Volume 1: CKD Analytical Methods

Contents

Introduction

In this chapter, we describe the data sources, preparation and management, variable definitions, and analytical methods used to produce the statistics presented in Volume 1 of the 2017 USRDS Annual Data Report (ADR), which focuses on chronic kidney disease (CKD) prior to end-stage renal disease (ESRD). We outline the detail regarding the datasets and methods used for ESRD analyses in the *ESRD Analytical Methods* chapter of Volume 2.

Enhancements for the 2017 ADR included conversion of our data and analyses from ICD-9-CM diagnosis and procedure codes to the newly introduced ICD-10-CM, and expansion of our application of Optum Clinformatics™ and Veterans Health Administration data. This CKD Methods chapter does not address Chapter 8 of Volume 1, which were the product of a Special Study Center. Relevant methods are included within those chapters.

Data Sources

The USRDS uses several data sources to describe pre-ESRD kidney disease in the U.S. These contain data regarding patient diagnoses, demographic characteristics, healthcare procedures, prescription drug plan participation, and filled prescriptions. Data on the non-institutionalized, general population are 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 healthcare systems were used: the standard Centers for Medicare and Medicaid Services (CMS) Medicare 5% sample, the Optum Clinformatics™ Data Mart Database of people with commercial health insurance and Medicare Advantage plans, and the Veterans Health Administration (VHA) beneficiary data.

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. In 1999, NHANES became a continuous, annual survey to provide for more timely and regular estimates; public-use data files are released every two years.

NHANES 1999–2014 are nationally-representative, cross-sectional surveys with a complex, stratified, multi-stage probability cluster sampling design that includes the selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households (Johnson et al., 2013). Survey participants are interviewed in their homes and/or receive standardized medical examinations in mobile examination centers. African Americans, Mexican Americans, and individuals aged 60 or older are over-sampled 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 landline subscribers, cell phone users are included in the sample frame. A question regarding kidney health was added starting in 2012—specifically, respondents are 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%). Data from 2012-2015 are used in the 2017 ADR.

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

The Optum Clinformatics™ Data Mart provides paid medical and prescription claims and enrollment information for participants in the commercial insurance plans and Medicare Advantage plans of a

large U.S. managed-care health insurance company. Included plan members are enrolled in both a medical and a prescription plan, and the sample represents all areas of the country.

The USRDS purchased data from OptumInsight. With our data delivery in 2017, OptumInsight expanded the number of diagnosis and procedure codes in the MEDICAL claims table from eight (five diagnosis codes and three procedure codes) to 25. This provides us the potential to detect more disease conditions and procedures than in the 2016 ADR.

The Optum Clinformatics™ data license requires that their 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 earliest 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 10.1 for specific code values.

We present Optum Clinformatics™ data from 2005 through 2015 in the 2017 ADR. To comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) 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 use the Date of Death (DOD) view—detailed geographic and socio-economic data are not available in the files, but date of death is included. The other available data views do not contain date of death. Enrollment and member information, such as year of birth, sex, race/ethnicity, state of residence, and plan participation are contained in the MEMBER and MEMBER_DETAIL data tables.

All services for both inpatient and outpatient care are located in the MEDICAL claims data table, with the confinement ID (*conf_id*) variable indicating inpatient institutional claims. Combined with the admission and discharge dates from the inpatient institutional claims, we identify all inpatient medical services performed for the patient during that time.

vol 1 Table 10.1 ICD diagnosis, CPT procedure, and DRG codes used to define ESRD in the Optum Clinformatics™ and VHA 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
ICD-10-CM Diagnosis codes		N18.9, T86.10-T86.13, T86.19
HCPCS 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: DRG, diagnosis related group, FY, fiscal year (10/1/yy to 9/30/yy), HCPCS, Healthcare Common Procedure Coding System, ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification.

The MEMBER and MEMBER_DETAIL tables were 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 were dropped if (1) the year of birth variable, *yrdob*, was missing or zero, (2) the year of the plan coverage effective date, *eligeff*, was before the year of birth, (3) the year of plan coverage effective date was after the year of the death date, (4) the coverage ending date, *eligend*, was the same as or earlier than the coverage start date, or (5) the member had more than one year of birth reported and these 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, not as a specific date. We have set all deaths to the first day of the reported month to create a specific death date from the month and year combination. 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. However, the Optum augments information in the Clinformatics™ Data Mart with data from the Social Security Death Master File (SSDMF). In November of 2011, 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). This may overstate the survival statistics, as more deaths will go undetected. For this reason, we do not present analysis of mortality rates for the Optum Clinformatics™ dataset, although other chapters do use date of death to censor time to event analyses.

Information on Optum Clinformatics™ expenditures for medical services is included in the 2017 ADR for the first time, as are analyses of prescription drug usage. To account for differences in pricing across health plans and provider contracts, OptumInsight applies standard pricing algorithms to the claims data in the Optum Clinformatics™ Data Mart. These algorithms are designed to create standard prices that reflect allowed payments across all provider services. Standard pricing amounts are included in the MEDICAL and the RX claims tables.

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 by healthcare providers for reimbursement. CMS and its contractors produce the 5% datasets by selecting all final action claims for Medicare beneficiaries whose CMS Health Insurance Claim (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 creates a built-in longitudinal panel dataset as well as a nationally representative, yearly cross-section sample. 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 2017 ADR includes all claims for care occurring up to December 31, 2015, that were submitted and processed by June of 2016.

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 are divided into two groups based on the type of healthcare provider—institutional or non-institutional (physician/supplier and durable medical equipment). Institutional claims are 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 receive 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) are received in one set for durable medical equipment (DME) and another for all other Part B covered services (BCARRIER). For each of these, we receive 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 receive files on beneficiary information and prescription drug events (records of each prescription fill and refill, similar to a claim), 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 events related to final action claims for prescription drugs submitted by pharmacies on behalf of the Part D beneficiary. This dataset 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 2017 ADR, we used the Plan Characteristics file (PLAN_CHAR) and premium (PREMIUM) files to report on the coverage gap and distribution of premiums.

Veterans Health Administration (VHA) Data

In 2016, we introduced data on kidney disease from the Veterans Health Administration's (VHA), and we update those analyses and present new tabulations for the 2017 ADR. Data are primarily from the VHA 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 VHA's electronic medical record, and the analyses in the 2017 ADR were based on a cohort created by the VINCI data manager on April 21, 2017. Our basic cohort was defined as all patients with at least one outpatient encounter (a record in the VISIT table in the OUTPAT domain) during calendar year 2015. Age, sex, race, and date of death were taken from the PATIENT.PATIENT table, and race was supplemented with data from the PATSUB.PATIENTRACE table. Ethnicity is from PATSUB.PATIENTETHNICITY.

In the CDW, various types of inpatient care provided by the VHA 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 admissions 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 *medical_service* variable to have one of the following values: medicine, surgery, psychiatry, spinal cord injury, intermediate medicine, or neurology. Additionally, the *specialty* variable must also have had a value related to the type of care provided in short-term hospitals[1].

Serum creatinine laboratory test results are 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 are 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.) are dropped, as are those with values less than 0.4 mg/dL or greater than

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

15.0 mg/dL for the CKD analyses (20.0 mg/dL for the AKI analyses).

ESRD Medical Evidence Form (CMS 2728)

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, we search the USRDS ESRD databases for the beneficiaries in the Medicare 5% files. The date of ESRD is determined from the ESRD Medical Evidence form (CMS 2728), the official form for registering ESRD patients, that must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. First service date for ESRD is reported on this form; for analyses in Volume 2 it is used as the date when ESRD began. See Volume 2, *ESRD Analytical Methods* for additional information on how the Medical Evidence form was used in analyses of ESRD patients.

ESRD Death Notification Form (CMS 2746)

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 supplement 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, dialysis or transplant providers must submit this form 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. The race variables for the CKD volume are different from those available in the ESRD volume, so we are unable to replicate the new race/ethnicity categories implemented in the 2017 ADR. Table 10.2 shows the categories included in the original data files. For the Medicare 5% files and Optum 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 cannot identify Native Americans in the Optum Clinformatics™ data. The NHANES, BRFSS, and VHA data report two variables, one with race categories, and a second designating Hispanic ethnicity. These categories are combined for some analyses due to the small sample sizes in some datasets.

vol 1 Table 10.2 Race and ethnicity variables in the Volume 1 data sources

Race/Ethnicity Variables	NHANES	BRFSS	Medicare 5% data	Clinformatics™ Data Mart	Veterans Health 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 are applied to the claims data files to create a sample cohort. The individual restrictions that are used for each figure and table are detailed in the chapter-specific sections of this chapter. 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 datasets is to reimburse healthcare 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 commonly 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) and 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 are often limited to beneficiaries that are enrolled in both Parts A and B and are not enrolled in a Medicare Advantage plan (Part C). In the Optum 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 datasets, the cohort is limited to patients who meet these plan participation requirements on a certain date, such as January 1 of the reported year. In other cases the sample may have been limited to beneficiaries who meet those enrollment requirements during the entire calendar year.

In most analyses that are limited to patients with a certain disease or disorder, such as CKD, Medicare beneficiaries must be 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 Optum Clinformatics™ patients must be enrolled in their plan for the year. This ensures that each patient has 12 months of claims from which to determine the presence of the disorder. The outcome under analysis is then determined from claims in the year following the entry period ('year two'). Prevalence analyses, however, are not subject to this requirement and use 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 are restricted to beneficiaries that were age-eligible for Medicare and, therefore, aged 65 and older. Beneficiaries under the age of 65 may qualify for Medicare based on 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 that accompany this Volume include 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 are excluded. The Optum 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 do 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 censor a patient at the start of ESRD. Censoring also often occurs at death, upon change in plan enrollment (for Medicare beneficiaries, the disenrollment from Parts A and B of Medicare orwhen switching to a Medicare Advantage plan, and for Optum Clinformatics™ patients at the end of plan participation as reported by the *eligend* variable). The start of ESRD is 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 for Optum Clinformatics™ plan members (starting in 2004 through the most recent year).

Identification of Major Comorbidities

We employ a previously validated method (Herbert et al., 1999) to identify diabetic patients through Medicare claims. A patient is considered diabetic if, within a one-year observation period, he or she had a qualifying ICD-9-CM or ICD-10-CM diagnosis code of diabetes mellitus (DM) on one or more Part A institutional claims (inpatient, skilled nursing facility, or home health agency), or on 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—is 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 is also applied to the claim data in the Optum Clinformatics™ Data Mart with the inpatient/outpatient determination made by determining if the service date fell within an inpatient confinement identified by the confinement ID (admission and discharge dates calculated from the first and last date of the claims with a specific confinement ID). Tables 10.3 and 10.4 list these conditions and the ICD-9-CM and ICD-10-CM diagnostic codes used to define them. Additionally, the overall grouping of cardiovascular disease (CVD) includes patients with at least one of these individual conditions: coronary artery disease (formerly called atherosclerotic heart disease), heart failure (HF; formerly called 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 10.3 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the health insurance claim data files throughout Volume 1 of the ADR

	ICD-9-CM codes	ICD-10-CM codes
Chronic kidney disease (CKD)	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	A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N17.x, N18.1-N18.5, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4
Staging of chronic kidney disease		
Stage 1	585.1	N18.1
Stage 2	585.2	N18.2
Stage 3	585.3	N18.3
Stage 4	585.4	N18.4
Stage 5	585.5 or 585.6 with no CMS 2728 form	N18.5
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	Patient has no claims with codes N18.1-N18.6 but has: A18.11, A52.75, B52.0, C64.x, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.2x, E09.2x, E10.2x, E10.65, E11.2x, E11.65, E13.2x, E74.8, I12.xx, I13.0, I13.1x, I13.2, K76.7, M10.3x, M32.14, M32.15, N01.x-N08.x, N13.1, N13.1x-N13.39, N14.x,N15.0, N15.8, N15.9, N16, N18.8, N18.9, N19, N25.xx, N26.1, N26.9, O10.4xx, O12.xx, O26.83x, O90.89, Q61.02, Q61.1x-Q61.8, Q26.0-Q26.39, R94.4

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. 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 10.4 ICD-9-CM and ICD-10-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	ICD-10-CM codes
Anemia	280-285	D50.0-D64.9
Cancer	140-172; 174-208; 230-231; 233-234	C00.0-C43.9; C45.0-C75.9; C76.0-D03.9; D05.00-D09.9
Cardiac, other	420-424; 429; 785.0-785.3; V42.2; V43.3	A18.84; I23.0-I23.8; I25.10; I30.0-I39; I51.0-I52; I97.0-I97.191; M32.11; M32.12; R00.0; R00.2-R01.2; Z95.2-Z95.4
Cerebrovascular accident (CVA) / transient ischemic attack (TIA)	430-438	G45.0-G45.2; G45.4-G46.8; I60.00-I66.9; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998
Chronic obstructive pulmonary disorder (COPD)	491-494; 496; 510	J41.0-J47.9; J86.0; J86.9
Coronary artery disease (CAD)	410-414; V45.81; V45.82	I12.00-I22.9; I24.0-I25.9; Z95.1; Z95.5; Z98.61
Diabetes mellitus (DM)	250; 357.2; 362.0; 366.41	E08.311-E08.36; E08.40; E08.42; E09.311-E09.36; E09.40; E09.42; E10.10-E13.9
Dysrhythmia	426-427; V45.0; V53.3	I44.0-I49.9; R00.1; Z45.0-Z45.09; Z95.0; Z95.810; Z95.818; Z95.9
Gastrointestinal bleeding disorders (GI)	456.0-456.2; 530.7; 531-534; 569.84-569.85; 578	I85.00-I85.11; K22.6; K25.0-K28.9; K55.20; K55.21; K56.60; K92.0-K92.2
Heart failure (HF)	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	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1-I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Hypertension (HTN)	362.11; 401-405; 437.2	H35.031-H35.039, I10-I13.2, I15.0-I15.9, I67.4, N26.2
Liver disease	570-571;572.1, 572.4; 573.1-573.3; V42.7	B25.1; K70.0-K72.01; K73.0-K74.69; K77; Z48.23; Z94.4
Peripheral vascular disease (PVD)	440-444; 447; 451-453; 557	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; I67.0; I70.0-I74.9; I77.0-I77.9; I79.0-I82.91; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits. Transition from ICD-9-CM to ICD-10-CM.

The U.S. federal government changed from using the International Classification of Diseases, Ninth Revision (ICD-9) coding system to using the ICD-10 coding system at the start of fiscal year 2016, which was October 1, 2015. Therefore, there are 3 months of claims in calendar year 2015 that use the ICD-10-CM code frame. To identify the ICD-10 codes that indicated the chronic conditions previously identified by ICD-9 codes, we used the CMS General Equivalence Mapping (GEM) dataset. There is not a one-to-one match between ICD-9 and ICD-10 codes in the GEM, but rather a one-to-many match in both directions; an ICD-9 code can match to multiple ICD-10 codes and an ICD-10 code can match to multiple ICD-9 codes. We then looked at counts and percentages for each comorbidity for 2013, 2014, and 2015 to note any changes in the monthly pattern starting in October 2015.While the overall numbers

reasonably matched the results from prior years, a detailed review of the ICD-10-CM codes will be performed in the coming year.

Chapter 1: CKD in the General Population

Analyses in this chapter use 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). Starting in 1999-2000, 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 four clusters of NHANES continuous cycle years 1999-2002, 2003-2006, 2007–2010, and 2011-2014. The statistical software package SAS® was used to analyze all NHANES data, incorporating the sampling weights and survey design through its survey procedures.

In this chapter, age is defined as the participant's age at the time of the NHANES household interview, categorized into the following age groups: 20 to 39, 40 to 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 is based on the 2012 guidelines from the Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group (KDIGO, 2013), which was 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 m², 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 use the urine albumin creatinine ratio (uACR) to measure albuminuria, but there is no information regarding the other markers of kidney damage. Also, the NHANES only includes a single measurement of both serum creatinine (sCR, used to generate eGFR) and uACR, so we cannot address the three-month persistence criteria for defining CKD; the implications of this are discussed in detail in the chapter.

The eGFR (measured in ml/min/1.73 m²) 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 if otherwise

AGE is measured in yearsThe uACR is the ratio of urinary albumin (mg/L) to urinary creatinine (mg/dL). Based on an NCHS suggestion, the urine creatinine value is adjusted to NHANES 2007-2008 (CDC, 2009).

Staging of CKD was first introduced in 2002 through the National Kidney Foundation's Kidney Disease Outcomes and Quality Improvement Guidelines (NKF, 2002). Following these guidelines, we define 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, not ESRD

NHANES respondents are also asked, *"Have you ever been told by a doctor or other health professional that you had weak or failing kidneys? Do not include kidney stones, bladder infections, or incontinence."* When a respondent endorses CKD as measured above, we call this question awareness of kidney disease. Those answering "yes" are aware of their CKD.

Participants with diabetes mellitus (DM) include 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 (HgbA1c; glycohemoglobin) ≥7%. Participants with self-reported diabetes mellitus (SR DM) are those who report having been told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). Participants answering "borderline" are classified as non-diabetic. Control of DM is assessed as a HgbA1c less than 7%.

Patients with hypertension (HTN) are 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) is identified through an affirmative answer to the question *"Have you ever been told by a doctor or other health professional that you had hypertension, also called high blood pressure?"* Patients are classified as <u>aware of</u> their HTN if they report having been told they have high blood pressure, as <u>treated for</u> their HTN if they reported currently taking a prescription medication to control HTN, and as <u>in control of</u> 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 are considered to have self-reported cardiovascular disease (SR CVD): angina, myocardial infarction, stroke, coronary heart disease, or congestive heart failure. Hyperlipidemia is measured in the medical examination. We assess whether total cholesterol falls into one of three categories: <200 (desirable), 200–239 (borderline high), and ≥240 (high). Individuals were classified as current smokers if they give an affirmative answer to the question *"Do you now smoke cigarettes?"* and former smokers if they respond negatively to the previous question, but affirmatively to the question *"Have you smoked at least 100 cigarettes in your life?"*

New to the 2017 ADR is the examination of CKD by socioeconomic variables and additional health-related behaviors. Three socioeconomic variables were added: health insurance status, annual family income, and education. First, health insurance as a yes/no variable is determined by the answer to the question, *"Are you covered by health insurance or some kind of healthcare plan? [Include health insurance obtained through employment or purchased directly as well as government programs like Medicare and Medicaid that provide medical care or help pay medical bills]."* The category private insurance is determined by a "yes" answer to *"Are you covered by private insurance?"* Medicare coverage is a "yes" answer to *"Are you covered by Medicare?"* Other government coverage is defined by a "yes" answer to having coverage through Medigap, Medicaid, State Child Health Insurance Program (SCHIP), military healthcare, Indian Health Service, or other government insurance. Answers to these questions are categorized as private only, Medicare only, other government insurance only, private and any government (Medicare or other government insurance), and other/unknown.

Income was total annual family income (*indfminc*) in the 1999-2006 NHANES, reported in ranges of $5,000 increments up to a top range of "$75,000 and over". In 2007-2008 the variable *indfmin2* contained annual family income with two additional categories on the upper end of the distribution—$75,000 to $99,999 and $100,000 and over. We collapsed reported income levels into categories of less than $10,000, $10.000-$24,999, $25,000-$44,999, $45,000-$74,999, and $75,000 or more.

Education was derived from the question, *"What is the highest grade or level of school you have completed or the highest degree you have received?"* Valid answers are less than 9th grade, 9th-11th grade (including 12th grade with no diploma), high school grad/GED (general educational development) or equivalent,

some college or AA (associate) degree, college graduate or above. We collapse these categories into less than high school, high school grad/GED, and at least some college.

Physical activity was defined using several questions from the NHANES survey. For the 1999-2006 and 2001-2002 NHANES, vigorous activity was defined as a yes answer to the question, *"Over the past 30 days, did you do any vigorous activities for at least 10 minutes that caused heavy sweating, or large increases in breathing or heart rate? Some examples are running, lap swimming, aerobics classes or fast bicycling"* while moderate activity is a yes answer to *"Over the past 30 days, did you do any moderate activities for at least 10 minutes that caused only light sweating, or a slight to moderate increase in breathing or heart rate? Some examples are brisk walking, bicycling for pleasure, golf, and dancing"*. Starting with the 2007-2008 NHANES, different questions are asked about physical activity; separate questions ask about work (paid, unpaid, volunteer, house and yardwork), transportation (walking or using a bicycle) and recreational activities. The questions are phrased similarly to the previous NHANES questions but with reference to work and recreation. Vigorous activity in the ADR was defined as answering "yes" to either work or recreational vigorous activity, with moderate activity defined the same way. The final physical activity categorical variable was defined in a hierarchical manner; if a person reported both vigorous and moderate activity, they are classified as "vigorous" activity level. Sedentary was defined as having neither vigorous nor moderate activity.

Sleep is another health behavior examined this year. Sleep amount was determined by the answer to the question, *"How much sleep do you usually get at night on weekdays or workdays?"* Valid answers were one to 11 or "12 hours or more". A categorical variable was then made with ranges of less than six hours, six hours, seven to eight hours, and nine or more hours. Self-reported special diet was indicated by an answer of "yes" to the question, *"What kind of diet are you on? (Is it a weight loss or low calorie diet; low fat or cholesterol diet; low salt or sodium diet; sugar free or low sugar diet; low fiber diet; high fiber diet; diabetic diet; or another type of diet?*).

In the chapter, Figure 1.1 shows the weighted percentage of NHANES respondents with each stage of CKD, defined as above, for four time periods, 1999-2002, 2003-2006, 2007-2010, 2011-2014. The whisker bars show the 95% confidence interval around each estimate of the U.S. civilian, noninstitutionalized population fraction with each stage of kidney disease. The test for trends noted in the text is a logistic regression with appropriate accounting for survey design elements, including weights, with the four time periods forming a continuous variable with values 1 to 4 in order of calendar time. Figure 1.2, panel a shows the distribution of estimated eGFR for all NHANES respondents and Figure 1.2, panel b, shows the distribution for those aged 60 and over. These figures are box plots. The structure of the box is as follows:

vol 1 Figure 10.1 Interpretation of a box plot

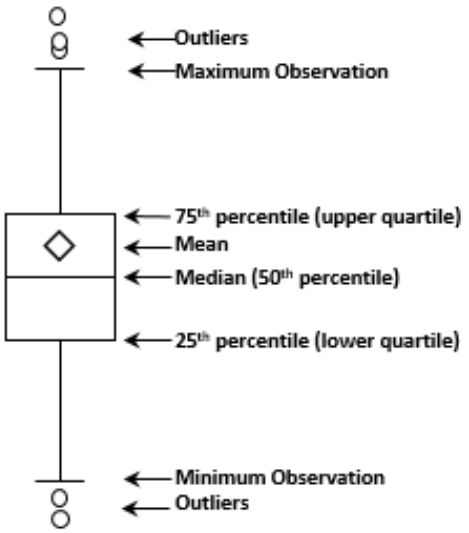

Figure 1.3 shows the urine albumin creatinine ratio (uACR) for NHANES respondents in four categories: less than 10 mg/g, 10 to 29 mg/g, 30-300 mg/g (also known as microalbuminuria), and greater than 300 (macroalbuminuria) for the four periods used in Figure 1.1. Figure 1.4 shows the percent of NHANES respondents with uACR of 30 mg/g or higher by level of eGFR and time period. Table 1.1, panel a shows updated statistics for Figure 8 from Chapter 1: Definition and Classification of CKD of the KDIGO 2012 Clinical Practice Guideline for CKD Evaluation and Management (KDIGO, 2013) using data for 2011-2014. Panel b summarizes the results by the risk categories shown in panel a—low risk, moderately high risk, high risk and very high risk, over the four time periods.

Table 1.2 shows demographic variables (age, race, sex) and clinical risk factors and consequences of CKD (DM, SR DM, HTN, SR HTN, SR CVD, and obesity) by three definitions of CKD—the standard definition using eGFR and uACR (All CKD), using reduced eGFR alone (<60 ml/min/1.73m^2), and using the albuminuria criterion alone (uACR $\geq$ 30mg/g). This table shows what percent of the group described by the row label has CKD, for example, 32.6% of those aged 60 or older in 2011-2014 had CKD by the eGFR and uACR criteria combined. The test for trends noted in the text is a logistic regression with appropriate accounting for survey design elements, including weights, with the four periods forming a continuous variable with values 1 to 4 in order of calendar time. The Figure 1.5 shows the prevalence of each measure of CKD, reduced eGFR only, elevated uACR only, or both reduced eGFR and elevated uACR, among each risk factor group. For example, 15.8% of those aged 60 or older met the reduced eGFR criterion only, 10% met the elevated uACR criterion only; and 6.8% had both reduced eGFR and elevated uACR.

Adjusted odds ratios in Figures 1.6-1.8 are calculated using logistic regression, incorporating the sampling weight and survey design. In Figures 1.6 and 1.8 we display the results of seven logistic models. Figure 1.7 splits the models into two panels with age in panel a, and the CKD risk factors in panel b. The model for age includes age (20 to 39/40 to 59/60 and older), 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) include age (20 to 39/40 to 59/60 and older), sex (male/female), race (White/Black/other) and presence of the risk factor shown (yes vs. no). Ninety-five percent confidence intervals are displayed and results shown for the four periods.

Table 1.3 shows the distribution of three socioeconomic variables among those with CKD—either the standard definition, reduced eGFR, or elevated uACR—for the four periods. The column percentages of not insured and insured add up to 100%, the types of insurance add up to the percentage insured, and the income and education categories each add to 100%. Table 1.4 shows the distribution of health risk behaviors in a manner similar to Table 1.3. Sleep amount and self-reported special diet are not available for the 1999-2002 period. Figure 1.9 shows the percent of NHANES respondents who are physically active (defined as moderate or vigorous activity) by CKD definition/components and the four periods.

Table 1.5 shows the distribution of several measures of awareness, treatment, and control for the CKD risk factors of HTN, high cholesterol, and DM. Again, these column percentages sum to 100% within each panel. Figure 1.10 shows the percent of NHANES respondents whose blood pressure at the medical exam was at the target level, by CKD definition/components and the four periods. Figure 1.11 shows the percentage with cholesterol levels within target range, and Figure 1.12 shows the percentage with HgbA1c within target range.

Figure 1.13 shows the percent of NHANES respondents that report having a health professional tell them they had kidney disease, which we define as being aware of their kidney disease, by the four periods. Figure 1.13, panel a shows this by stage and panel b by reduced eGFR, elevated uACR, and both. Figure 1.14 tabulates responses to the 2012-2015 Behavioral Risk Factor Surveillance System question, *"Has a doctor, nurse, or other health professional ever told you have kidney disease?"* by U.S. state for each of the past four years of available data.

Chapter 2: Identification and Care of Patients with CKD

All of the analyses in the chapter sections *Patients Characteristics across Datasets, Comparison of CKD Prevalence across Datasets, and Longitudinal Change in CKD Status and Outcomes, Based on Diagnosis Codes,* include point prevalent patients who survived all of the reported year (2015 for most of the figures and tables) and who did not have or develop ESRD during the 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. Optum Clinformatics™ analyses additionally required the plan member to be enrolled for the entire reported year. The age range of members varied by table, with Tables 2.1 and 2.4 including all ages and the remaining tables and figures including adults aged 22 to 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), the Optum Clinformatics™ dataset (all ages), and the VHA (all ages). Comorbidities included 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, coronary artery disease (formerly called atherosclerotic heart disease), heart failure, dysrhythmia, or other cardiac comorbidities. Each comorbidity was defined by at least one inpatient or two outpatient medical 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 10.3 and 10.4 for a list of ICD-9-CM and ICD-10-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 to 64 in the Optum Clinformatics™ and VHA datasets. 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, plus the number and percentage who had at least one or at least two comorbidities.

Table 2.3 shows a comparison of the percent of patients with CKD by demographic characteristics, in different datasets. The survey-based NHANES data (see the section *Chapter 1: CKD in the General Population* in this chapter for methods), include the 2011-2014 survey years and are restricted to participants aged 65 or older. CKD is determined by eGFR<60 ml/min/1.73m^2. In the claim-based datasets of Optum Clinformatics™ (2015) and the Medicare 5% sample (2015), CKD is determined by ICD-9-CM or ICD-10-CM diagnosis codes. In the claim and lab-based VHA dataset (2105) patients are considered to have CKD via either a diagnosis or eGFR<60 ml/min/1.73m^2, as determined by routine blood testing for serum creatinine.

Table 2.4 shows the 2015 unadjusted prevalence of diagnosed CKD by age, sex (male/female), race (White/Black/Native American/Asian/Hispanic [Optum Clinformatics™ only]/other), and comorbidity for the Medicare 5% sample, Optum Clinformatics™, and the VHA. Comorbidities include DM with or without HTN and HTN without DM. Figure 2.1 has two map panels for (a) the Medicare 5% sample and (b) the Optum Clinformatics™ dataset, showing the prevalence of diagnosed CKD across the U.S.

Figure 2.1 shows the 2015 distribution of CKD prevalence, among the Medicare 5% sample (aged 65+ years) and Optum Clinformatics™ (all ages) patients in 2015, by states.

Figure 2.2 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 2.5 shows progression of kidney disease by CKD stage, end-stage renal disease (ESRD), or death in 2014-2015 for the fee-for-service, age-eligible

Medicare population of 2010. The analysis cohort required patients to be alive and eligible for Medicare Parts A and B with no HMO coverage for all of 2010. Death and ESRD status were examined yearly between 2011 and 2015, and carried forward if present. The ESRD and death information were combined to create three categories: ESRD-alive, ESRD-death, and Death without ESRD. For patients who did not progressto death or ESRD by 2015 the last CKD diagnosis claim in 2015 was used; if this was not available, the last CKD diagnosis claim from 2014 was used. Lost to follow-up status represents the patients who were not enrolled in Medicare Part A and B during 2014 or 2015 and who had no indication of death or ESRD.

Figures 2.3–2.4 show the proportion of patients tested for urine albumin from 2005-2015, for patients with (Figure 2.4) and without (Figure 2.3) CKD by the comorbidities of DM without HTN, HTN without DM, both DM and HTN, or neither. 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 been enrolled in their plan (for Medicare, Parts A and B coverage, and no Medicare Advantage plans), not have ESRD, and alive for all of year one through to January 1 of year two. Additionally, the sample is limited to patients residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories. First urinary microalbumin measurement is 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. Panel a shows the Medicare 5% sample and panel b the Optum Clinformatics™ data.

Table 2.6 examines physician visits in the year after a diagnosis of CKD. Similar to the laboratory testing, the sample includeed patients who were alive, without ESRD, did not have a Medicare Advantage plan, and had both Parts A and B coverage for all of 2014. The date of the earliest CKD claim (any CKD or Stage 3/4/5 [585.3–585.6, ICD-10 codes were not used in 2014]) in 2014 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, or 11. Cardiologist visits were defined based on specialty code 06, and nephrology visits based on specialty code 36.

Figure 2.5 presents the proportion of CKD patients in the fee-for-service, age-eligible Medicare population in 2015 (based on diagnostic code) who were tested for urine albumin in 2015, according to whether they saw a primary care physician, a nephrologist, or neither in 2014. The analysis cohort required patients to be alive and eligible for all of 2015 with a CKD diagnosis claim in 2014.

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, enrolled in their plan (for Medicare, covered by Parts A and B with no Medicare Advantage plan (Part C)) 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 the above criteria and be aged 66 or older on January 1 of the following year (year two). We then determined patient mortality and/or hospitalization for the period January 2 to December 31 of year two. Analyses were 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 their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage plan), or December 31 of year two. The analyses of Optum Clinformatics™ data employed similar selection criteria, except patients must have been enrolled in their Optum Clinformatics™ plan for all of year one and January 1 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. Figure 3.1 shows trends in unadjusted and adjusted all-cause mortality by CKD status from 2003 to 2015, and Figure 3.2 shows rates for 2015 by CKD status and stage. We calculated unadjusted mortality as the number of deaths divided by the number of patient-years at risk, and express this as "per 1,000 patient years." Adjusted mortality was based on a Cox regression model and adjusted for age (66 to less than 70, 70 to less than 75, 75 to less than 85, or 85 years and older), race (White, Black or African American, other), and sex. We have applied this modified set of adjustment covariates 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 2015 formed the reference cohort for Table 3.1 and Figures 3.1-3.6. Optum Clinformatics™ data were not used in mortality analyses as the date of death determination is now limited to information from the Social Security Death Master file. Since 2012, the Social Security Administration no longer releases death dates derived from state sources. The number of deaths reported has dropped by over 30%, indicating artificially low mortality rates.

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 1) overlapping claims (two claims covering the same time frame), 2) consecutive claims (one claim's admission date on the day following the previous claim's discharge date), 3) transfers (patient discharge status of 02 on the claim), and 4) interim claims (claim sequence number, the third digit of the 'type of bill' code, of 2, 3, or 4). In such 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).

We calculated unadjusted admission rates as the number of hospitalizations divided by the number of patient years at risk, and express this as "per 1,000 patient years." Adjusted admission rates in this chapter included the following variables as adjustments: age (66 to less than 70, 70 to less than 75, 75 to less than 85, or 85 years or older), race (White, Black, or other), and sex (male, or 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 applied. Adjusted rates reflect the distribution of a reference cohort, as specified below in the discussion of the specific 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 and 3.8 show adjusted all-cause admission rates for fee-for-service Medicare patients aged 66 and older and Optum Clinformatics™ patients aged 22 and older. Table 3.2 also shows the unadjusted rates. As mentioned above, DM and CVD were ascertained in 2014 for the analysis of hospital admissions in 2015, as described in the *Identification of Major Comorbidities* section of this chapter. All Medicare patients in the cohort were 66 years or older (22 and older for Optum Clinformatics™), did not have ESRD on 1/1/2015, had Medicare Parts A and B coverage (for Optum Clinformatics™, plan enrollment) for all of 2014, and did not participate in a Medicare Advantage plan from 1/1/2014 through 1/1/2015. Rates presented by one factor were adjusted for the others. The reference cohort for Medicare analyses included all 2015 Medicare patients aged 66 and older. The reference cohort for Optum Clinformatics™ analyses includes all patients in 2015.

vol 1 Table 10.5 ICD-9-CM and ICD-10-CM diagnosis codes used to define cause of hospitalization

Cause of hospitalization	Principle diagnosis for hospital stay	
	ICD-9-CM diagnosis codes	ICD-10-CM diagnosis codes
Cardiovascular diseases	276.6; 394-398; 401-405; 410-438; 440-459	A18.84; E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G46.8; I05.0-I09.1; I09.81-I67.82; I67.841-I87.9; I89.0-I97.2; I99.8; I99.9; K64.0-K64.9; M30.0-M31.9;M32.11; M32.12; N26.2; R00.0; R58; T80.0XXA; T81.72XA; T82.817A;T82.818A
Infections	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	A00.0-A32.9; A35-B99.9; D86.0-D86.9; E32.1; E83.2; G00.0-G04.02;G04.2-G09; G14; G37.4; G92; G93.7; H00.011-H10.9; H16.251-H16.269; H32; H66.001-H66.43; H67.1-H67.9; H70.001-H70.93; H75.00-H75.83; H83.01-H83.09; H92.10-H92.13; H95.00-H95.199; I00-I02.9; I09.2; I32; I33.0; I39-I40.8; I41;I67.3; J00-J18.1; J18.8-J21.9; J31.0-J32.9; J35.01-J35.03; J36;J37.0; J37.1; J39.0-J39.2; J40; J41.1; J47.0-J47.9; J85.0-J85.2;J86.0-J92.9; J94.0-J94.9; J95.02; K04.6; K04.7; K11.3; K12.2;K35.2-K37; K50.014; K50.114; K50.814; K50.914; K51.014;K51.214; K51.314; K51.414; K51.514; K51.814; K51.914; K57.00; K57.01; K57.20; K57.21; K57.40; K57.41; K57.80;K57.81; K61.0-K61.4; K63.0; K65.0-K65.9; K67-K68.9; K71.0-K71.9; K75.0-K75.3; K75.81-K75.9; K76.4; K77; K81.0-K81.9; K90.81; L01.0-L08.9; L44.4; L70.2; L88; L92.8; L94.6; L98.0;L98.3; M00.00-M01.X9; M02.10-M02.19; M02.30-M02.89;M35.2; M46.20-M46.39; M86.00-M86.9; M90.80-M90.89;N10-N12; N13.6; N15.1; N15.9; N16; N28.84-N28.86; N30.0- N30.31; N30.80; N30.81; N34.0-N34.3; N35.111-N35.12; N37-N39.0; N41.0-N41.9; N45.1-N45.4; N47.6; N48.1-N48.29; N49.0-N49.9; N51; N61; N70.01-N74; N75.1; N76.0-N76.4; N77.1; N98.0; O85; O86.12; O86.81; O86.89; R09.1; R11.11; R78.81;T80.211A-T80.29A; T81.4XXA; T82.6XXA; T82.7XXA; T83.51xXA-T83.6XXA; T84.50XA-T84.7XXA; T85.71XA-T85.79XAT86.842; T87.40-T87.44; T88.0XXA
Other causes	All codes except those in cardiovascular or infection.	All codes except those in cardiovascular or infection.

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. Codes listed with three digits include all existing 4th and 5th digits, and those listed with four digits include all existing 5th digits.

Figures 3.9-3.15 show adjusted, cause-specific admission rates by CKD status and stage for Medicare and Optum Clinformatics™ patients. Cause-specific rates reflect hospital admissions for the purpose of treating the specified condition—cardiovascular or infectious—and are identified using the principal ICD-9-CM or ICD-10-CM diagnosis code on the claim. Code values are shown in Table 10.5. The 'other cause' of hospitalization is a residual category consisting of all hospitalizations other than those for cardiovascular or infectious conditions.

READMISSION

Analyses of readmissions focus on the 30 days following discharge from a hospitalization in year two, the year reported in the figure. As for all the analyses in this chapter, comorbidities, including CKD, are 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 were identified; the latter date (12/1) was chosen as a cutoff to allow a 30-day follow-up period after discharge to evaluate readmission. 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 readmission for the entire 30 day period, so results are presented as percentages.

Since death and readmission are competing risks, the outcome was presented as: (1) the percent of hospital discharges where the patient both returned to the hospital and died within 30 days, (2) the percent where the patient was rehospitalized within 30 days but remained alive on day 30, and (3) the percent where the patient died within 30 days without a readmission. Table 3.3 shows the unadjusted percentage who were rehospitalized (both alive and dead on day 30) for age, sex, and race groups, plus the composite death and readmission outcome described above by CKD status and stage. Figure 3.16 adds a fourth category to the three described above for those who did not have a readmission and were still alive at day 30. It shows the adjusted percentages for the four readmission and death outcomes across time from 2003 to 2015. Live hospital discharges from January 1 to December 1 of each year were included. Rates were adjusted for age, sex, and race using direct adjustment, with a reference group of discharges in 2015. Figure 3.17 shows results for 2015 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, and Figure 3.23 by race group.

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 include coronary artery disease (CAD; formerly referred to as atherosclerotic heart disease, ASHD), acute myocardial infarction (AMI), heart failure (HF; formerly congestive heart failure, CHF), valvular heart disease (VHD), cerebrovascular accident/transient ischemic attack (CVA/TIA), peripheral artery 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 10.6. The presence of CKD, CKD staging, and comorbidities such as diabetes mellitus (DM) and hypertension (HTN) were also defined as described in the *Identification of Major Comorbidities* section of this chapter and Tables 10.3 and 10.4.

vol 1 Table 10.6 ICD-9-CM and ICD-10-CM diagnosis codes used to define cardiovascular disorders in Volume 1, Chapter 4 of the ADR

Condition	ICD-9-CM diagnosis codes	ICD-10-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	A18.84; E08.51 E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; G45.0-G45.2; G45.4-G46.8; I09.81; I11.0; I12.00-I22.9; I13.0; I13.2; I21.01-I22.9; I24.0-I25.9; I25.2; I34.0-I39; I40.0-I43; I46.2-I47.0; I47.2; I48.0-I48.92; I49.01; I49.02; I49.3; I49.49; I50.1-I50.9; I60.00-I66.9; I67.0; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; I81-I82.91; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9; M32.11; Z48.21; Z48.280; Z94.1; Z94.3; Z95.1; Z95.5; Z98.61
Acute myocardial infarction (AMI)	410; 412	I21.01-I22.9; I25.2
Atrial fibrillation (AFIB)	427.3	I48.0-I48.92
Cerebrovascular accident/transitory ischemic attack (CVA/TIA)	430–438	G45.0-G45.2; G45.4-G46.8; I60.00-I66.9; I67.1; I67.2; I67.4-I67.82; I67.841-I69.998
Coronary artery disease (CAD)	410-414; V45.81, V45.82	I12.00-I22.9; I24.0-I25.9; Z95.1; Z95.5; Z98.61
Heart failure (HF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428; V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1-I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Systolic or both systolic & diastolic	428.2, 428.4	I50.20-I50.23; i50.40-I50.43
Diastolic only	428.3	I50.30-I50.33
Heart failure, unspecified	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422[a]; 425[a]; 428 (not 428.2-428.4); V42.1[a]	A18.84; I09.81; I11.0; I13.0; I13.2; I40.0-I43; I50.1; I50.9; Z48.21; Z48.280; Z94.1; Z94.3
Peripheral arterial disease (PAD)	440–444; 447; 557	E08.51; E08.52; E09.51; E09.52; E10.51; E10.52; E11.51; E11.52; E13.51; E13.52; I67.0; I70.0-I74.9; I77.0-I77.9; I79.0-I79.8; K55.0; K55.1; K55.8; K55.9; M31.8; M31.9
Sudden cardiac arrest/ventricular arrhythmias (SCA/VA)	427.1, 427.4, 427.41, 427.42, 427.5, 427.69	I46.2-I47.0; I47.2; I49.01; I49.02; I49.3; I49.49
Valvular heart disease (VHD)	424	A18.84; I34.0-I39; M32.11
Venous thromboembolism and pulmonary embolism (VTE/PE)	452-453.9	I81-I82.91

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. ICD-9-CM diagnosis codes can have up to five digits with a decimal point between the 3rd and 4th digit, while ICD-10-CM codes have seven digits. 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 include revascularization – percutaneous coronary interventions (PCI), revascularization – coronary artery bypass graft (CABG), the placement of implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy with defibrillator (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 10.7 shows the codes and type of claims used to identify each procedure

vol 1 Table 10.7 Procedure codes (ICD-9/10-CM and HCPCS) and claims files used to define cardiovascular procedures in Volume 1, Chapter 4

Data Sources (Claims files searched)	Values
Peripheral arterial disease (PAD)	
ICD-9-CM Procedure codes (IP, OP, SN)	*39.25, 39.26, 39.29; 84.0, 84.1, 84.91*
ICD-10-CM Procedure codes (IP, OP, SN)	*All of: 0312090-031309K; 0315091-031G0ZG; 031K09J-031N0ZK; 0414093-041N4ZS; 051707Y-051V4ZY; 061307Y-061V4ZY; 061307Y-0X6W0Z3; 0Y620ZZ-0Y6Y0Z3. All except xxxxxx3, xxxxxx4, xxxxxx5: 0410090-04104ZR; All except xxxxxxM, xxxxxxN: 03130J0-03140ZK; All except xxxxxxG: 031H09J-031J0ZK.*
HCPCS codes (PB, OP-revenue)	*24900, 24920, 25900, 25905, 25920, 25927, 27295, 27590, 27591, 27592, 27598, 27880, 27881, 27882, 27888, 27889, 28800, 28805, 34900, 35131, 35132, 35141, 35142, 35151, 35152, 34051, 34151, 34201, 34203, 34800–34834, 35081–35103, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35480, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671*
Percutaneous coronary interventions (PCI)	
ICD-9-CM Procedure codes (IP, OP, SN)	*00.66; 36.01, 36.02, 36.05, 36.06, 36.07*
ICD-10-CM Procedure codes (IP, OP, SN)	*02703ZZ; 02704ZZ; 02713ZZ; 02714ZZ; 02723ZZ; 02724ZZ; 02733ZZ; 02734ZZ*
HCPCS codes (PB, OP-revenue)	*92980-92982, 92984, 92995-92996, G0290, G0291*
Coronary artery bypass graft (CABG)	
ICD-9-CM Procedure codes (IP)	*36.1*
ICD-10-CM Procedure code (IP, OP, SN)	All of: 0210083-02100ZF; 0210483-02104ZF; 211088-021108C; 021208C; 021208W; 021209C; 021209W; 02120AC; 02120AW; 02120JC; 02120JW; 02120KC; 02120KW; 02120ZC; 021248C; 021248W; 021249C; 021249W; 02124AC; 02124AW; 02124JC; 02124JW; 02124KC; 02124KW; 02124ZC; 021308C; 021308W; 021309C; 021309W; 02130AC; 02130AW; 02130JC; 02130JW; 02130KC; 02130KW; 02130ZC; 021348C; 021348W; 021349C; 021349W; 02134AC; 02134AW; 02134JC-02134JW; 02134KC; 02134KW; 02134ZC; All except xxxxxxF, xxxxxx3, xxxxxx4: 211088-02110ZC; 211488-02114ZC;
Implantable cardioverter defibrillators & cardiac resynchronization therapy with defibrillator (ICD/CRT-D)	
ICD-9-CM Procedure codes (IP, OP, SN)	*00.51; 37.94*
ICD-10-CM Procedure code (IP, OP, SN)	*02H60KZ; 02H63KZ; 02H64KZ; 02H70KZ; 02H73KZ; 02H74KZ; 02HK0KZ; 02HL3KZ; 02HL4KZ; 02PA0MZ; 02PA3MZ; 02PA4MZ; 02PAXMZ; 0JH608Z; 0JH609Z; 0JH638Z; 0JH639Z; 0JH808Z; 0JH809Z; 0JH838Z; 0JH839Z; 0JPT0PZ; 0JPT3PZ*
Carotid artery stunting and carotid artery endarterectomy (CAS/CEA)	
ICD-9-CM Procedure codes (IP, OP, SN)	*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*
ICD-10-CM Procedure codes (IP, OP, SN)	*037x34Z, 037x3DZ, 037x3ZZ, 037x44Z, 037x4DZ, 037x4ZZ, for x=G to Q, except I & O; 03Bx0ZZ, 03Bx4ZZ, for x=G to V, except I & O; 03CG0ZZ, 03CG3Z6, 03CG3ZZ, 03CG4Z6, 03CG4ZZ, 03Cx0ZZ, 03Cx3ZZ, 03Cx4Z6, 03Cx4ZZ for x=H to V, except I & 0; 03Cx3Z6 for x=R to V; 03RG07Z-03RV4KZ; 057L3DZ, 057L4DZ, 057M3DZ, 057M4DZ, 057N3DZ, 057N4DZ, 057P3DZ, 057P4DZ,057Q3DZ, 057Q4DZ, 057R3DZ, 057R4DZ, 057S3DZ, 057S4DZ, 057T3DZ, 057T4DZ, 05Bx0ZZ, 05BLx4ZZ for x=L to V, except O. 05RL07Z-05RV4KZ; 06R307Z-06R34KZ*
HCPCS codes (PB, OP-revenue)	*37215, 37216*

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth 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, while ICD-10-CM codes have seven 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, were residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, did not have ESRD on December 31, 2015, and who were continuously enrolled in Medicare Parts A and B but not in a Medicare Advantage plan for all of 2015. Cardiovascular conditions, CKD, and CKD staging were determined from claims in 2015.

Table 4.1 presents the prevalence data shown in Figure 4.1 by age, race, sex, and CKD status (panel a), and data on cardiovascular procedures performed in 2015 (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 in this table was only of the cohort members with CAD, the percent with ICD/CRT-D was of cohort members with HF, and the percent with CAS/CEA was of the cohort members with CAD, CVA, or PAD.

Figures 4.2 and 4.3 present the two-year survival of patients with cardiovascular conditions (Figure 4.2) or cardiovascular procedures (Figure 4.3) adjusted for age and sex. We again used the adjusted algorithm explained in the 2016 ADR. We assessed conditions in a baseline year (2013), the origin for survival time was January 1 of the following year (1/1/2014), and there was no attempt to isolate incident diagnoses. Procedures used the same algorithm as in the past.

To form the study cohort for each condition in Figure 4.2, we searched 2013 Medicare claims for the diagnoses (and procedure codes for PAD) specified in Tables 10.6 and 10.7. To be retained in the analysis cohort, the patient must have been alive without ESRD and aged 66 and older on 1/1/2014, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, be enrolled in Medicare Parts A and B, but not enrolled in a Medicare Advantage plan for all of 2013. Patients were then followed from 1/1/2014 until the earliest of date of death, ESRD diagnosis, or December 31, 2015. The Kaplan-Meier method was used to estimate survival. Table 4.2 shows the numeric values for two-year survival for each condition by CKD status and stage.

To form the study cohort for each procedure in Figure 4.3, Medicare claims from 1/1/2012 through 12/31/2015 were searched for the procedure codes specified in Tables 10.7, and the date of the first claim with a specified code was considered as the index date. To be retained in the analysis cohort, the patient must have been aged 66 and older on the index date, reside in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, be enrolled in Medicare Parts A and B, and not enrolled in a Medicare Advantage plan. 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, two years after the index date, ESRD diagnosis, or December 31, 2015. The Kaplan-Meier method was used to estimate survival. Table 4.3 shows the numeric values for two-year survival for each procedure by CKD status and stage.

Cardiovascular Disease and Pharmacological Treatments

New to the 2017 ADR, this section of the chapter uses data from the Medicare Part D program, which include enrollment information and claims for prescription fills and refills for medication prescribed by a healthcare professional and filled through Part D insurance (the prescription drug event, PDE, file). Enrollees are not required to fill all of their medications through Part D, and may pay out of pocket for some. Use of over the counter medications is not included in the Part D data; therefore, we have no information on such medication use.

Creation of the cohort for Table 4.4 begins with the cohort described for Table 4.1 and then excludes patients who are not enrolled in a Part D prescription plan for all of the reported calendar year (2015). All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service Pharmacologic-Therapeutic

Classification©. Claims for 2015 were searched for each drug class and a patient was defined as having a medication in a given drug class if they had a claim for at least one filled or refilled medication in the drug classes during 2015. The prescription must be part of the AFHS Classification group and have a generic name as specified in Table 10.8.

Table 10.8 Drug classes used in Volume 1, Chapter 4

Drug class	AFHS classification	Generic drug name
Beta blockers	242400	*<no restriction>*
Statins	240608	*<no restriction>*
$P2Y_{12}$ inhibitors	201218	prasugrel, ticagrelor, or clopidogrel
Warfarin	201204	warfarin
Direct oral anticoagulants	201204	apixaban, rivaroxaban, dabigatran
Angiotensin converting enzyme inhibitors (ACEs) or angiotensin II receptor blockers (ARBs)	243204, 243208	*<no restriction>*

Heart Failure and Chronic Kidney Disease

The type of heart failure (HF) for the calendar year was determined by frequency of diagnoses and a hierarchy. The presence of systolic (ICD-9: 428.2x, 428.4; ICD-10: I50.2, I50.4), diastolic (ICD-9:428.3x; ICD-10: I50.3) and unspecified diagnoses (all other HF diagnosis codes listed in Table 10.6) 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 predominant type of HF for the year was then determined by a hierarchy similar to that applied for each calendar day. If the patient had any systolic HF and no diastolic-only heart failure, he/she was classified as systolic heart failure; if the patient had diastolic HF 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 the HF type that was most frequent during the year.

Figure 4.4 shows the distribution of type by CKD status in 2015. The study cohort included Medicare enrollees who were alive, aged 66 and older, were residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, who did not have ESRD on December 31, 2015, and who were continuously enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage plan for all of 2015. 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 HF type within that CKD status or stage group.

Figure 4.5 presents the adjusted, two-year survival of patients with and without CKD and HF. 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 HF and CKD status. We determined heart failure, CKD, DM, and HTN statuses from 2013 claims data. The study cohort included Medicare enrollees who were alive and aged 66 or older on December 31, 2013, residents of 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 2013. Patients with ESRD on or before December 31, 2013 were excluded. Follow-up began on 1/1/2014, and continued until death or 12/31/2015. Type of HF was determined by the same procedure as the previous figures, using claims from 2013. Codes used to define DM and HTN are listed in Table 10.4 of this chapter. Age was defined as of

12/31/2013. As the interaction between HF status and CKD status was significant in the Cox model, adjusted survival curves were created for the four combination groups of HF status and CKD status (no CKD and no HF, CKD and no HF, HF and no CKD, and CKD with HF). The survival curves were adjusted for the other significant factors in the model listed above.

Atrial Fibrillation and Chronic Kidney Disease

Table 4.5 presents the prevalence of AFIB by CKD stage, age, race, sex, diabetic status, HTN status, and HF status for 2015. The cohort was the same used for Figure 4.1.

Chapter 5: Acute Kidney Injury

Three sources of data were used for the AKI chapter: the Medicare 5% sample, Optum Clinformatics™ Data Mart, and the VHA data. Both the Medicare and Optum Clinformatics™ datasets contain only diagnosis code information on AKI, but 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 VHA datasets contain serum creatinine measurements for both routine outpatient visits and inpatient stays, but not urine output measurements. This allowed calculation of the serum creatinine criteria of the KDIGO consensus definition of AKI, and episodes to be classified by stage (KDIGO 2012). Diagnosis codes are also available in the VHA data. As in prior ADRs, this chapter only examined AKI as identified during an inpatient hospital stay.

In the Optum Clinformatics™ dataset, inpatient stays were identified by a non-missing confinement ID variable (*conf_id*) in the MEDICAL claims data table. Previously, we identified more patients with at least one or more inpatient stays from the MEDICAL claims data table than the CONFINEMENT data table, so we continued to use the MEDICAL claims data table. Admission and discharge dates are not available in the MEDICAL claims data table and must be generated. 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. Review of inpatient stays that were included in the CONFINEMENT data table verified that this process created appropriate dates.

Dialysis during the hospitalization with AKI is defined from the Medicare 5% sample using diagnosis, procedure, and revenue center codes. 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-10-CM diagnosis codes Z49.01, Z49.31, Z91.15, and Z99.2, ICD-9-CM procedure codes 39.95 and 54.98, ICD-10-CM procedure codes 5A1D00Z, 5A1D60Z, and 3E1M39Z, 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 Clinformatics™ Data Mart, we searched for both inpatient and outpatient dialysis procedures in the MEDICAL claims data table that were performed between the admission and discharge dates of the inpatient stay. Similarly, the VHA datasetwas searched for dialysis procedures during the time frame of the inpatient stay. Patients with ESRD prior to the inpatient stay were not considered to have AKI.

Characteristics of Patients with AKI

The cohort for Figures 5.1, 5.3.a, 5.4.a, 5.5.a, and Table 5.1 (Medicare) included all patients 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 of the reported year. The Optum Clinformatics™ cohort for Figures 5.2, 5.3.b, 5.4.b, 5.5.b, and Table 5.1 (Optum Clinformatics™) included all patients who were 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 10.3 and 10.4), using claims from a one-year entry period (year one, the calendar year *before* the year in which hospitalization was assessed for AKI). Hospitalization was then assessed in the following year (year two, the year reported in the figures and tables). Figures 5.1 and 5.2 and Table 5.1 show statistics on people who had at least one hospitalization with an AKI diagnosis anywhere on the claim. Information specific to the AKI hospitalization used the first AKI hospitalization in the calendar year. Each calendar

year formed a separate cohort, so that a patient can have a "first" AKI hospitalization in multiple years. This process was used for both the Medicare and Optum Clinformatics™ datasets. For the 2017 ADR, Figures 5.3, 5.4, and 5.5 show the rate of all AKI hospitalizations, with an individual allowed to have more than one AKI during the calendar year. The denominator was the same as in previous years, with time at risk calculated for each person.

Figures 5.1 and 5.2 illustrate the same statistics, but for Medicare (Figure 5.1) and the Optum Clinformatics™ (Figure 5.2) datasets. 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 any position on the claim) in each year, and by whether the hospitalization with the AKI diagnosis contained a stay in the ICU. 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 who received a dialysis procedure during that hospitalization, and whether that hospitalization contained a stay in the ICU. ICU stays were determined by revenue center codes falling between 0200 and 0204, or between 0207 and 0209. We could not determine ICU stays for Optum Clinformatics™ beneficiaries.

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 uses 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 Optum Clinformatics™.

Table 5.2 shows data from the VHA. Data are from fiscal year 2015 (October 1, 2014 through September 30, 2015) as retrieved from the Corporate Data Warehouse. Short-term hospital stays were isolated from the INPAT.INPATIENT table for discharges within the fiscal year (see *Veterans Health Administration (VHA) 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) the mean of all outpatient SCR measurements collected between seven and 365 days prior to admission, or (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, or (3) if no outpatient SCR values were available within the year before the AKI hospitalization, the first inpatient SCR was assigned as the baseline SCR. Patients without at least one inpatient SCR measurement were excluded from the analysis. Serum creatinine 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 or no AKI. Table 10.9 shows the criteria for AKI from the KDIGO guidelines.

vol 1 Table 10.9 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 seven days; or urine volume <0.5ml/kg/h for six hours.

AKI 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 SCR 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 an increase to 1.5 times baseline within seven days. A person's first SCR measurement on the day of admission was compared to their baseline to determine if that SCR is 0.3 mg/dL or 1.5 times higher. If so, the patient was said to have AKI. If not, the second SCR measurement was examined to determine if it was measured 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 an SCR measure was more than 48 hours from admission, it was compared to all previous SCR measurement that occurred within 48 hours of its measurement, rather than to the patient's baseline.

For example, a patient with a baseline SCR of 0.8 mg/dL is admitted. On January 1 they have a first inpatientSCR of 0.8 mg/dL, then another on January 2nd measuring 0.7 mg/dL, another on January 4th of 0.9 mg/dL, and then 1.5 mg/dL on January 5$^{th.}$. The January 5th measurement is compared to the January 4th, where it meets the criteria for AKI. It would not be compared to the measures of January 1st or 2nd, or the baseline for the 0.3 mg/dL increase condition. Similarly, for the increase to 1.5 times baseline over seven days, 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.

Once the patient was determined to have experienced an AKI based on SCR changes, the hospitalization as a whole was used to assign the stage of AKI. The highest SCR during the hospitalization was compared to the baseline. If the difference was greater than three times the baseline, the highest SCR was greater than 4.0 mg/dL, or renal replacement therapy was used during the stay, that hospitalization was classified as Stage 3. If the AKI episode was not Stage 3 and the difference between the maximum SCR and baseline was more than two times baseline but less than three, the hospitalization was classified as Stage 2. If the AKI episode was not Stage 2 or 3, it was Stage 1, an increase of at least 0.3 mg/dL but less than two times baseline.

Figures 5.3-5.5 used the entire analysis cohort as the denominator to calculate rates of AKI per 1,000 patient years at risk for Medicare (panel a) and Optum Clinformatics™ (panel b) beneficiaries. Each hospitalization with an AKI diagnosis (any position on the claim) for a patient was counted as an event, and years at risk were calculated for each patient as the time during the reported year (year two) censored at the development of 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. For the 2017 ADR, a Poisson model was used to model the number of AKI events and the denominator was the sum of the time at risk of every cohort member.

Rehospitalization 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 Optum Clinformatics™ (Figure 5.7) beneficiaries. The sample for this figure began with the 2013 cohort from 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 1/1/2013. The first hospitalization with AKI in 2013 was identified. Age was as of 1/1/2013, 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 10.3 and 10.4 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 2013 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. For the 2017 ADR, we also present this data for the Optum Clinformatics™ dataset. To increase the precision of these estimates, we created a cohort for this figure that included patients with a first hospitalization with AKI in 2013 or 2014. Patients were alive, aged 66 or older, without ESRD, enrolled in their plan (for Medicare, 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 are 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 their plan (for Medicare, Parts A or B or a 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 their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage program), or 365 days following discharge.

Figures 5.9 presents the probability of a nephrology clinic visit within the first six months after a live discharge from a hospitalization with AKI. Claims were searched for services provided by nephrologists for 180 days following the discharge date of the hospitalization with AKI. In the Medicare data, visits with a nephrologist have the provider specialty code 36, while in the Optum Clinformatics™ data they are identified by a provider category code for nephrologist (PROVCAT 0597-0604). Time to visit begins on the date of discharge listed on the claim for the hospitalization with AKI and continues until the earlier of the visit, 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 defined as (1-survival).

Figure 5.10 shows the renal status after one year for Medicare and Optum Clinformatics™ patients discharged alive from their first hospitalization with AKI. To increase the precision of the estimates, we created a cohort for this figure of patients who had a first hospitalization with AKI in 2013 or 2014. Patients were alive, aged 66 or older, without ESRD, with plan coverage (for Medicare, 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 or N18.x claim closest to 365 days after discharge, while ESRD determination used the first service date on the ESRD Medical Evidence form.

Figure 5.11 shows discharge status following a Medicare patient's first hospitalization in 2015. Panel a shows patients whose hospitalization contained an AKI episode while panel b shows those whose hospital stay did not. The cohort includes all patients who experienced a hospitalization during 2015 and are alive, aged 66 or older, enrolled in Medicare Parts A and B and not enrolled in a Medicare Advantage program, and without ESRD on January 1, 2015. For Medicare, 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) are 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: Healthcare Expenditures for Persons with CKD

This chapter used a cohort that continued the methodology introduced in the 2010 ADR, which we 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 2015 (year two) included all costs incurred by patients with a CKD diagnosis in 2014 (year one). Prior to the 2010 ADR, patients newly diagnosed with CKD during year two were also included in the total.

The same general point prevalent cohort was used to create all the Medicare tables and figures in this chapter, and a similar cohort was created for the Optum Clinformatics™ tables and figures. Each year's cohorts included patients aged 65 and older who were alive and without ESRD on January 1 of the reported year (year two). Cohort members were continuously enrolled in their plan (for Medicare, Medicare Parts A and B and not enrolled in a Medicare Advantage plan) for all of year one (the one-year entry period prior to the year in which costs were assessed). Costs were then 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 their plan (for Medicare, Parts A or B or a switch to a Medicare Advantage program), or December 31 of year two. Per-person-per-year (PPPY) costs are produced by dividing the total cost amount by the number of patient years at risk. Since total costs and the numbers of patients for Medicare were based on the 5% Medicare files, we multiplied counts and expenditures by 20 in order to represent 100% of Medicare fee-for-service Parts A, B, and D expenditures. These were age-eligible patients who continuously enrolled in Parts A and B, and not enrolled in a Medicare Advantage plan, for all of the previous year (year one). The Optum Clinformatics™ data represents 100% of their beneficiaries, thus there was no need to weight the data to population totals.

New to the 2017 ADR, we are no longer attributing only a fraction of claims that span the calendar year to each year, but rather we place the entire payment for a claim spanning a calendar year in the year corresponding to the admission date.

The disease conditions of CKD, heart failure (HF), diabetes mellitus (DM), and the stage of CKD were determined from the claims in the year prior to the reported year (year one) using the algorithm described in the *Identification of Major Comorbidities* section of

this chapter and the diagnosis codes listed in Tables 10.3 and 10.4. Age was determined as of December 31 of year one. Table 6.1 shows the Medicare population aged 65 and older, total spending, per-patient, per-year spending, the fraction of the total Medicare population with the given disease conditions, and the fraction of total Medicare spending for the given disease conditions. Table 6.2 shows the Optum Clinformatics™ data for members aged 65 and older covered by their commercial insurance and Medicare Advantage plans. For each plan type, the per-patient, per-year spending is shown, as is the fraction of the total plan members with each given condition and the fraction of total plan spending for each condition. Tables 6.3 and 6.4 show the same statistics for beneficiaries and members who were under the age of 65. Figure 6.1 shows the information in Table 6.1 graphically, along with the same information for the previous year.

Table 6.5 shows two years of per-person, per-year spending for any stage of CKD and by CKD stage for Medicare fee-for-service coverage, and Table 6.6 shows this for Optum Clinformatics™ commercial insurance and Optum Clinformatics™ Medicare Advantage plans. Costs and conditions were determined as in Tables 6.1, 6.2 and Figure 6.1 while race and sex were provided by the Master Beneficiary Summary File. Figure 6.2 displays this information graphically and for four years. Table 6.7 shows data similar to Table 6.5 but for those with CKD and DM. Table 6.8 shows the same statistics as Table 6.7 but for the Optum Clinformatics™ Medicare Advantage and commercial insurance enrollees. Table 6.9 repeats Table 6.7, but for those with CKD and HF rather than DM. Table 6.10 presents the same results as Table 6.9, but for the Optum Clinformatics™ Medicare Advantage and commercial insurance enrollees.

The focus of Figures 6.3 through 6.6 is expenditure trends. Figure 6.3 shows the spending on fee-for-service Parts A, B, and D for all Medicare patients and Medicare patients with CKD for all patients (panel a), patients with DM (panel b) and patients with HF (panel c). Figure 6.4 shows Medicare spending for fee-for-service enrollees with CKD by the type of Medicare claim, which corresponds to the type of medical service delivered. The categories include inpatient institutional claims (billed by the hospital or other facility), outpatient claims billed by facilities, physician/supplier claims (services from non-institutional providers, mostly covered under Part B), skilled nursing facilities (Medicare covers short term stays for rehabilitation after medical procedures or surgery but not long-term care), home health agencies (another service provided following medical procedures or surgeries), hospice care, and Part D prescription drug claims. Figure 6.5 shows inpatient institutional costs by the cause of hospitalization, which was determined using the same methods as in Chapter 3, using the codes displayed in Table 10.5. Figure 6.6 shows per-person, per-year (PPPY) spending by a combination of chronic conditions. We included all patients regardless of condition—those without DM and HF, those with CKD and DM, CKD and HF, and those with all three (CKD, DM, and HF). Panel a shows Medicare fee-for-service spending, panel b shows Optum Clinformatics™ commercial insurance plan members, and panel c shows Optum Clinformatics™ Medicare Advantage spending.

Chapter 7: Prescription Drug Coverage in Patients with CKD

This chapter describes prescription drug coverage and usage. New for the 2017 ADR, it shows prescription drug utilization from the Optum Clinformatics™ dataset for both those in Medicare Advantage plans and those in commercial plans as well as Medicare 5% sample beneficiaries. CKD was determined as described in the *Identification of Major Comorbidities* section of this chapter and Table 10.3, using claims from a one-year entry period (year one, the calendar year before the year in which prescription drug coverage participation and utilization was assessed). Prescription drug utilization and enrollment (for Part D coverage only) were assessed in the following year (year two, the year reported in the figures and tables), while ESRD was determined by the ESRD first service date. In this Prescription Drug Coverage 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 their plan (for Medicare, 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 their plan 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 for the Medicare cohort 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 in the Medicare cohort, 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 was related to amyotrophic lateral sclerosis, and thus should not be viewed as representative of the U.S. general population under age 65. On the other hand, the Optum Clinformatics™ dataset represents those of prime working age in the country and is representative of the younger age groups.

Figures 7.1-7.3 summarize the prescription drug insurance coverage for Medicare beneficiaries by source, comparing the General Medicare and CKD populations, showing results overall and by age and race categories. The sources of coverage across the calendar year are combined into mutually exclusive and exhaustive categories in a hierarchical manner. Enrollment in a Part D plan is 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 are several options for non-Medicare prescription drug coverage, as reported to the Medicare program. Beneficiaries were 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 had 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 subsequently enroll in Part D. If a beneficiary meets none of the situations described above, he or she is classified as "No Known Coverage." Figure 7.1 presents the distribution of this categorical variable for the General Medicare and CKD cohorts described above.

Table 7.1 shows the percent of beneficiaries with Part D coverage for the past five years in the General Medicare and CKD cohorts. Table 7.2 is an adaptation of data presented in the 2015 Medicare Outlook section of the www.q1medicare.com web site, and has no analyses. Figure 7.2 shows the categories of prescription drug coverage (described above for Figure 7.1) by age groups (20 to 44, 45 to 64, 65 to 74, and 75 and older) for General Medicare (panel a) and CKD (panel b), while Figure 7.3 shows the coverage categories by race groups (White, Black or African American, Asian, Other.

Table 7.3 is 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

Figure 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 is 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 and CKD cohorts.

Table 7.4 and Figure 7.5 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 is paid by the Part D low-income subsidy (LIS Amount) and the net amount that the Part D plan pays for the PDE (Covered Part D Plan Paid Amount). Table 7.4 shows the total Medicare Part D benefit expenditures for the General Medicare and CKD cohorts (defined above) for beneficiaries enrolled in stand-alone Part D plans (i.e., spending for Medicare Advantage prescription drug plans is 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 7.5, panel a shows spending and patient out-of-pocket amounts per-person, per-year (PPPY) for the General Medicare members and CKD cohorts for those in fee-for-service Part D plans, Optum Clinformatics™ Medicare Advantage plans, and Optum Clinformatics™ commercial insurance plans. Out-of-pocket cost is the sum of the amounts the patient pays without being reimbursed by a third party (for fee-for-service Medicare, the Patient Payment Amount) which includes all copayments, coinsurance, deductible, or other patient payment amounts. For fee-for-service Medicare, this includes the amount of any payment made by other third-party payers that reduced the beneficiary's liability for the PDE or prescription claim (Other True Out-of-Pocket Amount). Two examples of this are payments by qualified state pharmacy assistance programs or charities. Panel b breaks out these costs by whether the patient received any low income subsidies. Table 7.5 shows PPPY spending by age, sex, and race for the General and CKD cohorts by fee-for-service Medicare with LIS, fee-for-service Medicare without LIS, Optum Clinformatics™ Medicare Advantage plans and Optum Clinformatics™ commercial insurance plans.

All drugs in the PDE file and Optum Clinformatics™ RX table were matched to a therapeutic category according to the American Hospital Formulary Service classification system. The Medicare cohort for Tables 7.6 and 7.7 was limited to those in the CKD cohort who had 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 or the plans in the Optum Clinformatics™ dataset on each drug class and its percentage of total prescription drug plan expenditures. Table 7.6 shows the top 15 drug classes ranked by the highest percent of CKD patients with at least one prescription filled in that class for fee-for-service Medicare, Optum Clinformatics™, Medicare Advantage, and Optum Clinformatics™ commercial insurance. 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 (panel a), Optum Clinformatics™ Medicare Advantage (panel b) and Optum Clinformatics™ commercial insurance (panel c) on each drug class for CKD patients. The next column shows that drug class' cost as a percentage of all plan expenditures for these patients.

New in the 2017 ADR, this chapter has a special focus on analgesic drugs. Analgesics were identified as members of the AHFS classes 280804 – nonsteroidal anti-inflammatory agents (NSAIDs), 280808 – opiate agonists, and 280812 – opiate partial agonists. The cohort was the same as the Medicare cohort used in Tables 7.6 and 7.7; it excluded those with Medicare Advantage Part D plans as we are unable to identify CKD in those patients. Analgesic use in patients with CKD was defined as having filled or refilled at least one prescription of a drug in the drug classes listed above. The state of residence was from the Medicare Beneficiary Summary File. Figure 7.6 tabulates the use of NSAIDs (yes/no) by state, divides the states by quintiles, and shows the results in a map. Figure 7.7 does the same with the use of opiates.

Reference Tables

CKD Reference Tables

Reference Table B: Prevalence

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 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, heart failure (HF), and diabetes mellitus (DM) and the stage of CKD were determined from 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 10.3 and 10.4. Counts were multiplied by 20 to represent 100% of the Medicare population meeting the cohort definition.

Reference Tables B.7-B.10 were 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 was 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 may 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, diabetes mellitus (DM) was defined as in Chapter 1, and eGFR and ACR as described for Table B.8. Table B.10 presents results for heart failure (HF), 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?"

Reference Table K: Medicare Expenditures

In Tables K.1–5 we present estimates of the 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 included 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. Optum 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.