Volume 1: CKD Analytical Methods

Contents

Introduction

In this chapter we describe the data sources, preparation and management, variable definition, and analytic methods used to produce the statistics presented in Volume 1 of the 2016 USRDS Annual Data Report (ADR), which focuses on chronic kidney disease (CKD) prior to end-stage renal disease (ESRD). Datasets and methods used for ESRD analyses are described in the ESRD Analytic Methods chapter of Volume 2.

Data Sources

The USRDS uses several data sources to describe pre-ESRD kidney disease in the United States (U.S.), through obtaining data on diagnoses, demographic characteristics, health care procedures, prescription drug plan participation, and filled prescriptions. Data on the non-institutionalized, general population were obtained from the National Health and Nutrition Examination Survey (NHANES) and the Behavioral Risk Factor Surveillance System (BRFSS). For patients with CKD, acute kidney injury (AKI) and related comorbidities, data from three health care systems were used: the standard Centers for Medicare and Medicaid Services (CMS) Medicare 5% sample, the Clinformatics™ Data Mart Database of people with commercial health insurance plans as obtained from OptumInsight, and the Veterans Administration.

National Health and Nutrition Examination Survey

NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the U.S. Centers for Disease Control and Prevention (CDC). Begun in 1959, NHANES was designed to monitor the health and nutritional status of the non-institutionalized civilian population in the U.S.. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous, annual survey to provide for regular estimates, with the release of public-use data files every two years. Both NHANES III and NHANES 1999–2014 were nationally-representative, cross-sectional surveys with a complex, stratified, multi-stage probability cluster sampling design that included the selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households (Johnson et al., 2013). Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both sets of surveys over-sampled African Americans, Mexican Americans, and individuals aged 60 or older to improve the estimates for these subgroups.

Behavioral Risk Factor Surveillance System

The BRFSS is a series of telephone-based surveys of health-related risk behaviors, chronic health conditions, and use of preventive services; BRFSS sampling is designed to provide state-specific estimates (CDC, 2015). Like NHANES, it is also conducted by the CDC through the NCHS. BRFSS began in 1984 with 15 states, and expanded nationwide in 1993. As of 2011, in addition to traditional land-line subscribers, cell phone users were included in the sample frame. A question regarding kidney health was added in 2012—specifically, respondents were asked, "Has a doctor, nurse, or other health professional ever told you have kidney disease? Do NOT include kidney stones, bladder infection or incontinence (Incontinence is not being able to control urine flow)." Allowable responses were "yes", "no", and "not sure", with additional coding for "refused to answer" and "missing/not asked." Of the 475,687 respondents in 2012, only 202 respondents refused to answer (0.04%), three were missing, and 1,322 answered "not sure" (0.28%).

Clinformatics™ Data Mart Database (OptumInsight, Eden Prairie, MN)

The Clinformatics™ Data Mart data provides paid medical and prescription claims and enrollment information for national participants in commercial insurance plans of a large U.S. managed care health insurance company. The data is purchased from OptumInsight, and participants are enrolled in both a medical and a prescription plan.

The Clinformatics™ data license requires that data not be merged with any other data files, so we are unable to match these individuals with the USRDS ESRD databases to comprehensively identify ESRD patients. Therefore, we assign these individuals a first service date for ESRD as the date of either the first

claim with a diagnosis of ESRD, a procedure code for outpatient dialysis, or a diagnosis related group (DRG) code for a kidney transplant surgery. See Table m.1 for specific code values. We present Clinformatics™ data from 2005 through 2014 in the 2016 ADR.

To comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) and prevent the re-identification of individuals in the database, certain combinations of sensitive data elements are not allowed. OptumInsight provides the data as different "views", each containing a limited amount of sensitive data. For this report, we used the Date of Death (DOD) view of the data; detailed geographic and socio-economic data were not available in the files, but date of death was included. The other available data views do not contain death date. Enrollment and member information, such as year of birth, gender, race/ethnicity, state of residence, and plan participation, are contained in the MEMBER and MEMBER_DETAIL data tables. A summarized facility detail record for each inpatient episode occurring in an acute care hospitalization or skilled nursing facility setting is contained the inpatient CONFINEMENT data table, while all services for both inpatient and outpatient care are located in the MEDICAL claims data table.

vol 1 Table m.1 ICD-9-CM diagnosis, CPT procedure, and DRG codes used to define ESRD in the Clinformatics™ and VA datasets throughout Volume 1 of the ADR

Type of Code		Code Values
ICD-9-CM Diagnosis codes		585.6, 996.81, V42.0, V45.1, V56.0, V56.1, V56.2, V56.3, V56.31, V56.32, V56.8, E879.1
CPT Procedure codes		90935, 90937,90940, 90945, 90947, 90951-90970, 90989, 90993, 90997, 90999; *codes from earlier years: 90918-90925*
DRG Codes	Prior to FY2007:	302,512
	FY2007-present:	652,008

Abbreviations: CPT, current procedural terminology, DRG, diagnosis related group, FY, fiscal year (10/1/06 to 9/30/07), ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification.

The MEMBER and MEMBER_DETAIL are processed to create an enrollment table by deleting observations with data inconsistencies and combining enrollment periods with a non-coverage gap of less than one month. Enrollment observations are dropped if: (1) the year of birth variable, YRDOB, is missing or zero, (2) the year of the plan coverage effective date, ELIGEFF, is *before* the year of birth, (3) the year of plan coverage effective date is *after* the year of the death date, (4) the coverage ending date, ELIGEND, is the *same as or earlier than* the coverage start date, or (5) the member has more than one year of birth reported and they differ by more than one year. Observations from MEMBER_DETAIL with overlapping enrollment periods (defined as ELIGEFF through ELIGEND) are combined into one. Observations where the gap between the end date (ELIGEND) of the first period (i.e., observation) and the start (ELIGEFF) of the second period is less than one month are also combined, as beneficiaries with brief coverage lapses do not present as significantly different than those with continuous coverage.

Date of death information is provided as month and year only and not a specific date. Insurance claims do not have information on death unless the death occurred during a covered inpatient stay as identified through the discharge status (DSTATUS). The insurance company may only be informed that the member's coverage has ended. The Clinformatics™ Data Mart is augmented with data from the Social Security Death Master File (SSDMF). In November of 2011, however, some states stopped reporting death information to the SSDMF, causing a 30% drop in the number of death records contained in the database (OptumInsight 2015).

Centers for Medicare and Medicaid Services Medicare 5% Sample

These files contain billing data from final action claims on behalf of Medicare beneficiaries; all adjustments have been resolved and submitted to Medicare for reimbursement by health care providers. CMS and its contractors produce the 5% data sets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claims (HIC) number has the last two digits of 05, 20, 45, 70 or 95. These five two-digit pairs were randomly selected to create a sample containing five percent of the total number of Medicare beneficiaries (Merriman and Asper, 2007). The sample design has the effect of creating a built-in longitudinal panel dataset. Once in the sample, a beneficiary will remain a part of all future-year data files until death or a change to their HIC number. Since 2015, the USRDS Coordinating Center has received the data files from the Medicare Chronic Conditions Warehouse contractor. The files, described below, are collectively referred to in the ADR as the Medicare 5% files. The 2016 ADR includes all claims for care occurring up to December 31, 2014, that were submitted and processed by June of 2015.

Enrollment Data (Denominator File)

Since 2015, we have received two data files from the Master Beneficiary Summary File—one for Medicare Parts A and B (MBSF_AB_SUMMARY; formerly called the Denominator file) and another for Part D (MBSF_D_CMPNTS). The files provide demographic information on each beneficiary in the sample, as well as dates of enrollment in the various Medicare programs (Hospital Insurance [Part A], Supplemental Medical Insurance [Part B], Medicare Advantage managed care plans [Part C] and Prescription Drug Benefit [Part D]).

Medicare Parts A and B Claims Files

Claims files for Medicare Parts A and B were divided into two groups based on the type of healthcare provider—institutional or physician/supplier. Institutional claims were divided into five sets of files based on the type of medical service: INPATIENT, OUTPATIENT, and HHA: home health agency, HOSPICE, and SNF: skilled nursing facility care. For each type of medical service, we received six files corresponding to different parts of the claim (<*type of service*>_BASE_CLAIMS_J: the base claim file, <*type of service*>_REVENUE_CENTER_J: revenue center file, <*type of service*>_CONDITION_CODES: condition code file, <*type of service*>_OCCURRNCE_CODE: occurrence code file, <*type of service*>_SPAN_CODES: span code file, and <*type of service*>_VALUE_CODES: value code file).

Physician and supplier claims (also referred to as carrier claims) were received in one set for durable medical equipment (DME) and another for all other Part B covered services (BCARRIER). For each of these, we received two files corresponding to different parts

of the claim (<*type of service*>_CLAIMS_J: the base claim file and <*type of service*>_LINE_J: the line item file).

MEDICARE PART D FILES

For Part D, we received files on beneficiary information and claims, as well as information about plan characteristics and premiums. The MBSF_D_CMPNTS file, mentioned above, contains monthly enrollment information for Part D program participation, type of plan, creditable coverage, eligibility for cost sharing and low income subsidies, and additional information. The Part D Events (PDE) file contains all final action claims for prescription drugs submitted by pharmacies on behalf of the Part D beneficiary. This data set contains details about the drug (name, days supplied, dose, strength, quantity, etc.) and payment amounts.

In addition to these beneficiary and beneficiary-prescription fill level datasets, we also received files containing data about the Part D plan, prescribers, and pharmacies. For the 2016 ADR, we used the Plan Characteristics file (PLAN_CHAR) and premium (PREMIUM) files to report on the coverage gap and distribution of premiums.

VETERANS ADMINISTRATION HEATH CARE DATA

The 2016 ADR is the first year we present data on kidney disease from the Veterans Administration's health care system. Data is primarily from the Corporate Data Warehouse (CDW) supplemented by laboratory results from the Managerial Cost Accounting (MCA, formerly Decision Support System, DSS) National Data Extract LAR file. Data is accessed through and stored in the VA Informatics and Computing Infrastructure (VINCI). Data in the CDW is refreshed nightly from the VA's electronic medical record and the analyses in the 2016 ADR are based on a cohort created by the VINCI data manager on June 24, 2016. Our basic cohort is defined as all patients with at least one outpatient encounter (a record in the VISIT table in the OUTPAT domain) during calendar year 2014. Age, gender, race, and date of death are taken from the PATIENT .PATIENT table and race was supplemented with data from the PATSUB.PATIENTRACE table. Ethnicity was from PATSUB.PATIENTETHNICITY.

In the CDW, various types of inpatient care provided by the VA are included in the INPAT.INPATIENT table. These include the stays at short-term hospitals that are commonly thought of when referring to hospital care, but also admission to rehabilitation hospitals, long-term care facilities, and the VA's Domiciliary Residential Rehabilitation Treatment Programs, among others. We identified short-term hospital stays by requiring the MEDICALSERVICE variable to have one of the following values: medicine, surgery, psychiatric, spinal cord injury, intermediate medicine, or neurology. Additionally, the Specialty variable must also have a value related to the type of care provided in short-term hospitals[1].

Serum creatinine laboratory test results were obtained from the MCA LAR file. The variable DSSLARNO denotes the type of laboratory test result in each observation; a value of '31' denotes serum creatinine. Lab results were categorized using the result date variable (res_date) rather than the order date, collection time, or date of the visit associated with the lab order. Records with text in the result field (such as COMMENT, CANC, PENDING, etc.) were dropped, as were those with values less than 0.4 mg/dL or greater than 15.0 mg/dL for the CKD analyses (20.0 mg/dL for the acute kidney injury analyses).

[1] Contact usrds@usrds.org to request a detailed listing of all SPECIALTY variable values.

ESRD MEDICAL EVIDENCE FORM

The analyses in this volume of the ADR often exclude patients with ESRD or censor time-dependent outcomes at the point when a patient reaches ESRD. To obtain this information on ESRD, we searched the USRDS ESRD databases for the beneficiaries in the Medicare 5% files. The date of ESRD was determined from the ESRD Medical Evidence form (CMS 2728), the official form for registering ESRD patients, which must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. First service date for ESRD is reported on this form, and for analyses in this Volume was used as the date when ESRD began. See Volume 2 for additional information on how the Medical Evidence form was used in analyses of ESRD patients.

ESRD DEATH NOTIFICATION FORM

The Master Beneficiary Summary File delivered with the Medicare 5% sample files contains the date of death as reported to Medicare. For this volume, we supplemented this date of death for patients in the Medicare 5% file who experienced ESRD prior to death with information from the ESRD Death Notification form (CMS 2746; the official form for reporting the death of a patient with ESRD). According to CMS policy, this form must be submitted by dialysis or transplant providers within 30 days of a patient's death.

Race and Ethnicity

Throughout the ADR, race and ethnicity categorizations are limited by what distinctions are available in the original data sources. Table m.2 shows the categories included in the original data files. For the Medicare 5% files and Clinformatics™ Data Mart, we were unable to consider ethnicity as separate from race or to separate Pacific Islanders from other categories (Asian or Other). Additionally, we could not identify Native Americans in the Clinformatics™ data. The NHANES, BRFSS, and VA data report two variables, one with race categories and a second designating Hispanic ethnicity. These categories are combined for some analyses due to small sample sizes in some data sets.

vol 1 Table m.2 Race and ethnicity categories reported in the data sources of Volume 1 of the ADR

Race/Ethnicity Variables	NHANES	BRFSS	Medicare 5% data	Clinformatics™ Data Mart	Veterans Administration
Separate variable for Hispanic?	X	X			X
Race Variable Categories					
White	X	X	X	X	X
Black/African American	X	X	X	X	X
Hispanic	Separate	Separate	X	X	Separate
Native American	X	X	X		X
Asian	X	X	X	X	X
Pacific Islander/Native Hawaiian	X	X			X
Other	X	X	X		X
Unknown/missing/refused	X	X	X	X	X

General Methods for Health Insurance Claim Data Files

For the purpose of analysis, several restrictions were applied to the claims data files to create a sample cohort. The specific restrictions used for each figure and table are detailed in the chapter-specific sections. The general rationale and explanation of these restrictions apply to all analyses with the health system data files, and are detailed here. It is important to remember that the primary purpose of the data collection underlying these dataset was to reimburse health care providers for services performed for beneficiaries; information that is not necessary to facilitate payment for services, such as results of lab tests, family medical history, or health behaviors such as smoking, generally is not available in the dataset.

PLAN PARTICIPATION

Medicare currently provides medical benefits through four programs known by the part of Title XVIII of the Social Security Act that created them—Part A provides hospital insurance, Part B provides supplemental medical insurance (including physician services, durable medical equipment, ambulance, radiology, and laboratory services), Part C is for enrollment in managed care plans (which provide all part A and part B services), and Part D provides prescription drug coverage (CMS, 2014). Part A coverage is free to beneficiaries, while the other parts can have premiums paid by the beneficiary and are optional. Beneficiaries are also allowed to switch between original Medicare (fee-for-service) to Medicare Advantage plans (Part C) during open enrollment. Medicare Advantage plan providers are not paid through the claims submission process, therefore, there are no data in the Medicare 5% claims files for these patients. Over the course of a year, people become newly eligible for Medicare (e.g., reach age 65) and enroll in the program, people die and therefore are not eligible during part of the year, and people drop their coverage. To create appropriate denominators for the statistics that are presented, samples were often limited to beneficiaries that were enrolled in both Parts A and B and were not enrolled in a Medicare Advantage plan (Part C). In the Clinformatics™ Data Mart, plan enrollment intervals are provided in the MEMBER_DETAIL table with a start date (ELIGEFF) and an end date (ELIGEND). In some analyses for both data sets, the cohort was limited to patients who met these plan participation requirement on a certain date, such as January 1 of the reported year. In other cases the sample may have been limited to beneficiaries meeting those enrollment requirements during entire calendar year.

In most analyses that were limited to patients with a certain disease or disorder, such as CKD, Medicare beneficiaries must have been enrolled in Parts A and B and not Part C for the year prior to the reported year (the entry period or 'year one'), while Clinformatics™ patients must have been enrolled in their plan for that time. This ensures that each patient has 12 months of claims from which to determine the presence of the disorder. The outcome under analysis was then determined from claims in the year following the entry period ('year two'). Prevalence analyses, however, were not subject to this requirement and used claims during the reported year (the typical year two) to determine the presence of the disorder.

MEDICARE REASON FOR ENTITLEMENT

In this volume, the majority of analyses were restricted to beneficiaries that were age-eligible for Medicare and, therefore, aged 65 and older. Beneficiaries under the age of 65 may have qualified for Medicare on the basis of disability (meeting requirements for one of the Social Security Administration's income support programs for disabled individuals) or diagnosis of ESRD (patients that are excluded from the CKD volume) and are not representative of the U.S. population of the same age. In contrast, 98% of the U.S. population aged 65 and older is eligible for Medicare (McBean, 2012). However, unlike the chapter-specific figures and tables, the reference tables for this Volume included all adult (aged 20 or older), non-ESRD Medicare beneficiaries regardless of reason for entitlement.

ESRD

As the focus of this volume is on patients that do not have ESRD, Medicare patients under age 65 who were only eligible for Medicare due to ESRD were excluded. The Clinformatics™ Data Mart cannot be linked to the USRDS ESRD database due to licensing

restrictions, so the identification of ESRD patients is from diagnosis and procedure codes from claims. Most analyses for both data sources restrict the sample to beneficiaries/plan members that did not have ESRD, either as of a certain date or for the entire calendar year. Additionally, analyses of time-to-event outcomes (e.g., mortality, hospitalization, readmission, time to the performance of a laboratory test) often censored a patient at the start of ESRD, as well as at death, or change in plan enrollment (for Medicare beneficiaries, the disenrollment from Parts A and B of Medicare, or switch to a Medicare Advantage plan and for Clinformatics™ patients, the end of plan participation as reported by the ELIGEND variable. The start of ESRD was the date of first service from the CMS 2728 form for Medicare patients and the date of the first claim with an ESRD diagnosis, outpatient dialysis procedure, or transplant hospitalization starting in 2004 for Clinformatics™ plan members.

Identification of Major Comorbidities

According to a previously validated method for using Medicare claims to identify diabetic patients (Herbert et al., 1999), a patient is considered diabetic if, within a one-year observation period, he or she had a qualifying ICD-9-CM diagnosis code of diabetes mellitus (DM) on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or two or more institutional outpatient claims and/or Part B physician/supplier claims. This algorithm—one inpatient claim, or two outpatient claims with specified diagnosis codes—was used to determine the presence of CKD and 13 other conditions commonly associated with CKD as risk factors, co-occurring conditions, or consequences of the disease. This same algorithm was also applied to the claim data in the Clinformatics™ Data Mart with the inpatient/outpatient determination made by determining if the service date fell within an inpatient confinement defined by the admission and discharge dates. Tables m.3 and m.4 list these conditions and the ICD-9-CM diagnostic codes used to define them. Additionally, the overall grouping of cardiovascular disease (CVD) included patients with at least one of these individual conditions: atherosclerotic heart disease, congestive heart failure, cerebrovascular accident/transient ischemic attack, peripheral vascular disease, dysrhythmias, or other cardiac conditions. Analyses within individual chapters also defined additional conditions using the same algorithmic structure, as described in the chapter-specific sections below.

vol 1 Table m.3 ICD-9-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files throughout Volume 1 of the ADR

Condition name	ICD-9-CM codes
Chronic kidney disease	016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4
Staging of chronic kidney disease	
Stage 1	585.1
Stage 2	585.2
Stage 3	585.3
Stage 4	585.4
Stage 5	585.5 or 585.6 with no CMS 2728 form
Stage unknown or unspecified	Patient has no claims with codes 585.1-585.6 but has: 016.0; 095.4; 189.0,189.9; 223.0; 236.91; 250.4; 271.4; 274.1; 283.11; 403; 404; 440.1; 442.1; 477.3; 572.4; 581-584; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4

Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

vol 1 Table m.4 ICD-9-CM diagnosis codes used to define medical conditions in the health insurance claim data files throughout Volume 1 of the ADR

Condition name	ICD-9-CM codes
Anemia	280-285
Atherosclerotic heart disease (ASHD)	410-414; V45.81; V45.82
Cancer	140-172; 174-208; 230-231; 233-234
Cardiac, other	420-424; 429; 785.0-785.3; V42.2; V43.3
Cerebrovascular accident (CVA) / transient ischemic attack (TIA)	430-438
Chronic obstructive pulmonary disorder (COPD)	491-494; 496; 510
Congestive heart failure (CHF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428; V42.1
Diabetes mellitus (DM)	250; 357.2; 362.0; 366.41
Dysrhythmia	426-427; V45.0; V53.3
Gastrointestinal bleeding disorders (GI)	456.0-456.2; 530.7; 531-534; 569.84-569.85; 578
Hypertension (HTN)	362.11; 401-405; 437.2
Liver disease	570-571; 572.1, 572.4; 573.1-573.3; V42.7
Peripheral vascular disease (PVD)	440-444; 447; 451-453; 557

Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

Chapter 1: CKD in the General Population

Analyses in this chapter used data collected through the NHANES, a nationally representative survey that combines interviews and medical examinations to assess the health of the U.S. non-institutionalized civilian population (Johnson et al., 2013). NHANES III was fielded in 1988-1994; starting in 1999 and continuing to the present, the NHANES collects data continuously and releases public-use data files in two-year cycles. Data for this chapter represents participants 20 years and older in the NHANES continuous cycle years 1999-2002, 2003-2006, 2005–2006, 2007–2010, and 2011-2014. The statistical software package SAS®, version 9.3, was used to analyze all NHANES data, incorporating the sampling weights and survey design through its survey procedures.

In this chapter, age was 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 and ethnicity are self-reported and categorized as non-Hispanic White, non-Hispanic African American, or other.

The identification of CKD was based on the 2012 guidelines from the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group (KDIGO, 2013)

implemented with the data available in NHANES. KDIGO defines CKD as "abnormalities of kidney structure or function, present for >3 months, with implications for health." Decreased glomerular filtration rate (GFR) is defined as GFR less than 60 ml/min/1.73 m^2, which was calculated using the Chronic Kidney Disease-Epidemiology Collaboration (CKD-EPI) estimated glomerular filtration rate (eGFR) equation (Levey et al., 2009). Markers of kidney damage include albuminuria, a history of kidney transplantation, and abnormalities as detected by histology or in urine sediment, electrolytes (due to tubular disorders), or structure (detected by imaging). With NHANES data we used the urine albumin creatinine ratio (ACR) to measure albuminuria, but did not have information regarding the other markers of kidney damage. Also, the NHANES only included a single measurement of both serum creatinine (sCR, used to generate eGFR) and ACR, so we could not address the three-month persistence criteria for defining CKD.

The eGFR (measured in ml/min/1.73 m^2) was calculated using the CKD-EPI equation, based on the NCHS-recommended standardized creatinine values (Selvin et al., 2007). The CKD-EPI equation is:

$$\text{eGFR} = 141 * \min\left(\frac{\text{sCR}}{\kappa}, 1\right)^{\alpha} * \max\left(\frac{\text{sCR}}{\kappa}, 1\right)^{-1.209} * 0.993^{\text{AGE}} * 1.018 * \text{F} * 1.159 * \text{B}$$

where:

sCR = serum creatinine in mg/dL

κ = 0.7 if female, 0.9 if male

α = -0.329 if female, -0.411 if male

F = 1 if female, 0 if male

B = 1 if Black/African American, 0 otherwise

AGE is measured in years

The ACR is the ratio of urinary albumin (mg/L) to urinary creatinine (mg/dL). Based on an NCHS suggestion, the urine creatinine value was adjusted to NHANES 2007-2008 (CDC, 2009).

Staging of CKD was first introduced by the National Kidney Foundation's Kidney Disease Outcomes and Quality Improvement Guidelines in 2002 (NKF, 2002). Following these guidelines, we defined stages of CKD in this chapter as:

- 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 mellitus (DM) included 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) hemoglobin A1c (HbA1c; glycohemoglobin) ≥7%. Participants with self-reported diabetes mellitus (SR DM) were those who reported having been told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). In NHANES 2005–2012, participants answering "borderline" were classified as non-diabetic, to agree with NHANES III coding. Control of DM is assessed as an HbA1c less than 7%.

Patients with hypertension (HTN) were those with either (1) high blood pressure, defined as systolic blood pressure above 140 mmHg (>130 mmHg for

those with CKD or SR DM) or diastolic blood pressure above 90 mmHg (>80 mmHg for those with CKD or SR DM) or (2) an affirmative answer to the question "Are you now taking prescribed medicine for high blood pressure?" Self-reported hypertension (SR HTN) was 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 were classified as aware of their HTN if they reported having been told they have high blood pressure, as treated for their HTN if they reported currently taking a prescription medication to control HTN, and as in control of their HTN if their blood pressure at time of medical examination was ≤140/≤90 (≤130/≤80 for CKD or SR DM).

Participants who self-reported any of the following diseases were considered to have self-reported cardiovascular disease (SR CVD): angina, myocardial infarction, stroke, coronary heart disease, or congestive heart failure. Hyperlipidemia was measured in the medical examination. We assessed whether total cholesterol fell into one of three categories: <200 (desirable), 200–239 (borderline high), and ≥240 (high). Individuals were classified as current smokers if they gave an affirmative answer to the question "Do you now smoke cigarettes?" and former smokers if they responded negatively to the previous question, but affirmatively to the question "Have you smoked at least 100 cigarettes in your life?"

Adjusted odds ratios in Figures 1.9-1.11 were calculated using logistic regression, incorporating the sampling weight and survey design. Each figure displays the results of seven logistic models. The model for age included age (20-39/40-59/60+), sex (male/female) and race (White/Black/other). Models for the six other factors shown in the figure (DM, SR DM, HTN, SR HTN, SR CVD, and body mass index [BMI] greater than 30) included age (20-39/40-59/60+), sex (male/female), race (White/Black/other) and presence of the risk factor shown (yes vs. no). Ninety-five percent confidence intervals are displayed.

Figure 1.17 tabulates responses to the 2012 and 2014 Behavioral Risk Factor Surveillance System question, "Has a doctor, nurse, or other health professional ever told you have kidney disease?" by U.S. state.

Figure 1.18 shows the expected remaining lifetime of patients with and without CKD given survival to various ages. Life expectancy was calculated from publically available, mortality-linked NHANES data from 1999-2010, with follow-up through 2013.

Chapter 2: Identification and Care of Patients with CKD

All of the analyses in the *Prevalence of Recognized CKD* and *Longitudinal Change in CKD Status and Outcomes, Based on Diagnosis Codes* sections of this chapter included point prevalent patients who survived all of the reported year (2014 for most of the figures and tables) and did not have or develop ESRD during reported year. Medicare analyses also required the beneficiary to be continuously enrolled in Medicare Parts A and B in the reported year, not enrolled in a Medicare Advantage plan (Part C), and aged 65 or older as of January 1 of the reported year. Clinformatics™ analyses additionally required the plan member be enrolled the entire reported year, while the age range of included members varied by table, with Tables 2.1 and 2.3 including all ages and the remaining tables and figures including adults age 22-64. The sections *Laboratory Testing of Patients With and Without CKD* and Table 2.6 of *Visits with a Physician after CKD Diagnosis* include patients meeting the restrictions described above, for a one-year entry period (year one) before the reported year (year two) and on January 1 of year two. Patients were then censored in the analysis if they died, developed ESRD, switched to a Medicare Advantage plan (Part C), or disenrolled from Parts A and B during year two.

Table 2.1 presents demographic and comorbidity characteristics of individuals in the Medicare 5% sample (aged 65 and older) and the Clinformatics™ dataset. Comorbidities included are diabetes mellitus (DM), hypertension (HTN), and cardiovascular disease (CVD). CVD was defined as the presence of any of the following comorbidities: cerebrovascular accident, peripheral vascular disease, atherosclerotic heart disease, congestive heart failure, dysrhythmia or other cardiac comorbidities. Each comorbidity is defined by medical claims (at least one inpatient or two outpatient claims) during the reported year. Refer to the *Identification of Major Comorbidities* section of this

chapter for the complete methodology used to identify these comorbidities and Tables m.3 and m.4 for a list of ICD-9-CM codes used.

Table 2.2 presents the prevalence of coded CKD, DM, and CVD in the fee-for-service, age-eligible Medicare population and patients aged 22-64 in the Clinformatics™ dataset. Panel A shows the sample counts and percent of all patients with the condition for each condition separately. Panel B shows the interaction between all three conditions identifying those with all combinations of the conditions.

Table 2.3 shows the unadjusted prevalence of diagnosed CKD by age, sex (male/female), race (White/Black/Native American/Asian/Hispanic [Clinformatics™ only]/other), and comorbidity in 2014. Comorbidities included were DM, HTN and CVD. Figure 2.1 illustrates the prevalence of CKD over time in the fee-for-service, age-eligible Medicare population—overall (any code) and by CKD stage-specific codes.

Table 2.4 shows the percent of patients with CKD by demographic characteristics, among patients overall, those with DM (with or without HTN), and those with HTN without DM, in the NHANES (2011-2014, see the section *Chapter 1: CKD in the General Population* in this chapter for methods), the Medicare 5% sample (2014), and the VA (2014). NHANES data included the 2011-2014 survey years and were restricted to participants aged 65 or older. CKD was determined by eGFR<60 ml/min/1.73m^2 for the NHANES data, by ICD-9-CM diagnosis code in the Medicare 5% sample, and by both methods in the VA data.

Table 2.5 shows progression of kidney disease by CKD stage, end-stage renal disease (ESRD), or death in 2013-2014 for the fee-for-service, age-eligible Medicare population in 2009. The analysis cohort required patients to be alive and eligible for Medicare Parts A and B with no HMO coverage for all of 2009. Death and ESRD status were examined yearly between 2010 and 2014, and carried forward if present. In the 2016 ADR, the ESRD and death information are combined to create the three categories of ESRD-Alive, ESRD-Death, and Death without ESRD. For patients without death or ESRD by 2014 the last CKD diagnosis claim in 2014 was used; if this was not available, the last CKD diagnosis claim from 2013 was used. Lost to follow-up status represents the patients who were not enrolled in Medicare Part A and B during 2013 or 2014 and who had no indication of death or ESRD.

Figures 2.2–2.3 show statistics on laboratory testing for serum creatinine and urine albumin among various patient populations and by patient characteristics. For these analyses, a one-year period was used to define comorbid conditions (year one) and laboratory testing was assessed in the following year (year two, the year reported in the figures). Patients must have had Medicare Parts A and B coverage, no Part C participation (Medicare Advantage plans), no ESRD, and have been alive for all of year one through to January 1 of year two. Additionally, the sample was limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. First urinary microalbumin measurement was defined as the first claim with a Healthcare Common Procedure Coding System (HCPCS, similar to the Current Procedural Terminology, CPT®, system) code of 82042, 82043, 82044, or 84156. Likewise, first serum creatinine measurement was defined as the first claim with a HCPCS code of 80047, 80048, 80049, 80050, 80053, 80054, 80069, or 82565.

Figures 2.3 and 2.4 show the proportion of patients tested across time, from 2000-2013 for patients with (Figure 2.4) and without (Figure 2.3) CKD. Figures 2.5 and 2.6 show the adjusted prevalence of testing in 2013 for those with (Figure 2.6) and without (Figure 2.5) CKD, by comorbidity status: (1) the patient has neither DM nor HTN; (2) the patient has HTN but not DM; (3) the patient has DM but not HTN; and (4) the patient has both DM and HTN. Adjustments were made for age (65-<75/75-<85/85+), sex (male/female), and race (White/Black/Native American/Asian /Hispanic/other/unknown).

Table 2.6 examined physician visits in the year after a diagnosis of CKD. Similar to the laboratory testing, the sample included patients who were alive, without ESRD, did not have a Medicare Advantage plan, and had both Parts A and B coverage for all of 2012. The date of the earliest CKD claim (any CKD or Stage 3/4/5 [585.3–585.6]) in 2012 was used as the date of CKD diagnosis, and claims were then searched for services provided by primary care physicians, nephrologists, and cardiologists for the 365 days following that date.

Primary care visits were defined based on a physician specialty code of 01, 08 and 11. Cardiologist visits were defined based on specialty code 06, and nephrology visits were defined based on specialty code 36.

Table 2.7 presented the proportion of patients in the fee-for-service, age-eligible Medicare population in 2013 with CKD (based on diagnostic code), who were tested for urine albumin or serum creatinine in 2013, according to whether they saw a primary care physician or nephrologist in 2012. The analysis cohort required patients to be alive and eligible for all of 2013 with a CKD diagnosis claim in 2012.

Chapter 3: Morbidity and Mortality

The analyses in this chapter used a one-year entry period to determine disease conditions prior to hospitalization, referred to as 'year one'. Patients were required to be alive, aged 65 or older on January 1, without ESRD, not in a Medicare Advantage plan (Part C) and covered by Parts A and B for all of year one. Claims from year one were then searched for diagnoses as described in the *Identification of Major Comorbidities* section of this chapter. Additionally, patients must have met these criteria and be aged 66 or older on January 1 of the following year (year two). Mortality and hospitalization were then determined from January 2 to December 31 of year two. Analyses were also limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. The calculation of years at risk began on January 1 of year two, and was censored at the earliest of the date of death, start of ESRD, disenrollment from Medicare Parts A or B, switch to a Medicare Advantage plan (Part C), or December 31 of year two.

MORTALITY

The date of death was provided by CMS in the Master Beneficiary Summary File. If the patient experienced ESRD prior to death, the date of death from the USRDS ESRD database was also used in the analysis; this date is found in the integrated data from the ESRD Death Notification form CMS 2746, and the Social Security Death Master file. Figure 3.1 shows time trends in unadjusted and adjusted all-cause mortality by CKD status from 2002 to 2014, and Figure 3.2 shows rates for 2014 by CKD status and stage.

Unadjusted mortality was calculated as the number of deaths divided by the number of patient-years at risk, and expressed as "per 1,000 patient years." Adjusted mortality was based on a Cox regression model and adjusted for age (66-<70/70-<75/75-<85/85+ years), race (White/Black or African American/other), and sex. This modified set of adjustment covariates has been used since the 2014 ADR— prior year hospitalization and comorbidities are no longer included. These differ from those used in the 2013 and older ADRs; therefore, differences between adjusted rates in the 2014-present ADRs and rates from the 2013 and older ADRs may be notable. All patients in 2013 were used as the reference cohort for Figure 3.1, while all patients in 2014 formed the reference cohort for Table 3.1 and Figures 3.2, 3.3, 3.4, 3.5 and 3.6.

HOSPITALIZATION

For the hospitalization analysis, additional processing was performed on the inpatient claims data. A patient's inpatient claims were ordered by date, and compared to identify overlapping claims (two claims covering the same time frame), consecutive claims (one claim's admission date on the day following the previous claim's discharge date), transfers (patient discharge status of 02 on the claim), and interim claims (claim sequence number, the third digit of the 'type of bill' code, of 2, 3, or 4). In these cases, the claims were consolidated into one claim with dates, diagnoses, and procedures combined. Analyses excluded claims from non-acute care facilities such as rehabilitation hospitals (the last four digits of the provider number between 2500 and 3999, or the third digit of R or T).

Unadjusted admission rates were calculated as the number of hospitalizations divided by the number of patient years at risk, and expressed as "per 1,000 patient years." Adjusted admission rates in this chapter included the following variables as adjustments: age (66-<70/70-<74/75-<85/85+), race (White/Black/other), and sex (male/female). As with mortality, a different set of adjustment covariates were applied starting with the 2014 ADR, thus adjusted rates may differ substantially from the 2013 and older ADRs. A model-based adjustment method was used with a generalized linear model using a Poisson distribution and log link function. The sample

included data from the current and previous two years, with respective weights of 1.0, 0.25 and 0.125. Adjusted rates reflected the distribution of a reference cohort, specified below in the discussion of the respective figures. With this method, the parameter estimates from the model were used to calculate an estimated admission rate for each patient in the reference cohort. Overall adjusted rates were then computed as the weighted average of these individual rates, using the time at risk of each patient in the reference cohort as the weight.

Table 3.2 and Figures 3.7, 3.8, and 3.12-3.15 show adjusted all-cause admission rates for fee-for-service Medicare patients aged 66 and older. Table 3.2 also shows the unadjusted rates. As mentioned above, diabetes and cardiovascular disease were ascertained in 2013 for the analysis of hospital admissions in 2014, as described in the *Identification of Major Comorbidities* section of this chapter. All patients must have been 66 years or older, not have had ESRD on 1/1/2014, had Medicare Parts A and B coverage for all of 2013 and on 1/1/2014, and were not participating in a Medicare Advantage plan from 1/1/2013 through 1/1/2014. Rates presented by one factor were adjusted for the others. The reference cohort included Medicare patients in 2014, aged 66 and older.

vol 1 Table m.5 ICD-9-CM diagnosis codes used to define cause of hospitalization

Hospitalization cause	Primary claim diagnosis for hospital stay, ICD-9-CM codes
Cardiovascular hospitalizations	276.6; 394-398; 401-405; 410-438; 440-459
Infectious hospitalizations	001-139; 254.1; 320-326; 331.81; 372.0-372.3; 373.0-373.3; 382.0-382.4; 383; 386.33, 386.35; 388.6; 390-391; 392.0, 392.9; 393; 421.0, 421.1; 422.0, 422.91-422.93; 460-466; 472-473; 474.0; 475; 476.0, 476.1;478.21, 478.22, 478.24, 478.29; 480-490; 491.1; 494; 510; 511; 513.0; 518.6; 519.01; 522.5, 522.7; 527.3; 528.3; 540-542; 566-567; 569.5; 572.0-572.1; 573.1-573.3; 575.0-575.12; 590; 595.1-595.4; 597; 598.0; 599.0; 601; 604; 607.1-607.2; 608.0, 608.4; 611.0; 614-616.1, 616.3, 616.4, 616.8; 670; 680-686; 706.0; 711; 730.0-730.3, 730.8-730.9; 790.7, 790.8; 996.6; 998.5; 999.3
Other causes of hospitalization	All codes except those included in Cardiovascular or Infectious above.

Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

Figures 3.9-3.11 show adjusted, cause-specific admission rates by CKD status and stage. Cause-specific rates reflect hospital admissions for the purpose of the specified condition—cardiovascular or infectious—and were identified using the principal ICD-9-CM diagnosis code on the claim. Code values are shown in Table m.5. The 'other cause' of hospitalization is a residual category consisting of all hospitalizations other than cardiovascular or infectious.

REHOSPITALIZATION

Analyses of rehospitalization focused on the 30 days following discharge from a hospitalization in year two, the year reported in the figure. As in all the analyses in this chapter, comorbidities, including CKD, were defined during year one, the year prior to that reported in the figure. Each of a person's hospitalizations between January 1 and December 1 of year two was identified; the latter date (12/1) was a cutoff to allow a 30-day follow-up period after discharge to evaluate rehospitalization. The unit of analysis was a hospital discharge rather than a patient. Hospital stays were excluded if the patient died before discharge, developed ESRD within 30 days of discharge, switched to a Medicare Advantage (Part C) plan or disenrolled from Parts A and B coverage within 30 days of discharge (unless the Parts A and B coverage loss was due to death). Due to the December 1 cutoff, all patients were at risk of death or rehospitalization for the entire 30 day period, so results are presented as percentages. Since death and rehospitalization are competing risks, the outcome is presented as: (1) the percent of hospital discharges that had the patient both return to the hospital and die within 30 days, (2) the percent with the patient rehospitalized within 30 days but alive on day 30, and (3) the percent where the patient died within 30 days without a rehospitalization. Table 3.3 shows the unadjusted percentage rehospitalized (both alive and dead on day 30) for age, sex, and race groups, plus the composite death and rehospitalization outcome described above by CKD status and stage. Figure 3.16 shows the adjusted percentages for the three-part rehospitalization and death outcome across time from 2002 to 2014. Live hospital discharges from January 1 to December 1 of each year are included. Rates were adjusted for age, sex, and race using direct adjustment, with a reference group of discharges in 2014. Figure 3.17 shows results for 2014 for patients with and without CKD before the all-cause index hospitalization, while Figures 3.18-3.20 show this for cardiovascular, infection, and other cause-specific index hospitalizations. Figure 3.21 illustrates this by age group, Figure 3.22 by sex, Figure 3.23 by race group, and Figure 3.15 for cardiovascular-related hospitalization instead of all-cause. Figure 3.14 displays annual trends in rates of rehospitalization and/or death within 30 days after hospital discharge among CKD patients.

Chapter 4: Cardiovascular Disease in Patients with CKD

This chapter describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, age-eligible Medicare enrollees. Cardiovascular comorbidities included atherosclerotic heart disease (ASHD), acute myocardial infarction (AMI), congestive heart failure (CHF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral arterial disease (PAD), atrial fibrillation (AFIB), sudden cardiac arrest and ventricular arrhythmias (SCA/VA), and venous thromboembolism and pulmonary embolism (VTE/PE). The same algorithm described in the *Identification of Major Comorbidities* section of this chapter (one inpatient or two outpatient claims with the specific diagnosis) was used to define these cardiovascular conditions. Code values are shown in Table m.6. The presence of CKD, CKD staging, and comorbidities such as diabetes mellitus (DM) and hypertension (HTN) are also defined as described in the *Identification of Major Comorbidities* section of this chapter and Tables m.3 and m.4.

vol 1 Table m.6 ICD-9-CM diagnosis codes used to define cardiovascular disorders in Volume 1, Chapter 4 of the ADR

Condition name	ICD-9-CM diagnosis codes
Any cardiovascular disease (CVD)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 410-414; 422; 425-428; 430-438; 440-444; 447; 451-453; 557; V42.1, V45.0, V45.81, V45.82, V53.3
Atherosclerotic heart disease (ASHD)	410-414; V45.81, V45.82
Acute myocardial infarction (AMI)	410; 412
Congestive heart failure (CHF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428; V42.1
Systolic or both systolic & diastolic	428.2, 428.4
Diastolic only	428.3
Heart failure, unspecified	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422; 425; 428 (not 428.2-428.4); V42.1
Valvular heart disease (VHD)	424
Cerebrovascular accident/transitory ischemic attack (CVA/TIA)	430–438
Peripheral arterial disease (PAD)	440–444; 447; 557
Atrial fibrillation (AFIB)	427.3
Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)	427.1, 427.4, 427.41, 427.42, 427.5, 427.69
Venous thromboembolism and pulmonary embolism (VTE/PE)	452, 453

Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification. Diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Peripheral arterial disease is defined as having a diagnosis and/or a procedure.

Cardiovascular procedures included percutaneous coronary interventions (PCI), coronary artery bypass grafting (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization devices with defibrillators (CRT-D), and carotid artery stenting and carotid endarterectomy (CAS/CEA). Procedures required only one claim with the procedure code. The presence of PAD was determined by the diagnosis or a claim for a procedure. Table m.7 shows the codes and type of claims used to identify each procedure.

vol 1 Table m.7 Procedure codes (ICD-9-CM and HCPCS) & claims files used to define cardiovascular procedures in Volume 1, Chapter 4 of the ADR

Peripheral arterial disease (PAD)	
ICD-9-CM Procedure codes:	
Claims files searched:	IP, OP, SN
Values:	*39.25, 39.26, 39.29; 84.0, 84.1, 84.91*
HCPCS codes:	
Claims files searched:	PB, OP-revenue
Values:	*24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651,*
Percutaneous coronary interventions (PCI)	
ICD-9-CM Procedure codes:	
Claims files searched:	IP, OP, SN
Values:	*00.66; 36.01, 36.02, 36.05, 36.06, 36.07*
HCPCS codes:	
Claims files searched:	PB, OP-revenue
Values:	*92980-92982, 92984, 92995-92996, G0290, G0291*
Coronary artery bypass graft (CABG)	
ICD-9-CM Procedure codes:	
Claims files searched:	IP
Values:	*36.1*
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)	
ICD-9-CM Procedure codes:	
Claims files searched:	IP, OP, SN
Values:	*00.51; 37.94*
Carotid artery stenting and carotid endarterectomy (CAS/CEA)	
ICD-9-CM Procedure codes:	
Claims files searched:	IP, OP, SN
Values:	*00.61, 00.62, 00.63, 00.64, 00.65; 17.53, 17.54,38.11,38.12,38.31,38.32,38.41,38.42;39.74*
HCPCS codes:	
Claims files searched:	PB, OP-revenue
Values:	*37215; 37216*

Source: ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; HCPCS, Healthcare Common Procedure Coding System, IP, inpatient, OP, outpatient services during inpatient stay, SN, skilled nursing facility, PB, physician and supplier services covered by Part B, OP-revenue, outpatient revenue claims during inpatient stay. ICD-9-CM procedure codes have up to four digits with a decimal point between the 2nd and 3rd digits. Codes listed with three digits include all possible 4th digits. HCPCS codes have 5 digits without a decimal point. Peripheral arterial disease is defined as having a diagnosis and/or a procedure.

Cardiovascular Disease Prevalence and Outcomes in CKD

For Figure 4.1, the study cohort included Medicare enrollees who were alive, aged 66 and older, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, did not have ESRD on December 31, 2014, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of 2014. Cardiovascular conditions, CKD, and CKD staging were determined from claims in 2014.

Table 4.1 presents the prevalence data shown in Figure 4.1 by age, race, sex, and CKD status (Panel a), and presents data on cardiovascular procedures performed in 2014 (Panel b). The cohort was the same as that used for Figure 4.1. However, the denominators for the cardiovascular procedures were not "all patients in the cohort", which was the denominator for the prevalence statistics. The percent with PCI or CABG were out of cohort members with ASHD, the percent with ICD/CRT-D was out of cohort members with CHF, and the percent with CAS/CEA was out of the cohort members with ASHD, CVA or PAD.

Figures 4.2 and 4.3 present the unadjusted, two-year survival of patients with cardiovascular conditions (Figure 4.2) or cardiovascular procedures (Figure 4.3). The methods for calculating these figures have changed for this 2016 ADR; conditions are assessed in a baseline year (2012), the origin for survival time is January 1 of the following year (1/1/2013), and there is no attempt to isolate incident diagnoses, so all the diagnosis codes listed for CHF in Table m.6 are used to define CHF for Figure 4.2. Methods for the procedures in Figure 4.3 are the same as in past years.

To form the study cohort for each condition in Figure 4.2, Medicare claims from 2012 were searched for the diagnoses (and procedure codes for PAD) specified in Tables m.6 and m.7. To be retained in the analysis cohort, the patient must have been alive without ESRD and aged 66 or older on 1/1/2013, and resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, was enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan (Part C) for all of 2012. Patients were then followed from 1/1/2013 until the earliest of date of death, ESRD diagnosis, or December 31, 2014. The Kaplan-Meier method was used to estimate survival.

To form the study cohort for each procedure in Figure 4.3, Medicare claims from 1/1/2011 through 12/31/2014 were searched for the procedure codes specified in Tables m.7, and the date of the first claim with a specified code was considered the index date. To be retained in the analysis cohort, the patient must have been aged 66 or older on the index date, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, was enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan (Part C). Patients with ESRD on or before the index date were excluded. Claims for the patient in the 365 days prior to the index date were then searched for a prior occurrence of the given condition/procedure, and these patients were excluded from the analysis. CKD status and stage were also determined from the patient's claims in the 365 days prior to the index date. Patients were then followed from the index date until the earliest of date of death, three years after the index date, ESRD diagnosis, or December 31, 2014. The Kaplan-Meier method was used to estimate survival.

Congestive Heart Failure and Chronic Kidney Disease

The type of heart failure for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (428.2x or 428.4), diastolic (428.3x) and unspecified (all other CHF diagnosis codes in Table m.6) diagnoses was determined by searching all reported diagnoses on all claims for a given calendar day. Each day was counted as systolic if there were any systolic diagnoses, as diastolic if there were no systolic diagnoses but at least one diastolic diagnosis, and as unspecified if there were no systolic or diastolic diagnoses but at least one unspecified diagnosis. The number of days with systolic, diastolic, and unspecified diagnoses was then summed for the calendar year. The patient's type of heart failure for the year was then determined by a hierarchy similar to that applied for each calendar day: if the patient had any systolic heart failure and no diastolic-only heart failure, he/she was classified as systolic heart failure; if the patient had diastolic heart failure and no systolic, he/she was classified as diastolic heart failure; and if

the patient had only unspecified heart failure, he/she was classified as unspecified heart failure. When a patient had both systolic and diastolic-only diagnosis days during the year, he/she was assigned to the heart failure type that was most frequent during the year.

Figure 4.4 shows the distribution of heart failure type by CKD status in 2014. The study cohort included Medicare enrollees who were alive, aged 66 and older, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, who did not have ESRD on December 31, 2014, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of 2014. The denominators were the total numbers of patients in each CKD status or stage group, and the numerators were the numbers of patients with the given heart failure type within that CKD status or stage group.

Figure 4.5 presents the adjusted, two-year survival of patients with and without CKD and CHF. The adjusted probability of survival was calculated using the results of a Cox model, in which significant factors included age group, sex, race, diabetic (DM) status, hypertension (HTN) status, and a four-category variable summarizing CHF and CKD status. CHF, CKD, DM and HTN statuses were determined from claims for 2012; the study cohort included Medicare enrollees who were alive and aged 66 or older on December 31, 2012, resided in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, were continuously enrolled in Medicare Parts A and B, and were not enrolled in a Medicare Advantage plan for all of 2012. Patients with ESRD on or before December 31, 2012 were excluded. Follow-up began on 1/1/2013 and continued until death or 12/31/2014. Type of heart failure was determined by the same procedure as the previous figures using claims from 2012. Codes used to define DM and HTN can be found in Table m.4 of this chapter. Age was defined as of 12/31/2012. Since the interaction between CHF status and CKD status was significant in the Cox model, adjusted survival curves were created for the four combination groups of CHF status and CKD status (No CKD and no CHF, CKD and no CHF, CHF and no CKD, and CKD and CHF). The survival curves were adjusted for the other significant factors in the model listed above.

ATRIAL FIBRILLATION AND CHRONIC KIDNEY DISEASE

Table 4.2 presents the prevalence of AFIB by CKD stage, age, race, sex, diabetic status, hypertension status, and heart failure (CHF) status for 2013. The cohort was the same used for Figure 4.1.

Chapter 5: Acute Kidney Injury

For the 2016 ADR, three sources of data were used for the AKI chapter: the Medicare 5% sample, Clinformatics™ Data Mart, and the Veterans Administration Healthcare data. Both the Medicare and Clinformatics™ datasets contain only diagnosis code information on AKI, and no laboratory measurements. For these two sources, a hospitalization with AKI was defined as an inpatient stay with any diagnosis code for AKI, not necessarily as the primary diagnosis. The Veterans Administration data sets contain serum creatinine measurements for both routine outpatient visits and inpatient stays, allowing the KDIGO consensus definition of AKI to be calculated (although the data do not contain urine output measurements), and AKI episodes to be classified by stage (KDIGO 2012). Diagnosis codes are also available in the VA data. As in prior years, this chapter only examined AKI as identified during an inpatient hospital stay.

In the Clinformatics™ data set, inpatient stays were identified by a non-missing confinement ID variable (CONF_ID) in the MEDICAL claims data table. We identified more patients with at least one or more inpatient stays from the MEDICAL claims data table than were contained in the CONFINEMENT data table, so the MEDICAL claims data table was used. Admission and discharge dates are not available in the MEDICAL claims data table and must be generated. Since the combination of patient ID (PATID) and confinement ID uniquely identified a hospitalization in the CONFINEMENT data table, we created the admission date as the minimum "claim from" date (FST_DT) and the discharge date as the maximum "claim through" date (LST_DT) for all claims with a given PATID-CONF_ID combination for CONF_ID observations that were not in the CONFINEMENT data table. Review of inpatient stays that were included in the CONFINEMENT data table verified that this process created

appropriate dates. A second disadvantage of using the MEDICAL claims data table is that each inpatient claim only contains three ICD-9-CM procedure codes, as compared to the five procedure codes per claim in the CONFINEMENT data table. This may result in a systematic underestimation of dialysis-requiring AKI for all years of Clinformatics™ data.

Dialysis during the hospitalization with AKI was defined using diagnosis, procedure, and revenue center codes (for Medicare 5% sample). For the Medicare 5% sample, the inpatient claims file was searched for ICD-9-CM diagnosis codes V45.1, V56.0, and V56.1, ICD-9-CM procedure codes 39.95 and 54.98, and Medicare revenue center codes 0800–0809. Additionally, physician and supplier claims were searched for HCPCS codes 90935, 90937, 90945, and 90947, with service dates that corresponded to the patient's inpatient stay. In the Clinfomatics™ Data Mart, we searched for both inpatient (ICD-9-CM procedure codes 39.95 and 54.98) and outpatient procedures (HCPCS codes 90935, 90937, 90945, and 90947) in the MEDICAL claims data table that were performed between the admission and discharge dates of the inpatient stay. Similarly, the Veterans Administration data was searched for dialysis procedures during the time frame of the inpatient stay. Patients with ESRD prior to the inpatient stay were not counted as having AKI.

Characteristics of Patients with AKI

The cohort used for Figures 5.1, 5.3a, 5.4a, 5.5a and Table 5.1 (Medicare) included all patients alive, aged 66 or older, enrolled in Medicare Parts A and B, not enrolled in a Medicare Advantage (Part C) program, and without ESRD on January 1 of the reported year. The Clinformatics™ cohort for Figures 5.2, 5.3b, 5.4b, 5.5b and Table 5.1 (Clinformatics™) included all patients alive, aged 22 or older, enrolled in their plan, and without ESRD on January 1 of the reported year. The comorbidities of CKD and diabetes mellitus (DM) were determined as described in the *Identification of Major Comorbidities* section of this chapter and Tables m.3 and m.4, using claims from a one-year entry period (year one, the calendar year *before* the year in which hospitalization was assessed for AKI) and then assessed hospitalization in the following year (year two, the year reported in the figures and tables). While a patient can have more than one hospitalization with AKI during a given calendar year, the figures and table in this section counted only the first AKI hospitalization per patient, per year. Each calendar year formed a separate cohort; so a patient can have a "first" AKI hospitalization in multiple years. This process was used for both Medicare and Clinformatics™ data sets.

Figures 5.1 and 5.2 show the same statistics but for Medicare (Figure 5.1) and the Clinformatics™ (Figure 5.2) data sets. Each figure has two panels that employ different denominators. Panel A shows the fraction of the entire cohort (described in the previous paragraph) that had a hospitalization with a diagnosis of AKI in each year. Panel B, however, used the numerator of Panel A as its denominator, showing the fraction of cohort patients with at least one hospitalization with AKI that received a dialysis procedure during that hospitalization. Note that these percentages did not take into account each patient's individualized time at risk—for example, a patient who died in February was still included in the denominator for the entire year, even though he/she was not at risk of having an AKI hospitalization after February. These percentages answered the question, "What percent of people (meeting the cohort inclusion criteria in the previous paragraph) alive on January 1 experienced an AKI hospitalization during the year?" Table 5.1 also used the total number of cohort patients with at least one hospitalization with AKI as the denominator, and presents the distribution of age, sex, race, DM, and CKD for those with AKI for Medicare and Clinformatics™.

Table 5.2 shows data from the Veterans Administration Health system. Data is from fiscal year 2014 (October 1, 2013 through September 30, 2014) as retrieved from the Corporate Data Warehouse. Short-term hospital stays were isolated from the INPAT.INPATIENT for discharges within the fiscal year. (see Veterans Administration Heath Care Data earlier in this chapter). All outpatient serum creatinine (SCR) measurements within the 365 days prior to the admission date were obtained from the MCA (formerly DSS) national data extract of laboratory results (LAR file; DSSLARNO=31 and IN_OUT="O"). SCR results containing text ("CANC", "N.A.", etc.) and those with values greater than 20.0 mg/dL or less than 0.4 mg/dL were set to missing. Each patient was

assigned a baseline SCR by this hierarchy: (1) mean SCR of all outpatient measurements done at least seven days prior to admission up to 365 days prior to admission; (2) if the patient had no outpatient SCR values before seven days prior to admission, they were assigned the outpatient SCR value within seven days of admission, using the one farthest from admission if more than one measure was available; (3) if no outpatient SCR values were available, the first inpatient SCR was assigned as the baseline SCR. Patients without at least one inpatient SCR were excluded from the analysis. SCR measurements within the inpatient stay were then compared to the baseline SCR, and each other, to identify episodes of AKI and to stage those episodes. We did not distinguish multiple episodes of AKI within one inpatient stay, only whether there was any AKI or no AKI. Table m.8 shows the criteria for AKI from the KDIGO guidelines.

vol 1 Table m.8. KDIGO definition and staging of acute kidney injury

Definition of AKI:		
An increase in serum creatinine (SCR) by ≥ 0.3mg/dL (≥ 26.5 µmol/l) within 48 hours; or an increase in SCR to ≥ 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume <0.5ml/kg/h for 6 hours.		
Stage	**Serum creatinine**	**Urine output**
1	1.5–1.9 times baseline OR ≥0.3 mg/dL (≥26.5 µmol/l) increase	<0.5 ml/kg/h for 6-12 hours
2	2.0–2.9 times baseline	<0.5 ml/kg/h for ≥12 hours
3	3.0 times baseline OR increase in SCR to >4.0 mg/dL (≥353.6 µmol/l) OR initiation of renal replacement therapy OR, in patients <18 years, decrease in eGFR to <35 ml/min/1.73m^2	<0.3 ml/kg/h for ≥24 hours OR anuria for ≥12 hours

Adapted from KDIGO (2012). Abbreviations: eGFR, estimated glomerular filtration rate; SCR, serum creatinine.

The consensus criteria in the KDIGO guidelines contain two conditions to identify AKI. One is a rise by 0.3 mg/dL within 48 hours and the second is the increase to 1.5 times baseline within seven days. A person's first SCR measurement on the day of admission is compared to their baseline to determine if that SCR is 0.3 mg/dL or 1.5 times higher. If so, the patient is said to have AKI. If not, the second SCR measurement is examined to see if its date is within two days of the admission and if so, whether the second SCR is 0.3 mg/dL or 1.5 times higher than the baseline or the first inpatient measurement. This continues and when a SCR measure is more than 48 hours from admission, it is compared to all previous SCR measurement that occurred within 48 hours of its measurement, rather than the patient's baseline. For example, if a patient with a baseline SCR of 0.8 mg/dL is admitted on January 1 and has a first SCR of 0.8 mg/dL, then one on January 2nd measuring 0.7 mg/dL, another on January 4th of 0.9 mg/dL and then 1.5 on January 5th, the January 5th measurement is compared to the January 4th and determined to have AKI, but it would not be compared to the ones on January 1st or 2nd or the baseline for the 0.3 mg/dL increase condition. Similarly for the seven day increase to 1.5 times baseline, each SCR measurement is compared to all other SCR measurements within seven days of its date. If a patient experiences either the 48 hour increase or the seven day increase he or she is said to have had a hospitalization with AKI.

One the patient is determined to have experienced an AKI based on SCR changes, the hospitalization as a whole is used to assign the stage of AKI. The highest SCR during the hospitalization is compared to the baseline. If the difference is greater then 3 times the baseline, or the highest SCR is greater than 4.0 mg/dL or renal replacement therapy was used during the stay, that hospitalization is classified as Stage 3. If the AKI episode is not Stage 3 and the difference between the maximum SCR and baseline is more than 2 times baseline but less than 3, the hospitalization is classified as Stage 2. If the AKI episode is not Stage 2

or 3, it is Stage 1, an increase of at least 0.3 mg/dL but less than 2 times baseline.

Figures 5.3-5.5 used the entire analysis cohort as the denominator to calculate rates of first AKI per 1,000 patient years at risk for Medicare (Panel A) and Clinformatics™ (Panel B) beneficiaries. Only the first hospitalization with AKI for a patient was counted as an event, and years at risk were calculated for each patient as the time (total days divided by 365.25) between January 1 of the reported year (year two) to the earliest date of hospitalization with AKI, ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), death, or December 31 of year two. Age was as of January 1 of year two, while CKD and DM status were determined by claims in year one. A Cox proportional hazard model with no covariates, stratified by the variable of interest, was used to estimate survival, and the rate was calculated as –[log(survival)] and multiplied by 1,000 to generate the rate per 1000 patient years at risk.

Hospitalization with an AKI Episode

Figures 5.6 and 5.7 show the probability of having a second hospitalization with AKI within 24 months of the first hospitalization with AKI for Medicare (Figure 5.6) and Clinformatics™ (Figure 5.7) beneficiaries. The sample for this figure began with the 2012 cohort as used in the *Characteristics of Patients with Acute Kidney Injury* section above—alive, aged 66 or older, without ESRD, and enrolled in their plan (for Medicare, Parts A and B and no Medicare Advantage plan) on 1/1/2012. The first hospitalization with AKI in 2012 was identified. Age was as of 1/1/2012, and comorbidities were defined by searching claims one year prior to the AKI admission date (admission date-365 through one day before admission). Within this customized date range, CKD and DM status were defined according to the algorithm and codes described in the *Identification of Major Comorbidities* section and Tables m.3 and m.4 of this chapter. The final cohort for Figures 5.6 and 5.7 included only those patients with at least one hospitalization with AKI in 2012 who were discharged alive. Follow-up began on the date of discharge listed on the claim for the hospitalization with AKI, and continued until the earlier of a second hospitalization with AKI, death, ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), or 730 days following the first AKI discharge. Kaplan Meier methods were used to estimate survival with the cumulative probability of a recurrent hospitalization with AKI defined as (1-survival).

Patient Care and Outcomes

Figure 5.8 shows the outcomes of death or ESRD within one year of a live discharge from a hospitalization with AKI. To increase the precision of these estimates, we created the cohort for this figure to include patients with a first hospitalization with AKI in 2012 or 2013. Patients were alive, aged 66 or older, without ESRD, with Parts A and B coverage, and with no Medicare Advantage plan on January 1 of the year of their first hospitalization with AKI. Those who were discharged alive from their hospitalization with AKI were followed from the date of discharge until 365 days after discharge. For the models of time to ESRD and time to the composite end point of ESRD or death, the survival time was calculated from the date of discharge of the hospitalization with AKI to the earliest date of ESRD, death, disenrollment from Parts A or B, switch to a Medicare Advantage program, or 365 days following discharge. Note that the mortality model in this year's ADR was not censored at the start of ESRD. For the mortality model, survival time was calculated from the date of discharge from the first hospitalization with AKI to the earliest of death, disenrollment from Parts A or B, switch to a Medicare Advantage program, or 365 days following discharge.

Figures 5.9-5.11 present physician visits and laboratory tests within the first six months after a live discharge from a hospitalization with AKI. For Figure 5.9, claims were searched for services provided by nephrologists for 180 days following the discharge date of the hospitalization with AKI. In the Medicare data, nephrology visits were a provider specialty code 36, while in the Clinformatics™ data they were identified by a provider category code for nephrologist (PROVCAT 0597-0604). Figures 5.10 and 5.11 show time-to-first-claim for specified laboratory tests. A first serum creatinine measurement was defined as the first claim with a Healthcare Common Procedure Coding System (HCPCS) code of 80047, 80048, 80049, 80050, 80053, 80054, 80069, or 82565. Likewise, first urinary microalbumin measurement was defined as the first claim with an HCPCS code of 82042, 82043, 82044, or

84156. Time to visit or lab test began on the date of discharge listed on the claim for the hospitalization with AKI, and continued until the earlier of the visit or test, death, ESRD, disenrollment from their plan (for Medicare, Parts A and B or a switch to a Medicare Advantage plan), or 180 days following the first AKI discharge. Kaplan Meier methods were used to estimate survival with the cumulative probability of a nephrology visit or lab test defined as (1-survival).

Figure 5.12 shows the renal status after one year for Medicare patients discharged alive from their first hospitalization with AKI. To increase the precision of the estimates, we created the cohort for this figure from patients with a first hospitalization with AKI in 2012 or 2013. Patients were alive, aged 66 or older, without ESRD, with Parts A and B coverage, with no Medicare Advantage plan on January 1 of the year of their hospitalization with AKI, and did not have any claims with a diagnosis of CKD in the 365 days prior to that admission. Renal status after AKI was determined from claims occurring between discharge from the hospitalization with AKI and 365 days after discharge. CKD stage was determined by the 585.x claim closest to 365 days after discharge and ESRD by first service date on the ESRD Medical Evidence form.

Figure 5.13 shows discharge status following a Medicare patient's first hospitalization in 2014. Panel A shows patients whose hospitalization contained an AKI episode while Panel B shows those whose hospital stay did not. The cohort included all patients who experienced a hospitalization during 2014 and who were alive, aged 66 or older, enrolled in Medicare Parts A and B, not enrolled in a Medicare Advantage program, and without ESRD on January 1, 2014. Patients admitted to an acute care hospital from a long-term care facility ('point of origin for admission,' previously named 'source of admission,' is 5) were excluded. Patients with a 'patient discharge status' code of 01 (routine discharge to home) or 06 (discharged to home under care of a home health service organization in anticipation of covered skilled care) were identified as being discharged home. Those with a 'patient discharge status' of 50 (discharged to routine or continuous hospice at home) or 51 (transferred to an inpatient hospice program or facility) were identified as being discharged to hospice. Those identified as being discharged to an institution were those whose 'patient discharge status' was 03 (transferred to a Skilled Nursing Facility with Medicare certification in anticipation of skilled care), 62 (transferred to an inpatient rehabilitation facility including distinct part units of a hospital), or 63 (transferred to long term care hospital). Death was determined both by the date of death from the Master Beneficiary Summary File and the 'patient discharge status' of 20 (expired—this code is used only when the patient dies). 'Other' is a residual category that includes all discharges not identified by the previous categories.

Chapter 6: Medicare Expenditures for CKD

The cohort used for this chapter continued the methodology introduced in the 2010 ADR, which only tabulated CKD costs for patients with CKD diagnoses (minimum of one inpatient and/or two outpatient) among their claims in the year prior to the reported year (year one). For example, the total costs of CKD for 2014 (year two) included all costs incurred by patients with a CKD diagnosis in 2012 (year one). Prior to the 2010 ADR, patients newly diagnosed with CKD during year two were also included in the total.

The same general Medicare point prevalent cohort was used to create all the tables and figures in this chapter. Each year's cohort included patients aged 65 and older (except for Table 6.2 which includes only those under age 65) who were alive and without ESRD on January 1 of the reported year (year two). Cohort members were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan (Part C) for all of year one (the one-year entry period prior to the year in which costs were assessed). Costs were aggregated for the reported year (year two). Patient years at risk were calculated as the number of days (divided by 365.25) between January 1 of year two and the earliest of death, development of ESRD, disenrollment from Parts A or B, switch to a Medicare Advantage program, or December 31 of year two. Dividing the total cost amount by the patient years at risk yielded the per person per year (PPPY) costs. Since these total costs and number of patients were based on the 5% Medicare files, counts and

expenditures were multiplied by 20 to represent 100% of Medicare fee-for-service Parts A, B, and D expenditures for age-eligible patients who were continuously enrolled in Parts A and B and not enrolled in a Medicare Advantage plan for all of the previous year (year one).

Claims can be submitted for episodes of care that span calendar years. The expenditures for these claims are spilt across calendar years based on the fraction of the claim's total days that occurred in the reported year. For example, if a claim began on December 29, 2013, and ended on January 7, 2014, it spanned 10 days, with three days in 2013 and seven days in 2014. Seventy percent of that claim's total expenditure amount would be added to total expenditures for 2014 and 30% to total expenditures for 2013.

The disease conditions of CKD, congestive heart failure (CHF), diabetes mellitus (DM), and the stage of CKD are determined from the claims in the year prior to the reported year (year one) with the algorithm described in the *Identification of Major Comorbidities* section of this chapter, using the diagnosis codes listed in Tables m.3 and m.4. Age was determined as of December 31 of year one. Race and sex were provided by the Master Beneficiary Summary File. The cause of hospitalization presented in Figure 6.4 was determined using the same methods as in Chapter 3, using the codes displayed in Table m.5.

Chapter 7: Medicare Part D Prescription Drug Coverage in Patients with CKD

This chapter describes the participation in the Medicare Part D program by Medicare beneficiaries overall, and by those with CKD and ESRD. CKD was determined as described in the *Identification of Major Comorbidities* section of this chapter and Table m.3, using claims from a one-year entry period (year one, the calendar year before the year in which Part D utilization was assessed).Part D utilization was assessed in the following year (year two, the year reported in the figures and tables), while ESRD was determined by the date of first ESRD service. In this Part D chapter in Volume 1, both the General Medicare cohort and the CKD cohort had the same inclusion criteria, representing a change from the 2013 and earlier ADRs. This is also different from the sample used to describe General Medicare patients in Volume 2, Chapter 12, which does not apply restrictions based on year-one Medicare participation.

In this chapter, beneficiaries must have been enrolled in Parts A and B and not enrolled in a Medicare Advantage plan for all of year one, and be alive, without ESRD, and enrolled in Parts A and B on January 1 of year two. Note that those with a Medicare Advantage plan in January of year two were not specifically excluded; if a beneficiary was not in a Medicare Advantage plan for all of year one, but switched to Medicare Advantage for year two, they were still included in the analysis cohort. These criteria were necessary to enable CKD identification, as diagnosis codes were only available for those with fee-for-service Medicare. In order to have an appropriate comparison for the CKD cohort, the same exclusion criteria were applied to the General Medicare group. Unlike the other chapters in Volume 1, this chapter includes all beneficiaries aged 20 years and older. For inclusion, those under age 65 must have been eligible for Medicare through participation in federal disability programs (Social Security Disability Insurance or Supplemental Security Income) or their entitlement related to amyotrophic lateral sclerosis, and thus should not be viewed as representative of the U.S. general population under age 65.

For comparison, several figures and tables also include the ESRD population. Patients were selected from the USRDS ESRD database who had Medicare as either their primary or secondary payer, and had ESRD for at least 90 days by January 1 of the analysis year (year two). See the ESRD Methods chapter for more information on the USRDS ESRD database.

Figures 7.1-7.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing General Medicare, CKD, and ESRD populations and by showing results by age and race categories. The sources of coverage across the calendar year were combined into mutually exclusive and exhaustive categories in a hierarchical manner. Enrollment in a Part D plan was determined by the first digit of the Part D Plan Contract Number variable (one for each month) being "E" (an employer direct plan, a valid value starting in 2007), "H" (a managed care organization other than a regional preferred

provider organization (PPO)), "R" (a regional PPO), or "S" (a stand-alone prescription drug plan). A beneficiary was considered to be enrolled in a Part D plan for the year if he or she was enrolled for one month or more of the analysis year. If a beneficiary was enrolled in a Part D plan and received a low-income subsidy (LIS) in at least one month, he or she was classified as "Part D with LIS", and as "Part D without LIS" otherwise. The receipt of a low income subsidy was determined by the monthly Cost Sharing Group Code values "01" through "08." For beneficiaries not enrolled in a Part D plan, there were several options for non-Medicare prescription drug coverage as reported to the Medicare program. A beneficiary was classified as "Retiree Drug Subsidy" if they were not enrolled in a Part D plan but had at least one month with a Part D Retiree Drug Subsidy Indicator value of "Y" (yes), indicating he or she was enrolled in an employer-sponsored prescription drug plan that qualified for Part D's retiree drug subsidy. If the patient was not in a Part D plan or employer-sponsored plan, they were classified as "Other Creditable Coverage" if the Creditable Coverage Switch has a value of "1", indicating another form of drug coverage that was at least as generous as the Part D benefit. This alternate coverage is known as creditable coverage because beneficiaries who maintain it do not have to pay a late enrollment penalty if they later enroll in Part D. If a beneficiary met none of the situations described above, he or she was classified as "No Known Coverage." Figure 7.1 presents the distribution of this categorical variable for the General Medicare, CKD, and ESRD cohorts described above.

Table 7.1 is an adaptation of data presented in the 2014 Medicare Outlook section of the www.q1medicare.com web site, and has no analyses. Table 7.2 shows the percent of beneficiaries with Part D coverage for the past three years in the General Medicare, CKD, and ESRD cohorts. A beneficiary was considered enrolled in Part D if at least one month's Part D Plan Contract Number had the first digit of "E","H","R", or "S." Figure 7.2 shows the categories of prescription drug coverage (described above for Figure 7.1) by age groups (20-44/45-64/65-74/75+) for General Medicare (Panel A) and CKD (Panel B), while Figure 7.3 shows it by race groups (White/Black or African American/Asian/Other).

Table 7.3 was limited to beneficiaries who were enrolled in Part D prescription plans for at least one month of the analysis year. Part D plan enrollment and receipt of LIS were determined as described for Figures 7.1. Table 7.3 shows the percent of Part D enrollees with LIS within each race group ("all ages" row) and by age groups within the race group (also defined as above) for the General Medicare cohort and the CKD cohort. Figure 7.4 was limited to those enrolled in a Part D plan with LIS and shows the different types of LIS, as determined by the values of the Cost Sharing Group Code, for the General Medicare, CKD, and ESRD cohorts.

The next several tables and figures present data on Medicare spending for Part D benefits. The Part D benefit expenditure for a prescription drug event (PDE) is the sum of the amount of cost sharing for the drug that was paid by the Part D low-income subsidy (LIS Amount) and the net amount that the Part D plan paid for the PDE (Covered Part D Plan Paid Amount). Table 7.4 shows the total Medicare Part D benefit expenditures for the General Medicare, CKD, and ESRD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans was not included). These cost numbers are, therefore, comparable to the statistics presented in Chapter 6, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

Figure 7.5a shows Medicare spending and patient out-of-pocket amounts per patient per year for the General Medicare, CKD, and ESRD cohorts, again for only those who were in stand-alone Part D plans. Out of pocket cost was the sum of the amounts paid by the patient without being reimbursed by a third party (Patient Payment Amount) which included all copayments, coinsurance, deductible, or other patient payment amounts, and the amount of any payment made by other third-party payers that reduced the beneficiary's liability for the PDE (Other True Out-of-Pocket Amount). Two examples of this were payments by qualified state pharmacy assistance programs or charities. Figure 7.5b breaks out these costs by whether the patient received any low income

subsidies. Table 7.5 stratifies these costs by age, sex, and race.

All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service classification system. The cohort for Tables 7.6 and 7.7 was limited to those in the CKD cohort who have stand-alone Part D prescription drug coverage. Each therapeutic category was summarized and the percent of patients with CKD who filled at least one prescription for a drug in the given class was calculated, as well as the total amount spent by Medicare on each drug class and its percentage of total Part D costs. Table 7.6 shows the top 15 drug classes ranked by the highest percent of CKD patients with at least 1 prescription filled in that class. Table 7.7 shows the top 15 drug classes ranked by spending. The column following the drug class name shows the total amount spent by Medicare on each drug class for CKD patients with stand-alone Part D plans and the next column shows that drug class' cost as a percentage of all Medicare Part D costs for these patients.

Reference Tables: CKD

Reference Tables B.1–B.6 present estimated point prevalent (December 31) counts of the Medicare non-ESRD population, based on the 5% Medicare sample, for adults aged 20 and older rather than the age-eligible (aged 65 and older) cohort presented in Chapter 2. Each year's cohort included all patients alive and without ESRD, who were continuously enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage program (Part C) for the entire year. Age was calculated as of December 31 of the reported year. Race and sex were provided by the Master Beneficiary Summary File. The disease conditions of CKD, congestive heart failure (CHF), and diabetes mellitus (DM) and the stage of CKD were determined from the claims in the reported year, using the methods described in the *Identification of Major Comorbidities* section of this chapter and the diagnosis codes listed in Tables m.3 and m.4. Counts were multiplied by 20 to represent 100% of the Medicare population meeting the cohort definition.

Reference Tables B.7-B.10 are based on NHANES data (see the NHANES methods description in the *Chapter 1: CKD in the General Population* section, above). For Table B.8, CKD is defined as an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73m^2 (which identifies Stages 3 and 4) or urine albumin creatinine ratio (ACR) greater than 30 mg/g (which identifies Stages 1 and 2). eGFR was estimated from one serum creatinine measurement using the CKD-EPI equation (Levey et al., 2009). The consensus definition of CKD requires two measurements of both eGFR and ACR meeting the criteria above, within a three-month period, but only one measurement of each is available in NHANES. Therefore, the resulting numbers overestimate the true number of CKD patients in the general U.S. population. CKD staging is as defined by the Kidney Disease Outcomes and Quality Improvement (KDOQI) CKD guidelines (NKF, 2002). In Table B.9, DM was defined as in Chapter 1, and eGFR and ACR as described for Table B.8. Table B.10 presents results for CHF, which is self-reported in NHANES as an affirmative answer to, "Has a doctor or other health professional ever told you that you have congestive heart failure?"

Tables K.1–5 present estimates of per-person per-year Parts A, B, and D Medicare expenditures for point prevalent (December 31) general Medicare patients, also derived from the 5% Medicare sample. Methods for these tables were the same as those described in the *Chapter 6: Medicare Expenditures for CKD* section of this document. The reference tables include all adult patients aged 20 and older, while the chapter presents these costs only for those age-eligible for Medicare (aged 65 or older).

References

Centers for Disease Control and Prevention (CDC). National Center for Health Statistics, Behavioral Risk Factors Surveillance System (BRFSS), 2015. Accessed 10/15/2015. http://www.cdc.gov/brfss/index.html

Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey. 2007-2008 data documentation, codebook, and frequencies – urinary albumin and urinary creatinine. 2009. Accessed 10/22/2015. http://www.cdc.gov/nchs/nhanes/nhanes2007-2008/ALB_CR_E.htm.

Centers for Medicare and Medicare Services. *Medicare and You 2015*. Publication No. CMS-10050. Baltimore: Centers for Medicare and Medicaid Services.

Herbert PL, Geiss LS, Tierney EF, Engelgau MM, Yawn BP, McBean AM. Identifying persons with diabetes using Medicare claims data. *American Journal of Medical Quality* 1999 Nov/Dec: 14(6): 270-277.

Johnson CL, Paulose-Ram R, Ogden CL, Carroll MD, Kruszon-Moran D, Dohrmann S, Curtin LR. National Health and Nutrition Examination Survey: analytic guidelines, 1999-2010. National Center for Health Statistics. Vital and Health Statistics 2013: 2(161):1-16. Available at http://www.cdc.gov/nchs/data/series/sr_02/sr02_161.pdf

Kidney Disease: Improving Global Outcomes (KDIGO) Acute Kidney Injury Workgroup. KDIGO clinical practice guideline for acute kidney injury. *Kidney Int*. 2012;2:1-138.

Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group, 2012. KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int., Suppl*. 2013; 3: 1–150.

Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF, Feldman HI, Kusek JW, Eggers P, Van Lente F, Greene T, Coresh J. A new equation to estimate glomerular filtration rate. *Annals of Internal Medicine* 2009 May: 150(9): 604-612.

McBean M. *Introduction to the Use of Medicare Data for Research*. Workshop, Research Data Assistance Center, University of Minnesota, Minneapolis, MN. October 15, 2012, available at: http://www.resdac.org/training/workshops/intro-medicare/media.

Merriman K, Asper M. *Differences in How the Medicare 5% Files are Generated*. Technical Brief, ResDAC Publication Number TN-011, March 2007. Research Data Assistance Center, University of Minnesota, Minneapolis, MN. http://www.resdac.umn.edu.

National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. *American Journal of Kidney Diseases* 2002: suppl 1 (39): S1-S266.

OptumInsight. Clinformatics Data Mart Training May 2015 – Prepared for University of Michigan. Presentation on May 11, 2015, North Campus Research Complex, Building 10, Research Auditorium, Ann Arbor, MI.

Selvin E, Manzi J, Stevens LA, Van Lente F, Lacher DA, Levey AS, Coresh J. Calibration of serum creatinine in the National Health and Nurtition Examinations Surveys (NHANES) 1988-1994, 1999-2004. 2007 Dec: 50(6): 918-926.

Notes