

# ESRD Analytical Methods

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## Introduction

In this appendix we present details on the USRDS database, its standardized working datasets and specialized code definitions, and our common data processing practices applied to the data used in the production of this Annual Data Report (ADR). We also describe the statistical methods used. The researcher's guide to the United States Renal Data Service (USRDS) database, available through [www.usrds.org](http://www.usrds.org), provides additional information about the database and standard analysis files (SAF).

## Data Sources

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

### **Consolidated Renal Operations in a Web-enabled Network**

The major source of end-stage renal disease (ESRD) patient information for the USRDS is currently the Centers for Medicare and Medicaid Services (CMS) Consolidated Renal Operations in a Web-enabled Network (CROWN) data system. This database system contains demographic, diagnostic and treatment history information for all Medicare beneficiaries with ESRD. Data for non-Medicare patients have also been included since 1995, when ESRD Medical Evidence Report forms (ME; CMS 2728) became mandatory for all ESRD patients.

The original CMS ESRD database was called the Program Management and Medical Information System (PMMIS); this was replaced by the Renal Beneficiary and Utilization System (REBUS) in 1995. Having advanced its database technology, CMS migrated the REBUS database into an Oracle relational database in the fall of 2003. This database is known as the Renal Management Information System (REMIS). In 2003, the Standard Information Management System (SIMS) database of the ESRD networks was also established; SIMS includes information to track patient movement in and out of ESRD facilities, and their transitions from one treatment modality to another. Together, REMIS and SIMS comprise the CROWN system. In May 2012, internet-based access to the data system, CROWNWeb, was rolled

out nationally. It replaced the functionality of SIMS, interfaces with REMIS, and also provides new data to support calculation of clinical measures.

CMS updates the REMIS/CROWNWeb database on a regular basis, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the Organ Procurement and Transplantation Network (OPTN) transplant database, ESRD Medical Evidence Report forms (ME; CMS 2728), and ESRD Death Notification forms (CMS 2746). CMS has also established data-integrity rules to ensure accurate identification of patients in the CMS databases.

### **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 payer (MSP) and employer group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code cross-referencing.

### **ESRD Medical Evidence Form**

The ESRD Medical Evidence Report form (ME; CMS 2728) is used to register patients at the onset of ESRD, and must be submitted by dialysis or transplant providers within 45 days of treatment 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. Prior to 1995, units were required to file the ME form only for Medicare-eligible patients. Since the 1995 revision, however, providers are required to complete the form for all new ESRD patients.

The third major revision of the ME form, in May 2005, remedied several shortcomings of the 1995 form and its earlier versions. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on glycosylated hemoglobin (HgbA1c) and lipid testing, on the frequency of hemodialysis (HD) 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**

The ESRD Death Notification form (CMS 2746) 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 several supplemental data sources for ascertaining death (see the Death Date Determination section below for more details).

### **Organ Procurement and Transplantation Network Database**

In the early 1980s CMS began collecting data on all Medicare kidney transplants in the PMMIS data system. In 1984, the National Organ Transplant Act established the Organ Procurement and Transplant Network (OPTN) to collect data and maintain a registry for organ matching and transplantation. These two efforts were consolidated in 1994, and only OPTN continued to collect data on transplant donors and recipients. In addition to these sources, transplants are also identified from ME forms that indicate transplant as the initial modality, from CROWNWeb/SIMS transplant events, and from institutional inpatient claims. To resolve any conflicts among these sources, the USRDS uses the following algorithm, processing the transplants in the order listed below, and accepting a new transplant only if no transplant within the previous 63 days has already been accepted:

- OPTN transplants
- CROWNWeb/SIMS transplant events
- 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 63 days of the CMS transplant.
- Transplants indicated on ME forms as the initial

modality

- Transplants indicated on institutional inpatient claims

### **CMS Standard Analytical Files**

CMS Standard Analytical files (SAF) contain billing data from final action claims submitted by Medicare beneficiaries with ESRD in which all adjustments are resolved. For inpatient/outpatient (Part A) institutional claims, we use the following 100 percent SAF claims data: inpatient, outpatient, home health agency, hospice, and skilled nursing facility (SNF). For physician/supplier and durable medical equipment (DME) (Part B) claims, we also use the 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 they are finalized at 18 months. The USRDS also uses claims to supplement first service dates, transplant dates, and transplant failure dates.

### **CMS 5 Percent Standard Analytical Files**

CMS 5 percent SAFs contain billing data from final action claims submitted for Medicare beneficiaries in which all adjustments have been resolved. CMS and its contractors produce the 5 percent data sets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (HIC) number ends in 05, 20, 45, 70, or 95. These five two-digit pairs were randomly selected to create a sample containing 5 percent of the total number of Medicare beneficiaries (Merriman and Asper, 2007). The sample design has the effect of creating a built-in longitudinal panel dataset. Once in the sample, a beneficiary will remain a part of all future year data files until death or a change to his/her HIC number. Since 2012, we receive the Master Beneficiary Summary File (formerly the Denominator file), containing demographic information on each beneficiary in the sample, as well as dates of enrollment in the various Medicare programs (Hospital Insurance [Part A], Supplemental Medical Insurance [Part B], Medicare Advantage managed care plans [Part C] and Prescription Drug Benefit [Part D]). Institutional claims for beneficiaries in the 5 percent sample are received in five files, based on type of medical service: inpatient, outpatient, home health agency, hospice,

and skilled nursing facility (SNF). Physician and supplier claims (also referred to as carrier claims) are received in one file for durable medical equipment and another for all other Part B covered services. These files collectively are referred to as the Medicare 5 percent files in this ADR.

### **Standard Information Management System Database**

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 can establish the first ESRD service date but cannot generate a more detailed treatment history. With the integration of the SIMS event data into the USRDS database, however, we can better track patients beyond the initiation of treatment. The SIMS events data, along with the mandate for the ME form, allows us to include patients for whom there previously were no data on initial modality or death. We can now address issues in the non-Medicare ESRD population, such as the large and growing number of lost-to-follow-up patients. This data integration is detailed in the section on data management and preparation. In 2012, the functionality of SIMS was replaced by CROWNWeb.

### **CROWNWeb**

CROWNWeb is a web-based data collection system that captures clinical and administrative data from Medicare-certified dialysis facilities, and allows authorized users to securely submit, update, and verify data provided to Medicare. This system was rolled out nationally in June 2012. While CROWNWeb replaces the patient tracking functionality of SIMS, it also provides new data to support calculation of clinical measures.

### **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).

### **National Health and Nutrition Examination Survey**

The National Health and Nutrition Examination Survey (NHANES) is a series of health examination surveys conducted by the National Center for Health Statistics 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 1999–2012 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 Blacks/African Americans, Mexican Americans, and individuals aged 60 or older to improve the estimates for these subgroups.

### **Annual Facility Survey**

Independent ESRD patient counts are available not only from the CROWN database, but also from CMS's Annual Facility Survey (AFS; CMS 2744), which all Medicare-certified dialysis units must complete. The AFS reports the 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 internet. Beginning with the 2007 ADR, the USRDS extracted the relevant facility survey data directly from the SIMS database. Beginning in 2012, when SIMS was replaced by CROWNWeb, the USRDS received the facility survey data directly from CROWNWeb.

## **CDC Surveillance**

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

## **United States Census**

In rate calculations throughout this year's ADR we use data from the 2000 and 2010 U.S. Census, and also incorporate CDC population estimates by race. Estimates for 1990–1999 were back-calculated based on the actual 2000 census. Later data, however, include racial groups that do not coincide with those in the ESRD data. For rate calculations throughout the ADR we thus use the CDC's Bridged Race Intercensal Estimates Dataset, which estimates White, Black/African American, Native American, and Asian populations. The data and methods for these estimates are available at <http://tinyurl.com/28kpp9j>. For state and network rates, we use Vintage 2013 Bridged-Race Postcensal Population Estimates. Both intercensal and postcensal estimate datasets are available at [http://www.cdc.gov/nchs/nvss/bridged\\_race/data\\_documentation.htm](http://www.cdc.gov/nchs/nvss/bridged_race/data_documentation.htm).

## **Data Management and Preparation**

For this ADR, data are reported through December 31, 2012.

## **ESRD Patient Determination**

A person is identified as having ESRD when a physician certifies the disease on the 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 subsequently 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 miss inclusion in the dataset.

The ESRD first service date is the single most important data element in the USRDS database,

and each patient must, at a minimum, have a valid first service date. This date is used to determine the incident year of each patient and the first year in which the patient is counted as prevalent. The date 90 days after the first service date is used as the starting point for most survival analyses.

In most cases the first service date is derived by identifying the earliest date of various potential indicators:

- the start of dialysis for chronic kidney failure as reported on the ME form,
- the first CROWNWeb/SIMS event,
- a kidney transplant as reported on a CMS or OPTN transplant form, a ME form, or a hospital inpatient claim, or
- the first Medicare dialysis claim.

There are three exceptions to this rule:

- If the CROWNWeb/SIMS event and ME form agree (within 30 days of each other) and are more than 90 days after the first Medicare dialysis claim, and, if in addition, there is no transplant event between the first dialysis claim and the earlier of the CROWNWeb/SIMS event date and ME form date, then first service date is defined as the earlier of the CROWNWeb/SIMS event date and ME form date.
- If the ME form date is one year earlier than the first CROWNWeb/SIMS event date, and if the first claim date or first transplant date agrees with the first CROWNWeb/SIMS event date, then the CROWNWeb/SIMS first event date is used as the first service date.
- If all events for a patient are after January 1, 1995, and the modality of the first event is not “transplant” or “Center Self HD”, then the ME form is used to supply the first service date.

## **Medicare and Non-Medicare 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 who meets one of these four criteria is eligible to apply for Medicare: aged 65 and over, who has certain disabilities and illnesses, who has ESRD, or who is eligible for services of the Railroad Retirement Board.

Most ESRD patients are eligible to apply for Medicare as their primary insurance payer. Some, however, are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by employer group health plans (EGHPs) and must wait 30–33 months before becoming eligible to have Medicare as their primary payer. Some of these patients, particularly new patients since 1995, have first service dates established by ME forms or CROWNWeb/SIMS events but have no dialysis claims or hospitalization events in the CMS claims database. In the REMIS 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 these non-Medicare patients are true ESRD patients and should be included in patient counts for incidence, prevalence, and modality, as well as mortality and transplant rate calculations. Calculations of hospitalization statistics, 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.

The USRDS, in working with CMS, has been able to resolve most of the non-Medicare ESRD patients since the release of the ESRD Patient Database, REMIS, in the fall of 2003. According to our most recent assessment—performed during production of the 2007 ADR—we have determined that at least 99 percent of these patients have been resolved due to significant advancements in the REMIS 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 and 2728, the OPTN transplant follow-up form, CROWNWeb/SIMS database, the Social Security Death Master File, and inpatient claims. Because multiple sources report death information for the same patient, one patient may have several reported dates. For these patients, we primarily use the median of the various death dates reported. However, in the small number of cases where

there are only two death dates and they are more than 70 days apart, we use instead the most recent of the two dates.

### **Integration of the CROWNWeb and CMS Claim Databases**

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. The CROWNWeb/SIMS event database is the primary source of the modality sequence file, and the dialysis claims are used as a way of confirming placements and identifying problem cases. As described in previous sections, we use all available sources to determine first service dates, deaths, transplants, and transplant failures.

For patients who either do not appear in the CROWNWeb/SIMS events file or for whom the only event is “New ESRD Patient”, and patients who have transfer-out gaps, the Medicare dialysis claim file is used. For “Transfer Out” and “Transfer Out for a Transplant” events with large gaps (seven days or more), claims falling in gaps are included, with the exception that no claims data are included if the “Transfer Out for a Transplant” event has a corresponding transplant/transplant failure event that occurred within (before or after) 30 days. Claims data are also included for the periods after “Transplant Failure” events and “Discontinued Dialysis” modality if the periods are longer than seven days.

Because the claims data capture the modality “Center Self Hemodialysis” more accurately than the CROWNWeb/SIMS data, this claims-based designation overrides other dialysis modalities from CROWNWeb/SIMS. Any CROWNWeb/SIMS dialysis event that falls into a “Center Self Hemodialysis” period as determined by claims is recoded as “Center Self Hemodialysis.”

Some events that do not make sense are removed. These include events that occur before a patient’s first service date, those falling between “Transplant” and “Transplant Failure,” and “Transfer Out for A Transplant” events that occur 60 days or less after the corresponding “Transplant.”

We have identified errors in the CROWNWeb data modality conversion that cause the wrong coding for peritoneal subcategories, including continuous



ambulatory PD (CAPD), continuous cycling PD (CCPD) and intermittent PD (IPD). To correct this problem, we employ historical data (pre CROWNWeb conversion) for years prior to 2012, and a combination of historical data and more complete CROWNWeb data for 2012. In future ADRs, CROWNWeb data will be used exclusively for years 2013 and beyond.

### **Lost-to-follow-up Methodology**

Gaps frequently exist in the CROWNWeb/SIMS and 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 new CROWNWeb/SIMS event, claim event, or death date is encountered in the data. A dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim, in the absence of a death date or dialysis claims. After this period the patient is declared lost-to-follow-up, until the occurrence of a new CROWNWeb/SIMS event, dialysis claim, or transplant event.

Patients are considered lost-to-follow-up beginning 365 days after a “Transplant Failure” event or “Discontinued Dialysis” modality. Patients for whom the only event is an first service date, and who do not exist in any other files were also treated as lost-to-follow-up, beginning one year after the first service date. 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 first service date, and the RRF period must persist for at least 90 days.
- The patient may no longer reside in the U.S.
- The patient’s death may not have been reported to the Social Security Administration or to CMS.

### **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. Beginning 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 applying this rule. In contrast, certain analyses of patient outcomes such as hospitalization and mortality do apply this rule, unless the cohort is strictly incident.

### **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 to 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. This initial period of treatment is an unstable time for new patients as renal providers try to determine the best treatment modality. In addition, data are incomplete during this period because in-center HD patients who are younger than 65 and not disabled, cannot bill Medicare for their treatments and hospitalizations until 90 days after the first ESRD service date. Such patients receiving PD 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 patient 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 form a representative cohort sample, with demographic distributions by age, sex, race, and cause of ESRD similar to those of the overall ESRD population. For all figures in the 2005 and later ADRs that 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 groups have worked extensively on methods of categorizing patients by ESRD modality. The initial modality for a patient is determined using an algorithm based on a hierarchy of data sources. This hierarchy of sources used is also dependent on the specific year the patient was incident and entered the CMS ESRD program. For patients entering into the ESRD program before 1995, dialysis claim information is given first priority to supply the modality at first service date. In the absence of a claim date, other sources are evaluated in the following order: ME form, CROWNWeb/SIMS data, and transplant data. For patients entering the ESRD program in 1995 or later, the ME form is given first priority

While the ME form is the primary source of data identifying modality at ESRD initiation for patients incident in 1995 or later, the modality it indicates may be temporary, as patients often change to a new one during the first 90 days of treatment, and it can be difficult to track modality during this time. Patients aged 65 and older have Medicare claims in the first 90 days that contain revenue codes designating modality. Patients younger than 65 and in EGHPs or Medicare risk programs, however, have no such early claims. Thus, modality may not be determined until Medicare becomes the primary payer at day 91 or, for EGHP patients, at 30–33 months after the ESRD first service date. These limitations influence our ability to determine a patient’s modality at any one point in time.

Of particular concern are patients categorized as having an unstable modality (i.e., on a modality for fewer than 60 consecutive days) in the first 90 days of treatment, and who are thus not recognized as being HD or PD patients. Because these patients tend to have higher death and hospitalization rates, interpretations of modality-specific outcome data including them should be viewed with caution. These patients are included in the “all ESRD” category, which provides a more complete view of mortality and hospitalization with the least biasing of the data.

As mentioned earlier, a new modality/event—recovered renal function (RRF)—was introduced in the 2007 ADR. This event can be established only if it occurs within the first 180 days following the first

service date, 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 will not be included in the prevalent populations for outcomes analyses. However, as with lost-to-follow-up events, we retain them in the modality sequence so that subsequent renal failure episodes can be tracked closely and in a timely manner.

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

### Payers

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

The construction of this file is similar to that of the treatment history file. Payer status is maintained for each ESRD patient from the ESRD first service date until death or the end of the study period. Payer data are used to categorize a patient as MPP, Medicare as secondary payer (MSP) with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payers. With this approach, the USRDS is now able to apply payer status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter 9, Costs of ESRD).

### 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 corresponding ICD-9-CM codes as follows:

- diabetes: 250.00 and 250.01
- hypertension: 403.9, 440.1, and 593.81
- glomerulonephritis: 580.0, 580.4, 582.0, 582.1, 582.9, 583.1, 583.2, 583.4, and 583.81
- cystic kidney: 753.13, 753.14, and 753.16

- other urologic: 223.0, 223.9, 590.0, 592.0, 592.9, and 599.6
- other cause: all other ICD-9-CM codes covered in the list of primary causes on the ME form, with the exception of 799.9
- unknown cause: 799.9 and ICD-9-CM codes not covered in the list of primary causes on the ME form
- missing cause: no ICD-9-CM code listed

### **Race and Ethnicity**

Data on patient race and ethnicity are obtained from the ME form, the CMS Medicare Enrollment Database, the REMIS patient identification file, and the CROWNWeb/SIMS patient roster. 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, Black/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.

### **Introduction to Volume 2—ESRD**

Data sources are indicated in the footnotes of each table and figure in Volume 2. Additional information on these sources is available in the Data Sources section above. Methodology used for the figures and tables in Volume 2 is described below in the corresponding chapter or reference table section. When figure or table data come directly from a particular reference table, please refer to the appropriate reference table methods section for additional detail.

Wait list counts in Table i.3 are restricted to ESRD-certified patients. New waiting list counts include all ESRD-certified patients added to the list for a kidney-alone or kidney-pancreas transplant in 2012; patients added at multiple centers are counted once. The total number of patients on the waiting list includes all ESRD-certified patients listed for a kidney-alone as of

December 31, 2012, regardless of when the first listing occurred. If patients are added to the list early in the year and are removed before the end of the year, it is possible for a group to have more new patients than existing patients. Median waiting time is shown for patients on the kidney-alone waiting list on December 31, 2007.

Data for Figure i.1 (a-d) are from the CMS Annual Facility Survey.

Prevalence counts in Figure i.2 are based on patients alive on December 31 of the year.

## **Chapter 1: Incidence, Prevalence, Patient Characteristics and Modalities**

### **INCIDENCE AND PREVALENCE**

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

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

Rate adjustments in this chapter are as follows: overall rates (including those in the maps) are adjusted for age, sex, and race; rates by age are adjusted for sex and race; rates by race or ethnicity are adjusted for age and sex; and rates by primary diagnosis are adjusted for age, sex, and race. Census data rate and prevalence calculations are now based on intercensal estimates;

for details, see the section on the United States Census in the Data Sources section of this appendix.

For Figures 1.4-1.7, incident cases and incidence rates are taken directly from Reference Table A. More specifically, cases come from A.1 and rates come from A.2(2) and A.2(3). Similarly, data for Figures 1.12-1.15 come directly from Reference Table B. Specifically, prevalent cases correspond to those found in B.1 and prevalence corresponds to that found B.2(2) and B.2(3). For details on the methods used, refer to the sections for Reference Tables A and B and the section for statistical methods used for rate calculations.

Figures 1.19 and 1.20 show the patient distribution by modality and payer, among ESRD incident and point prevalent patients, respectively. For Figure 1.19, payer is determined at the time of incidence. For Figure 1.20, payer is determined on December 31 of each year. Consequent to the previous two statements, the payer type does not account for changes in payer within the year. The detailed discussion of payer categories can be found in the database definitions section at the beginning of this appendix.

Figures 1.17 and 1.18 report the home dialysis patient distribution, by therapy type and among incident and point prevalent populations, respectively.

#### PATIENT CARE AND LABORATORY VALUES

Table 1.6 includes data on pre-ESRD nephrologist care of incident ESRD patients who have ME forms.

Data for Figures 1.21(a), 1.21(b), and Table 1.7 are obtained from the ME form.

Data for Figure 1.23 results from the calculation of eGFR, using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation, from data acquired from the ME form.

#### REFERENCE SECTION A

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

of which present data specific to patients in Puerto Rico and the U.S. territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Rates in Table A.2, A.9 and A.11 are adjusted for age, sex, and race, with the 2011 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. Rates in Table B.2, B.9 and B.11 are adjusted for age, sex, and race, with the 2011 national population as reference.

#### REFERENCE SECTION C

Data in these tables are based on information collected with the 1995 and 2005 ME forms. Table C.1 contains data on biochemical markers from 2004–2012. A new ME form was introduced in 2005 that included glycosylated hemoglobin (HbA<sub>1c</sub>), total cholesterol, low-density lipoprotein, and high-density lipoprotein. Because these data elements had not been collected on the previous form, values are not available for 2004 and the first few months of 2005. Data prior to 2005 on mean values reported for these markers may be unreliable due to low numbers of patients. Blood urea nitrogen was dropped from the new 2005 form.

#### TREATMENT MODALITIES

Modality figures and the associated reference tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up or having recovered renal function (RRF). The RRF event, introduced in the 2007 ADR, is defined as an event that occurs within the first 180 days of ESRD initiation and lasts for at least 90 days. By definition, patients classified as having RRF post-initiation are included in the incident counts. Unless noted otherwise, incident and point prevalent cohorts without the 60-day stable modality rule are used in the analyses. Treatment modalities are defined as follows:

- center hemodialysis: HD treatment received at a dialysis center
- center self-hemodialysis: HD administered by

the patient at a dialysis center; a category usually combined with center HD

- home hemodialysis: HD administered by the patient at home; cannot always be reliably identified in the database
- CAPD: continuous ambulatory peritoneal dialysis; usually combined with CCPD and other PD
- CCPD: continuous cycling peritoneal dialysis; usually combined with CAPD and other PD
- peritoneal dialysis: analyses typically consist of CAPD, CCPD and intermittent peritoneal dialysis (IPD)
- other peritoneal dialysis: primarily intermittent peritoneal dialysis (IPD), a small category except among very young children; usually combined with CAPD and CCPD to form PD category
- uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but none last 60 days; usually combined with 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 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)

Facilities began submitting patient data via CROWNWeb beginning in 2012. This information was previously submitted by facilities via the ESRD Networks. The new method of data input and submission may lead to unanticipated changes in trends beginning in 2012.

#### 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 2008 to 2010. 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. 2004, 2008, 2012), by demographic characteristics, payer category, and treatment modality. Again, age is computed as of the start of ESRD for incident patients and as of December 31 for point prevalent patients. The payer categories are:

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

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

**Chapter 2: Healthy People 2020****OBJECTIVE CKD-3**

Data for this objective include all patients in the 5 percent Medicare sample who are aged 65 and older and who have hospitalized acute kidney injury (AKI) events in the given year (1992–2012). Hospitalized AKI is defined by ICD-9-CM diagnosis code 584 in inpatient claims, and renal evaluation is identified by a microalbumin test. Patients are followed from the discharge date to the earliest date of death, ESRD, end of Medicare coverage, or six months after the discharge date. CPT codes for urinary microalbumin measurement are identified from HEDIS 2008 specifications (HEDIS 2008, an NCQA program, is used to monitor the performance of managed health care plans), and include 82042, 82043, 82044, and 84156.

**OBJECTIVE D-12**

The cohort includes general Medicare patients diagnosed with DM in each year, continuously enrolled in Medicare Parts A and B during the whole year, and aged 65 or older at the beginning of the year. CPT codes for urinary microalbumin measurement are those used in Objective CKD-3, above. Testing is tracked during each year. Diabetes is defined by a qualifying ICD-9-CM diagnosis code of DM on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims within a one year observation period. Qualifying ICD-9-CM codes for diabetes mellitus are 250.XX, 357.2, 362.0X, and 366.41.

**OBJECTIVE CKD-4.1**

The cohort here is similar to that used for Objective D-12, but includes all CKD patients. Testing is tracked during each year. Patients are excluded if they are enrolled in a managed care program (HMO), acquire Medicare as secondary payer, are diagnosed with ESRD during the year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Racial and ethnic categories are mutually exclusive. Methods of defining CKD are described in the appendix of the CKD volume. Serum creatinine is identified through

CPT codes 80047–80050, 80053–80054, 80069, and 82565, while lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83705, 83715–83721, 84478, 83700, 83701, and 83704. CPT codes for urinary microalbumin measurement are the same as those used for Objective CKD-3, above.

**OBJECTIVE CKD-4.2**

Methods and codes used to determine rates of HbA<sub>1c</sub> testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HbA<sub>1c</sub> testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, 67101, 67105, 67107, 67108, 67110, 67112, 67141, 67145, 67208, 67210, 67218, 67227, 67228, 67028, 67030, 67031, 67036, 67038, 67039, 67041, 67042, 67043, 67113, 67121, 67221, 67228, S0625, S0620, S0621, and S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. The cohort is similar to that used for Objective CKD-4.1, but includes all diabetic CKD patients. Methods of defining DM are described in the appendix of the CKD volume.

**OBJECTIVE CKD-8**

Incident rates are calculated using the methods described for Chapter 1. Overall rates are adjusted by age, sex, and race; rates by age are adjusted for sex and race; rates by sex are adjusted for age and race; and rates by race and ethnicity are adjusted by age and sex.

**OBJECTIVE CKD-9.1**

Rates of kidney failure due to DM are also calculated using the methods described for Chapter 1, and adjustments are the same as those described for Objective CKD-8, above.

**OBJECTIVE CKD-9.2**

This table uses data from the National Health Interview Survey; all ages are included. Three-year data are used to estimate the prevalence of DM in the middle year, and the size of the population with DM is based on U.S. census data. The incident rate per million of ESRD caused by DM is calculated as the number

of incident ESRD patients with a primary diagnosis of DM, divided by the size of the population with DM in that group.

#### **OBJECTIVES CKD-10 & CKD-11.3**

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

#### **OBJECTIVE CKD-12**

The cohort includes patients from 2000–2011 who are younger than 70 at the initiation of ESRD. Percentages are calculated as the number of patients placed on the deceased donor organ waiting list or receiving a deceased donor transplant within one year of 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 methodology.

#### **OBJECTIVE CKD-13.1**

The cohort includes patients from 1998–2009 who are younger than 70 at the initiation of ESRD. Patients are followed for three years, from ESRD certification until the first event of death, transplant, or censoring at three years after the initiation of ESRD. Percentages are calculated using the Kaplan-Meier methodology.

#### **OBJECTIVE CKD-13.2**

The cohort includes patients from 2001–2012 who are younger than 70 at the initiation of ESRD. Pre-emptive transplants are those in which ESRD initiation date is the date of transplant. Percentages are calculated as  $100(N/D)$ , where  $N$ =the number of preemptive transplants in the year and  $D$ =the number of ESRD patients in the year.

#### **OBJECTIVES CKD-14.1 & CKD-14.3**

Cohorts for these tables include period prevalent dialysis patients in each calendar year, 2001–2011, whose first ESRD service date is at least 90 days prior to the beginning of the year (point prevalent patients on January 1) or who reach day 91 of ESRD treatment

during the year (incident patients). We exclude patients with unknown age or sex and those with an age calculated to be less than zero, as well as patients who are not residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Age is calculated on January 1, and race is defined from the ME form. Cardiovascular mortality is defined using codes from past and current Death Notification forms: 01, 02, 03, 04, 1, 2, 3, 4, 23, 25, 26, 27, 28, 29, 30, 31, 32, 36, and 37. Patients are followed from January 1 (for point prevalent dialysis patients) or day 91 of ESRD (for incident dialysis patients) until death, transplant, or December 31 of the year. Rates are estimated as the number of patients who die from any cause (Objective 14.1) and who die from cardiovascular disease (Objective 14.3) in each year, per 1,000 patient years at risk.

#### **OBJECTIVE CKD-14.2**

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

#### **OBJECTIVES CKD-14.4–5**

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

### Chapter 3: Clinical Indicators and Preventive Care

In Figure 3.1, all data are obtained from CROWNWeb clinical extracts for December 2013. The adequacy analyses are restricted to patients at least 18 years old as of December 1, 2013. Patients must have been alive as of December 31, 2013 and must have had ESRD for at least one year as of the time of the measurement. If multiple measurements were available for a patient, the last one in the month was used. In Figure 3.1b, all adult (aged 18 or older) patients who are on dialysis for at least 90 days as of December 1, 2013 and alive as of December 31, 2013 are included. If multiple hemoglobin (Hgb) measurements were available for a patient, the last one in the month was used. The categorical distribution of Hgb is shown for both HD and PD patients. In Figure 3.1c, all HD patients who had ESRD at least 90 days at the time vascular access was reported were included. Patients must have been alive as of December 31, 2013.

#### ANEMIA TREATMENT

All of the findings in this section are based on Medicare claims data. Efforts have been made for the figures and tables to be as fully representative as possible of the U.S. dialysis patient population represented by CMS claims data, resulting in substantially larger sample sizes in some of the tables associated with this anemia section as compared with the 2013 ADR. The modality of the patient in each month is determined from the primary modality that is indicated on the claims file associated with each claim for Hgb, iron dose, and epoetin alfa (EPO) dose variables in the given month. For transfusion analyses, patients were assigned to HD or PD if having at least one claim for HD or PD therapy, respectively, in that month. There were very few patients having dual modality use within the same month. The frequency of a patient having dual modalities in a particular year-month ranges from 0.3 percent to 0.8 percent over 1995 to 2012.

Calculation of Hgb levels are shown in Figures 3.2A, 3.3, 3.5A, and 3.6. Hgb values were based upon the first reported claim in each month for HD patients (Figure 3.2A, 3.3) or for PD patients (Figure 3.5A, 3.6). When Hgb levels were not available in claims data, hematocrit values, if available, were divided by 3 to serve as a proxy estimate. Patients were excluded in a given month if the Hgb level (or Hgb values estimated from hematocrit values) was < 5 g/dL or >20 g/dL.

Results are shown for erythropoiesis-stimulating agent (ESA)-treated patients in Figures 3.2A, 3.3, 3.5A, and 3.6, in which case analyses were restricted to patients who: (1) within the indicated month had a claim for ESA use and a claim for either Hgb or hematocrit level, and (2) at the start of the month, were on dialysis for 90 days or more and were aged 18 or older. In Figures 3.2A and 3.5A, Hgb levels are also provided for all patients, in which case the same restrictions were used as described in the latter sentence, but not limiting to patients with an ESA claim within the given month in 2012.

Calculation of mean EPO dose levels is shown in Figures 3.2A and 3.5A. Mean monthly EPO dose is provided for HD patients in Figure 3.2A and for PD patients in Figure 3.5A. Mean monthly EPO dose is shown for patients who within a given month had an EPO claim, were on dialysis for 90 days or longer were 18 years or older at the start of the month. EPO dose is expressed as mean EPO units per week, averaged over all EPO claims within a given month. Patients were excluded from these calculations for a given month if their monthly average EPO dose was either less than 250 units per week (resulting in 0.4 percent excluded) or if their monthly average EPO dose was greater than 400,000 units per week; these criteria resulted in <0.001 percent of patients being excluded.

Calculation of intravenous iron use is shown in Figures 3.2B and 3.5B. Intravenous iron use for HD patients is presented in Figure 3.2B and for PD patients in Figure 3.5B. Monthly intravenous iron use was among patients on dialysis for 90 days or longer and 18 years or older at the start of the given month.

Calculations of the percentage of dialysis patients with one or more claims for a red blood cell (RBC) transfusion in a given month from 2010-2012 are shown in Figures 3.4 (HD patients) and 3.7 (PD patients). For this calculation, the numerator consisted of dialysis patients with one or more RBC transfusion claims in a given month; the denominator included all patients having a claim for at least one dialysis session during the month and who were 18 years or older at the start of the month.



vol 2 Table m.1 Transfusion codes used in defining a red blood cell transfusion

Code	Code Type	Code Description
36430	CPT	Transfusion, blood or blood components
P9010	HCPCS	Blood (whole), for transfusion, per unit
P9011	HCPCS	Blood, split unit
P9016	HCPCS	Red blood cells, leukocytes reduced, each unit
P9021	HCPCS	Red blood cells, each unit
P9022	HCPCS	Red blood cells, washed, each unit
P9038	HCPCS	Red blood cells, irradiated, each unit
P9039	HCPCS	Red blood cells, deglycerolized, each unit
P9040	HCPCS	Red blood cells, leukocytes reduced, irradiated, each unit
P9051	HCPCS	Whole blood or red blood cells, leukocytes reduced, cmv-negative, each unit
P9054	HCPCS	Whole blood or red blood cells, leukocytes reduced, frozen, deglycerol, washed, each unit
P9056	HCPCS	Whole blood, leukocytes reduced, irradiated, each unit
P9057	HCPCS	Red blood cells, frozen/deglycerolized/washed, leukocytes reduced, irradiated, each unit
P9058	HCPCS	Red blood cells, leukocytes reduced, cmv-negative, irradiated, each unit
99.03	ICD9	Other transfusion of whole blood; transfusion: blood NOS, hemodilution, NOS
99.04	ICD9	Transfusion of packed cells

Hgb levels were also calculated for adult ESRD incident patients—those aged 18 years or older at any time during 2012, who during that year were new to ESRD and initiated chronic dialysis therapy. Analyses were provided separately for incident HD and PD patients, with modality based on that reported on the ME form for the patient’s initial chronic dialysis session. Hgb values for incident patients were based upon that of the first reported claim within 2012, among Hgb values occurring within 30 days of a patient’s initial chronic dialysis treatment. For incident patient analyses, approximately 25 percent of incident HD patients and 22 percent of incident PD patients did not have a reported Hgb value within 30 days of starting dialysis in 2012 claims data.

**PREVENTIVE CARE**

Figure 3.8 presents data on diabetic preventive care. 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 DM in the first year.

Testing is tracked in the second year of each study period; tests are at least 30 days apart. ESRD patients without Medicare inpatient/outpatient and physician/supplier coverage during the entire study period are omitted, as are general Medicare patients enrolled in an HMO or diagnosed with ESRD during the study period. Also omitted are those who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. 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 calculated at the end of the study period.

Patients are defined as having DM either through medical claims (one inpatient/home health/SNF claim, or two outpatient or physician/supplier claims), or through a listing of DM on the ME form as the primary cause of ESRD or as a comorbid condition. ICD-9-CM diagnosis codes used to define DM are 250, 357.2, 362.0x, and 366.41. Methods and codes used to determine rates of HgbA1c testing and eye examinations are taken from HEDIS 2008 specifications. CPT codes 83036 and 83037 are used to identify HgbA1c testing. Codes used to identify diabetic eye examinations are as follows: CPT codes, 67028, 67030, 67031, 67036, 67038, 67039, 67040, 67041, 67042, 67043, 67101, 67105, 67107, 67108, 67110, 67112, “67113, 67121, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260, S0620, S0621, S0625, S3000; ICD-9-CM procedure codes, 14.1–14.5, 14.9, 95.02, 95.03, 95.04, 95.11, 95.12, and 95.16; and ICD-9-CM diagnosis code V72.0. Lipid testing is identified through CPT codes 80061, 82465, 82470, 83695, 83700, 83701, 83704, 83705, 83715, 83716, 83717, 83718, 83719, 83720, 83721, 84478. Comprehensive diabetic care includes at least one HgbA1c test, at least one lipids test, and at least one eye exam. HgbA1c and lipid tests occur at least 30 days apart.

Figures 3.9–3.12 present data on influenza vaccinations for prevalent ESRD patients by age, race/ethnicity, modality, and time period. The cohort for influenza vaccinations includes all ESRD patients initiating therapy at least 90 days prior to August 1 of the first year of the study period and alive on April 30 of the second year. Patients without Medicare inpatient/outpatient and physician/supplier coverage during the study period are omitted, as are those who do

not reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. Also omitted are those who have a missing date of birth; who have ESRD for fewer than 90 days prior to the start of the study period; or who are lost-to-follow-up during the study period. Age is calculated at the end of the study period. Influenza vaccinations are tracked between August 1 of the first year and April 30 of the second year in the study period. Influenza vaccinations are identified by CPT codes 90724, 90657, 90658, 90659, and 90660, and HCPCS code G0008.

### VASCULAR ACCESS

Data for Figures 3.13-3.15 and Table 3.1 are obtained from the ME form; data are restricted to the most recent version. Figure 3.15 also includes data from CROWNWeb. Patients with missing vascular access data are excluded. Figure 3.13 presents data for patients who began dialysis from 2005 to 2012; Table 3.1 and Figure 3.14 present data for patients beginning dialysis in 2012. Age is calculated as of the date regular chronic dialysis began. Figure 3.14 excludes patients not living in the 50 states or the District of Columbia; Figure 3.15 includes a cross-section of patients alive at each time point. Vascular access at initiation includes data obtained from the ME form for patients beginning dialysis between January 1, 2012 and December 31, 2012; vascular access data for all other time points are obtained from CROWNWeb. The time points from initiation include three months (patients starting dialysis between October 1, 2012 and December 31, 2012), six months (starting dialysis between July 1, 2012 and December 31, 2012), nine months (between April 1, 2012 and December 31, 2012), and one year after initiation (starting dialysis between January 1, 2012 and December 31, 2012). For the three, six, and nine month time points, there is a 30 day look-back and 30 day look-forward time period to determine vascular access at that time point. For the one year time point, there is a three month look-back and 30 day look-forward time period to determine vascular access.

### Chapter 4: 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 Section G of patients of races that are unknown or other than White, Black/African American, Native American, or Asian; these patients are included in the Chapter 4 figures. Included patients have Medicare as primary payer, with Parts A and B coverage at the start of follow-up, and without HMO coverage. Rates include total admissions or hospital days during the time at risk, divided by patient years at risk. The period at risk begins at the latest of January 1 or day 91 of ESRD, and censoring occurs at death, end of Medicare Parts A and B coverage, or December 31, in addition to other censoring criteria which vary by modality as described below. Since a currently hospitalized patient is not at risk for admission, hospital days are subtracted from the time at risk for hospital admissions. Additionally, rehospitalization rates include the percentage of live hospital discharges that are followed by a subsequent hospital admission within 30 days.

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

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

Methods in Figures 4.1-2 follow those for Reference Section G. Figure 4.1 shows the percent change in admission rates since 1993 for period prevalent ESRD patients. Included patients have Medicare as primary payer and are residents of the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients with missing age or sex information. Rates are adjusted for age, sex, race, and primary diagnosis using the model-based adjustment method. The reference cohort includes period prevalent ESRD patients, 2010. New dialysis access codes for PD patients appeared in late 1998; dialysis access values are therefore shown

for PD patients as a change since 1999 rather than 1993. For PD patients, dialysis access hospitalizations are those defined as “pure” inpatient vascular/dialysis access events, as described for Tables G.11–15. For HD patients, vascular access hospitalizations include “pure” inpatient vascular access events, and vascular access for HD patients excludes codes specific to PD catheters (996.56, 996.68, and V56.2). Principal ICD-9-CM diagnosis codes are used to identify cardiovascular and infectious admissions. The cardiovascular category consists of codes 276.6, 394–398.99, 401–405, 410–420, 421.9, 422.90, 422.99, 423–428, and 440–459, while infection is indicated by codes 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.24, 478.29, 480–490, 491.1, 494, 510–511, 513.0, 518.6, 519.01, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.1, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598.0, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 996.60–996.69, 997.62, 998.5, and 999.3.

Figure 4.2 presents adjusted rates of total hospital admissions and days per patient year. Prevalent ESRD patients are included, and rates are adjusted for age, sex, race, and primary diagnosis, with the 2010 ESRD cohort used as the reference.

Table 4.1 presents unadjusted and adjusted admission rates among adult (aged 20 and older) period prevalent HD patients. Principal ICD-9-CM diagnosis codes are used to identify cause-specific admissions: codes for cardiovascular and infectious admissions are listed in the discussion of Figure 4.1, while codes for vascular access infection are 996.62 and 999.31. Rates are adjusted for age, sex, race, and primary ESRD diagnosis; values presented by one factor are adjusted for the other three. For adjusted rates, HD patients in 2010 are used as the reference cohort. Values by age, sex, race, and primary diagnosis are shown for 2011–2012 prevalent HD patients.

Figures 4.4–7 show adjusted infectious admission rates among period prevalent ESRD patients. These figures illustrate two different methods of classifying infection by diagnosis code type. The traditional method defines cause-specific admissions based on principal ICD-9-CM diagnoses, and these rates are interpreted as admissions for the reason of the stated

condition. The other method uses both principal and secondary inpatient ICD-9-CM diagnoses recorded for hospital stays. In contrast, these rates are interpreted as admissions with the condition, and by definition, are more inclusive than those restricted to principal diagnoses. ICD-9-CM codes for infectious hospitalizations are listed in the discussion of Figure 4.1, and those for vascular access infection are listed for Table 4.1. Other infectious groups are as follows: bacteremia/sepsis, 038.0–038.9 and 790.7; peritonitis (PD patients only), 567; and pneumonia, 480–486 and 487.0. Rates are adjusted for age, sex, race, and primary ESRD diagnosis. The reference cohort includes ESRD patients in 2010.

Figure 4.8 illustrates infectious hospital admission rates among period prevalent home HD and center HD patients. Rates are presented for admissions with infection and admissions for infection, by diagnosis code type as described for Figures 4.4–7 and using the ICD-9-CM codes for infection listed for Figure 4.1. Similar to Figures 4.4–7, analyses are intent-to-treat regarding dialysis modality, and patients are followed from January 1 or day 91 of ESRD until the earliest of death, three days prior to transplant, end of Medicare Parts A and B coverage, or December 31. Rates in Figure 4.8, however, are unadjusted.

Figures 4.3–9 show rates of rehospitalization and/or death among prevalent HD patients of all ages (aged 66 and older in Figure 4.9), 30 days after hospital discharge. Live hospital discharges from January 1 to December 1 of the year are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude rehabilitation claims and transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For HD patients in Figures 4.3–8, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For ESRD patients in Figure 3.9, the same exclusions apply except as related to transplant; discharges from transplant patients are excluded if they occur after two years and 11 months following the most recent transplant to ensure that complete claims are available during the 30-day post-discharge period.

Figures 4.3-5 and 4.7-8 indicate the percentage of discharges with readmission and/or death within 30 days after discharge. The groups indicate status at day 30 after discharge from the index hospitalization, and do not consider events after day 30. Figures 4.3-4 include all-cause index hospitalizations, while in 4.5, categories of cause-specific admissions are based on principal ICD-9-CM diagnosis codes of the index hospitalization. Codes for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 4.1; vascular access infection codes are 996.62 and 999.31. Figures 4.7-8 include the codes for discharges from cardiovascular hospitalizations listed for Figure 4.1, and Figure 4.8 includes the codes for acute myocardial infarction (AMI), congestive heart failure (CHF), stroke and dysrhythmia. ICD-9 CM codes for AMI: 410.x0 and 410.x1; CHF: 398.91, 402.x1, 404.x1, 404.x3, 425, and 428; CVA/TIA: 430-437; stroke: 430-434 and dysrhythmia: 426-427. Figure 4.6 indicates the percentage of hospital discharges followed by a 30-day rehospitalization by cause-specific groups for both the index hospitalization and the rehospitalization. Categories of cause-specific rehospitalization also include non-vascular access infections, defined by infection codes excluding 996.62 and 999.31, and other, defined by codes other than cardiovascular and infectious.

Figure 4.9 shows overall percentages of discharges with 30-day rehospitalization and/or death in the general Medicare, chronic kidney disease (CKD), and ESRD populations. Data include point prevalent Medicare patients on December 31, 2011 who are aged 66 and older. For general Medicare patients with and without CKD, CKD is defined during 2011, and patients remain who are without ESRD, with continuous enrollment in Medicare Parts A and B, and without HMO coverage. Live hospital discharges from January 1 to December 1, 2012 are included.

### REFERENCE SECTION G

Hospitalization reference tables present adjusted total admission and hospital day rates, by year, 1993-2012. They begin in 1993 because Medicare inpatient claims are available beginning in 1991, and the model-based adjustment method uses data from the current and previous two years to obtain the predicted rates. This method is further discussed later in this section and in the statistical methods section at the end of this appendix.

Because hospitalization data for non-Medicare patients may be incomplete, analyses in this section include only patients with Medicare as their primary payer. Hospitalization data are obtained from institutional inpatient claims. As in Chapter 4, hospitalization data in Reference Section G also exclude inpatient stays for the purpose of rehabilitation therapy.

Tables G.1-15 include dialysis and transplant patients who are 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 U.S. territories. Excluded are patients with AIDS as a primary or secondary cause of death; patients with missing values for age, sex, or race; and patients of races that are unknown or other than White, Black/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 DM mellitus (DM), hypertension, or glomerulonephritis.

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

- all dialysis: patients on HD, 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 HD for at least 60 days as of the start of the period at risk
- CAPD/CCPD: patients on CAPD/CCPD for at least 60 days as of the start of the period at risk
- transplant: patients with a functioning transplant, and who received the transplant less than three years prior to the start of the period at risk
- all-ESRD: all patients

To limit the contribution of patient years at risk from patients who do not have Medicare coverage but do have Medicare as a secondary payer or HMO coverage, and who therefore have incomplete hospitalization data, cohorts include only patients with Medicare Parts A and B coverage at the start of follow-up. The follow-up period is censored when a patient's payer status changes to no longer having Medicare Parts A and B coverage or Medicare as a primary payer.

For patients in the all-dialysis, HD, and PD 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 value. Since a currently hospitalized patient is not, however, at risk for new admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of a hospitalization in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

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

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

claim. In the case of two hospitalizations combined into one, the principal diagnosis and procedure codes are retained from the first of the two hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date.

The methodology for computing adjusted total admission and hospital day rates uses the model-based adjustment method (discussed in the section on statistical methods). Predicted rates for each subgroup combination of age, sex, 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,  $\frac{1}{4}$ , and  $\frac{1}{4}$ . Adjusted rates are then calculated using the direct adjustment method, with all 2010 ESRD patients as the reference cohort.

Tables G.11–15 show inpatient utilization in the period prevalent ESRD patients. Methods—including modality definitions, inclusion criteria, data cleaning, follow-up time definitions, and rate calculations—generally follow those described for the total admission rates in Tables G.1–5, but some differences do exist. While patients of races other than White, Black/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 2004–2006, 2007–2009, and 2010–2012 (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 PD 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 Diagnosis Related Group (DRG) code. Codes are listed in Table a.2. 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.

**vol 2 Table m.2 DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access variables****DRG codes<sup>a</sup>: 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<sup>a</sup>: after September 30, 2007**

252 Other vascular procedures with Major complicating conditions (MCC)  
 264 Other circulatory system O.R. procedures  
 673 Other kidney & urinary tract procedures with MCC  
 674 Other kidney & urinary tract procedures with CC  
 675 Other kidney & urinary tract procedures without CC/MCC  
 907 Other O.R. procedures for injuries with MCC  
 908 Other O.R. procedures for injuries with CC  
 909 Other O.R. procedures for injuries without CC/Medicare

**ICD-9-CM procedure codes<sup>a</sup>**

38.95 Venous catheterization for renal dialysis  
 39.27 Arteriovenostomy for renal dialysis  
 39.42 Revision of arteriovenous shunt for renal dialysis  
 39.43 Removal of arteriovenous shunt for renal dialysis  
 39.93 Placement of vessel-to-vessel cannula  
 39.94 Replacement of vessel-to-vessel cannula  
 86.07 Placement of totally implantable vascular access device

**ICD-9-CM diagnosis codes<sup>b</sup>**

996.1 Mechanical complication of vascular device, implant, graft  
 996.56 Mechanical complication due to peritoneal dialysis catheter  
 996.62 Infectious complication of vascular device, implant, graft  
 996.68 Infectious complication due to peritoneal dialysis catheter  
 996.73 Other complication due to renal dialysis device, implant, graft  
 999.31 Infection due to central venous catheter  
 V56.1 Fitting and adjustment of extracorporeal dialysis catheter  
 V56.2 Fitting and adjustment of peritoneal dialysis catheter

<sup>a</sup> DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present).

<sup>b</sup> 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.

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.

**Chapter 5: Mortality**

Unless otherwise specified, patient cohorts underlying the analyses presented in Chapter 5 include Medicare and non-Medicare patients living in the 50 states, the District of Columbia, Puerto Rico, and the U.S. territories.

Figure 5.1 shows trends in mortality rates by modality among incident ESRD patients during 1980–2011. Modalities include HD, CAPD/CCPD, and first transplant; results aggregating across modalities are also presented. Patients are classified by year based on date of ESRD onset. Dialysis patients are followed from ESRD onset (i.e., day one) censored at the earliest of date of transplant, loss to follow-up, recovery of native renal function or December 31, 2012. Transplant patients begin follow-up at the date of transplant and are censored on December 31, 2012. Adjusted mortality rates for each period after first treatment are computed separately by taking an appropriate weighted average of Cox-regression based predicted rates. The adjustment is made through model-based direct standardization, and is described later in the Statistical Methods section of this appendix. The Cox proportional hazard model serves as the basis for the predicted rates, adjusted for age, sex, race, and primary diagnosis. The reference population consists of 2011 incident ESRD patients. Figure 5.2 shows adjusted age-specific all-cause mortality for 2012 among prevalent ESRD patients and subpopulations (dialysis, transplant), as well as the general Medicare population. The rates are based on predicted values from a generalized linear mixed model, adjusted for sex and race using 2011 Medicare patients as the reference cohort.

Figure 5.3 displays adjusted all-cause and cause-specific mortality for incident HD patients. Patients are followed from ESRD onset (day one; as reflected by first service date) up to one year, and censored at loss to follow-up, transplant, or recovery of kidney function. Note that patients with unknown age, sex, or primary diagnosis are excluded from the analysis.

Rates are adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis, with the 2011 incident HD patients serving as the reference population

Figure 5.4 illustrates calendar time trends in mortality rates, by patient vintage. Within a given calendar year, patients begin follow-up on January 1 or the date of first ESRD service (if within that year) until death, transplantation, loss to follow-up, recovery of function, or the end of the year. Patients are excluded if their age or sex is unknown, or if they are of a race other than White, Black/African American, Native American, or Asian. All-cause rates are based on predicted values from a generalized linear mixed model, adjusted for age, sex, race, and primary diagnosis with the reference population being 2011 prevalent dialysis patients. Note that adjusted year-specific mortality rates are comparable across vintages.

Table 5.1 presents expected remaining lifetimes in years for the 2010 general U.S. population, and for 2012 prevalent dialysis and transplant patients. For period prevalent ESRD patients in 2012, expected lifetimes are calculated using the death rates from a generalized linear mixed model with 16 age groups, assuming a constant mortality rate within each age group. The method for calculating expected remaining lifetimes is described in the Statistical Methods section at the end of this appendix. Data for the general population are obtained from the CDC's National Vital Statistics Reports, Table 7 (Murphy et al., 2013; "Life expectancy at selected ages, by race, Hispanic origin, race for non-Hispanic population, and sex: United States, 2010").

Table 5.2 presents five-year survival by modality. Dialysis patients are classified by year of first service and initial modality. Transplants are classified by calendar year of transplantation, with only first transplants included. Patients with unknown age or sex are excluded. Dialysis patients are followed from day one until the earliest of death, transplantation, loss to follow-up, recovery of function, or the end of 2012, while transplant patients are followed from the date of transplantation until the earliest of death, or the end of 2012. All survival probabilities are adjusted for age, sex, Hispanic ethnicity, race, and primary diagnosis. The reference population consists of 2011 incident ESRD patients. Note that adjusted five-year survival probabilities are comparable across modalities.

Table 5.3 presents both unadjusted and adjusted all-cause mortality in the ESRD, dialysis, transplant,

and general Medicare patients with cancer, DM, CHF, cerebrovascular accident/transient ischemic attack (CVA/TIA), and AMI. All cohorts are defined on January 1, and include patients aged 65 and older. Follow-up for ESRD patients is from January 1 to December 31 of each year. For general Medicare patients, follow-up is from January 1 to December 31 of each year, censored at ESRD and at the end of Medicare entitlement. Adjusted mortality is adjusted for age, sex, and race, with 2011 ESRD patients serving as the reference. Figures 5.5–6 present adjusted all-cause mortality in the ESRD, dialysis, transplant, and general Medicare populations in 2012. The cohorts and adjustment method are same as those used in Table 5.3; 2012 ESRD patients are used as the reference cohort.

## REFERENCE SECTION H

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

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

Tables H.1, H.2, and H.2.1 present mortality data for all ESRD patients. Total deaths are presented in Table H.1. Overall unadjusted and adjusted annual mortality rates by age, sex, race/ethnicity, primary diagnosis, and vintage are presented in Table H.2. Category-specific unadjusted mortality rates are calculated as total patient deaths divided by total follow-up time. Adjusted rates are computed by an appropriately weighted average of predicted category-specific rates, with the predicted rates based on generalized linear mixed models. Such methods, akin to direct standardization, are described in the Statistical Methods section later in this appendix. Overall

mortality rates are adjusted for age, sex, race, primary diagnosis, and vintage, while rates for each individual category are adjusted for the remaining four. The reference population includes 2011 prevalent ESRD patients. Table H.2.1 presents unadjusted mortality rates by age, sex, race, and primary diagnosis for 2011 prevalent ESRD patients; rates are again smoothed using a generalized linear 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 waiting list); H.6 (dialysis patients on transplant waiting list); H.7 (dialysis patients, returned to dialysis from transplant); H.8 and H.8.1 (HD); H.9 and H.9.1 (CAPD/CCPD); and H.10 and H.10.1 (transplant).

### REFERENCE SECTION I

These tables present patient survival probabilities, based on incident cohorts. 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 U.S. territories. Patients were excluded if sex is unknown, or if age is unknown or listed as greater than 110. All new ESRD patients with a first ESRD service date between January 1, 1980, and December 31, 2011 are included in the analysis. These patients are followed from day one (ESRD onset) until death, loss to follow-up, or December 31, 2012. For dialysis patients, both HD and PD, follow-up is also censored at recovery of native renal function and at receipt of a kidney transplant. Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while adjusted survival is computed through model-based direct standardization using Cox regression. Incident 2011 ESRD patients served as the reference population for both overall and subgroup-specific adjusted survival.

## Chapter 6: Transplantation

### TRENDS IN KIDNEY TRANSPLANTATION

Figure 6.1 presents an overview of trends in kidney transplantation. Figure 6.1.a juxtaposes the percent of prevalent dialysis patients wait-listed for a kidney transplant with the falling rate of transplantation in dialysis patients at all ages, 1989–2012. Figure 6.1.b shows the number of ESRD-certified candidates on the OPTN kidney transplant waiting list on December 31 of each year, for first and subsequent kidney-alone

or kidney plus other organ transplants. Figure 6.1.b also shows the median waiting time from wait-listing to kidney transplantation for candidates for kidney-alone transplants (i.e., the time by which 50 percent of these candidates had received a kidney transplant). Candidates listed at more than one center on December 31 are counted only once. Median waiting time is reported for candidates newly listed in each given year. Figure 6.1.c presents transplant counts for all recipients, by donor type. Figure 6.1.d shows cumulative counts of functioning kidney-alone and kidney-pancreas transplants.

### WAITING LIST

Figure 6.2 shows the percentage of patients wait-listed or receiving a deceased or live donor kidney-alone or kidney plus other organ transplant within one year of ESRD initiation, stratified by age.

Figure 6.3 shows the annual mortality rates of dialysis patients who were wait-listed for a kidney-alone or kidney plus other organ transplant, per 1,000 dialysis patient years at risk, by time since listing.

### TRANSPLANT EVENTS

Figure 6.4 illustrates the number of deceased kidney-alone and simultaneous kidney-pancreas transplants. Figure 6.5 presents unadjusted rates of deceased kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary diagnosis, per 100 dialysis patient years. Figure 6.6 portrays the number of live donor kidney-alone and simultaneous kidney-pancreas transplants. Figure 6.7 shows unadjusted rates of live kidney-alone and simultaneous kidney-pancreas transplants by age, sex, race, and primary diagnosis, per 100 dialysis patient years. Diagnosis of cystic disease is included in the other diagnoses.

### TRANSPLANT OUTCOMES

Figures 6.8 and 6.9 present one-, five-, and ten-year graft and patient outcomes for recipients who received a first kidney transplant from a deceased or living donor, respectively. Data are reported as unadjusted probabilities of each outcome, computed using Kaplan-Meier methods. All-cause graft failure includes repeat transplantation, return to dialysis, and death. The death outcome is not censored at graft failure, and assigns deaths that occur after repeat transplantation or return to dialysis to the transplant cohort.



Figure 6.10 presents the percent of acute rejections reported during the first post-transplant year in adult, first-time, kidney-alone transplant patients after discharge from the initial transplant hospitalization with a functioning graft. A recipient 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 (3) that acute rejection was the primary cause of graft failure. Biopsy-proven rejection is available starting in 1991 on the OPTN Transplant Recipient Registration Form; it was not, however, added to the Transplant Recipient Follow-up form until April, 2003, so the incidence of biopsy-proven rejection is reported for 2004 and later. If multiple rejection episodes are reported during the first year, only one rejection is counted in the numerator.

Figure 6.11 presents the post-transplant total hospital admission rates per 1,000 patient years for all kidney transplant recipients by year.

Figure 6.12 displays mortality rate by primary cause of death for patients who received a deceased or live donor kidney-alone or kidney plus other organ transplant during 2010–2012. Causes of death are ascertained from the CMS 2746.

#### FOLLOW-UP CARE

Figure 6.13 presents data on immunosuppressive medications used in adult recipients at the time of transplantation, as reported to the OPTN. Recipients who received the same type of medication multiple times were counted once. Mycophenolate data include mycophenolate mofetil and mycophenolate sodium, and mTOR inhibitors include sirolimus and everolimus. Data on mTOR inhibitors and steroids are also shown at one year post-transplantation.

#### REFERENCE SECTION E

Tables E.1–5 present data regarding the kidney transplant waiting list. The OPTN began to collect waiting list data in 1987. Table E.1 presents counts of ESRD-certified candidates newly added to the waiting list for a kidney or kidney-pancreas transplant during the given year. Patients listed at multiple transplant centers are counted only once. Table E.2 presents waiting times, defined as the median time in days from listing to transplantation among ESRD-certified candidates newly added to the kidney-alone waiting

list during the given year, and estimated with the Kaplan-Meier method. Patients listed at multiple centers are counted from the time of the first listing. Table E.3 presents counts of ESRD-certified patients on the waiting list at any center on December 31 of the given year, regardless of when the first listing occurred. Table E.4 includes point prevalent dialysis patients wait-listed for a kidney 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 deceased donor kidney transplant are included in Tables E.5, E.5.3, and E.5.4, and patients receiving a deceased or live donor kidney transplant are included in Tables E.5.2, E.5.5, and E.5.6. Percentages in Tables E.2 and E.5 are calculated using the Kaplan-Meier method.

Transplant counts are presented in Tables E.6–8. All kidney transplants, including kidney-alone and kidney plus at least one other organ, are included unless specified in the footnote, and all counts include non-Medicare patients. Table E.8 illustrates the distribution of recipients by donor type and panel reactive antibody level, determined from the OPTN Recipient Histocompatibility form, and shows a cross-tabulation of recipients and donors in terms of cytomegalovirus antibody status, hepatitis C antibody status, and Epstein-Barr antibody status at the time of transplantation. A recipient/donor is considered positive for any of these antibodies if any applicable OPTN data source indicates positive. Unknown status is applied when no applicable data fields indicate “positive” or “negative.” Cold ischemia time (in hours; Table E.8.2) 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 HD patients, PD (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare dialysis 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 within the specified year, until the first of transplant, death, or the end of the year. Dialysis time for patients returning to dialysis from transplant is counted. Transplant rates are calculated as the number of transplants, including kidney-alone and kidney plus at least one other organ, 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 repeat transplantation, by donor type, age, sex, race, ethnicity, primary diagnosis, and first versus subsequent transplant. Data are presented for outcomes at 90 days, one year, two years, three years, five years, and ten years post-transplant. This section seeks to address two major issues: the probability of graft survival at various times post-transplant, and the probability that a recipient will return to dialysis or require repeat transplantation at various times post-transplant. Recipients are followed from the transplant date to graft failure, death, or the end of the follow-up period (December 31, 2011). In the analysis of graft survival, death is considered a graft failure. In the analysis of graft failure necessitating dialysis or repeat transplantation, 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 sex are omitted. Unknown age is defined as a missing age at transplant, or an age calculated to be less than zero or greater than 100 years. Patients are also excluded if their first ESRD service date is prior to 1977.

Unadjusted survival probabilities are estimated using the Kaplan-Meier method, while the Cox proportional hazards model is used for adjusted probabilities. Probabilities are adjusted for age, sex, race, primary diagnosis, and first versus subsequent transplant, and standardized to 2011 recipient characteristics.

### Chapter 7: Pediatric ESRD

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

## HOSPITALIZATION

Figures 7.4-6 present adjusted admission rates in the first year of ESRD, by age, and modality, for 2002-2006 and 2007-2011 incident patients younger than 20. The patients are divided into four age groups (age 0-4, 5-9, 10-14, and 15-19) or three modality groups (HD, PD, and transplant). Since in-center hemodialysis patients who are younger than 65 and not disabled cannot bill for hospitalizations until 90 days after ESRD initiation, the 90-day rule is applied. Patients

are required to survive the first 90 days after initiation, and are followed for admissions for up to one year after day 90. Data cleaning and counting of admissions and time at risk for admissions generally follow methods described for Reference Section G. Censoring occurs at death, loss to follow-up, end of payer status, December 31, 2012, or at one year. Censoring also occurs three days prior to transplant for dialysis patients, and three years after the transplant date for transplant patients. Rates are adjusted for sex, race, Hispanic ethnicity, and primary diagnosis. Adjusted rates are calculated with a model-based adjustment method and an interval Poisson model. The reference cohort includes incident ESRD patients aged 0-19 in 2010-2011. Principal ICD-9-CM diagnosis codes used for cardiovascular and infectious hospitalizations are listed in the discussion of Figure 4.1.

## MORTALITY AND SURVIVAL

Figures 7.8-10 present adjusted all-cause and cause-specific mortality in the first months of ESRD, by age, modality, and ethnicity, for 2002-2006 and 2007-2011 incident patients younger than 20. The patients are divided into four age groups (age 0-4, 5-9, 10-14, and 15-19) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2012, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date to December 31, 2012. Rates by age are adjusted for sex, race, Hispanic ethnicity, and primary diagnosis; rates by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis. Incident ESRD patients who were younger than 20 years in 2010-2011 are used as the reference cohort.

Figure 7.11 presents five-year survival for 2003-2007 incident ESRD patients aged 0-19, by age, modality, and ethnicity. The patients are divided into four age groups (age 0-4, 5-9, 10-14, and 15-19) or three modality groups (HD, PD, and transplant). Dialysis patients are followed from the day of ESRD onset until December 31, 2012, and censored at loss to follow-up, transplantation, or recovered function. Transplant patients who receive a first transplant in a calendar year are followed from the transplant date until December 31, 2012. Probabilities by age are adjusted for sex, race, Hispanic ethnicity, and primary diagnosis; probabilities by modality are adjusted for age, sex, race, Hispanic ethnicity, and primary diagnosis. The

reference population consists of 2010–2011 incident pediatric ESRD patients.

### TRANSPLANTATION

Figure 7.2 presents an overview of the pediatric transplant population.

Figure 7.2.a shows the rate of ESRD among the U.S. population aged 0-19, and the rate of transplantation in dialysis patients aged 0-19 at transplant, 1988–2012.

Figure 7.2.b shows the number of ESRD-certified pediatric candidates (0-19 years old) on the OPTN kidney transplant waiting list on December 31 of each year, and the median waiting time from wait-listing to kidney transplantation for new candidates (i.e., the time by which 50 percent of newly wait-listed candidates had received a kidney). Candidates listed at more than one center on December 31 are counted only once. Median waiting time is reported for patients listed in each given year.

Figure 7.2.c presents transplant counts for all pediatric (0-19 years old) recipients, by donor type. Figure 7.2.d shows cumulative counts of functioning transplants in pediatric patients, ages 0-19.

### TRANSPLANT AND OUTCOMES

Figures 7.3 presents transplant rates per 100 dialysis patient years among pediatric patients on dialysis (ages 0-19). Figure 7.3a presents rates by age group. Figure 7.3b presents rates by sex, and Figure 7.3c presents rates by race. Rates were calculated among dialysis patient years in that specific subgroup.

Figure 7.7 presents one-year graft and patient outcomes for pediatric recipients (ages 0-19) who received a kidney transplant from a deceased or living donor, respectively. Death outcome probabilities are among first-time transplants. Data are reported as adjusted probabilities of each outcome, computed using Cox proportional hazards models. The death outcome is not censored at graft failure, and includes deaths that occur after repeat transplantation or return to dialysis. These probabilities are adjusted as described below.

For the all-cause graft failure analyses, data are reported as adjusted probabilities of each outcome, computed using Cox proportional hazards models. Probabilities are adjusted for age, sex, race, primary

diagnosis, and first versus subsequent transplant, and standardized to 2011 patient characteristics. All-cause graft failure includes retransplant, return to dialysis, and death.

For the probability of death analyses, the Cox model and the model-based adjustment method are used for adjusted probabilities. The adjusted survival probability for a cohort is based on expected survival probability for the cohort and the reference population. The survival/conditional probabilities are modeled separately for each period: 0–90 days, 91 day to one year, one year to two years, two years to three years, three years to five years, and five years to ten years. The expected survival probabilities for 90 days, one year, two years, and so on are calculated based on the survival/conditional survival probabilities. We fit one model for each cohort to obtain adjusted probabilities overall and for age, sex, race, and primary cause of ESRD. The reference population consists of 2011 incident ESRD patients. The death outcome is not censored at graft failure, and includes deaths that occur after retransplant or return to dialysis.

### Chapter 8: Providers

In Reference Section J, we define a chain-affiliated unit as a freestanding dialysis unit owned or operated by a corporation at the end of a year. The category of small dialysis organization (SDO) includes all organizations meeting our definition of a chain but not owned by DaVita, Fresenius Medical Care (Fresenius), or Dialysis Clinic, Inc. (DCI).

Data are obtained from CMS's Annual Facility Survey (1988 to the present), Renal Dialysis Facilities Cost Report (Form 265–94, 1994–2000), and Dialysis Facility Compare (DFC) database (2001 to the present), as well as 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.

A facility's hospital-based or freestanding status is determined from the third and fourth digits of the provider number assigned to each unit by CMS. For years prior to 2001, we determine profit status through the ownership type field on the CMS survey. For subsequent years we use the profit status field of the DFC database.

Figure 8.1 shows the counts of units and patients for all provider types from the 2010—2012 Annual Facility Survey. Figure 8.2 presents the percentage of patients by provider type being treated by each type of dialysis: in-center HD, PD and home HD.

Figure 8.3 presents the percentage of patient-months in May—December 2012 during which a provider's patients had a particular type of access: catheter, fistula, graft or other/missing type. The figure shows these percentages among all patient-months ("Among Prevalent Dialysis Patients") and only among those patient-months during which a HD patient was new to dialysis ("Among Incident Dialysis Patients").

Figure 8.4 shows the percentage of dialysis patients on the kidney transplant waiting list in 2010, 2011 and 2012. This figure only measures wait-listing among patients younger than 70 because transplants in people aged 70 or older occur much less frequently.

#### HOSPITALIZATION AND MORTALITY

Tables 8.1 and 8.2 compare mortality and hospitalization among dialysis provider types and chains, using standardized mortality ratios (SMRs) and standardized hospitalization ratios (SHRs). Both are estimated using a two-stage Cox proportional hazards model (described below). SMR and SHR calculations include all 2010, 2011 and 2012 period prevalent dialysis patients; SHR calculations include only dialysis patients with Medicare as primary payer.

#### ADJUSTMENT

Both SMRs and SHRs are adjusted for patient age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence, and body mass index (BMI) at incidence. The SMR is additionally adjusted for race-specific population death rates.

Unlike previous ADRs reporting these standardized measures, to facilitate comparison of the SMR and SHR across years, this year's ADR reports these measures with the year adjustment removed from the model. That is, the measures are not standardized to a national norm annually, but are rather standardized across the reporting period (e.g., three years) in order to facilitate identifying short-term trends over time.

#### CONFIDENCE INTERVALS

Given the large number of observations that go into the SMR and SHR models, we choose to approximate rather than directly calculate the 95 percent confidence intervals for the respective measure. This approach gains efficiency with minimal loss of precision. In particular, the exact 95 percent confidence intervals are derived by applying the Wilson-Hilferty Approximation (Wilson and Hilferty, 1931), which approximates chi-square percentiles using percentiles of the standard normal distribution (Breslow and Day, 1987).

#### PATIENT PLACEMENT

We identified each patient's dialysis provider at each point in time using data from a combination of Medicare-paid dialysis claims, the ME, and paid dialysis claims. Starting with day 91 after onset of ESRD, we attribute a patient to a facility according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the new facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. If a period of one year passed with neither paid dialysis claims nor CROWNWeb/SIMS information to indicate that a patient was receiving dialysis treatment, we considered the patient lost to follow-up and did not continue that patient in the analysis. When dialysis claims or other evidence of dialysis reappeared, the patient was entered into analysis after 60 days of continuous therapy at a single facility.

## Chapter 9: Costs of ESRD

Data used to estimate HMO and EGHP costs as well as Medicare Part D Prescription Drug cost data were not available for inclusion in the 2014 ADR.

Figure 9.1 includes total costs to Medicare and expected patient obligation based on Medicare claims data. Figure 9.2 includes total Medicare spending for all programs and the fraction of total spending related to the ESRD program. Figure 9.3 presents counts of Medicare and Non-Medicare ESRD patients by year. These counts are also available in Chapter 1: Incidence, Prevalence, Patient Characteristics and Modalities.

Figure 9.4 describes the growth in total Medicare Part A and B spending each year; part D costs are not included. Figure 9.5 shows the Total Medicare ESRD expenditures by type of service (see also Reference Table K.2).

### REFERENCE SECTION K: MEDICARE CLAIMS DATA

Cost information in this section is derived from Medicare inpatient/outpatient, physician/supplier and Part D claims data in the CMS SAFs, which are created annually six months after the end of each calendar year. 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 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. These analyses also include the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and organ acquisition costs.

The reference tables in section K include previously reported values for years prior to 2012. Values for 2012 are calculated using the same methods as in prior years with exceptions noted below. Values for 2012 exclude patients who were classified as MSP and individuals with missing values for demographics, modality, or payer status, unless otherwise specified.

### PAYER SEQUENCE

The payer sequence is similar in concept to the USRDS treatment history. Payer 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 and dialysis claims information are used to categorize payer status as Medicare primary payer (MPP), Medicare secondary payer (MSP), or non-Medicare. The claims database contains data only for MPP and MSP patients, so economic analyses are restricted to these categories. In addition, as it is impossible to determine the complete cost of care for ESRD patients with MSP coverage, analyses of costs per person per year exclude patients during the periods when they have this coverage.

### PAYMENT CATEGORIES

Medicare payments are broken into several categories. Estimates of costs from the outpatient SAF are derived for the individual services provided. For claims prior to 2000, actual payment amounts are provided only for the entire claim. Cost estimates for these years for dialysis, EPO, iron, and so forth are calculated from the claim-level “Total Charge,” the payment amount, and the revenue line-level “Total Charge,” as follows:

payment (line) = [total charge (line) / total charge (claim)] \* payment (claim). In August, 2000, CMS added to the outpatient SAF a field containing line-item payment amounts. According to CMS documentation, the total of these payments may not equal the total paid amount for the claim. In such cases, each line-item cost is discounted by the ratio of the sum of line-item payment amounts to the total paid amount for the claim. Since complete data on line-item payments are available starting with the 2001 outpatient SAF, the estimates for outpatient payment categories are taken directly from the claims data for calendar years 2001–2012, 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 initial modality is censored, and a new observation with the new modality is created. Under this method, aggregation of Medicare payments is done on an as-treated basis, attributing all payments for a particular claim to the

patient's modality at the time of the claim.

Prior to 2012, the first 60 days after a change were attributed to the previous modality, to account for any carryover effects. This carryover period did not apply to changes from dialysis to transplant. For the 2012 calculations, no carryover period was used for any modality change. In Section K of the Reference Tables, we classify patients into four as-treated modality categories: HD, CAPD/CCPD, other dialysis, and transplant. The "other dialysis" category includes cases in which the dialysis modality is unknown or is not HD 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 (HD, CAPD/CCPD, and other dialysis) and all ESRD (all-dialysis and transplant).

The study spans the 20 years from January 1, 1991, to December 31, 2011, and ESRD patients prevalent on January 1, 1991 or incident at any time during the period are potentially eligible for inclusion. The initial study start date for a given patient is defined as the latest of January 1, 1991, the first ESRD service date in the USRDS database for that patient, or the earliest Medicare eligibility date from the payer sequence. Patients who are non-Medicare or enrolled in a Medicare Advantage program are excluded until their payer status changes to Medicare (either as primary or secondary payer). Claims during periods that a patient is classified as MSP are included in Tables K.1-4, and are excluded for the rest of the tables in Section K.

For each modality period, Medicare payments are aggregated from the modality start date until the earliest of death, transplant, modality change, loss to follow-up, or December 31, 2010. Patients incurring no inpatient/outpatient or physician/supplier Medicare costs for the entire period are excluded. Prior to 2012, Medicare payment amounts are linearly prorated for claims that span the start or end date of a modality period or of the study itself; for 2012, the payment amount is included for the period in which the claim begins.

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, sex, race, modality, and diabetic status (based on the patient's primary diagnosis).

## Model 2: categorical calendar year model

This model, described in the Health Care Financing Administration (now CMS) research report on ESRD (1993-1995), is used for Reference Tables K.10-13. With this method, patients are classified into four mutually exclusive treatment groups:

- dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive and with ESRD.
- transplant: ESRD patients receiving a kidney transplant during the calendar year.
- functioning graft: ESRD patients with a functioning graft for the entire calendar year, or for that part of the year in which they are alive and with ESRD.
- 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 trans-plant category.

## Chapter 10: International Comparisons

### DATA COLLECTION

Each country was provided a data-collection form spreadsheet (Microsoft Excel) to complete for years 2008 through 2012. Countries were asked to report patient count data for each year, if available, for the entire population or by 5 different age categories (0-19, 20-44, 45-64, 65-74, 75+) for: (1) the country's or region's general population, (2) patients new to ESRD during the year, (3) patients new to ESRD during the year among new ESRD patients for whom DM was the primary cause of ESRD, (4) the point-prevalent count of ESRD patients living on December 31 of the given year, (5) total number of patients with a functioning kidney transplant on December 31st of the given year, (6) total number of kidney transplants performed during the year, by type of kidney transplant (cadaveric, living donor, other donor), (7) the number of dialysis patients, HD patients, CAPD/CCPD patients, and home HD patients on December 31st of the indicated year. Prevalence was reported for all patients at the end of the calendar year (December 31, 2012) except where otherwise noted. Data for Australia, New Zealand, Italy, South Africa, and Lebanon were

taken directly from the respective registry's annual report (McDonald et al., 2013; Italian Registry of Dialysis and Transplant, 2014; Davids et al., 2014; Elzein, 2012). Information for Ukraine was based on a recent publication of registry data from the Ukraine (Kolesnyk et al., 2014). Data provided by Argentina may be supplemented by Marinovich et al., 2013.

#### DATA LOADING AND CLEANING

The data were imported into SAS from Microsoft Excel and data quality checks were performed, with follow-up with registries as needed.

#### STATISTICAL ANALYSES

Rates were calculated as the count divided by the total population for that year, multiplied by one million. For age-specific categories, rates were calculated as the count in each category divided by the total population in the age category, multiplied by one million.

To contribute data from your country's registry, please contact [international@usrds.org](mailto:international@usrds.org).

#### Chapters 11 and 12: Special Studies

Methods for the creation of the figures and tables in Chapters 11, USRDS Special Study Center on Palliative and End-of-Life Care and 12, Transition of Care in Chronic Kidney Disease are described within the chapters themselves.

#### Vascular Access

##### REFERENCE SECTION L

Tables L.1-L.6 include period prevalent HD patients with Medicare as primary payer. Placements are identified from Medicare claims, and rates represent the total number of events divided by the time at risk. Follow-up is censored at death, change in modality, change in payer status, or the end of the prevalent year.

Tables L.7-L.8 include point prevalent PD patients with Medicare as primary payer. Complications are obtained from claims during the time at risk in the prevalent year, and rates represent the total number of events divided by the time at risk. Follow-up time is censored at death, a change in modality, a change in payer status, a claim for HD vascular access placement, or at the end of the prevalent year.

## Statistical Methods

### Methods for Calculating Rates

The calculation of observed rates is straightforward, with some rates based on counts and others on follow-up time. The ESRD incident rate in 2009, for example, is the observed incident count divided by the 2009 population size and, if the unit is per million population, multiplied by one million. The 2009 death rate for prevalent ESRD patients is the number of deaths in 2009 divided by the total follow-up time (patient years) in 2009 of the 2009 prevalent patients, and, if the unit is per thousand patient years, multiplied by one thousand. Standard errors of estimated rates are based on the assumption of the data; the observed count has a Poisson or binomial distribution. The count-based rate describes the proportion having the "event", and the time-based rate tells how often the "event" occurs.

#### MODEL-BASED RATES

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

#### MEASUREMENT UNIT FOR RATES

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

Take, for example, a calculation of 2010 first hospitalization rates for two groups of patients, all receiving dialysis therapy on January 1, 2010. Group A consists of three patients: Patient one had a first hospitalization on March 31, 2010, Patient two was hospitalized on June 30, 2010, and Patient three was on dialysis through December 31, 2010, with no hospitalizations. Group B also has three patients: Patient four was first hospitalized on December 31,

2010, Patient five was hospitalized on September 30, 2010, and Patient six was on HD the entire year, with no hospitalizations through December 31, 2010.

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

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

**Methods for Adjusting Rates**

Because each cohort contains a different patient mix, observed event rates may not be comparable across cohorts. Adjusted analyses make results comparable by reporting rates that would have arisen had each cohort contained patients with the same distribution of confounders—such as age, sex, 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 & White, 1995). 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 sex and there are three race groups (White, Black/African American, and Other) and two sex groups, there are six categories: White males, White females, Black/African American males, Black/African American females, males of other races, and females of other races.

Suppose we try to compare state-level incidence rates in 2009 after removing the difference caused by race. To do this, we need to calculate the incidence rate, adjusted for race, for each state. Because racial distributions in each state are quite different, we use as reference the national population—here, the population at the end of 2009—with five race groups (White, Black/African American, Native American, Asian, and Other).

Assuming the incidence rate of state A in 2009 is 173 per million population, and the race-specific rates and race distribution of the national populations are as shown in the following table, the adjusted incidence 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 incidence rate would be 158.73 instead of 173. If state B had an adjusted incidence rate of 205, we could say that state B had a higher incidence rate than state A if they both had the same racial distribution as the whole country.

**vol 2 Table m.3 Example of adjusted incident rate calculation**

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

This method is used to produce some adjusted incidence and prevalence rates in Chapters 1 and 3, and in Reference Sections A and B, as well as in the model-based adjustment method.

**MODEL-BASED ADJUSTMENT**

Under some circumstances there are disadvantages to the direct adjustment method. Suppose we are calculating mortality rates for a set of groups, and adjusting for potential confounding variables. If one category in a group has only a few patients or deaths, its estimated category-specific mortality rate will be unstable, likely making the adjusted rate unstable as well. In addition, if one includes a category with 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). As in previous ADRs, standard errors of the adjusted rates are calculated using a bootstrap approach. In general, the bootstrap approach works well, but is time consuming. Convergence problems occur in a few bootstrap replications and such cases are ignored in the calculation. In this ADR we use model-based adjustments to calculate adjusted mortality rates, adjusted hospitalization rates, and state-level adjusted incidence and prevalence rates using the Poisson model and some other rates, as described in the text on the individual figures.

**Survival Probabilities and 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 & Prentice, 2002.). Survival probabilities in Reference Section I are expressed as percentages from 0 to 100. The mortality/event rate in the period of (0,t) is calculated by  $-\ln(\text{Survivor at time } t)$ . This event rate will be the same as that estimated by event time divided by follow-up time after adjustment of the unit if the event rate is a constant over time.

**SURVIVAL PROBABILITY WITH COMPETING RISKS**

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

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

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

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

where  $\lambda_k(t_j)=D_{kj}/n_j$ ,  $\hat{S}(t_{j-1})$  is the Kaplan-Meier estimate of survival at time  $t_{j-1}$ ,  $D_{kj}$  is the number of patients failing from cause k at time  $t_j$ , and  $n_j$  is the number of patients at risk at prior time  $t_j$  (Putter et al., 2007).

**ADJUSTED SURVIVAL PROBABILITIES**

Adjusted survival probabilities are reported in Reference Section I, with age, sex, race, Hispanic ethnicity, and primary diagnosis used as adjusting risk factors. The model-based adjustment method is used, with survival probabilities/conditional survival probabilities predicted from the Cox regression model (Kalbfleisch & Prentice, 1980, 2002). 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, sex, race, Hispanic ethnicity, and primary diagnosis. The adjusted mortality rates for incident cohorts in Reference Section H are calculated using similar methods.

**Generalized Linear Models**

**GENERALIZED LINEAR MIXED MODEL FOR MORTALITY RATES**

We use the generalized linear mixed model with log link and Poisson distribution to calculate mortality and first transplant rates for prevalent patients. While rates are reported for a year, data from the previous two years with different weights are also used to improve the stability of the estimates.

The generalized linear mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX. Rates for the intersections of age, sex, 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, sex, race, and primary diagnosis, and all two-way interactions among age, sex, 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, sex, race, and primary diagnosis. Age is used as a categorical variable.

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

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

#### **GENERALIZED LINEAR MODEL FOR HOSPITALIZATION RATES**

In this ADR, hospitalization reference tables present rates of total admissions and hospital days. We use a generalized linear model with log link and Poisson distribution; the model includes age, sex, race, primary diagnosis, and their two-way interactions.

To stabilize the estimates, three years of data are used with different weights. Year is also included in the model as a covariate. The adjusted hospitalization rates are calculated using the direct adjustment method, based on the category-specific admission rate from the generalized linear models.

#### **Standardized Mortality Ratios**

The standardized mortality ratio (SMR) compares the mortality of a group of patients relative to a specific norm, or reference, after adjusting for some important risk factors. For example, the dialysis chain-level SMR is used to compare mortality in prevalent dialysis patients—after adjusting for age, race, ethnicity, sex, DM, duration of ESRD, nursing home status, patient comorbidities at incidence and BMI at incidence in each dialysis chain. Qualitatively, the degree to which the facility's SMR varies from 1.00 is the degree to which it exceeds ( $>1.00$ ) or is under ( $<1.00$ ) the national death rates for patients with the same characteristics as those in the facility. For example, an  $SMR=1.10$  would indicate that the facility's death rates typically exceed national death rates by 10 percent (e.g., 22 deaths observed where 20 were expected,

according to the facility's patient mix). Similarly, an  $SMR=0.95$  would indicate that the facility's death rates are typically 5 percent below the national death rates (e.g., 19 observed versus 20 expected deaths). An  $SMR=1.00$  would indicate that the facility's death rates equal the national death rates, on average.

#### **METHOD OF SMR CALCULATION**

The SMR is designed to reflect the number of deaths for the patients at a facility, relative to the number of deaths that would be expected based on overall national rates and the characteristics of the patients at that facility. Specifically, the SMR is calculated as the ratio of two numbers; the numerator ("observed") is the actual number of deaths, excluding deaths due to abused drugs and accidents unrelated to treatment, over a specified time period. The denominator ("expected") is the number of deaths that would be expected if patients at that facility died at the national rate for patients with similar characteristics. The expected mortality is calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The Stage I model is a Cox model stratified by facility and adjusted for patient characteristics. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the Stage II model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

#### **Standardized Hospitalization Ratios**

The Standardized Hospitalization Ratios (SHR) for Admissions is designed to reflect the number of hospital admissions for the patients at a dialysis facility, relative to the number of hospital admissions that would be expected based on overall national rates and the characteristics of the patients at that facility. Numerically, the SHR is calculated as the ratio of two numbers: the numerator ("observed") is the

actual number of hospital admissions for the patients in a facility over a specified time period, and the denominator (“expected”) is the number of hospital admissions that would have been expected for the same patients if they were in a facility conforming to the national norm.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g., Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012). The modeling process has two stages. At Stage I, a stratified model is fitted to the national data with piecewise-constant baseline rates, stratification by facility and adjusting for age, sex, DM, duration of ESRD, nursing home status, comorbidities at incidence, BMI at incidence, and calendar year. The baseline rate function is assumed to be a step function with break points at 6 months, 1 year, 2 years, 3 years and 5 years since the onset of dialysis. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The stratification on facilities is important in this phase to avoid bias due to possible confounding between covariates and facility effects. At Stage II, the relative risk estimates from the first stage are used to create offsets, and an unstratified model is fitted to obtain estimates of an overall baseline rate function.

**Expected Remaining Lifetimes**

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

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, estimated for the group. Let

$S(A)$  denote the survival function of patients at age  $A$ . Among patients alive at age  $A$ , the probability of surviving  $X$  more years is  $S(X|A) = S(A+X)/S(A)$ . For a given starting age  $A$ , the expected remaining lifetime is then equal to the area under the curve of  $S(X|A)$  plotted versus  $X$ . Because few patients live beyond 100, this area is truncated at the upper age limit  $A + X = 100$ .

**Half-lives (Median Time)**

**CONDITIONAL HALF-LIFE**

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

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

Estimate the survival probabilities  $S(t_0)$  and  $S(t_1)$  using the Kaplan-Meier method from the data available, where  $t_0 < t_1$  and  $T_1$  is within the follow-up

$$\mu = (t_1 - t_0) / (\ln[S(t_0)] - \ln[S(t_1)])$$

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

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

**Mapping Methods**

Throughout the ADR, data in maps and graphs are unadjusted unless otherwise noted. 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.

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