferrin saturation, 83550, 83540, and 84466; and parathyroid hormone testing, 83970.

Figures 10.13–15 use the same cohort as Figure 5.10, here for 2007–2008; Figure 10.16 uses the cohort from Figure 5.14, here for 2005 and 2008; Figure 10.17 uses the 2003–2004 and 2007–2008 cohorts from Figure 5.15; and Figure 10.18 uses the cohort from Figure 5.16, here for 2005 and 2008. All are limited to dialysis patients.

Figures 10.19–21 use the Model 1 (as-treated actuarial model) methods described for Chapter Eleven. Costs for clinical services (Figures 10.19–20) are taken from outpatient facility claims for period prevalent dialysis patients, and expressed as per person per month costs. Costs for preventive care (Figure 10.21) are obtained from the outpatient facility claims as well as physician/supplier claims, and are identified using CPT codes: A1c testing, 83036 and 83037; lipid testing, 80061, 82465, 83715–83721, and 84478; diabetic eye examinations, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, and 92260; influenza vaccinations, 90645, 90646, 90647, 90648, 90565, 90656, 90657, 90658, 90659, 90660, 90724, 90737, 90661–90663 and G0008; and pneumococcal pneumonia vaccinations, 90669, 90732, J6065, and G0009. Comprehensive diabetic monitoring includes at least four A1c tests, at least two lipid tests, and at least one diabetic eye examination per year.

Figures 10.22–25 present rates of hospitalization for vascular access infection. The cohort includes 2007 incident hemodialysis patients with Medicare as primary payor. Catheter access and internal access (arteriovenous graft or arteriovenous fistula) are identified from the ME form. Patients are followed from the date of initiation until the earliest of death, modality change, payor change, loss to follow-up, or one year. Hospitalization for vascular access infection is identified from inpatient claims by ICD-9-CM principal diagnosis code 99662.

Figures 10.26–29 show rates of hospitalization for fluid overload, heart failure, and pulmonary edema. The overall cohort includes 2008 point prevalent hemodialysis patients with Medicare as primary payor. Patients are followed from January 1, 2008, to the earliest of death, modality change, payor change, loss to follow-up, or December 31, 2008. The initial cohort for “extra dialysis” is the same, but the first four weeks of 2008 are used as the entry period to identify patients receiving extra dialysis, defined as more than three dialysis sessions in at least three of the four weeks. These patients are followed from the day after the entry period to the earliest of death, modality change, payor change date, loss to follow-up, or December 31, 2008. Hospitalization for fluid overload, heart failure, or pulmonary edema is identified using the method of Arneson, et al.

Figures 10.30–37 compare mortality and hospitalization among dialysis provider types, chains, and regions, 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, 2008. Patients are followed from January 1, 2008, to the first of death, transplant, or December 31, 2008. Patients dying of AIDS are excluded; those dying of drug overdose (street drugs) or an accident not related to treatment are censored at the date of death. SMR calculations include all January 1, 2008, point prevalent hemodialysis patients, while SHR calculations include only hemodialysis patients with Medicare as primary payor, 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 the 2008 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; K TABLES

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

PAYOR SEQUENCE

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

CHAPTER ELEVEN

Table p.a in the Précis summarizes data on the costs of ESRD treatment. Total 2008 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 2008 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 2008 (obtained from the CMS managed care organization file) in conjunction with the 2008 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 2008. Patient obligations are estimated as the difference between Medicare allowable and net payment amounts. Non-Medicare patient spending is estimated as the number of patient months at risk for non-Medicare patients (determined from the USRDS payor sequence) multiplied by the AAPCC rate.

Changes in Medicare spending from 2007 to 2008 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 payor during the study period (Table K.e), again using non-inflated results. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (3.8 percent) and Medical Consumer Price Index (4.2 percent).

Data on costs for vascular access physician/supplier services (Figures 11.16–17) are obtained directly from the physician/supplier Standard Analytical Files (SAF), and do not include facility charges.

Physician/supplier vascular access procedures and costs are identified through CPT codes (Table a.b). Because some CPT codes are not specific to an ESRD access (e.g., central venous catheter, radiological procedures), our selection process requires that certain CPT codes be accompanied by a renal-related diagnosis code for inclusion in the analysis (these codes are identified with an asterisk in Table a.b). PPPY total vascular access costs (Figure 11.18) are obtained from event-based analyses, and include both physician/supplier costs as described above, and facility costs that can be attributed to vascular access services. Facility costs are difficult to identify. For inpatient facility costs, vascular access procedures in the inpatient setting (identified from the physician/supplier SAF) are matched with inpatient claims, and all procedures performed during a given inpatient stay (admission date through discharge date) are considered a single vascular access event. Because vascular access procedures are often performed when a patient is hospitalized for another reason, costs for inpatient facilities are included in the analysis only if the cause of hospitalization can be reasonably attributed to vascular access, using DRG and ICD-9-CM principal procedure codes, or ICD-9-CM principal diagnosis codes (Table a.b). Such hospitalizations are labeled “pure” inpatient vascular access events.

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

Although vascular access procedures can be identified from claims data, it is not possible to determine with certainty the type of access being used for dialysis at any given time. In order to compare overall and vascular access costs by type of access, data are analyzed for the hemodialysis cohort from the CMS ESRD Clinical Performance Measures Project for 1999–2008. The CPM project collects data annually on a random sample of hemodialysis and peritoneal dialysis patients, including the type of vascular access being used for hemodialysis at the time of data collection. The CPM data for hemodialysis patients are collected from October through December of the year prior to the cohort year (e.g., CPM data were collected from October through December, 2007, for the 2008 cohort). For Figures 11.18–19 we classify patients by the vascular access in use at the time of the CPM data collection, and aggregate costs for the following calendar year, with follow-up until the earliest of death, transplant, modality change, or the end of the calendar year. This analysis is limited to patients with Medicare as primary payor.

Figure 11.20 includes period prevalent hemodialysis patients with Medicare as primary payor, not enrolled in Medicare Advantage, and residing in the United States. Inpatient hospital stays during calendar year 2008 are identified as being for a vascular access infection if the principal diagnosis is 996.62, “Infection of Internal Device.” The total payment amount from these inpatient stays is used to calculate a PPPY cost.

Figures 11.21–27 describe PPPY costs for items billed in the outpatient SAFs, particularly injectable drugs, for period prevalent dialysis patients with Medicare as primary payor. And Figures 11.28–33 detail PPPY costs billed in the inpatient SAF for this population, focusing on infectious hospitalizations. The causes of these hospitalizations are determined from the principal ICD-9-CM codes.

Figures 11.34–46 present PPPY costs for the services described in Figures 11.28–33, by modality and race. Modalities are determined



^a a.i 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 (1991–2008).

^a b.ii DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access services

DRG codes^a: 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^a: 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^a
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^b
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

a Cii Medicare categories of payment & basis for categorizing claim

Total Sum of all payments

Total inpatient 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

Total outpatient 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

Total physician/supplier 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

using model 1 (as-treated actuarial model) methodology, as described below. Data are also presented for a subset of hemodialysis patients who are matched to peritoneal dialysis patients, using a propensity score technique. In the cohort of dialysis patients, we first estimate the propensity for peritoneal dialysis prescription by fitting a logistic model of dialytic modality, with age, race (white, black, other), gender, primary cause of ESRD (diabetes, hypertension, glomerulonephritis, cystic kidney disease, other known, unknown), cumulative ESRD duration, and seven diagnosed comorbid conditions (cardiovascular disease, hypertension, diabetes, COPD or tobacco use, cancer, alcohol or drug dependence, and in need of assistance) as predictors. Age and ESRD duration are parameterized with quadratic polynomials. The propensity for peritoneal dialysis prescription is defined as the estimated probability of peritoneal dialysis as dialytic modality. We then assemble a matched cohort by matching to each peritoneal dialysis patient with propensity p a hemodialysis patient with propensity q , such that $|p - q|$ is minimized, and we use a greedy matching algorithm.

Figures 11.47–59 present cost data for the Medicare Part D prescription drug benefit. Data are currently available only for calendar years 2006 (the first year of the benefit) and 2007. Costs are estimated net pay, calculated as the sum of the plan payment amount and the low income subsidy; they do not include out-of-pocket expenditures. Figure 11.47 and Table 11.a include all Part D costs for ESRD patients, starting on January 1, 2006 (or the first ESRD service date if after this date), regardless of payor status. Figures 11.48–59 include December 31, 2006 point prevalent ESRD patients enrolled in Part D for all of 2007. Costs are estimated net pay (expressed as per person per month), are presented separately for dialysis and transplant patients, and are restricted to drugs in the specific categories addressed in each figure; combination drugs which cross categories (e.g., a beta blocker with a lipid lowering agent) are not included, unless specifically noted in the figure caption.

REFERENCE SECTION K: MEDICARE CLAIMS DATA

Cost information in this section is derived from Medicare inpatient/outpatient and physician/supplier claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. The data for 2004–2008 are comprised of approximately 43 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 370 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, as shown in Table a.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: $\text{payment (line)} = [\text{total charge (line)} / \text{total charge (claim)}] * \text{payment (claim)}$. In August of 2000 CMS added to the Outpatient SAF a field containing line item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line item cost is discounted by the ratio of the sum of line item payment amounts to the total paid amount for the claim. Since complete data on line item payments are available starting with the 2001 Outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2001–2008, 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 18 years from January 1, 1991, to December 31, 2008, and ESRD patients prevalent on January 1, 1991, or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payor sequence. Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor at any time during the study period are classified as MSP for the duration of the MSP status in the payor sequence. If the payor status changes to Medicare as primary payor, a new sequence begins at the change date. Patients who are non-Medicare or enrolled in a Medicare Advantage program are excluded until their payor status changes to Medicare (either as primary or secondary payor). Patients classified as MSP are included in Tables K.1–3, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2008. 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 calculated at the study start date, and patients with a missing date of birth are excluded from the analysis.

MODEL 2: CATEGORICAL CALENDAR YEAR MODEL

This model, described in the HCFA (now CMS) research report on ESRD (1993–1995), is used for Figure 11.12, as well as Reference Tables K.9–12. With this method, patients are classified into four mutually exclusive treatment groups:

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

EGHP PATIENTS

Several figures in the Précis and Chapter Eleven include data for EGHP patients. Patients in the MarketScan database who are identified as having ESRD, are under 65 years of age, and do not have evidence of Medicare payments (either as primary or secondary payor) are included in these analyses. Medicare payments are identified in the MarketScan 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 international data for this ADR have been collected from the following sources, using the data form at the end of this section:

- ♦ the Sociedad Argentina de Nefrología (SAN) and Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI; Marinovich et al.)
- ♦ 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)
- ♦ the Chilean Renal Registry
- ♦ the Croatian Society of Nephrology, Dialysis, and Transplantation



- ◆ the Czech Dialysis Registry
- ◆ 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 Department of Transplantation and Surgery in Hungary
- ◆ 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
- ◆ Registre Néphrologique du Grand Duché de Luxembourg
- ◆ the National Renal Registry, Malaysia
- ◆ Instituto Mexicano De Trasplantes, Cuernavaca Morelos, Mexico
- ◆ the Netherlands Dialysis Registry
- ◆ the Norwegian National Hospital
- ◆ the Philippines Renal Disease Registry Project
- ◆ the Polish Renal Registry
- ◆ the Romanian Renal Registry
- ◆ the Society of Dialysis, Russia
- ◆ the Scottish Renal Registry
- ◆ 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 Dr. Kitty Jager and Anneke Kramer at the ERA-EDTA Registry for their help in coordinating much of the European data presented in this chapter. Data for some countries do not represent 100 percent of the ESRD population; interpretation of changes in incident and prevalent rates must therefore be performed with caution. Notations are made in the captions for those countries reporting data only for dialysis patients. Data from Belgium do not include patients younger than 20, and data from England, Wales and N. Ireland do not include patients younger than 18.

To contribute data from your country's registry, please complete the International Data Collection Form and return it to the USRDs at usrds@usrds.org.

ESRD IN ASIAN & INDIGENOUS POPULATIONS

Figures 12.9–11 examine the incidence of ESRD in the U.S. Asian population and in Japan and Taiwan. Unadjusted rates are expressed as the number of incident ESRD patients on dialysis per million population. U.S. data are obtained from the ME form, while data from Japan and Taiwan are provided by the Japanese Society of Dialysis Therapy and the Taiwan Society of Nephrology.

In Figures 12.12–14, the Canadian indigenous population includes First Nation, Metis, and Inuit; data are provided by the Canadian Organ Replacement Registry. Data for Australia and New Zealand are provided by the Australian and New Zealand Dialysis

and Transplant Registry (ANZDATA). Since the general population for the indigenous populations in Canada and New Zealand is available only for selected census years, the population for years without census data is estimated by the formula, $P_{t+n} = P_t(1+r)^n$. It is assumed that the general population increases or decreases over time with a consistent rate (r) based on the existing total population (P_t).

VASCULAR ACCESS

TABLES

Tables L.1–3 include period prevalent hemodialysis patients, 1999–2007, who have Medicare as their 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 payor status, or the end of the prevalent year. Tables L.4–6 include January 1, 2007 point prevalent hemodialysis patients. Vintage represents the amount of time between the first service date and January 1, 2007.

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

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

CENSUS POPULATIONS

The 2000 U.S. Census, available in 2002, introduced a new race category with additional 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 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>.

STATISTICAL METHODS

METHODS FOR CALCULATING RATES

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

model-based rates

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

measurement unit for rates

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

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

Patients 1 to 6 contribute 0.25, 0.5, 1.0, 1.0, 0.75, and 1.0 patient years at risk, respectively. The first hospitalization rate per thousand patients is 667 for both groups in 1997. But the first hospitalization rate per thousand patient years at risk is 1,143 for Group A and 727 for Group B (calculated as $[2 \text{ total events} / 1.75 \text{ total patient years at risk}] \times 1,000$ 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, unadjusted event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders — such as age, gender, race, and primary diagnosis — as the reference population.

direct adjustment

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

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

Assuming the incident rate of state A in 2001 is 173 per million population, and the race-specific rates and national populations are as shown in the following table, the adjusted incident rate of state A with the national population as reference is $(153 \times 75.1\%) + (250 \times 12.3\%) + (303 \times 0.9\%) + (174 \times 3.6\%) + (220 \times 8\%) = 158.73$ 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 Two and Three and in Reference Sections A and B, as well as in the model-based adjustment method.

model-based adjustment

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one 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 for some models; the bootstrap approach works well, but is time consuming.

In this ADR we use model-based adjustments to calculate adjusted mortality rates; adjusted survival probabilities based on the Cox regression model; adjusted hospitalization rates 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 . 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

$$\widehat{I}_k(t) = \sum_{j: t_j \leq t} \widehat{\lambda}_k(t_j) \widehat{S}(t_{j-1})$$

where $\widehat{\lambda}_k(t_j) = d_{kj}/n_j$, $\widehat{S}(t_{j-1})$ 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 Sections G and I, with age, gender, race, and primary diagnosis used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities predicted from the Cox regression model (Kalbfleisch JD, Prentice RL). This process yields estimates of probabilities that would have arisen in each year if the patients had had the same attributes as the reference population. Since the probabilities in each table are adjusted to the same reference set of patient attributes, any remaining differences among cohorts and years are due to factors other than age, gender, race, and primary diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

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 in main effect and four-way interactions, and as a continuous variable in the two-way interactions.

For tables with mortality rates for both intersecting and marginal groups we have used a single model to calculate all rates in

each table. The marginal rates are simply the weighted averages of the estimated, cross-classified rates, with cell-specific patient years as weights. For this approach the use of a single model means that GLIMMIX cannot give the standard errors for some of these estimated rates; the bootstrap method is therefore used instead.

The adjusted mortality rates for prevalent cohorts 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 state-level SMR is used to compare mortality in prevalent dialysis patients — after adjusting for age, gender, race, primary diagnosis, and ESRD vintage — in each state using the national dialysis population in the corresponding year as the reference. An SMR of 1.05 for a state indicates that patients in this state have a risk of death approximately five percent higher than that of patients in the reference population of all U.S. dialysis patients.

traditional method of SMR calculation

The traditional approach used to calculate unit-specific SMRs is straightforward: produce unit-specific expected death counts and compute the “observed/expected” ratio. There are two methods of producing unit-specific expected death counts. In the indirect method, the expected death count is the weighted sum of category-specific death rates in the reference population, and the weights are the category-specific total 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 time A . Among patients alive at age A , the probability of surviving X more years is $S(X|A) = S(A+X)/S(A)$. For a given starting age A , the expected remaining lifetime is then equal to the area under the

curve of $S(X|A)$ plotted versus X . Because few patients live beyond 100, this area is truncated at the upper age limit $A + X = 100$.

HALF-LIVES 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 $\ln(S(T_0)) - \ln(S(T_1))$.

adjusted conditional half-life

When comparing the conditional half-time of different groups, the difference of conditional half-lives may partially reflect the difference of patient characteristics among groups. To remove the part of the difference attributable to patient characteristics, the adjusted conditional half-life can be estimated. For example, if patient age, race, and gender are different among groups and are factors for survival, we can calculate the adjusted conditional half-life by adjusting for age, race, and gender with a given reference population. The method for estimating the adjusted conditional half-life is the same as described above for the unadjusted conditional half-life estimate, with the exception of step 1. Usually a Cox regression model is fit for each group, with age, race, and gender as the covariates. The log survival at time T_0 and T_1 is calculated from the Cox model estimates for each cross-sectional subgroup of age*race*gender. The weighted average of the $\ln(\text{survival})$ s over the subgroups at each time point is then calculated, with the patient proportion of each subgroup in the reference population as the weight. The $\ln(S(T_0))$ and the $\ln(S(T_1))$ in the first step above are replaced by the corresponding weighted averages.

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 & 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 UNITED STATES RENAL DATA SYSTEM TO SUPPORT THE work of the renal community are detailed in Table b.a. The entire ADR is available at www.usrds.org, with PowerPoint slides of all figures and Excel files of the data behind the graphs; included as well are PDF files of the Researcher's Guide. The site's RENDER system allows users to create customized data tables and regional maps. Data on website use are presented in Figure b.1.

DATA REQUESTS

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

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, payor 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 b.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 researchers must sign the USRDS "Agreement for Release of Data," on the same page. File prices are listed in Table b.c.

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

CORE DATASET

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

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

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

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

Treatment History/Modality Sequence Contains a new record for each patient at each change in modality or dialysis provider.

Medical Evidence Contains full data from the 1995 version of the CMS Medical Evidence form. 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.

Transplant Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant 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. 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 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 SAFs. The first two are included on the Core SAF, and the remaining six are included in the Transplant data 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 PMMS 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
- **TXFUUNOS** 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 the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all pre-1988 CMS transplants accepted next. CMS transplants from 1988–1993 are then ac-



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 following a short registration; a tutorial is also available on this site to help new users.

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

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

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

Custom data files Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of \$119.57 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK.

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

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

Data file contacts Shu-Cheng Chen, MS; schen@usrds.org
 Beth Forrest, BBA; 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.

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

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

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

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

Dialysis Morbidity and Mortality (DMMS; Special Study) Wave 1: 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.

cepted 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 on institutional claims are available for pre-1989 through 2007, while data on physician/supplier claims are available for 1991–2007. The 2008 claims will be available, along with other updated USRDS SAFS, by the end of 2010.

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 SURVEY

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 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 b.e, or you may contact the USRDS Coordinating Center for further information.

DISEASE-BASED COHORT DATA & 5 PERCENT GENERAL MEDICARE PAYMENT DATA

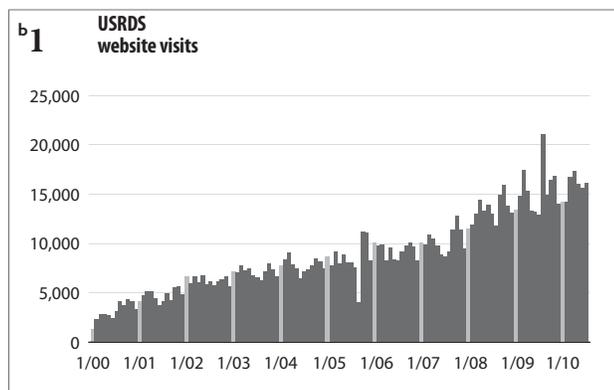
Three disease-based cohort data sets — for CKD, diabetes, and CHF — are built from the 5 percent general Medicare Claims SAFS. Each data set contains a patient master file, a payor sequence file, and a set of comorbidity files.

Separately, 5 percent general Medicare claims SAFS (inpatient, outpatient, skilled nursing facility, home health, hospice, Part B, and durable medical equipment) are also available for single or multiple years from 1992 to 2007; 2008 claims will be available by the end of 2010. 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. This dataset includes Medicare claims of ESRD patients from incident years 1995–2007 with 2008 data available by the end of 2010. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payor sequence is provided so 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 b.e.



b^c Prices for the USRDS Standard Analysis Files (checks must be made payable to the Minneapolis Medical Research Foundation)

Standard Analysis Files			Medicare payment data		
			Institutional	Physician/supplier	
Core dataset	\$1,275	Needed in order to use the other files.	pre-1989	\$250	
Transplant dataset	\$500	Detailed transplant data from CMS and UNOS.	1989	\$250	
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.	1990	\$250	
CDS survey dataset	\$750	Survey information and laboratory values from the Comprehensive Dialysis Survey	1991	\$375	\$500
			1992	\$375	\$500
			1993	\$375	\$500
			1994	\$375	\$625
			1995	\$500	\$625
			1996	\$500	\$750
			1997	\$500	\$875
			1998	\$500	\$875
			1999	\$500	\$875
			2000	\$750	\$875
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.	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
			2007	\$1,750	\$1,375
			2008	\$1,875	\$1,500
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.			

Pre-ESRD claims available for 1993 to 2008; price ranges from \$200 to \$600 per year and claim type. Prices subject to change.

b^d Prices for the 5 percent Medicare Sample Standard Analysis File CD-ROMs (checks must be made payable to the Minneapolis Medical Research Foundation)

	CKD		Diabetes		Congestive heart failure	
	Institutional	Physician/supplier	Institutional	Physician/supplier	Institutional	Physician/supplier
1992	\$375	\$375	\$375	\$500	\$375	\$625
1993	\$375	\$375	\$375	\$500	\$500	\$625
1994	\$375	\$375	\$375	\$500	\$500	\$625
1995	\$375	\$375	\$500	\$625	\$500	\$625
1996	\$375	\$500	\$500	\$625	\$500	\$750
1997	\$375	\$500	\$500	\$625	\$500	\$750
1998	\$375	\$500	\$500	\$625	\$625	\$750
1999	\$500	\$500	\$500	\$625	\$625	\$750
2000	\$500	\$500	\$500	\$625	\$625	\$750
2001	\$500	\$500	\$625	\$750	\$625	\$750
2002	\$500	\$500	\$625	\$750	\$625	\$750
2003	\$500	\$500	\$625	\$750	\$625	\$750
2004	\$500	\$500	\$625	\$875	\$625	\$750
2005	\$625	\$625	\$750	\$875	\$750	\$875
2006	\$750	\$625	\$750	\$1,000	\$750	\$875
2007	\$875	\$625	\$875	\$1,000	\$750	\$875
2008	\$1,000	\$750	\$1,000	\$1,125	\$875	\$1,000

b^e Prices for the ESRD CPM/USRDS files (checks must be made payable to the Minneapolis Medical Research Foundation)

ESRD CPM Survey data	
Includes 1994–2008 hemodialysis survey years and 1995–2008 peritoneal dialysis survey years	\$1,250
ESRD CPM/SAF linked files	
Core files	\$400
Hospital	\$200
Transplant	\$200
ESRD CPM Medicare participant Institutional & Physician/Supplier claims	
are available for the years pre-1989 through 2007; \$100–300 per year	

b^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

- I Research topic title and submission date.
- II Background information.
- III Study design: objectives, hypothesis(es), analytical methods.
- IV Data being requested: 1) List of Standard Analysis Files needed (if multiple years, please specify), or fields needed in custom data file. 2) Description of data security: responsible party, computer access, etc. 3) 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 Investigator information. For Principal Investigator and co-authors, supply:
 - Name
 - Affiliation
 - Business address
 - Business phone & fax
 - Email address

Submit to
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 6707 Democracy Blvd, Room 615
 Bethesda, MD 20892-5458
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 Fax 301.480.3510
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FILE MEDIA & FORMATS

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

COSTS

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

DOCUMENTATION

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

DATA USE ACKNOWLEDGEMENT

Publications using USRDS data should include an acknowledgment and this notice: The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the 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 b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the "Agreement for Release of Data," later in the appendices. With your completed research proposal, please include a signed agreement for release of information from each investigator and analyst who will use the data files.

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

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

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

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

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

CAVEATS

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

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

The USRDS CC will provide data in 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 (m²).

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

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

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.

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

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

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

Cerebrovascular 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 (GFR) 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 by using gravity to fill and empty the cavity 4–5 times each day.

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

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

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

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.

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

Glycosylated hemoglobin (HbA_{1c}) 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).

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.

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

Kidney Disease Outcomes Quality Initiative (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.

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

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

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

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

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.

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 somatotropin; 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.

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.

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

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.

abbreviations

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

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

Project title _____

In this agreement, "Recipient" means _____

- A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copies containing data extracted from the USRDS research database.
- B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.
- C. The Recipient shall not use the data to identify individuals on the file.
- D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.
- E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the data may not be used include, but are not limited to,
 - the identification and targeting of under- or over-served health service markets primarily for commercial benefit
 - the obtaining of information about providers or facilities for commercial benefit
 - insurance purposes such as redlining areas deemed to offer bad health insurance risks
 - adverse selection (e.g., identifying patients with high risk diagnoses)

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

- F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten individuals or fewer than five providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor, and (2) the contractor has signed a data release agreement with the PO.
- G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.
- H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.
- I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. The USRDS data files covered in this data use agreement may be retained by the Recipient until _____. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient's expense, and any derivative files and copies shall be destroyed.
- J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon request, be granted access to premises where data in this file are kept.

Recipient typed name, title, & organization

Recipient telephone number

Recipient signature & date

Contractor typed name, title, & organization, as appropriate

Contractor telephone number

Contractor signature & date

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

USRDS Project Officer signature & date

United States Renal Data System (USRDS) International Data Collection Form

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

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

- A) Population: the population of your country for the most recent year available
- B) Incidence: the count of patients who start any form of renal replacement therapy during the year. These are first-time patients only; patients who start dialysis after a failed transplant, for example, should not be included.
 - B2) The subset of total incident patients whose failure is due to diabetic nephropathy. Subtracting B2 from B1 should give the total number of incident patients for all non-diabetic nephropathy causes.
- C) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).
 - C1) All patients on some form of treatment, dialysis or transplantation.
 - C2) Patients with a functioning kidney transplant as of December 31.

- C3) All dialysis patients. C2 and C3 should sum to C1 unless there are lost-to-follow-up patients. If there are lost-to-follow-up patients, please note this fact and whether these patients are captured in C2.
- C4) All patients treated with in-center hemodialysis as of December 31.
- C5) All patients treated with CAPD or CCPD as of December 31.
- C6) All patients treated with home hemodialysis as of December 31.

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

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

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

Country _____

A) Population of country	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

B1) Incidence: Total number of incident (new) patients starting renal replacement therapy during the year	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

B2) Incidence: Total number of incident patients starting renal replacement therapy during the year due to diabetes	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C2) Prevalence: Total number of ESRD patients with a functioning graft at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C5) Prevalence: Total number of ESRD patients on CAPD/CCPD at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

C6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31)						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

D1) Transplant: Total number of cadaveric transplants during the year						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

D2) Transplant: Total number of living donor transplants during the year						
	0-19	20-44	45-64	65-74	75+	Total
2005	_____	_____	_____	_____	_____	_____
2006	_____	_____	_____	_____	_____	_____
2007	_____	_____	_____	_____	_____	_____
2008	_____	_____	_____	_____	_____	_____

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
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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 <small>Print Name of Enrolled/Principal Tribe _____ *complete Item 9</small>	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) <table style="width: 100%;"> <tr> <td style="text-align: center; width: 50%;">Prior</td> <td style="text-align: center; width: 50%;">Current</td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	Prior	Current	<input type="checkbox"/>	17. Co-Morbid Conditions (Check all that apply currently and/or during last 10 years)*See instructions <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> 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) </td> <td style="width: 50%; vertical-align: top;"> 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 </td> </tr> </table>	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																					
Prior	Current																										
<input type="checkbox"/>	<input type="checkbox"/>																										
<input type="checkbox"/>	<input type="checkbox"/>																										
<input type="checkbox"/>	<input type="checkbox"/>																										
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<input type="checkbox"/>	<input type="checkbox"/>																										
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																										

18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If Yes, answer: <input type="checkbox"/> 6-12 months <input type="checkbox"/> >12 months
b. Was patient under care of a nephrologist?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	If Yes, answer: <input type="checkbox"/> 6-12 months <input type="checkbox"/> >12 months
c. Was patient under care of kidney dietitian?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	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?	<input type="checkbox"/> 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"/> 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 Tuberosus 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

**END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION**

A. COMPLETE FOR ALL ESRD PATIENTS

1. Name (Last, First, Middle Initial)

2. Health Insurance Claim Number

3. Social Security Number

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

5. Phone Number
()

6. Date of Birth

MM / DD / YYYY

7. Sex

Male Female

8. Ethnicity

Hispanic: Mexican Hispanic: Other Non-Hispanic

9. Race (Check **one** box only)

White Mid-East/Arabian
 Black Indian sub-Continent
 American Indian/Alaskan Native Other, specify _____
 Asian
 Pacific Islander Unknown

10. Medical Coverage (Check **all** that apply)

a. Medicaid e. Other Medical Insurance
b. DVA f. None
c. Medicare
d. Employer Group Health Insurance

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

Yes No

CITY

STATE

ZIP

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

13. Height

INCHES OR CENTIMETERS

14. Dry Weight

POUNDS OR KILOGRAMS

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

Prior	Current	
<input type="checkbox"/>	<input type="checkbox"/>	Unemployed
<input type="checkbox"/>	<input type="checkbox"/>	Employed Full Time
<input type="checkbox"/>	<input type="checkbox"/>	Employed Part Time
<input type="checkbox"/>	<input type="checkbox"/>	Homemaker
<input type="checkbox"/>	<input type="checkbox"/>	Retired due to Age/Preference
<input type="checkbox"/>	<input type="checkbox"/>	Retired (Disability)
<input type="checkbox"/>	<input type="checkbox"/>	Medical Leave of Absence
<input type="checkbox"/>	<input type="checkbox"/>	Student

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

a. <input type="checkbox"/> Congestive heart failure	k. <input type="checkbox"/> Diabetes, currently on insulin
b. <input type="checkbox"/> Ischemic heart disease, CAD*	l. <input type="checkbox"/> Chronic obstructive pulmonary disease
c. <input type="checkbox"/> Myocardial infarction	m. <input type="checkbox"/> Tobacco use (current smoker)
d. <input type="checkbox"/> Cardiac arrest	n. <input type="checkbox"/> Malignant neoplasm, Cancer
e. <input type="checkbox"/> Cardiac dysrhythmia	o. <input type="checkbox"/> Alcohol dependence
f. <input type="checkbox"/> Pericarditis	p. <input type="checkbox"/> Drug dependence*
g. <input type="checkbox"/> Cerebrovascular disease, CVA, TIA*	q. <input type="checkbox"/> HIV positive status <input type="checkbox"/> Can't Disclose
h. <input type="checkbox"/> Peripheral vascular disease*	r. <input type="checkbox"/> AIDS <input type="checkbox"/> Can't Disclose
i. <input type="checkbox"/> History of hypertension	s. <input type="checkbox"/> Inability to ambulate
j. <input type="checkbox"/> Diabetes (primary or contributing)	t. <input type="checkbox"/> Inability to transfer

17. Was pre-dialysis/transplant EPO administered?

Yes No

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

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

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

19. Name of Provider

20. Medicare Provider Number

21. Primary Dialysis Setting

Hospital Inpatient Dialysis Facility/Center Home

22. Primary Type of Dialysis

Hemodialysis IPD CAPD CCPD Other

23. Date Regular Dialysis Began

MM / DD / YY

24. Date Patient Started Chronic Dialysis at Current Facility

MM / DD / YY

25. Date Dialysis Stopped

MM / DD / YY

26. Date of Death

MM / DD / YY

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

27. Date of Transplant MM / DD / YY	28. Name of Transplant Hospital	29. Medicare Provider Number for Item 28
Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.		
30. Enter Date MM / DD / YY	31. Name of Preparation Hospital	32. Medicare Provider Number for Item 31
33. Current Status of Transplant <input type="checkbox"/> Functioning <input type="checkbox"/> Non-Functioning		
34. If Nonfunctioning, Date of Return To Regular Dialysis MM / DD / YY	35. Current Dialysis Treatment Site <input type="checkbox"/> Hospital Inpatient <input type="checkbox"/> Dialysis Facility/Center <input type="checkbox"/> Home	

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

36. Name of Training Provider	37. Medicare Provider Number of Training Provider
38. Date Training Began MM / DD / YY	39. Type of Training <input type="checkbox"/> Hemodialysis <input type="checkbox"/> IPD <input type="checkbox"/> CAPD <input type="checkbox"/> CCPD
40. 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	41. Date When Patient Completed, or is Expected to Complete, Training MM / DD / YY

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.

42. Printed Name and Signature of Physician Personally Familiar with the Patient's Training	43. UPIN of Physician in Item 42
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E. PHYSICIAN IDENTIFICATION

44. Attending Physician (Print)	45. Physician's Phone No. ()	46. UPIN of Physician in Item 44
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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.

47. Attending Physician's Signature of Attestation (Same as Item 44)	48. Date MM / DD / YY
49. Remarks	

F. OBTAIN SIGNATURE FROM PATIENT

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

50. Signature of Patient (Signature by Mark Must Be Witnessed.)	51. Date MM / DD / YY
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G. PRIVACY ACT STATEMENT

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

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

52. Network Confirmed as ESRD <input type="checkbox"/> Yes <input type="checkbox"/> No	53. Authorized Signature	54. Date MM / DD / YY	55. Network Number
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LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

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

ICD-9	LTR	NARRATIVE	ICD-9	LTR	NARRATIVE
DIABETES			HYPERTENSION/LARGE VESSEL DISEASE		
25000	A	Type II, adult-onset type or unspecified type diabetes	4039	D	Renal disease due to hypertension (no primary renal disease)
25001	A	Type I, juvenile type, ketosis prone diabetes	4401	A	Renal artery stenosis
GLOMERULONEPHRITIS			59381	B	Renal artery occlusion
5829	A	Glomerulonephritis (GN) (histologically not examined)	59381	E	Cholesterol emboli, renal emboli
5821	A	Focal glomerulosclerosis, focal sclerosing GN	CYSTIC/HEREDITARY/CONGENITAL DISEASES		
5831	A	Membranous nephropathy	75313	A	Polycystic kidneys, adult type (dominant)
5832	A	Membranoproliferative GN type 1, diffuse MPGN	75314	A	Polycystic, infantile (recessive)
5832	C	Dense deposit disease, MPGN type 2	75316	A	Medullary cystic disease, including nephronophthisis
58381	B	IgA nephropathy, Berger's disease (proven by immunofluorescence)	7595	A	Tuberous sclerosis
58381	C	IgM nephropathy (proven by immunofluorescence)	7598	A	Hereditary nephritis, Alport's syndrome
5804	B	Rapidly progressive GN	2700	A	Cystinosis
5834	C	Goodpasture's Syndrome	2718	B	Primary oxalosis
5800	C	Post infectious GN, SBE	2727	A	Fabry's disease
5820	A	Other proliferative GN	7533	A	Congenital nephrotic syndrome
SECONDARY GN/VASCULITIS			5839	D	Drash syndrome, mesangial sclerosis
7100	E	Lupus erythematosus, (SLE nephritis)	7532	A	Congenital obstructive uropathy
2870	A	Henoch-Schonlein syndrome	7530	B	Renal hypoplasia, dysplasia, oligonephronia
7101	B	Scleroderma	7567	A	Prune belly syndrome
2831	A	Hemolytic uremic syndrome	7598	B	Hereditary/familial nephropathy
4460	C	Polyarteritis	NEOPLASMS/TUMORS		
4464	B	Wegener's granulomatosis	1890	B	Renal tumor (malignant)
5839	C	Nephropathy due to heroin abuse and related drugs	1899	A	Urinary tract tumor (malignant)
4462	A	Vasculitis and its derivatives	2230	A	Renal tumor (benign)
5839	B	Secondary GN, other	2239	A	Urinary tract tumor (benign)
INTERSTITIAL NEPHRITIS/PYELONEPHRITIS			2395	A	Renal tumor (unspecified)
9659	A	Analgesic abuse	2395	B	Urinary tract tumor (unspecified)
5830	B	Radiation nephritis	20280	A	Lymphoma of kidneys
9849	A	Lead nephropathy	2030	A	Multiple myeloma
5909	A	Nephropathy caused by other agents	2030	B	Light chain nephropathy
27410	A	Gouty nephropathy	2773	A	Amyloidosis
5920	C	Nephrolithiasis	99680	A	Complication post bone marrow or other transplant
5996	A	Acquired obstructive uropathy	MISCELLANEOUS CONDITIONS		
5900	A	Chronic pyelonephritis, reflux nephropathy	28260	A	Sickle cell disease/anemia
58389	B	Chronic interstitial nephritis	28269	A	Sickle cell trait and other sickle cell (HbS/Hb other)
58089	A	Acute interstitial nephritis	64620	A	Post partum renal failure
5929	B	Urolithiasis	0429	A	AIDS nephropathy
2754	A	Nephrocalcinosis	8660	A	Traumatic or surgical loss of kidney(s)
			5724	A	Hepatorenal syndrome
			5836	A	Tubular necrosis (no recovery)
			59389	A	Other renal disorders
			7999	A	Etiology uncertain

CHRONIC RENAL DISEASE MEDICAL EVIDENCE REPORT

IDENTIFYING INFORMATION

1. PATIENT'S NAME (LAST, FIRST, MIDDLE INITIAL)		2. PATIENT'S OWN SOCIAL SECURITY NUMBER	
3. PATIENT'S ADDRESS (STREET, CITY, STATE, ZIP)		4. PATIENT'S CLAIM NUMBER	
5. PHONE NO. *	6. DATE OF BIRTH	7. RACE * <input type="checkbox"/> a. AMERICAN INDIAN OR ALASKAN NATIVE <input type="checkbox"/> b. ASIAN OR PACIFIC ISLANDER <input type="checkbox"/> c. BLACK <input type="checkbox"/> d. WHITE <input type="checkbox"/> e. UNKNOWN	
8. ADDRESS OF SOCIAL SECURITY OFFICE		9. PATIENT'S SEX * <input type="checkbox"/> a. MALE <input type="checkbox"/> b. FEMALE	10. PRIMARY DIAGNOSIS (CAUSE OF ESRD) **
11. NAME, ADDRESS, AND PHONE NUMBER OF PHYSICIAN RESPONSIBLE FOR RENAL TREATMENT AT TIME OF CLAIM			

TREATMENT INFORMATION—DIALYSIS

TYPE OF DIALYSIS	DATE REGULAR DIALYSIS BEGAN	FREQUENCY SINCE REGULAR DIALYSIS BEGAN (TIMES PER WEEK)	HAS DIALYSIS ENDED?	IF ENDED, DATE OF LAST DIALYSIS
12a. <input type="checkbox"/> HEMODIALYSIS	12b.	12c.	12d. <input type="checkbox"/> YES <input type="checkbox"/> NO	12e.
13a. <input type="checkbox"/> PERITONEAL <input type="checkbox"/> CAPD <input type="checkbox"/> CCPD	13b.	13c.	13d. <input type="checkbox"/> YES <input type="checkbox"/> NO	13e.
14. NAME OF DIALYSIS PROVIDER			15. DIALYSIS PROVIDER NUMBER	

TREATMENT INFORMATION—TRANSPLANT

16. DATE(S) OF TRANSPLANT		17. NAME OF TRANSPLANT HOSPITAL		18. PROVIDER NO
19. WAS THE PATIENT ADMITTED AS AN INPATIENT TO A HOSPITAL IN PREPARATION FOR, OR ANTICIPATION OF, A KIDNEY TRANSPLANT PRIOR TO THE DATE OF ACTUAL TRANSPLANTATION? <input type="checkbox"/> YES <input type="checkbox"/> NO		20. IF YES, ENTER DATE(S)	21. NAME OF HOSPITAL FOR ITEM 19	
22. PROVIDER NO		23. CURRENT STATUS OF TRANSPLANT (IF b. CHECKED, ANSWER 24 OR EXPLAIN IN REMARKS) <input type="checkbox"/> a. FUNCTIONING <input type="checkbox"/> b. REJECTED		24. DATE OF RETURN TO REGULAR DIALYSIS
		25. CURRENT TREATMENT SITE <input type="checkbox"/> a. HOME <input type="checkbox"/> b. FACILITY		

MEDICAL CERTIFICATION

26. DO YOU CERTIFY THAT THIS PATIENT HAS REACHED THE STATE OF RENAL IMPAIRMENT THAT APPEARS IRREVERSIBLE AND PERMANENT AND REQUIRES A REGULAR COURSE OF DIALYSIS OR KIDNEY TRANSPLANTATION TO MAINTAIN LIFE? <input type="checkbox"/> YES <input type="checkbox"/> NO	SIGNATURE AND TITLE OF ATTENDING PHYSICIAN	DATE
--	--	------

CERTIFICATION OF SELF CARE DIALYSIS TRAINING

27. NAME ADDRESS OF TRAINING PROVIDER	PROVIDER NO.	28. DATE TRAINING BEGAN	29. TYPE OF TRAINING <input type="checkbox"/> a. HEMODIALYSIS <input type="checkbox"/> b. IPD <input type="checkbox"/> c. CAPD <input type="checkbox"/> d. CCPD
30. HAS THE PATIENT COMPLETED THE TRAINING PROGRAM? <input type="checkbox"/> YES <input type="checkbox"/> NO	IF NO, WHEN IS THE PATIENT EXPECTED TO COMPLETE THE PROGRAM?		31. DO YOU CERTIFY THAT THE PATIENT IS EXPECTED TO COMPLETE TRAINING SUCCESSFULLY AND SELF DIALYZE ON A REGULAR BASIS? <input type="checkbox"/> YES <input type="checkbox"/> NO
32. I CERTIFY THAT THE ABOVE SELF-DIALYSIS TRAINING INFORMATION IS BASED ON CONSIDERATION OF ALL PERTINENT MEDICAL, PSYCHOLOGICAL, AND SOCIOLOGICAL FACTORS AS REFLECTED IN RECORDS KEPT BY THIS TRAINING FACILITY, AND IS CORRECT.			
SIGNATURE OF PHYSICIAN PERSONALLY FAMILIAR WITH THE PATIENT'S TRAINING	TITLE	DATE	

33. REMARKS

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

SIGNATURE OF PATIENT (SIGNATURE BY MARK MUST BE WITNESSED)	DATE
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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 ____ / ____ / ____ <small>Month Day Year</small>		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 ____ / ____ / ____ <small>Month Day Year</small>
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>If yes, check one of the following:</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 ____ / ____ / ____ <small>Month Day Year</small></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>
<p>15. If deceased ever received a transplant:</p> <p>a. Date of most recent transplant ____ / ____ / ____ <input type="checkbox"/> Unknown <small>Month Day Year</small></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>

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

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

ESRD DEATH NOTIFICATION
END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

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 ____ / ____ / ____ <small>Month Day Year</small>		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 ____ / ____ / ____ <small>Month Day Year</small>
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>If yes, check one of the following:</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 ____ / ____ / ____ <small>Month Day Year</small></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>
<p>15. If deceased ever received a transplant:</p> <p>a. Date of most recent transplant ____ / ____ / ____ <input type="checkbox"/> Unknown <small>Month Day Year</small></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>

17. Name of Physician (Please print complete name)	18. Signature of Person Completing This Form	Date
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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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**ESRD DEATH NOTIFICATION
END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM**

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

1. PATIENT'S LAST NAME		FIRST	MI	2. HEALTH INSURANCE CLAIM NUMBER													
3. PATIENT'S SEX a. <input type="checkbox"/> Male b. <input type="checkbox"/> Female		4. PATIENT'S STATE OF RESIDENCE		5. DATE OF BIRTH <table style="display: inline-table; border: none;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td align="center" colspan="2">MONTH</td> <td align="center" colspan="2">DAY</td> <td align="center" colspan="2">YEAR</td> </tr> </table>								MONTH		DAY		YEAR	
MONTH		DAY		YEAR													
7. PROVIDER NAME AND ADDRESS (CITY AND STATE)																	
8. PROVIDER NUMBER		9. PLACE OF DEATH (Check one) a. <input type="checkbox"/> Hospital b. <input type="checkbox"/> Dialysis c. <input type="checkbox"/> Home d. <input type="checkbox"/> Other			10. WAS AN AUTOPSY PERFORMED? a. <input type="checkbox"/> Yes b. <input type="checkbox"/> No												
11. CAUSES OF DEATH (Enter code form List of Causes below.)																	
a. Primary Cause <input style="width: 80px;" type="text"/>		b. Were there Secondary Causes? <input type="checkbox"/> No <input type="checkbox"/> Yes, Specify		(1) <input style="width: 80px;" type="text"/>	(3) <input style="width: 80px;" type="text"/>												
				(2) <input style="width: 80px;" type="text"/>	(4) <input style="width: 80px;" type="text"/>												

LIST OF CAUSES

CARDIAC

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

VASCULAR

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

INFECTION

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

LIVER DISEASE

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

GASTRO-INTESTINAL (see also 50)

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

OTHER

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

<p>12. FOR ALL DEATHS INDICATE YES/NO Renal replacement therapy discontinued prior to death: <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, check one of the following:</p> <p>a. <input type="checkbox"/> Following HD and/or PD access failure d. <input type="checkbox"/> Following acute medical complication</p> <p>b. <input type="checkbox"/> Following transplant failure</p> <p>c. <input type="checkbox"/> Following chronic failure to thrive e. <input type="checkbox"/> Other</p>	<p>13. IF DECEASED RECEIVED A TRANSPLANT</p> <p>a. Date of most recent transplant <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> MONTH DAY YEAR</p> <p>b. Was kidney functioning (patient not on dialysis) at time of death? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown</p> <p>c. Did transplant patient resume chronic maintenance dialysis prior to death? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
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14. REMARKS	
15. NAME OF PHYSICIAN	16. SIGNATURE OF PERSON COMPLETING THIS FORM DATE

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**END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM
ESRD FACILITY SURVEY (DIALYSIS UNITS ONLY)**

FOR THE PERIOD _____

Facility Physical Address
(If different than mailing address) Suite/Room _____ Street _____ City _____ State/Zip Code _____

Number of Dialysis Stations: _____ **Facility Telephone:** (_____) _____

Facility Ownership Type: Profit Non-Profit

Facility Local/National Affiliation/Chain Information _____
(i.e. Gambro, etc.)

Types of dialysis services offered:
 Incenter Hemodialysis Peritoneal Dialysis Home Hemodialysis Training

Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?
 Yes 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	In-center	04A	05A	06A	07A	08A	09A	10A	11A	12A	13A
			Home	04B	05B	06B	07B	08B	09B	10B	11B	12B	13B

Patients Receiving Care at End of Survey Period												Total Patients
Incenter Dialysis		Self-Dialysis Training				Total Incenter Dialysis	Home Dialysis				Total Home Dialysis	Fields 20 and 25
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			Hemodialysis Patients Dialyzing More Than 4 Times Per Week			Vocational Rehabilitation			
Currently enrolled in Medicare	Medicare application pending	Non-Medicare	Setting	Day	Nocturnal	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
27	28	29	Incenter	30A	31A	32	33	34	35
			Home	30B	31B				

TREATMENT AND STAFFING

Incenter Dialysis Treatments (Include Training Treatments)		Staffing				
Hemodialysis	Other	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. _____

REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THE SURVEY
This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).
Form CMS-2744A (02/04)

**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			

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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

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45

46

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

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48

49

50

Patients Awaiting Transplant	
Dialysis	Nondialysis

51

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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).

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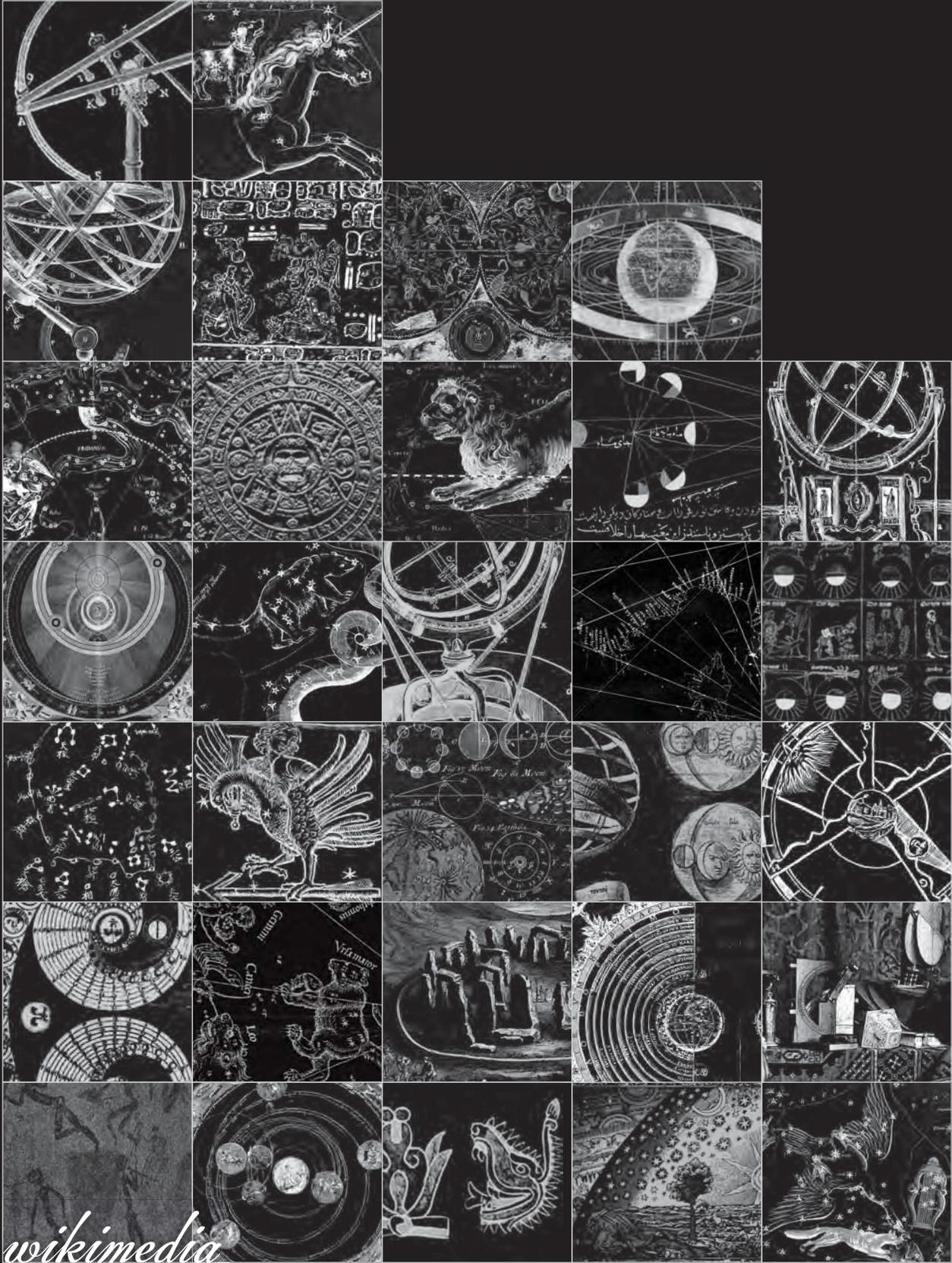
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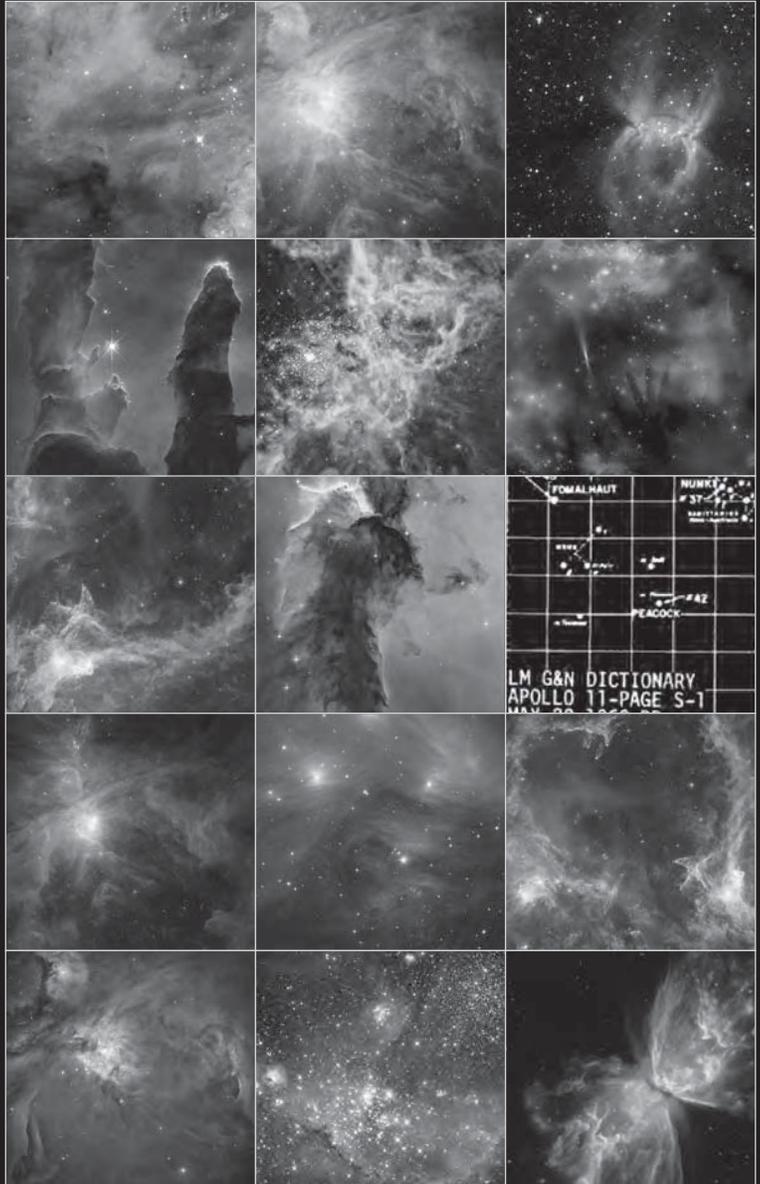
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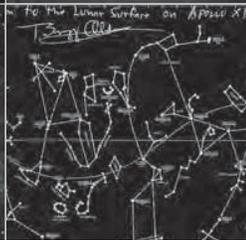
Different stories, a shared sky. Just as the stars have uniquely shaped the beliefs of each culture, so too can the same disease affect different populations in different ways. We frame the data of this year's ADR with images of the sky across times and cultures, illustrating some of the myriad perceptions of the stars, and showing, too, how knowledge and interpretation change over time, and how the juxtaposition of stories can enhance understanding and enlighten our views of the universe.



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COVER: CARINA NEBULA, HUBBLE

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