Methods: chronic kidney disease
data sources

One describes a tale best by telling the tale. You see? The way one describes a story, to oneself or to the world, is by telling the story. It is a balancing act and it is a dream. The more accurate the map, the more it resembles the territory. The most accurate map possible would be the territory, and thus would be perfectly accurate and perfectly useless. The tale is the map that is the territory.

You must remember this.

Neil Gaiman
American Gods

n this appendix we describe the datasets and methods used for CKD analyses. Data management and preparation, database definitions, and the data sources used for USRDS analyses are described in the appendix of Volume Two.

data sources

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

CMS MEDICARE ENROLLMENT DATABASE

The Enrollment Database (EDB) of the Centers for Medicare and Medicaid Services (CMS) 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 (BGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

ESRD MEDICAL EVIDENCE FORM (CMS 2728)

The ESRD Medical Evidence (ME) form is the official form for registering ESRD patients, and must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. The CMS, USRDS, and renal research communities rely on the ME form to ascertain basic patient demographic attributes, the primary cause of renal failure, major comorbidities, and biochemical test results at the time of ESRD initiation.

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

ESRD DEATH NOTIFICATION FORM (CMS 2746)

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

CMS 5 PERCENT STANDARD ANALYTICAL FILES (SAFS)

These files contain billing data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved. The claims data are selected randomly from general Medicare claims (i.e. final action claims) using five combinations of the last two digits of the CMS Health Insurance Claims (HIC) number: 05, 20, 45, 70, and 95. Since the same two-digit numbers are used each year to create the 5 percent general Medicare SAFS, one should expect to see the same beneficiaries in these annual datasets. These claims are categorized into the inpatient (IP), outpatient (OP), home health agency (HHA), hospice (HS), skilled nursing facility (SNF), physician/supplier (PB), and durable medical equipment (DME) SAFS.
Files are updated each quarter through June of the next year, when annual files are finalized.Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2013 ADR includes all claims up to December 31, 2011.

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

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

**CMS PRESCRIPTION DRUG EVENT (PDE) FILE**
In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. With this new Part D coverage, health plans must submit a summary record called the prescription drug event (PDE) record to CMS whenever a Medicare beneficiary fills a prescription. The PDE record contains 37 data elements; the USRDS receives PDE records with 30 elements, excluding a few non-critical fields. Each drug is identified by a National Drug Index (ndc) code; the record also contains prescription dosing information, drug costs above and below the out-of-pocket threshold, other true out-of-pocket (Toop) amounts, plan paid amounts, and low-income cost-sharing subsidy amounts.

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

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

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

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

The database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2011, and contains health data for about 14 million people annually. For details about what is contained in the Ingenix i3 data, please visit our website at [www.usrds.org](http://www.usrds.org).

**NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)**
NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1959, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2010 were nationally representative cross-sectional surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey
participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

PAYERS
Information on payers is obtained from the CMS EDR. We also examine Medicare outpatient claims to identify patients for whom the EDR 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 define payer history, and, starting with the 2003 ADR, we use this file to identify Medicare eligibility status and other payers.

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

UNITED STATES CENSUS
In rate calculations throughout this year’s ADR we use data from the 2000 and 2010 U.S. Census, and incorporate CDC population estimates by race.

database definitions
EGHP DATA
To examine the demographic segment represented by the EGHP data, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

ESRD COHORT IN THE EGHp POPULATION
Because the Truvent Health MarketScan and Clinformatics Datamart databases do not provide identifiable data elements, we are unable to link them directly to the USRDS ESRD registry. To identify ESRD patients, we therefore use a process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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

Identification of major comorbidities
According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-year observation period, he or she has a qualifying ICD-9-CM diagnosis code of diabetes on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or physician/supplier claims. We employ this method to identify major comorbidities: diabetes, 250.xx, 357.2, 362.xx, and 366.41; hypertension, 362.xx, 401.x–405.x, 437.2; CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 403.x0 (after October 1, 2006), 404.x2, 404.x3, 404.x4 and 404.x1 (after October 1, 2006), 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–751.17, 753.19, 753.2, and 794.4; congestive heart failure, 398.91, 402.x1, 404.x3, 422.xx, 425.xx 428.xx, V42.1 and CVD (other than CHF), 404.x1, 410–414, 420–421, 423–424, 426–427, 429, 430–438, 440–444, 447, 451–453, 557, 785.0–785.3, V42.2, V43.3, V45.0, V45.81, V45.82, and V53.3.

ESRD in the general population
chapter one

The statistical software package SUDAAN, version 10.0, was used to analyze all NHANES data, incorporating the sampling weights and survey design through Taylor Series Linearization.
In this chapter, age is defined as the participant’s age at the time of the household interview, categorized into the following age groups: 20–39, 40–59, or 60 and older. Race/ethnicity is self-reported and is categorized as non-Hispanic white, non-Hispanic African American, or other.

The estimated glomerular filtration rate (eGFR, measured in ml/min/1.73 m²) is calculated using the CKD-EPI equation, based on the National Center for Health Statistics recommended standardized creatinine values. The CKD-EPI equation is: 
\[
\text{eGFR} = 141 \times \min(\text{Scr}, 1)^{\alpha} \times \max(\text{Scr}/\text{κ}, 1)^{\beta} \times 0.993 \text{age} \times 1.018 \text{[if female]} \times 1.159 \text{[if black/African American]},
\]
where Scr is standardized serum creatinine in mg/dl, \( \alpha \) is 0.7 for females and 0.9 for males, \( \beta \) is -0.329 for females and -0.411 for males, \( \text{max}(\text{Scr}/\text{κ}, 1) \) indicates the minimum of Scr/κ or 1, and \( \min(\text{Scr}, 1) \) indicates the maximum of Scr/κ or 1 (Levey et al.).

Albumin/creatinine ratio (Acr) is the ratio of urinary albumin (mg/l) to urinary creatinine (mg/dl). Based on an NHANES suggestion, urine creatinine values is adjusted to
\[
\text{urine creatinine \times 1.159 [if black/African American],}
\]

The identification of ckd is based on both eGFR and Acr, and is defined as an eGFR less than 60 ml/min/1.73 m² or an Acr ≥ 30 mg/g. ckd includes stages 1–5, which are classified using the standard ckd definitions: 
- Stage 1: Acr ≥ 30 and eGFR ≥ 90
- Stage 2: Acr ≥ 30 and 60 ≤ eGFR < 90
- Stage 3: 30 ≤ eGFR < 60
- Stage 4: 15 ≤ eGFR < 60
- Stage 5: eGFR < 15

Participants with diabetes are those with any of the following: 1) an affirmative answer to the question “Have you ever been told by a doctor or other health professional that you have diabetes or sugar diabetes (other than during pregnancy)” 2) an affirmative response to either “are you now taking insulin?” or “are you now taking diabetic pills to lower your blood sugar?” or 3) glycohemoglobin ≥ 7 percent. Participants with self-reported diabetes are assessed by self-report of being told by a doctor that blood cholesterol level is high, and a patient is classified as being treated for hyperlipidemia if he or she reports currently taking a cholesterol medication to control cholesterol. Control is defined as meeting the ATP III LDL target for the appropriate risk category. HDL cholesterol is within ATP III target if it is less than 40 mg/dl. There are three categories of total cholesterol: <200 (desirable), 200–239 (borderline high), and ≥240 (high).

Figure 2.1 includes point prevalent patients who survive all of the prevalent year, are continuously enrolled in Medicare throughout the cohort year with Medicare as primary payer, and do not have esrd during the prevalent year. Medicare patients are age 65 and older, while those in the Truven Health MarketScan (tHMs) cohort are age 50–64.

Table 2.a compares the characteristics of prevalent general Medicare, tHMs, and Clinformatics DataMart (cDM) ckd patients by age, gender, race, ethnicity, and comorbidity in 2011. Table 2.b includes prevalent non-esrd Medicare patients age 65 and older, alive at the end of 2011, and prevalent tHMs and cDM patients age 20–64. Each comorbidity is defined by medical claims (one inpatient or two outpatient claims) during each calendar year.

Figures 2.2–4 illustrate the prevalence of ckd in the Medicare, tHMs, and cDM populations. The 5 percent Medicare sample includes patients age 65 and older, without esrd, who survive throughout the cohort year with Medicare as primary payer, and who are not enrolled in Medicare Advantage. The tHMs and cDM cohorts are constructed in a similar fashion, but are restricted to patients age 20–64 who are enrolled in a fee-for-service plan and who do not have esrd.
Figure 2.5 shows the cumulative probability of non-CKD patients receiving a first urinary microalbumin or creatinine measurement, or both measurements, by month 12 of the second year of each two-year period. The general Medicare population includes patients continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the first year. Patients are excluded if they are younger than 20 at the beginning of the second year, are enrolled in a managed care program (MCO), acquire Medicare as secondary payer, die, are diagnosed with CKD or ESRD during the first year, have a missing date of birth, or do not live in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients are followed from January 1 to December 31 of the second year. The Kaplan-Meier method is used to calculate the cumulative probability and patients are censored at death, development of ESRD, and change in payer status.

CPT codes used to define urinary microalbumin measurement are 82042, 82043, 82044, and 84156, while codes for creatinine measurement are 80047, 80048, 80049, 80050, 80053, 80054, 80069, and 82565. Diabetes and hypertension are defined in the first year. Methods of defining CKD, diabetes, and hypertension are the same as those described above in the section on identification of major comorbidities.

Table 2.c shows unadjusted and adjusted cumulative probabilities of non-CKD patients receiving a first urinary microalbumin or creatinine measurement, or both measurements, by month 12 of 2011. The cohort is the same as that described for Figure 2.5. Cardiovascular disease is defined as any combination of ASHD, CHF, CVD, PVD, dysrhythmia, or other cardiovascular disease, as described in the section on identification of major comorbidities. The Kaplan-Meier method is used to calculate the unadjusted cumulative probability, and the corrected groups prognosis methodology is used to calculate the adjusted cumulative probability for each patient characteristic category.

The Medicare and thms columns of Tables 2.d–e include patients who are alive with full coverage for all of 2011. The CKD diagnosis code (all or 585.3–585.6), as well as the disease burden, are determined from claims in 2011. Table 2.f and Figures 2.6–8 reflect the results of adjusted logistic regression on the Medicare and thms cohorts from Tables 2.d–e.

Figures 2.9–12 and Tables 2.g–i include patients who are alive with full coverage for all of 2010, to allow for up to one year of follow-up for physician claims. The date on the earliest CKD claim (all or 585.3–585.6) of 2010 is used as the date of CKD diagnosis, and physician claims are searched for 365 days following that date. The cumulative probability in Figure 2.9 represents unadjusted Kaplan-Meier estimates, while in Tables 2.g–h the adjusted cumulative probability is obtained from the corrected group prognosis method, implementing proportional hazards regression. Adjusted hazard ratios in Table 2.i and Figures 2.10–12 are obtained from proportional hazards regression.

Hospitalization & Mortality

Chapter Three

HOSPITALIZATION

Adjusted admission rates in this chapter include adjustment for baseline comorbidities and prior hospitalization in addition to patient demographics. A model-based adjustment method is used with a Poisson assumption, and includes data from the current and previous two years, with respective weights of 1, ¼, and ⅛. Adjusted rates reflect the distribution of a reference cohort, specified below in the discussion of the respective figures. With this method, the parameter estimates from the model are used to calculate an estimated admission rate for each patient in the reference cohort. Adjusted rates are then computed as the weighted average of these individual rates, using as the weight the time at risk of each patient in the reference cohort.

Figure 3.1 shows rates of rehospitalization and/or death 30 days after live hospital discharge among general Medicare patients without CKD, with CKD, and on hemodialysis. Data include point prevalent Medicare patients on January 1, 2011, who are age 66 and older on December 31, 2010. For the CKD and non-CKD cohorts, is defined during 2010 CKD and patients are continuously enrolled in Medicare Parts A and B without MCO coverage and without ESRD. Live hospital discharges from January 1 to December 1, 2011, are identified as index hospitalizations; the latter date provides a 30-day period following the latest discharge to evaluate rehospitalization. The units of analyses include hospital discharges rather than patients. Hospitalization data exclude rehabilitation claims and transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. For hemodialysis patients, discharges with a transplant, loss to follow-up, or end of payer status before day 30 after discharge are excluded. For general Medicare patients, discharges with a first ESRD service date or end of payer status (not due to death) before day 30 are excluded. Rates reflect the percentage of live discharges followed by a rehospitalization and/or death within 30 days.

Figures 3.2–3 and Table 3.a show adjusted all-cause admission rates in Medicare patients age 66 and older. The study design consists of a one-year period (2010) during which CKD, comorbidities, and prior hospitalization are defined from claims, followed by the cohort year (2011) when follow-up for admissions begins on January 1. The Medicare cohort includes patients who are age 66 and older on December 31, 2010, are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, are without MCO coverage, are without ESRD, and who survive the complete year prior to follow-up. Patients are followed for admissions from January 1, 2011, and are censored at the earliest of death, ESRD initiation, end of plan coverage, or December 31, 2011. Rates are adjusted for age, gender, race, prior hospitalization,
cOPd, hypertension, liver disease, gastrointestinal disease, cancer, anemia, and with diabetes and cardiovascular disease combinations rather than as separate factors. Groups for diabetes and cardiovascular disease are mutually exclusive. Rates presented by one factor are adjusted for the others. The reference cohort includes Medicare patients in 2011, age 66 and older.

Figures 3.4–7 show adjusted all-cause and cause-specific admission rates by cKD diagnosis code and dataset. Study design, censoring, and inclusion criteria generally follow the description for the Medicare cohort in Table 3.a and Figures 3.2–3. Additionally, Clininformatics DataMart and Truven Health MarketScan data include point prevalent patients on January 1, 2011, continuously enrolled in a fee-for-service or commercial health plan and without esRD during 2010, and age 50–64 on December 31, 2010. The group labeled “cKD” includes those with claims-based evidence of cKD in 2010, while “non-cKD” is defined as patients without claims-based evidence of cKD. Cause-specific rates reflect hospital admissions for the purpose of the stated condition, and are identified by the principal ICD-9-CM diagnosis codes for cardiovascular and infectious admissions listed in the description of Figure 3.1 in the methods section for Volume Two. The reference cohort includes Medicare patients in 2011, age 66 and older.

Figure 3.8 displays annual trends in rates of rehospitalization and/or death within 30 days after hospital discharge among cKD patients. Methods follow those described in Figure 3.1 for cKD patients in 2011. Here, however, point prevalent Medicare cKD patients are included on January 1 of each year, including those age 66 and older on December 31 of the prior year. Also, during each prior year, cKD is defined, and patients are continuously enrolled in Medicare Parts A and B without HMO coverage and without esRD. Live hospital discharges from January 1 to December 1 of each year are included. Rates are adjusted for age, gender, and race using direct adjustment, and the reference group includes discharges in 2010.

Table 3.b and Figures 3.9–12 show unadjusted rates of rehospitalization and/or death within 30 days after live hospital discharge. Methods follow those described for the cKD and non-cKD cohorts in Figure 3.1. Data include point prevalent Medicare patients on January 1, 2011, age 66 and older on December 31, 2010. Additionally, cKD stage is defined during 2010. While Table 3.b and Figures 3.9 and 3.11–12 include discharges from all-cause index hospitalizations, Figure 3.10 illustrates rehospitalization rates among discharges from cardiovascular index hospitalizations. Cardiovascular index hospitalizations are identified by the principal ICD-9-CM diagnosis codes listed for Figure 3.1 in the methods section for Volume Two.

Figure 3.13 illustrates unadjusted rehospitalization rates during the transition to esRD. The analysis includes incident esRD patients with a first esRD service date between January 1 and October 1, 2011, who are age 67 and older, and who are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. During the complete two years prior to esRD initiation, patients are alive and have Medicare as a primary payer with continuous Parts A and B coverage. Hospitalization data exclude rehabilitation claims and transfers. Discharges with a same-day admission to long-term care or a critical access hospital are excluded. During the first quarter after initiation, discharges are included with Medicare Parts A and B coverage during the 30 days after discharge. Quarterly rates are displayed for the two years prior and first quarter after initiation. To allow 30 days of follow-up for rehospitalization after discharge, live hospital discharges are included in only the first two months of each quarter. Cardiovascular and infectious index hospitalizations are identified by the principal ICD-9-CM diagnosis codes listed for Figure 3.1 in the methods section for Volume Two.

MORTALITY
Figure 3.14 illustrates trends, by cKD status, in unadjusted and adjusted all-cause mortality. The study cohort for 1995 includes point prevalent Medicare patients on January 1, 1995, age 66 or older. cKD status is identified from 1994 Medicare claims, and the cohort excludes patients enrolled in an HMO, with Medicare as secondary payer, or diagnosed with esRD in 1994. Follow-up extends from January 1, 1995, to December 31, 1995, and is censored at esRD and the end of Medicare entitlement. Patients not living in the 50 states or the District of Columbia are excluded. Cohorts for 1996–2011 are constructed in a similar manner. Adjusted mortality is based on a Cox regression model and adjusted for demographics, hospitalization in the prior year, and comorbidities and sources of comorbidities defined in the prior year. Medicare patients from 2010 are used as the reference cohort.

For Figures 3.15–17 and Table 3.c, the cohort definitions are same as those defined in Figure 3.14. Adjusted mortality is based on a Cox regression model; rates by age are adjusted for gender, race, and comorbidities; rates by gender are adjusted for age, race, and comorbidities; and rates by race are adjusted for age, gender, and comorbidities. All 2011 patients are used as the reference cohort.

cardiovascular disease
chapter four

Table 4.a describes the prevalence of cardiovascular disease and treatment in Medicare enrollees. Cardiovascular disease includes acute myocardial infarction (AMI), atrial fibrillation (AF), cerebrovascular accident/transient ischemic attack (CVA/TIA), congestive heart failure (CHF), and peripheral arterial disease (PAD), while treatment includes percutaneous coronary interventions (PCI), coronary artery bypass graft surgery (CABG), and use of
implantable cardioverter defibrillators and cardiac resynchronization therapy with defibrillator (ICD/CRT-D). The study cohort includes point prevalent Medicare enrollees on December 31, 2011 who are age 66 and older, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, and not enrolled in an HMO in 2011. Patients with ESRD on or before December 31, 2011 are excluded.

Patients with ckd are identified using the same methodology described above in the section on data sources (referred to in this chapter as the claims-based method). ckd stage is defined based on the fourth digit of ICD-9-cM diagnosis code 485.x. Using the claims-based method, we identify those with AMI, AF, cVA/TIA, or cHF in 2011. Various sources of claims and types of codes are used to identify cardiovascular treatments. cABG is defined through ICD-9-cM procedure codes in inpatient claims only, ICD/CRT-D is defined through ICD-9-cM procedure codes in inpatient/outpatient claims, and PCI is defined through ICD-9-cM procedure codes in inpatient/outpatient claims or cPT codes in outpatient revenue claims or physician/supplier claims. PAD is defined through either diagnosis codes or procedure codes; if defined through diagnosis codes, we use the claims-based method; if defined through procedure codes, we employ the method used for PCI. The codes used to identify cardiovascular diseases and procedures are as follows:

- **AF**: 427.3 (ICD-9-cM diagnosis codes)
- **AMI**: 410 and 412 (ICD-9-cM diagnosis codes)
- **cHF**: 398.91, 428, 402.x1, 404.x1, and 404.x3
- **cVA/TIA**: 430–438 (ICD-9-cM diagnosis codes)
- **PAD**: 440–444, 447, and 557 (ICD-9-cM diagnosis codes)
- **cPT**: 398.91, 428, 402.x1, 404.x1, and 404.x3 using the claims-based method
- **AsHd**: 429
- **PAd**: 35081–35103, 35331, 35341, 35351, 35361, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35483, 35484, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35542, 35544, 35549, 35551, 35555, 35556, 35558, 35563, 35565, 35566, 35571, 35573, 35575, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35665, 35666, and 35671 (cPT codes)
- **cABG surgery**: 36.1X (ICD-9-cM procedure codes)
- **PCI**: 00.66, 36.01, 36.02, 36.05, 36.06, and 36.07 (ICD-9-cM procedure codes); 92980–92982, 92984, 92995–92996, 92999, and 90290, and 90291 (cPT/HCPcs codes)
- **ICD/CRT-D**: 37.94 and 00.51 (ICD-9-cM procedure codes)

The overall prevalence and age- and race-specific prevalence of each cardiovascular disease and treatment in 2011 are calculated for patients with ckd (overall and by ckd stage) and without ckd, respectively. Prevalence is represented per 100 patients.

Figure 4.1 presents the burden of prevalent AMI, cHF, and cVA/TIA in the Medicare ckd and non-ckd populations with cardiovascular disease in 2011. Methods of cohort construction and identification of AMI, cHF, and cVA/TIA are the same as those described for Table 4.2. Patients with cardiovascular disease are identified if they have AsHd, cHF, cVA/TIA, dysrhythmia, PVD, or other cardiovascular disease. ICD-9-cM diagnosis codes used to identify AsHd, dysrhythmia, PVD, and other cardiovascular disease are as follows:

- **AsHd**: 410–414, V45.81, and V45.82
- **dysrhythmia**: 426–427, V45.0, and V53.3
- **PVD**: 440–444, 447, 451–453, and 557
- **other cardiovascular disease**: 420–421, 423–424, 429, 785.0–785.3, V42.2, and V43.3

Figure 4.2 illustrates, by ckd status, the unadjusted survival of patients with a first diagnosis of cardiovascular disease or a cardiovascular procedure in 2009–2011. The study cohort includes Medicare enrollees with a first cardiovascular event or procedure in 2009–2011 (index date), age 66 or older, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare Parts A and B, and not enrolled in an HMO in the year before the index date. Patients with ESRD on or before the index date are excluded, as are patients with a pre-existing condition of interest in the year before the index event.

Pre-existing conditions of AMI, cVA/TIA, cHF, PAD, PCI, cABG, and ICD/CRT-D are identified using the same method described for Table 4.1. The pre-existing condition of cardiac arrest is defined through ICD-9-cM diagnosis codes 427.4 and 427.5. Patients with incident cHF are identified through ICD-9-cM diagnosis codes 398.91, 428, 402.x1, 404.x1, and 404.x3 using the claims-based method. Of note, diagnosis codes 422 and 425 are included in the definition of cHF as a comorbid condition, but not in the definition of cHF as an incident event. For AMI, events are identified by codes 410, 410.x0, and 410.x1 on inpatient claims. A cVA/TIA event is defined using diagnosis codes 430–437. The same codes and method defined for in Table 4.1 are used to define PAD, cardiac arrest, PCI, cABG, and ICD/CRT-D. ckd status/stage is defined in the year before the index date, also using the methodology described for Table 4.2. The index date is defined on the date of the first appearance of a claim with the qualifying diagnosis or procedure code. Patients are followed from the index date until the earliest date of death, two years after the index date, ESRD diagnosis, or December 31, 2011. The Kaplan-Meier method is used to estimate all-cause survival.

Table 4.2 describes pharmacological interventions for cardiovascular disease in Medicare enrollees. The cohort includes Medicare enrollees (in both Parts A and B) on January 1, 2011; age 66 and without ESRD; followed until the earliest death, ESRD
onset, cessation of Medicare coverage (with either Part A or B), or December 31, 2011. First cardiovascular disease events in the follow-up interval are identified with the claims-based method, as described for Table 4.a. For CHF, events are identified by ICD-9-CM codes 398.91, 402.x1, 404.x1, 404.x3, 425.x, and 428.x. For AMI, events are identified by codes 410, 410.x0, and 410.x1 on inpatient claims. For CV/A/TIA, events are identified by codes 430–437. For all other diagnoses and procedures, events are identified with the codes used in Table 4.a. The index date of each event is defined as the admission or service date of the first claim in the follow-up interval with a qualifying diagnosis code. cKD status/stage and baseline cardiovascular disease are ascertained from claims during the one year preceding the index date, and, in the case of ascertainment of baseline cardiovascular disease, algorithms and codes are the same as those used in Table 4.a.

Because Table 4.b and Figures 4.3–5 describe pharmacological interventions, only a subset of cardiovascular disease events is retained for analysis. Specifically, each patient is required to be discharged within two weeks of the index date of the event (if the patient was hospitalized on the index date), to not be hospitalized at one month after the index date, and to carry continuous Medicare Part D coverage during the interval from one month before to one month after the index date. This set of requirements establishes prescription drug coverage during an interval of time around the index date of the event, and admits sufficient cumulative time outside the hospital for the patient to fill a prescription at an outpatient pharmacy. Use of a medication is defined by at least one prescription fill between one month before and one month after the index date. Drugs are identified from National Drug Codes linked to Generic Product Identifiers, using the Medi-Span Master Drug Database.

In Table 4.b, all cardiovascular disease events that satisfy inclusion criteria regarding Medicare Part D coverage and hospitalization are retained for analysis, regardless of baseline cardiovascular disease status, except for events with an index date between December 1 and December 31, 2011, as Part D data after December 31 were unavailable. Patients with no cardiac event include those whose entire follow-up interval is marked by no cardiovascular disease events. In Figures 4.3–5, only the subset of cardiovascular disease events not accompanied by baseline disease are retained for analysis.

Table 4.c describes, across types of heart failure, the characteristics of CHF patients by age, gender, race, diabetic status, and medication use. The study cohort includes point prevalent Medicare enrollees in Parts A, B, and D on December 31, 2011 who are age 66 and older, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, and not enrolled in an HMO in 2011. Patients with ESRD on or before December 31, 2011 are excluded.

The CHF event is defined using the same method as in Figure 4.2, while types of heart failure are further defined through ICD-9-CM diagnosis codes, as follows: systolic heart failure, 428.2x; diastolic heart failure, 428.3x; both systolic and diastolic heart failure, 428.4x; and unspecified heart failure, 398.91, 428.xx (excluding 428.2x–428.4x), 402.x1, 404.x1, and 404.x3.

With two exceptions, a hierarchy order, based on clinical practice, is used to assign a single type of heart failure to patients with claims indicating different types of heart failure on the same date or on different dates within a year: systolic heart failure > both systolic and diastolic heart failure > diastolic heart failure > unspecified heart failure. The exceptions are 1) a patient having at least one claim for systolic heart failure and at least one for diastolic heart failure, and 2), a patient having a combination of claims for systolic, diastolic, and unspecified heart failure. In these cases, the type of heart failure (systolic vs. diastolic) is determined by the frequency of each type of claim in that year. For example, if the total number of systolic heart failure claims for a patient is greater than or equal to that of the claims for diastolic heart failure, the type is classified as systolic heart failure.

Medication use described in Table 4.c is defined by at least one prescription fill during 2011.

Figure 4.6 shows the distribution of heart failure type by cKD status in 2011, and uses the same study cohort as in Table 4.c.

Table 4.d illustrates adjusted hazard ratios of all-cause death for patients with and without cKD, and includes data on patients with each type of heart failure compared to those with none. The study cohort includes point prevalent Medicare enrollees on December 31, 2009 who are age 66 or older on December 31, 2009, residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, and not enrolled in an HMO in 2009. Patients with ESRD on or before December 31, 2009 are excluded.

Figures 4.7–10 illustrate unadjusted survival for Medicare patients by cKD status across different types of congestive heart failure. The study cohort includes point prevalent Medicare enrollees on December 31, 2009 who are age 66 or older on that date, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage and not enrolled in an HMO in 2009, diagnosed for CHF during 2009, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with ESRD on or before December 31, 2009 are excluded. The definitions of heart failure types and cKD status/stage are those defined above for Table 4.c and Table 4.a, respectively. Follow-up time is from January 1, 2010 until death or December 31, 2011. The Kaplan-Meier method is used to estimate all-cause survival.

Follow-up time is from January 1, 2010 until death or December 31, 2011. The Cox model is used to estimate, among cKD and non-cKD patients, the hazard ratio of all-cause death for patients with
systolic, diastolic, both systolic and diastolic, and unspecified heart failure compared with patients without heart failure, adjusting for age, gender, race, diabetes, hypertension, and other comorbidities, including atherosclerotic heart disease (ASHD), CVA/TIA, peripheral vascular disease (PVD), other cardiac disease, chronic obstructive pulmonary disease (COPD), gastrointestinal (GI) disease, liver disease, dysrhythmia, anemia, and cancer; each is defined in the entry year 2009. The codes used to define ASHD, CVA/TIA, PVD, other cardiac disease, and dysrhythmia are the same as those described for Table 4.a. Other comorbidities are defined using the ICD-9-CM diagnosis codes, as follows: GI disease, 456.0–456.2, 510.7, 531–534, 569.84, 569.85, and 578; liver disease, 570, 571, 572.1, 572.4, 573.1–573.3, and v42.7; anemia, 280–285; and cancer, 140–172, 174–208, 230–231, and 233–234.

Prescription drug coverage
chapter five

In Figures 5.5 and Table 5.a, we classify Part D enrollees as LIIS recipients if there exists at least one calendar month in 2011 with receipt of the LIIS. In Figures 5.6–8, we consider only those Part D enrollees who were not LIIS recipients during any calendar month of the index year. In all figures, patients enrolled in Medicare Advantage Part D (MA-PD) plans are excluded.

In this chapter we present Part D costs for several different populations. The general Medicare population includes all Part D enrollees (estimated from the 5 percent Medicare sample), while the CKD population includes only persons who survive all of year one, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage for this period, are not enrolled in an MA-PD plan, and have a qualifying CKD diagnosis (but do not have ESRD) during year one; this cohort is also drawn from the 5 percent Medicare sample. CKD stage is defined from claims. Costs are aggregated for year two for all Part D enrollees with CKD, with censoring at the earliest of death, development of ESRD, or the end of year two.

In Figures 5.9–11 and Table 5.d, the ESRD cohort is drawn from the 100 percent ESRD population, and includes all ESRD patients enrolled in Part D. Costs are presented as total Part D expenditures, estimated as the sum of the Medicare covered amount and the low income subsidy (LIS) amount (Figure 5.9), or as per person per year expenditures (Figures 5.10–11 and Table 5.d), also estimated as above. Figure 5.10 also presents out-of-pocket expenditures obtained from the prescription drug event record.

In Figures 5.12 and Tables 5.e, we consider only those Part D enrollees who were not LIIS recipients during any calendar month of 2011. In all figures, patients enrolled in employer group waiver plans or national Programs of All-inclusive Care for the Elderly (PACE) are excluded, as these types of plans do not report data concerning coverage phase progression of enrollees. In Table 5.e, diagnoses of hypertension, cardiovascular disease, diabetes, and cancer are ascertained from claims during 2010.

Figures 5.13–16 include CKD patients in the 2010 entry period, and show the cumulative probability of medication use during the twelve-month study period in 2011. The study cohort includes patients from the Medicare 5 percent sample (age 65 and above). All comorbidities are defined by medical claims (one inpatient or two outpatient) during the entry period.

Figures 5.17–20 show the percentage of patients on specific drugs during the eight quarters prior to and one quarter after ESRD initiation, based on CKD diagnosis codes. The cohort includes 2011 incident Medicare ESRD patients age 67 and older at the initiation of ESRD. These patients have two years of prior coverage with Parts A and B, and Part D coverage during the nine quarters.

Acute kidney injury
chapter six

In this chapter, patients with a hospitalization for acute kidney injury (AKI), or for AKI requiring dialysis (AKI-D) are identified
from inpatient claims by the presence of ICD-9-CM code 584.x or by indication of dialysis through any of the following: ICD-9-CM procedure codes 39.95 and 54.98; ICD-9-CM diagnosis codes V45.1, V56.0, and V56.1; CPT codes 90935, 90937, 90945, and 90947; and revenue codes 0800–0809. AKI hospitalizations with ESRD diagnosed before the AKI hospitalization discharge are omitted. For patients with multiple AKI hospitalizations through the years, only the first one in the time frame (one year) is counted. Annual cohorts are used throughout, so if the same patient is included in multiple cohort years, they could have a record of first AKI in each year. The second or greater AKI within the year is not counted. The event rate is estimated as the number of events per 1,000 patient years at risk.

Figure 6.1 displays the percentage of patients with at least one hospitalization for AKI or AKI-D in a given year. The cohort includes general Medicare patients age 66 or older on December 31 of the cohort year, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, with no HMO coverage, and who survive and are without ESRD for the entire cohort year.

The study cohorts used for Figures 6.2–4 include the general Medicare patients described for Figure 6.1 (Figure 6.2 uses the 2011 cohort only), along with Truven Health MarketScan and Clinimatics DataMart patients age 0–64 on December 31 of the cohort year who are enrolled in a fee-for-service plan.

The Medicare cohorts in Figure 6.5 and in all remaining figures use a more inclusive cohort methodology. These cohorts include patients who are fully covered by Medicare, alive, and without ESRD on January 1, but patients are not required to maintain this status for the entire cohort year. Patients are censored at the first date of death, loss of coverage, ESRD, or December 31. As was described earlier, at most one AKI (the first) is counted per patient, within each cohort year.

Figure 6.5 shows the type of dialysis used by hospitalized AKI-D patients. Modality is defined as follows: peritoneal dialysis, CPT codes 90945 or 90947 and 49420; continuous venous-to-venous hemodialysis (CVVHD), dialysis with CPT codes 90945 or 90947 but without 49420; intermittent hemodialysis (IHD), dialysis with CPT codes 90935 or 90937 and intermittent in the first three days; and daily hemodialysis (DHD), dialysis with CPT codes 90935 or 90937 and with three consecutive dialysis sessions in the first three days. To define modality, we first determine if there is any peritoneal dialysis during the period of the AKI event, and then look for continuous dialysis to identify hemodialysis or DHD. Those who are not identified by the above methods are categorized as having an unknown dialysis type. Figure 6.6 illustrates the principle diagnosis that appears on the AKI claims studied.

Figures 6.7–8 present hazard ratios for AKI hospitalization (1st within cohort year) adjusted for age, gender, and race. The study cohort includes the 2011 general Medicare patients first described for Figure 6.5. Each patient is followed from January 1, 2011 to the earliest date of death, ESRD diagnosis, change of enrollment, or December 31, 2011.

Figures 6.9–6.11 and 6.13 are limited to patients with an AKI in 2010, who are followed for one year (following the AKI in 2010) to look for a recurrent AKI (6.9–11) or an outpatient visit to a nephrologist (6.13). Figure 6.12 includes all non-ESRD patients with a hospitalization of any kind in 2010, who are followed for one year to look for a recurrent hospital admission, ESRD, or death. Results are stratified by patient renal status at the time of the initial hospitalization.

Figure 6.14 is limited to patients with a recurrent AKI, and they are followed for one year to look for an outpatient nephrologist visit. In Figure 6.15, prior CKD status (yes/no) is shown for both index AKI and recurrent AKI, and CKD claims during the six months before each event are used to identify those with CKD.

Testing in Figures 6.16–17 is identified as follows: creatinine testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; urine protein testing: CPT codes 82042, 82043, 82044, and 84156.

Figures 6.18–20 examine the use of several prescription medications before and after AKI hospitalization, and include Medicare patients with Part D coverage and at least one AKI in 2010.

Figures 6.21–23 display changes in CKD status following an AKI in 2010 or recurrent AKI hospitalization within one year, based on CKD claims before and after the hospitalization. The cohort includes all Medicare patients age 66 or older on December 31, 2010. CKD claims are identified in the one year prior and one year following the AKI admission date and CKD stage is defined with the method described previously, under “identification of major comorbidities.” ESRD is defined by the ESRD date.

Figure 6.24 shows discharge status following an AKI hospitalization in 2011. Patients with a status of “home” or “home health” are identified as being discharged home, while those identified as institutionalized are those whose discharge status included “Skilled Nursing Facility,” “Long-term Care Hospital,” or “Rehabilitation.”

Costs of CKD

The general Medicare point prevalent cohort used in Figures 7.1–17 includes persons age 65 and older who survive all of year one, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage for this period, are not enrolled in an HMO, and do not have ESRD during year one. Costs are aggregated for year two, with censoring at the earliest of death, development of ESRD, change in payer status, or the end of year two. Figure 7.2 also includes Truven Health MarketScan (THMS) point prevalent CKD patients, and the cohort is constructed in a similar fashion, but limited to patients age 50–64.

Costs are categorized in several ways throughout this chapter. For Figures 7.1, 7.5–7, 7.9–12, 7.17–18, and Table 7.b, costs are
simply total claims-based expenditures, while those in 7.2–4, 7.8, 7.13–16, 7.19–7.25, and Table 7.a are claims-based expenditures on a person per person per year (PPPY) basis.

Important comorbidities (diabetes, CKD, and CHF) are determined for these cohorts from Medicare claims using a previously validated method, as described earlier in the section on identification of major comorbidities. Costs in Figures 7.5–8 are presented for the 1992–2010 cohorts; the cost year is always the year after the cohort year.

The THMS population used in Figure 7.2 includes patients age 50–64, and is constructed in the same fashion as that for the Medicare population, requiring continuous enrollment in a fee-for-service health plan. Patients identified as having ESRD are excluded, and the cohorts are from 2007 to 2010 (cost years 2008–2011).

Figures 7.9–18 and Tables 7.a–b present Medicare Part D costs. Populations used in these figures are derived from the point prevalent Medicare population (described above), with the further restriction that each individual included in the population is enrolled in Part D for the full 12 months of the analysis year and has a qualifying diagnosis of CKD. Costs are estimated Medicare net pay, which is the sum of plan covered payments and low income subsidy payments. Costs do not include out-of-pocket expenditures, which are displayed separately in Figures 7.13–14.

Figures 7.9–11 and 7.15 show total Part D expenditures, while other figures use PPPY expenditures.

Figures 7.19–25 present costs during the transition to ESRD. Medicare populations in these figures are limited to those who are age 67 or older at the time of ESRD initiation and who have Medicare as primary payer during the transition period. Figures 7.19–21 are also limited to those who have Part D coverage during the transition. THMS populations are limited to those younger than 65 as of ESRD initiation. Comorbidities of diabetes and hypertension in 7.20–21 are identified from claims prior to ESRD. Expenditures for inpatient services in Figures 7.22–25 represent costs from Part A inpatient claims (Medicare) or hospital claims (THMS) only.

Causes of hospitalization in Figures 7.23–25 are identified by the principal diagnosis code on the claim, and represent ICD-9-CM diagnosis codes presented throughout the methods section to identify cardiovascular and infectious causes. Vascular access cause is identified by diagnosis codes 996.62 or 996.73.

Figure 7.26 shows the cumulative probability of receiving the CMS Kidney Disease Education System benefit, implemented on January 1, 2010. Patients with CKD of Stages 4–5 and age 65 and older are identified from the Medicare 5 percent data, and followed for one year starting on January 1, 2011. ESRD patients are age 67 and older, with an initiation date between April 1, 2011 and December 31, 2011. Data from one year prior to the initiation date are examined for use of the education benefit prior to ESRD.

Tables 8.1–6 present estimated point prevalent (December 31) counts of the general Medicare non-ESRD population, based on the 5 percent Medicare sample.

Tables 8.1–5 present estimates of per person per year costs for point prevalent (December 31) general Medicare patients, also derived from the 5 percent Medicare sample. The cohorts include those who survive all of year one, are continuously enrolled with Medicare inpatient/outpatient and physician/supplier coverage, are not enrolled in Medicare Advantage, and do not have ESRD during year one. Costs are aggregated for year two, with censoring at the earliest of death, development of ESRD, change in payer status, or the end of year two. Important comorbidities are determined for these cohorts from Medicare claims using a previously validated method, as described earlier in the section on identification of major comorbidities. Expenditures are presented for the 1993–2011 cohorts, and the cost year is always the calendar year after the cohort year.

Hispanic ethnicity is considered a separate racial category in the general Medicare data. Patients younger than 20 are excluded. Cost data for 2006 and following years include Part D.