Science kills credulity and superstition, but to the well-balanced mind it enhances the feeling of wonder, of veneration, and of kinship which we feel in the presence of the miraculous universe.

JOHN BURROUGHS,
Accepting the Universe
In this appendix we describe the datasets and methods used for ckd analyses. Data management and preparation, database definitions, and the data sources used for esrd 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 (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

**ESRD MEDICAL EVIDENCE FORM (CMS 2728)**
The ESRD Medical Evidence (ME) form is 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.
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 (PS), 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 2012 ADR includes all claims up to December 31, 2010.

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 (1992–2009), and Cost and Use (1992–2008), with the 2009 and 2008 files, respectively, the latest updates for the 2012 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 (TROOP) amounts, plan paid amounts, and low-income cost-sharing subsidy amounts.

Due to delays in the availability of the data, only the 2006 and 2007 PDE files were available for the 2010 ADR. PDE data from 2008 were included in the 2011 ADR. Starting with the 2012 ADR, however, PDE data are in-sync with ESRD claims, so 2009 and 2010 PDE data are both included in this ADR.

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

The MarketScan database links billing and encounter data to detailed patient demographic and enrollment information across sites and types of providers, and over time from 1999 to 2010, and includes commercial health data from approximately 100 payors; about 80 percent of those covered are self-insured. Each year the database contains health data for about 10.5 million people. For details about the MarketScan data, please visit www.usrds.org.

Ingenix i3 Data
The Ingenix i3 database is a commercial, 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 Ingenix i3 database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2010, 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.

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 was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2010 were nationally representative cross-sectional surveys and used a complex, stratified, multi-stage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey
participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

**PAYORS**

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

The construction of this file is similar to that of the treatment history file. Payor status is maintained for each ESRD patient from the first ESRD service date until death or the end of the study period. Payor data are used to categorize a patient as MPP. Medicare as secondary payer (MSP) with EGHP, MSP non-EGHP, Medicare Advantage (Medicare + Choice), Medicaid, or a combination of payors. With this approach, the USRDS is now able to apply payor status information in all outcome analyses using the “as-treated” model (see the discussion of Chapter Eleven 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 MarketScan and Ingenix i3 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, 301.x–305.x, 372.0, 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.x0 and 404.x1 (after October 1, 2006), 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; congestive heart failure, 398.91, 402.x1, 404.x3, 422.xx, 425.xx, 428.xx, 424.2; and CVD (other than CHF), 404.x1, 410–414, 420–421, 423–424, 426–427, 429, 430–438, 440–444, 447.41–453.55, 757, 785.0–785.3, 452.2, 453.3, 455.0, 455.81, 455.82, and 753.3.

**CKD in the general population**

chapter one


The statistical software package SUDAAN, version 10.0.0, 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 or 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: eGFR = 141 × min(Scr/κ, 1) a × max(Scr/κ, 1) b × 0.993age × 1.018 [if female] × 1.21 [if black/African American], where Scr is standardized serum creatinine in mg/dl, α is 0.7 for females and 0.9 for males, and β is 0.359 for females and 0.411 for males, min(Scr/κ, 1) indicates the minimum of Scr/κ or 1, and max(Scr/κ, 1) indicates the maximum of Scr/κ or 1 (Levey et al.).

Albumin/creatinine ratio (ACR) is the ratio of urinary albumin (mg/g) to urinary creatinine (mg/dl). Based on an NCHS suggestion, urine creatinine value is adjusted to NHANES 2007–2008.

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

**estimated glomerular filtration rate (eGFR)**

The estimated glomerular filtration rate (eGFR) is calculated using the CKD-EPI equation, based on the National Center for Health Statistics recommended standardized creatinine values. The CKD-EPI equation is: eGFR = 141 × min(Scr/κ, 1) α × max(Scr/κ, 1) b × 0.993age × 1.018 [if female] × 1.21 [if black/African American], where Scr is standardized serum creatinine in mg/dl, α is 0.7 for females and 0.9 for males, β is 0.359 for females and 0.411 for males, min(Scr/κ, 1) indicates the minimum of Scr/κ or 1, and max(Scr/κ, 1) indicates the maximum of Scr/κ or 1 (Levey et al.).

**Ankle/arm blood pressure ratio (ACR)**

The ankle/arm blood pressure ratio (ACR) is the ratio of systolic blood pressure in the ankle to the systolic blood pressure in the arm. Based on a previously validated method, the ACR is defined as the ratio of systolic blood pressure in the ankle to the systolic blood pressure in the arm. The ACR is calculated using the following formula: ACR = (Systolic pressure in the ankle / Systolic pressure in the arm) × 100.

**center for disease control and prevention (CDC)**

The Center for Disease Control and Prevention (CDC) is a federal agency within the Department of Health and Human Services that provides national leadership for public health protection and promotion. The CDC's mission is to protect Americans from serious, chronic, and infectious diseases, injuries, and environmental exposures, and improve and extend their quality of life.
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) glycoshemoglobin ≥ 7 percent. Participants with self-reported diabetes are those who report having been told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). In NHANES 2005–2010, participants answering “borderline” are classified as non-diabetic to agree with NHANES III coding. Control of diabetes is assessed as a glycoshemoglobin of < 7 percent.

Patients with hypertension are those with either 1) high blood pressure, defined as systolic blood pressure above 140 mmHg (>130 mmHg for those with CKD or self-reported diabetes) or diastolic blood pressure above 90 mmHg (>80 mmHg for those with CKD or self-reported diabetes), or 2) an affirmative answer to the question “Are you now taking prescribed medicine for high blood pressure?” Self-reported hypertension is identified through an affirmative answer to the question “Have you ever been told by a doctor or other health professional that you had hypertension, also called high blood pressure?” Patients are classified as being aware of hypertension if they report having been told they have high blood pressure, are classified as being treated for hypertension if they report currently taking a prescription to control hypertension, and are considered in control of hypertension if current blood pressure is <140/<90 (<130/<80 for CKD or diabetic patients).

Participants who self-report any of the following diseases are considered to have cardiovascular disease: angina, myocardial infarction, stroke, coronary heart disease, or congestive heart failure.

Hypercholesterolemia (LDL cholesterol) is measured in the medical examination. We assess whether LDL falls within the ATP III target range (≤100 mg/dl for patients with coronary heart disease (CHD) and CHD risk equivalents, including CKD, ≤130 mg/dl for patients with two or more risk factors, and ≤160 mg/dl for patients with 0–1 risk factors) based on measured LDL level and associated risk factors (http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.pdf). Similar to hypertension, awareness of hypercholesterolemia is 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. LDL 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).

identification & care of patients with CKD

Chapter Two

Figure 2.1 illustrates the extent of point prevalent diabetes, cerebrovascular accident/transient ischemic attack, congestive heart failure, and CKD in the general Medicare population. Methods are the same as those described at the beginning of Chapter Six.

Table 2.1 compares the characteristics of prevalent general Medicare, MarketScan, and Ingenix CKD patients by age, gender, race, ethnicity, and comorbidity in 2010. Table 2.6 includes prevalent non-ESRD Medicare patients age 65 and older, alive at the end of 2010, and prevalent MarketScan and Ingenix 13 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, MarketScan, and Ingenix 13 populations. The 5 percent Medicare sample includes patients age 65 and older, without ESRD, who survive throughout the cohort year with Medicare as primary payor, and who are not enrolled in Medicare Advantage. The MarketScan and Ingenix 13 cohorts are constructed in a similar fashion, but are restricted to patients age 20–64, enrolled in a fee-for-service plan, and without 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, or are enrolled in a managed care program (HMO), acquire Medicare as secondary payor, 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 payor 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 2010. The cohort is the same as that described for 2009–2010 in 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 Medicare and MarketScan columns of Tables 2.d–e include patients who are alive with full coverage for all of 2010. The CKD diagnosis code (all or 585.3–585.6), as well as the disease burden, are determined from claims in 2010. Table 2.f and Figures 2.6–8 reflect the results of adjusted logistic regression on the Medicare and MarketScan 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 2009, 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 2009 is used as the date of 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. Figures 2.13–16 include CKD patients in the 2009 entry period, and show the cumulative probability of medication use during the twelve-month study period in 2010. The study cohort includes MarketScan patients (age 50–64) and patients from...
the Medicare 5 percent sample (age 65 and above); MarketScan patients have fee-for-service coverage during the entry period and medical coverage and drug insurance during the study period. All comorbidities are defined by medical claims (one inpatient or two outpatient) during the entry period.

Figures 2.17–20 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 2010 incident Medicare ESRD patients age 67 and older at the initiation of ESRD, and MarketScan patients age 20–64. Medicare ESRD patients have two years of prior coverage with Parts A and B, and have Part D coverage during the nine quarters, while MarketScan patients have fee-for-service coverage and drug insurance during the nine quarters.

general hospitalization & mortality
chapter three

general 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, 2010, who are age 66 and older on December 31, 2009. For the CKD and non-CKD cohorts, during 2009 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, 2010 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 are excluded with a transplant, loss to follow-up, or end of payor status before day 30 after discharge. For general Medicare patients, discharges are excluded with a first ESRD service date or end of payor status (not due to death) before day 30. Rates reflect the percentage of live discharges followed by a rehospitalization and/or death within 30 days.

Table 3.4 and Figures 3.2–3 show adjusted all-cause admission rates in Medicare patients age 66 and older. The study design consists of a one-year period (2009) during which CKD, comorbidities, and prior hospitalization are defined from claims, followed by the cohort year (2010) when follow-up for admissions begins on January 1. The Medicare cohort includes patients who are age 66 and older on December 31, 2009, 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 HMO coverage, are without ESRD, and who survive the complete year prior to follow-up. Patients are followed for admissions from January 1, 2010, and are censored at the earliest of death, ESRD initiation, end of plan coverage, or December 31, 2010. 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 2010, 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, Ingenix 13 and MarketScan data include point prevalent patients on January 1, 2010, continuously enrolled in a fee-for-service or commercial health plan and without ESRD during 2009, and age 50–64 on December 31, 2009. The group labeled "CKD" includes those with claims-based evidence of CKD in 2009, while "non-CKD" is defined as patients without claims-based evidence of CKD. Rates are adjusted for gender, prior hospitalization, ASHD, CHF, CVA, PVD, dysrhythmia, other cardiac disease, diabetes, COPD, hypertension, liver disease, gastrointestinal disease, cancer, and anemia. 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 Volume Two. The reference cohort includes Medicare patients in 2010, 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 2010. 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 2005.

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, 2010, age 66 and older on December 31, 2009. Additionally, CKD stage is defined during 2009. 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 principal ICD-9-CM diagnosis codes listed for Figure 3.1 in the Analytical 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, 2010, 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 PA and B coverage during the 30 days after discharge. Quarterly rates are displayed during 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 principal ICD-9-CM diagnosis codes listed for Figure 3.1 in the Analytical Methods section in the appendix 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 1996–2010 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 2005 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 2010 patients are used as the reference cohort.

cardiovascular disease in patients with CKD

chapter four

Table 4.a describes the prevalence of cardiovascular disease and treatment in Medicare enrollees. Cardiovascular disease include acute myocardial infarction (AMI), atrial fibrillation (AF), cerebrovascular accident/transient ischemic attack (CVA/TIA), congestive heart failure (CHF), and peripheral arterial disease (PAD), while treatment include 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, 2010 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 2010. Patients with ESRD on or before December 31, 2010 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 585.x. Using the claims-based method, we identify those with AMI, AF, CVA/TIA, or CHF in 2010. 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 outpatient claims, and PCI is identified through ICD-9-CM procedure codes in 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.x (ICD-9-CM diagnosis codes)
- **AMI**: 410 and 412 (ICD-9-CM diagnosis codes)
- **CHF**: 398.91, 422, 425, 428, 402.x1, 404.x1, and V42.1 (ICD-9-CM diagnosis codes)
- **CVA/TIA**: 430–438 (ICD-9-CM diagnosis codes)

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\text{PAD:} & \quad 440–444, 447, \text{and } 557 \text{ (ICD-9-CM diagnosis codes); } 84.0, 84.1, 84.91, 39.25, 39.26, \text{and } 39.29 \text{ (ICD-9-CM procedure codes); } 24900, 24920, 25900, 25905, 25920, 25927, 27395, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 24900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34205, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, and 35671 (CPT codes)
- **CABG surgery**: 36.1x (ICD-9-CM procedure codes)
- **PCI**: 00.66, 36.01, 36.02, 36.05, 36.06, and 36.07 (ICD-9-CM procedure codes); 92980–92982, 92984, 92995–92996, G0290, and G0291 (CPT/HCPCS codes)
- **ICD/CRT-D**: 3794 and 00.51 (ICD-9-CM procedure codes)

The overall prevalence and age- and race-specific prevalence of each cardiovascular disease and treatment in 2010 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 population with cardiovascular disease in 2005 and 2010. Methods of cohort construction and identification of AMI, CHF, and CVA/TIA are the same as those described for Table 4.a. Patients with cardiovascular disease are identified if they have ASHD, CHF, CVA/TIA, dysrhythmia, PVD, or other cardiac disease. ICD-9-CM diagnosis codes used to identify ASHD, dysrhythmia, PVD, and other cardiac 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 cardiac disease**: 420–421, 423–424, 429, 785.0–785.3, V42.2, and V43.3

Figure 4.2 describes the percentage of patients with incident CHF receiving diagnostic testing at or up to 90 days after CHF diagnosis in 2000 and 2010. The cohort of incident CHF patients in 2010 includes point prevalent Medicare enrollees on January 1, 2010, with their first CHF diagnosis (index event) during 2010, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, not enrolled in an HMO during the one-year period before the index event, age 66 or older on the date of the index event, and residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with incident CHF are identified through ICD-9-CM diagnosis codes 398.91, 425.x, 428.xx, 402.x1, 404.x1, and 404.x3 using the claims-based method, and the index date is defined on the date of the first appearance of a claim with the qualifying diagnosis codes. The twelve-month period prior to the index event
is the baseline period. Patients with ckd and pre-existing chf are identified during the baseline period using the method described for Table 4.a. We exclude patients who are diagnosed with esrd prior to the index event and those with pre-existing chf. Follow-up for testing begins on the chf diagnosis date and ends on the earliest of death, esrd diagnosis, change of enrollment status, 90 days after chf diagnosis, or December 31, 2010. The same methods are used to construct the cohort of incident chf patients in 2000.

Diagnostic testing for patients with chf includes resting echocardiogram, coronary angiography, non-invasive coronary angiography, or any stress test including stress echocardiograms, stress nuclear imaging, stress test, and stress electrocardiograms (ecgs). Patients received these tests are identified through icd-9-cm procedure codes in inpatient/outpatient claims or cpt/HCPCS codes in outpatient revenue claims or physician/supplier claims. Codes used to define these tests are as follows:

- resting echocardiogram: 93313, 93304, 93306–93308, 93312–93318, 93320, and 93321 (cpt codes)
- coronary angiography and/or catheterization: 37.22–37.23 and 88.53–88.57 (icd-9-cm procedure codes); 93508, 93510, 93511, 93524, 93526, 93527, 93529, 93531–93533, 93539, 93540, 93543, 93545, and 93555 (cpt codes)
- non-invasive coronary angiography: 75571–75574 (cpt codes; available in 2010)
- stress echocardiograms: 93350 (cpt code)
- stress nuclear imaging: 78459–78461, 78464, 78465, 78469, 78472, 78473, 78478, 78480, 78481, 78483, 78491, and 78492 (cpt codes)
- stress test: 89.41–89.44 (icd-9-cm procedure codes)
- stress ecgs: 93015–93018 (cpt codes)

The percentage of patients receiving each test is calculated as the number of patients tested during the follow-up period divided by the total number of patients at the beginning of follow-up; this is presented by ckd status for the 2000 cohort and by ckd status/stages for the 2010 cohort.

Figure 4.3 illustrates rates of fatal and non-fatal ami by ckd status. The study cohorts include patient prevalent Medicare enrollees on January 1 of 2007 or 2010, 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 the prior year. Patients with esrd on or before December 31 of the prior year are excluded. ami is identified through icd-9-cm diagnosis codes 410, 410.x0, and 410.x1 on inpatient claims. Fatal ami is defined if a patient died on the same day of admission for ami or one day later regardless of discharge status recorded on the inpatient claims, or if the patient died in the hospital. Follow-up for ami event begins on January 1 and ends on the earliest of ami hospitalization, death, esrd diagnosis, change of enrollment status, or December 31 of 2007 or 2010. Rates are unadjusted and estimated as the number of patients who have an ami event per 1,000 patient years at risk.

Figures 4.4–7 describe the three-year cumulative probability of death in Medicare patients with a first diagnosis of ami, cva/tia, chf, or a cv procedure (pci or cabs) (index event) in 2007–2008. The study cohorts are constructed as for Figure 4.2, except that the period searched for the index event is 2007–2008. As with Figure 4.2, patients with a pre-existing condition of interest in the year before the index event are excluded. Pre-existing conditions of ami, cva/tia, and chf are identified using the same method described for Table 4.a. Chf and ami events are defined using the methods described for Figures 4.2 and 4.3, respectively. A cva/tia event is defined using the method described for Table 4.a and diagnosis codes 430–437. The same method is used to define pre-existing conditions and events of pci or cabs. Follow-up begins on the index event date and ends at the earliest of death, esrd diagnosis, three years after the index event, or December 31, 2010. The Kaplan-Meier method is used to estimate all-cause survival. Cumulative probabilities of death are obtained by subtracting the cumulative survival probabilities from one. Table 4.b describes pharmacological interventions for cardiovascular disease in Medicare enrollees. For each year (2007 and 2010), the cohort includes Medicare enrollees (in both parts A and B) on January 1, age 66 and without esrd, followed until the earliest of death, esrd onset, cessation of Medicare coverage (with either Part A or B), or December 31. First cardiovascular disease events in the follow-up interval are identified with the claims-based method, as described for Figure 4.2. For ami, events are identified by icd-9-cm codes 410, 410.x0, and 410.x1 on inpatient claims. For cva/tia, events are identified by codes 430–437. And for all other diagnoses and procedures, events are identified with 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.

Because Table 4.b and Figures 4.8–10 describe pharmacological interventions, only a subset of cardiovascular disease events was 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 December 1 and December 31 of 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.

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. For 2007, events with an index date between January 1 and December 31 are analyzed, whereas for 2010, events with an index date between January 1 and November 30 are analyzed (as part d data after December 31, 2010, were unavailable). Patients with no cardiac event include those whose entire follow-up interval is marked by no cardiovascular disease events. In Figures 4.8–10, only the subset of cardiovascular disease events not accompanied by baseline disease are retained for analysis. In Figures 4.9–10, patients are followed from one month after the index date to the earliest of earliest of death, esrd onset, cessation of Medicare coverage (with either Part A or B), or December 31, 2010.

prescription drug coverage in ckd patients

In figures and tables regarding enrollment and utilization of Medicare part d, we analyze cohorts of Medicare enrollees in 2006–2010.
based on the 5 percent sample (general Medicare enrollees), and with non-dialysis-dependent chronic kidney diseases (CKD). We also analyze cohorts of Medicare enrollees receiving dialysis or with a functioning kidney transplant (based on 100 percent ESRD population). For general Medicare enrollees or enrollees with non-dialysis-dependent CKD, we require continuous enrollment in Medicare Parts A and B during the previous calendar year, no participation in Medicare Advantage during the previous year, and Medicare enrollment in January of the index year. CKD is identified from diagnosis codes on claims during the previous calendar year. For the dialysis and kidney transplant cohorts we retain all patients who were alive and enrolled in Medicare on January 1 of the index year and whose ESRD onset was at least 90 days earlier; treatment modality is identified on January 1.

In Figures 5.2–4, the type of prescription drug coverage is defined sequentially. That is, we first classify patients as “Part D with LIS” if there exists at least one calendar month in 2010 with Part D enrollment and receipt of low-income subsidy (LIS). In patients without one such month, we classify remaining patients as “Part D without LIS” if there exists at least one calendar month with Part D enrollment. In patients without one such month, we classify remaining patients as “retiree drug subsidy” if there exists at least one calendar month with employer receipt of the subsidy. In patients without one such month, we classify remaining patients as “other creditable coverage” if there exists at least one calendar month with enrollment in military, government employee, or employer group health plans.

In Figures 5.5 and Table 5.a, we classify Part D enrollees as LIS recipients if there exists at least one calendar month in 2010 with receipt of the LIS. In Figures 5.6–8, we consider only those Part D enrollees who were not LIS 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 Figures 5.12–14 and Tables 5.e–f, we consider only those Part D enrollees who were not LIS recipients during any calendar month of 2010. 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 Figure 5.13, follow-up begins on January 1, 2010, and in Figure 5.14, follow-up begins on the date of entry into the coverage gap. In Table 5.e, diagnoses of hypertension, cardiovascular disease, diabetes, and cancer are ascertained from claims during 2009. In Table 5.f, a fill is simply defined as a transaction billed to Part D.

Part D costs for several different populations are presented in this chapter. 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, and are not enrolled in a Medicare Advantage Part D (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. The ESRD population (Figures 5.9–11 and Table 5.d) are drawn from the 100 percent ESRD population. ESRD includes all ESRD patients enrolled in Part D. Costs are presented as total Part D expenditures, which are 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), also estimated as above. Figure 5.10 also presents out-of-pocket expenditures obtained from the prescription drug event record.

Tables 5.g–i show the top Part D drugs by frequency, as judged from the total days supply (obtained from the prescription drug event record), as well as by cost. Figures 5.15 (general Medicare), 5.16 (CKD) and 5.17 (ESRD) show the frequency of prescriptions for Part D drugs, by class (based on Medi-Span’s generic product identifier therapeutic classification system) as well as costs.

**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. Patients with ESRD diagnosed before the AKI hospitalization discharge are omitted, except as indicated. For patients with multiple AKI hospitalizations through the years, the first one in the time frame is 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 hospitalized 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 in the cohort year.

Figure 6.2 shows the demographic characteristics of patients suffering AKI. The study cohort includes the general Medicare patients described for Figure 6.1 (Figure 6.2 uses the 2010 cohort), along with MarketScan and Ingenix i3 patients age 20–64 on December 31 of the cohort year who are enrolled in a fee-for-service plan.

Figures 6.3–4 show rates per time at risk, while 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 AKI claims.

Figures 6.7–8 present hazard ratios for AKI hospitalization, adjusted for age, gender, and race. The study cohort includes 2010 general Medicare patients age 66 and older, along with 2010 MarketScan and Ingenix i3 patients age 20–64. Patients with ESRD before January 1, 2011, are excluded. Each patient is followed from this date to the earliest of death (Medicare patients only), ESRD diagnosis, change of enrollment, or December 31, 2010.

Figures 6.9–13 are limited to patients with an AKI in 2009, who are followed for one year to look for a recurrent AKI (6.9–11), ESRD or death (6.12), or an outpatient visit to a nephrologist (6.13). Figure 6.14 is limited to patients with a recurrent AKI in 2009, and they are followed for one year to look for an outpatient nephrologist.
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 payor status, or the end of year two. Figure 7.2 also features the MarketScan point prevalent CKD population, 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, 7.11, and 7.12–14, costs are simply total claims-based expenditures, while those in 7.2–4, 7.8, 7.15–16, and Table 7.4 are claims-based expenditures on a 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 1992–2009 cohorts; the cost year is always the year after the cohort year.

The MarketScan population used in Figure 7.2 includes patients age 50–64, and is constructed in the same fashion as that described 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 2006 to 2009 (cost years 2007–2010).

Figures 7.9, 7.11, 7.15–17, and Table 7.4 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 7.15 and 7.17. Figures 7.9 and 7.11–14 show total Part D expenditures, while other figures use PPPY expenditures.

reference tables: CKD

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 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 payor 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 1993–2010 cohorts, and the cost year is always the calendar year after the cohort year.