

Volume 1: CKD Analytical Methods

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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 2018 USRDS Annual Data Report (ADR), which focuses on chronic kidney disease (CKD) prior to end-stage renal disease (ESRD). For information regarding the datasets and methods used for ESRD analyses, see the <u>ESRD Analytical</u> <u>Methods</u> chapter in Volume 2. This CKD Methods chapter does not address Volume 1, <u>Chapter 9:</u> <u>Transition of Care in Chronic Kidney Disease</u>, which is the product of a USRDS Special Study Center. Relevant methods are included within that chapter.

Data Sources

The USRDS uses several data sources to describe kidney disease not requiring treatment by dialysis or kidney transplantation 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 are used: the standard Centers for Medicare & 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 1999–2016 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 (Ingram et al., 2018). 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, 2018). Like NHANES, it is also conducted by the CDC through 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." The response rate for this question was very good. Of the 475,687 respondents in 2012, for example, only 202 respondents refused to answer (0.04%), three were missing, and 1,322 answered "not sure" (0.28%). Data from 2012-2016 are used in the 2018 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.

In 2018, OptumInsight delivered a refreshed dataset for the years 2005-2016, which included more claims for earlier years. In addition, the death data was also refreshed with increased death ascertainment, especially for older years. Claims for encounters that are not billed separately, such as follow-up visits after a surgery, were newly added to the dataset this year. The physical structure of the data files also changed; instead of 25 diagnoses on each claim, the data set now had observations with one diagnosis code and each claim had up to 25 observations. In data analysis terms, the dataset went from wide to long. The inpatient procedure codes were also restructured this way. This had no effect on the identification of diseases or procedures. The data refreshment process, however, did results in some differences in trends this year compared to last year.

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 2006 through 2016 in the 2018 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 (month/year) 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 DOD_MEMBER_REVISED data table.

All services for both inpatient and outpatient care are located in the MED_<YEAR> claims data table, with the confinement ID (conf_id) variable indicating inpatient institutional claims. We create admission and discharge dates from the med_<year> file using the earliest date of a service performed for a *conf_id* as the admission date and discharge from the latest claim with the conf id. We validate this approach by comparing the confinement IDs that were in both the MED_<YEAR> and CONF_<YEAR> tables and check for matching admission and discharge dates. We do this because in our initial look at the data, we identified more hospitalizations (conf_id) in the MED <YEAR> than in the CONF <YEAR> table. We then use these dates to identify all institutional and noninstitutional medical services performed for the patient during that time.

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 Diagnosi	s codes	N18.6, T86.10-T86.13, T86.19, Y84.1, Z48.22, Z49.01, Z49.02, Z49.31, Z49.02, Z49.31, Z49.32, Z94.0	
HCPCS codes		90935, 90937,90940, 90945, 90947, 90951-90970, 90989, 90993, 90997, 90999; codes from earlier years: 90918-90925	
DPG Codes	Prior to FY2007:	302,512	
Drd Codes	FY2007-present:	652,008	

vol 1 Table 10.1 ICD diagnosis, CPT procedure, and DRG codes used to define ESRD in the Optur
Clinformatics™ and VHA datasets throughout Volume 1 of the ADR

Abbreviations: CPT, current procedural terminology; DRG, diagnosis related group; ESRD, end-stage renal disease; 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 DOD_MEMBER_REVISED table was 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 they differ by more than one year.

Observations from DOD_MEMBER_REVISED 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, 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 is given in real dollars with Optum providing cost factors and cost basis year for researchers to adjust across years and across cost basis years. 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 <u>allowed payments</u> across all provider services. Standard pricing amounts are included in the MED_<YEAR> and the PHARM_<YEAR> claims tables. Standard prices are determined for each service (CPT code) and are applied to every claim, regardless of whether actual payment was made for that service. This resulted in the addition of encounter claims. One needs to exclude these claims prior to summing up cost data to represent actual expenditures by the insurance company. The encounters are mostly health care services that are bundled with a more extensive procedure, like follow-up visits after surgery. They are paid within the payment for the surgery, but also added to the medical claims to document that a visit happened even though it was not billed for individually.

CENTERS FOR MEDICARE & 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 2018 ADR includes all claims for care occurring up to December 31, 2016, that were submitted and processed by June of 2017.

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 receive files containing data about the Part D plan, prescribers, and pharmacies. For the 2018 ADR, we use the Plan Characteristics file (PLAN_CHAR) to report on the coverage gap.

VETERANS HEALTH ADMINISTRATION DATA

In the 2018 ADR, we update analyses of Veterans Health Administration (VHA) data (first introduced in 2016) on kidney disease and present new tabulations. 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 2018 ADR are based on a cohort created by the VINCI data manager on January 18, 2018. Our basic cohort is defined as all patients with at least one outpatient encounter (a record in the VISIT table in the OUTPAT domain) during calendar year 2016. Age, sex, race, and date of death are taken from the PATIENT_PATIENT table, and race is taken from the PATSUB_PATIENTRACE table. Ethnicity is taken 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 shortterm hospitals¹. 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 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, which dialysis or transplant providers must submit within 45 days of ESRD initiation. First service date for ESRD is reported on this form; for analyses in Volume 2, this is used as the date when ESRD began. See Volume 2, <u>ESRD Analytical Methods</u> 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.

¹ Contact <u>usrds@usrds.org</u> to request a detailed listing of all specialty variable values.

Race and Ethnicity

Throughout the ADR, race and ethnicity categorizations are limited by the distinctions 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.

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

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

Abbreviations: NHANES, National Health and Nutrition Examination Survey; BRFSS, Behavioral Risk Factor Surveillance System.

General Methods for Health Insurance Claims 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 Medicare beneficiaries, while other parts require premiums to be paid by the beneficiary and are optional. Beneficiaries are also allowed to switch between Original Medicare (fee-forservice) 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 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 who were age-eligible for Medicare and, therefore, aged 65 and older. Beneficiaries under the age of 65 may qualify for Medicare based on disability status (meeting requirements for one of the Social Security Administration's income support programs for disabled individuals) or a diagnosis of ESRD (these patients 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 who 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 who 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 or when 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 oneyear 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 claims 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 define additional conditions using the same algorithmic structure, as described in the chapter-specific sections below.

	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; 581-583; 585- 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, 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 of N18.6 with no CMS 2728 form
Stage unknown or unspecified	Patient has <u>no</u> 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- 583; 585.9; 586-588; 591; 642.1; 646.2; 753.12-753.19; 753.2; 794.4	Patient has <u>no</u> 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, 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

vol 1 Table 10.3 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease in the health insurance claims data files throughout Volume 1 of the ADR

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 digits, 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.

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	420-421, 423-424; 429; 785.0-785.3; V42.2; V43.3	A18.84; I25.10; I31-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	185.00-185.11; 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

vol 1 Table 10.4 ICD-9-CM and ICD-10-CM diagnosis codes used to define medical conditions in the health insurance claims data files throughout Volume 1 of the ADR

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 digits, 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.

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. In calendar year 2016, all claims 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 *Volume 1, <u>Chapter 1: CKD in the General</u> <u>Population</u> 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 (Ingram et al., 2018). Starting in 1999-2000, the NHANES has collected data continuously, releasing public-use data files in two-year cycles. Data for <i>Volume 1, Chapter 1* represents participants 20 years and older in four clusters of NHANES continuous cycle years 2001-2004, 2005-2008, 2009–2012, and 2013-2016. *Note*: Data from NHANES III (1988-1994) and the first two years of continuous NHANES (1999-2001) can be found in previous Annual Data Reports (ADR).

The statistical software package SAS[®] was used to analyze all NHANES data, incorporating the sampling weights and survey design through its survey procedures.

In *Volume 1, Chapter 1*, age is defined as the participant's age at the time of the NHANES household interview, categorized into age groups: 20 to 39, 40 to 59, or 60 and older and as a dichotomous under age 60 or age 60 or higher. Race and ethnicity

are self-reported and categorized as non-Hispanic White, non-Hispanic Black/African American, Mexican-American, other Hispanic, and other non-Hispanic. 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 m^2) was calculated using the CKD-EPI equation, based on the NCHS-recommended standardized creatinine values (Selvin et al., 2007).

The CKD-EPI equation is:

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

 $\kappa = 0.7$ if female, 0.9 if male

 α = -0.329 if female, -0.411 if male

F = 1 if female, o if male

B = 1 if Black/African American, o if otherwise

AGE is measured in years. The 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 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 <29
- 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) glycosylated hemoglobin (HgbA1c) \geq 7%. Participants 264 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 HgbAic 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 aware of their HTN if they report having been told they have high blood pressure, as treated for their HTN if they reported currently taking a prescription medication to control HTN, and as in control of their HTN if their blood pressure at time of medical examination was ≤140/≤90 (≤130/≤80 for CKD or SR DM).

Participants who self-reported any of the following diseases are considered to have self-reported cardiovascular disease (SR CVD): angina, myocardial infarction, stroke, coronary heart disease, or heart failure (HF; formerly called 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 \geq 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?"

Since the 2017 ADR, the examination of CKD by socioeconomic variables and additional health-related behaviors is reported. Three socioeconomic variables were added in 2017: 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, and 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 1999-2001

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". 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 that was introduced in 2017. 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.

New in the 2018 ADR is the presentation of the intake of macronutrients from the dietary interview. NHANES collects extensive information on the foods consumed and the portion sizes of respondents through a dietary recall. The USDA's Food and Nutrient Database for Dietary Studies is used to calculate nutrient values for different foods. Macronutrients are shown by CKD status across time (CDC, 2018).

Figure 1.1 shows the weighted percentage of NHANES respondents with each stage of CKD,

defined as above, for four time periods, 2001-2004, 2005-2008, 2009-2012, and 2013-2016. The whisker bars show the 95% confidence interval around each estimate of fraction with each stage of kidney disease in the U.S. civilian, noninstitutionalized population. 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.a shows the distribution of estimated eGFR for all NHANES respondents, and Figure 1.2.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.a shows updated statistics for Figure 1.8: Definition and Classification of CKD of the KDIGO 2012 Clinical Practice Guideline for CKD Evaluation and Management (KDIGO, 2013) using data for 2013-2016. Table 1.1.b summarizes the results by the risk categories shown in Table 1.1.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/ethnicity, 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/1.73m²), and using the albuminuria criterion alone (uACR \geq 30 mg/g). This table shows what percent of the group described by the row label has CKD; for example, 32.2% of those aged 60 or older in 2013-2016 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. Figure 1.5 shows the distribution of the following markers of CKD: reduced eGFR only, elevated uACR only, or both reduced eGFR and elevated uACR, among each risk factor group.

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 the results of seven logistic models are shown. Figure 1.7 splits the model into two panels for ease of reading due to the differences in scale for the odds ratios for age compared to the other risk factors. The associations for age are shown in panel a, and other CKD risk factors in panel b. The model includes the following variables: 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 and without 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 up 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 2001-2003 period.

Macronurients are shown in Table 1.4 and include energy (total calories), fat, carbohydrates, protein, total sugars, sodium and potassium. The means are presented in Table 1.4.

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 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 at 140/90 (1.10.a) and at 130/80 (1.10.b) 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 or exceeding the target, <7% in 1.11.a and 8% or higher in 1.11.b.

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, across the four periods. Figure 1.13.a is among people with CKD (low eGFR or presence of albuminuria); 1.13.b shows awareness for those with low eGFR only, with uACR>30 only, and with both; 1.13.c shows awareness by diabetes and hypertension status – neither DM or HTN, DM only, HTN only and both DM and HTN – and 1.13.d by age group.

Figure 1.14 tabulates responses to the 2013-2016 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 *Volume 1*, *Chapter 2* 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 (2016 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 sections, Laboratory Testing of Patients with and without CKD and Physician Visits after a 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 (aged 22 and older), and the VHA (aged 22 and older). 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. Table 2.2.a shows the sample counts and percent of all patients with the condition, for each condition separately. Table 2.2.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 Data Sources section on <u>NHANES</u> in this chapter for methods) include the 2013-2016 survey years and are restricted to participants aged 65 or older. CKD is determined by eGFR<60 ml/min/1.73m². In the claims-based datasets of Optum Clinformatics[™] (2016) and the Medicare 5% sample (2016), CKD is determined by ICD-9-CM or ICD-10-CM diagnosis codes. In the claims- and lab-based VHA dataset (2016) patients are considered to have CKD via either a diagnosis or eGFR<60 ml/min/1.73m², as determined by routine blood testing for serum creatinine.

Table 2.4 shows the 2016 unadjusted prevalence of diagnosed CKD by age, sex (male/female), race (White/Black/Native American/Asian/Hispanic [Optum Clinformatics[™] only]/Other/Unknown), 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: (a) the Medicare 5% sample (aged 65+) and (b) the Optum Clinformatics[™] dataset (aged 22+), showing the prevalence of diagnosed CKD across the United States in 2016.

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 stagespecific codes.

Table 2.5 shows progression of kidney disease by CKD stage, end-stage renal disease (ESRD), or death in 2015-2016 for the fee-for-service, age-eligible Medicare population of 2011. The analysis cohort required patients to be alive and eligible for Medicare Parts A and B with no HMO coverage for all of 2011. Death and ESRD status were examined yearly between 2012 and 2016, 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 progress to death or ESRD by 2016 the last CKD diagnosis claim in 2016 was used; if this was not available, the last CKD diagnosis claim from 2015 was used. Lost to follow-up status represents the patients who were not enrolled in Medicare Part A and B during 2015 or 2016 and who had no indication of death or ESRD.

Figures 2.3–2.4 show the proportion of patients tested for urine albumin from 2006-2016, 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. For each figure, 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 included patients who were alive, without ESRD, did not have a Medicare Advantage plan, and had both Parts A and B coverage for all of 2015. The date of the earliest CKD claim (any CKD or Stage 3/4/5 [585.3–585.6, N18.3-N18.6) in 2015 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 o6, 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 2016 (based on diagnostic code) who were tested for urine albumin in 2016, according to whether they saw a primary care physician, a nephrologist, or neither in 2015. The analysis cohort required patients to be alive and eligible for all of 2016 with a CKD diagnosis claim in 2015.

Chapter 3: Morbidity and Mortality in Patients with CKD

The analyses in Volume 1, Chapter 3: Morbidity & Mortality in Patients with CKD 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, and 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 were required to meet the above criteria and to 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 1 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 rates by CKD status from 2004 to 2016, and Figure 3.2 shows rates for 2016 by CKD status and stage. We calculated unadjusted mortality as the number of deaths divided by the number of patientyears at risk, and express this as "per 1,000 patientyears." In Figures 3.1-3.6 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/African American, or Other), and sex (male or female). We have applied this modified set of adjustment covariates since the 2014 ADR—prior year hospitalization and comorbidities are no longer included. These adjustment covariates differ from those used in prior ADRs through the 2013 ADRs. Therefore, differences between adjusted rates in the ADRS since 2014 and rates in ADRs prior to 2014 may be notable.

All patients in 2016 formed the standard 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. In 2011, the Social Security Administration stopped releasing 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 analyses, 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 o2 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 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/African American, or Other), and sex (male or female). As with mortality, a different set of adjustment covariates were applied starting with the 2014 ADR. Adjusted rates in this ADR may thus differ from the adjusted rates in ADRs prior to 2014. 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 standard 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 standard cohort as the weight.

Table 3.2 and Figures 3.7 and 3.8 show adjusted allcause admission rates for fee-for-service Medicare patients aged 66 and older and Optum Clinformatics™ patients aged 22 and older. Table 3.2 and Figure 3.7 also show the unadjusted rates. As mentioned above, DM and CVD were ascertained in 2015 for the analysis of hospital admissions in 2016, as described in the Identification of Major Comorbidities section of this chapter. All Medicare patients in the cohort were 66 years and older (22 and older for Optum Clinformatics[™]), did not have ESRD on 1/1/2016, had Medicare Part A and B coverage (for Optum Clinformatics[™], plan enrollment) for all of 2015, and did not participate in a Medicare Advantage plan from 1/1/2015 through 1/1/2016. Rates presented by one factor were adjusted for the other covariates. The standard cohort for Medicare analyses included all 2016 Medicare patients aged 66 and older. The standard cohort for Optum Clinformatics[™] analyses includes all patients in 2016.

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

Cause of hospitalization	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-T85.79XA; T86.842; T87.40-T87.44; T88.0XXA
Other causes	All codes, except those in cardiovascular or infection.	All codes, except those in cardiovascular or infection.

Principle diagnosis for hospital stay

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 digits, 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.

HOSPITAL 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 *Volume 1, Chapter 3: Morbidity & Mortality in Patients with CKD*, 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, outcomes were 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 readmitted 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 readmitted (both alive and dead on day 30) for age, sex, and race groups, plus the composite death and readmission outcomes 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. This figure shows the adjusted percentages for the four readmission and death outcomes across time from 2004 to 2016. 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 2011. Figure 3.17 shows the unadjusted percentage of patients readmitted to the hospital within 30 days of discharge for 2016 patients with and without CKD before an 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.

Chapter 4: Cardiovascular Disease in Patients with CKD

Volume 1, <u>Chapter 4: Cardiovascular Disease in</u>

Patients with CKD describes the prevalence of cardiovascular comorbidities and selected cardiovascular procedures in fee-for-service, ageeligible 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 shown in Tables 10.3 and 10.4.

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.

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	121.01-122.9; 125.2
Atrial fibrillation (AFIB)	427.3	148.0-148.92
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	112.00-122.9; 124.0-125.9; 295.1; 295.5; 298.61
Heart failure (HF)	398.91; 402.01, 402.11, 402.91; 404.01, 404.03, 404.11, 404.13, 404.91, 404.93; 422ª; 425ª; 428; V42.1ª	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	150.20-150.23; 150.40-150.43
Diastolic only	428.3	150.30-150.33
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	146.2-147.0; 147.2; 149.01; 149.02; 149.3; 149.49
Valvular heart disease (VHD)	424	A18.84; I34.0-I39; M32.11
Venous thromboembolism and pulmonary embolism (VTE/PE)	452-453.9	181-182.91

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

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 digits, 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.

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, 35565, 35566, 35571, 35583, 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) ICD-10-CM Procedure code (IP, OP, SN)	36.1 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 xxxxxF, xxxxx3, xxxxxx4: 211088-02110ZC; 211488-02114ZC;
Implantable cardioverter defibrillators & cardia	ac 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 endarterect	comy (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, 037x44Z, 037x4ZZ, for x=G to Q, except I & O; 03Bx0ZZ, 03Bx4ZZ, for x=G to V, except I & O; 03CG0ZZ, 03CG3ZG, 03CG3ZZ, 03CG4ZG, 03CG4ZZ, 03Cx0ZZ, 03Cx3ZZ, 03Cx4ZZ, 03Cx4ZZ for x=H to V, except I & 0; 03Cx3ZG 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

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 of the ADR

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, 2016, and who were continuously enrolled in Medicare Parts A and B but not in a Medicare Advantage plan for all of 2016. Cardiovascular conditions, CKD, and CKD staging were determined from claims in 2016.

Table 4.1.a presents the Figure 4.1 prevalence data by age, race, sex, and CKD status, and Table 4.1.b presents data on cardiovascular procedures performed in 2016. The cohort was the same as that used for Figure 4.1. However, the denominator for each cardiovascular procedure was not "all patients in the cohort", which was the denominator for the prevalence statistics. The percent with PCI or CABG in Table 4.1.b 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 probability of patients with cardiovascular conditions (Figure 4.2) or cardiovascular procedures (Figure 4.3), adjusted for age and sex using Cox regression models. We assessed conditions in a baseline year (2014), the origin for survival time was January 1 of the following year (1/1/2015), 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 2014 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, aged 66 and older on 1/1/2015, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, and enrolled in Medicare Parts A and B, but not enrolled in a Medicare Advantage plan for all of 2014. Patients were then followed from 1/1/2015 until the earliest of date of death, ESRD diagnosis, or December 31, 2016. 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 1/1/2013 through 12/31/2016 were searched for the procedure codes specified in Tables 10.7, and the date of the first claim with a specified code was considered the index date. To be retained in the analysis cohort, on the index date, the patient must have been aged 66 or older, residing in the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, and enrolled in Medicare Parts A and B, but not enrolled in a Medicare Advantage plan. Patients with ESRD on or before the index date were excluded. The patient's claims from the 365 days preceding the index date were then searched for a prior occurrence of the given condition/procedure. 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, 2016. 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

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 (2016). All drugs in the PDE file were matched to a therapeutic category according to the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification©. Claims for 2016 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 2016. The prescription must be part of the AHFS Classification group and have a generic name as specified in Table 10.8.

Drug class	AHFS classification	Generic drug name
Beta blockers	242400	<no restriction=""></no>
Statins	240608	<no restriction=""></no>
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=""></no>

Table 10.8 Drug classes used in Volume 1, Chapter 4 of the ADR

Abbreviations: AHFS, American Hospital Formulary Service; P2Y12, a group of antiplatelet medications.

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 numbers of days with systolic, diastolic, and unspecified diagnoses were 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 2016. The study cohort included Medicare enrollees who were alive, aged 66 and older, residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, who did not have ESRD on

December 31, 2016, 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 probability 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 2014 claims data. The study cohort included Medicare enrollees who were alive and aged 66 or older on December 31, 2014, residents of the 50 states, the District of Columbia, Puerto Rico, or the U.S. territories, and continuously enrolled in Medicare Parts A and B, but not enrolled in a Medicare Advantage plan for all of 2014. Patients with ESRD on or before December 31, 2014 were excluded. Follow-up began on 1/1/2015 and continued until death or 12/31/2016. Type of HF was determined by the same procedure as the previous figures, using claims from 2014. Codes used to define DM and HTN are listed in Table 10.4 of this chapter. Age was defined as of 12/31/2014. 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 2016. This table uses the same cohort as Figure 4.1.

Chapter 5: Acute Kidney Injury

Three data sources were used for Volume 1, Chapter 5: Acute Kidney Injury: the Medicare 5% sample, Optum Clinformatics[™] Data Mart, and the VHA data. The Medicare and Optum Clinformatics[™] datasets only contain diagnosis code information on AKI, and no laboratory measurements. For these two sources, a hospitalization with AKI was defined as an inpatient stay with any diagnosis code for AKI, not necessarily as the primary diagnosis. The VHA data contain serum creatinine measurements for both routine outpatient visits and inpatient stays, but not urine output measurements. This allowed for calculation of the serum creatinine criteria of the KDIGO consensus definition of AKI, and for 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 from 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 5A1DooZ, 5A1D6oZ, and 3E1M39Z, and Medicare revenue center codes o800-o809. 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 DIAG_<YEAR>, PROC_<YEAR>, and MED_<YEAR> claims data tables that were performed between the admission and discharge dates of the inpatient stay. Similarly, the VHA dataset was 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, 5.3.b, 5.4.a, 5.4.b, 5.5.a, 5.5.b, 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.c, 5.4.c, 5.5.c, 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 2018 ADR, Figures 5.3, 5.4, and 5.5 show the rate of all AKI hospitalizations, or AKI requiring dialysis, 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.a and 5.2 illustrate similar statistics, but Figure 5.1.a uses Medicare data and 5.2 uses Optum Clinformatics[™] (Figure 5.2) data. Figures 5.1.a and 5.2 show 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. Figure 5.1.b, however, uses the numerator of Figure 5.1.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. Figure 5.1.c uses the same denominator as 5.1.b, showing the percent of patients with nephrology consultation during AKI hospitalization.

The nephrology consultation during the AKI hospitalization was defined from Part B physician/supplier claims by searching provider specialty code 39 and HCPCS codes (99218-99226, 99231-99236, 90935, 90937, 90945, 90947, 99251- 99255) between the AKI admission and discharge dates.

Note that these percentages do 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 answer 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 2016 (October 1, 2015 through September 30, 2016) 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 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 (AKI)

Definition of AKI

An increase in serum creatinine (SCR) by \geq 0.3 mg/dL (\geq 26.5 μ mol/l) within 48 hours; or an increase in SCR to \geq 1.5 times baseline, which is known or presumed to have occurred within the prior 7 days; or urine volume <0.5 ml/kg/h for 6 hours.

Stage	Serum creatinine	Urine output
1	1.5–1.9 times baseline <u>OR ></u> 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 <u>></u> 12 hours
3	3.0 times baseline <u>OR</u> increase in SCR to \geq 4.0 mg/dL (\geq 353.6 μ mol/l) <u>OR</u> initiation of renal replacement therapy <u>OR</u> , in patients <18 years, decrease in eGFR to <35 ml/min/1.73m ²	<0.3 ml/kg/h for <u>></u> 24 hours <u>OR</u> anuria for <u>></u> 12 hours

Adapted from KDIGO (2012). Abbreviations: eGFR, estimated glomerular filtration rate; SCR, serum creatinine. This is also Table A in Volume 1, Chapter 5.

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. To identify a hospitalization with AKI, a patient's first SCR measurement on the day of admission was compared to their baseline SCR. If the patient's first SCR measurement on the day of admission was 0.3 mg/dL or 1.5 times higher than baseline, the patient was said to have AKI. If not, the second inpatient SCR measurement was examined. If the second SCR measurement occurred within two days of the admission, and if the second SCR was 0.3 mg/dL or 1.5 times higher than the baseline or first inpatient measurement, the patient was said to have AKI. If not, this process continued. When an SCR measurement was taken more than 48 hours from admission, it was compared to all previous SCR measurements that occurred within the last 48 hours, rather than to the patient's baseline.

We present the following scenario to illustrate the 48-hour increase assessment. Let us suppose that a patient with a baseline SCR of o.8 mg/dL is admitted on January 1st, and has a first inpatient SCR of o.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 5th. The January 5th measurement is compared to the January 4th measurement, where it meets the criteria for AKI. The January 5th measurement would not be compared to those from January 1st or 2nd, nor would the January 5th measurement to those from January 1st or 2nd, nor would the January 5th measurement to the second to the baseline to

determine whether the 0.3 mg/dL increase condition is satisfied. Similarly, when assessing for an SCR 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, i.e. 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 c) beneficiaries, and to calculate rates of AKI requiring dialysis per 1,000 patient-years at risk for Medicare (panel b) beneficiaries. Each hospitalization with an AKI diagnosis (any position on the claim) for a patient was

counted as an event. 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, disenrollment from Parts A and B, or a switch to a Medicare Advantage plan), at death, or December 31 of year two. Age was determined on January 1 of year two, while CKD and DM status were determined by claims in year one. For the 2018 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.

READMISSION ASSOCIATED WITH AN AKI EPISODE

Figures 5.6 (Medicare beneficiaries) and 5.7 (Optum Clinformatics[™] beneficiaries) show the probability of having a second hospitalization with AKI within 24 months of the first hospitalization with AKI. The samples for these figures began with the 2014 Medicare and Optum Clinformatics[™] cohorts identified in the Characteristics of Patients with AKI section above-patients alive, aged 66+ years in the Medicare data or 22+ years in the Optum Clinformatics[™] data, without ESRD, and enrolled in their plan (for Medicare, Part A and B coverage with no Medicare Advantage plan) on 1/1/2014. The first hospitalization with AKI in 2013 was identified. Age was determined as of 1/1/2014, and comorbidities were defined by searching claims one year prior to the AKI admission date. The search period was determined as follows: admission date - (minus) 365 (days), 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 cohorts for Figures 5.6 and 5.7 included only those patients with at least one hospitalization with AKI in 2014 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.a shows the outcomes of death or ESRD within one year of a live discharge from a hospitalization with AKI for Medicare beneficiaries; Figure 5.8.b presents this data for the Optum Clinformatics[™] beneficiaries. To increase the precision of these estimates, we created cohorts that included Medicare or Optum Clinformatics[™] patients with a first hospitalization with AKI in 2014 or 2015. Patients were alive, aged 66 or older in the Medicare data or 22 years or older in the Optum Clinformatics[™] data, without ESRD, and enrolled in their plan (for Medicare, Parts A and B coverage with no Medicare Advantage plan) on January 1 of the year of their first hospitalization with AKI. Patients 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, starting with the 2017 ADR, the mortality model 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.

Figure 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 (Figure 5.9.a), visits with a nephrologist have the provider specialty code 36, while in the Optum Clinformatics[™] data (Figure 5.9.b), visits 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 earliest date of occurrence of the following: the follow-up 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).

Figures 5.10.a and 5.10.b show 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 2014 or 2015. Patients were alive, aged 66 or older in the Medicare data or 22 years or older in the Optum Clinformatics[™] data, 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 first hospitalization for Medicare beneficiaries in 2016. Figure 5.11.a shows patients whose hospitalization contained an AKI episode while 5.11.b shows those whose hospital stay did not. The cohort includes all patients who experienced a hospitalization during 2016 and were alive, aged 66 or older, enrolled in Medicare Parts A and B but not in a Medicare Advantage program, and without ESRD on January 1, 2016. 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 oi (routine discharge to home) or o6 (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 o3 (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: CKD among Children and Adolescents

The analyses in *Volume 1, <u>Chapter 6: CKD among</u> <u>Children and Adolescents</u> are based on the Optum Clinformatics[™] Data Mart cohort, a dataset of participants in the commercial insurance plans of a large U.S. managed-care health insurance company.*

The definition of CKD typically includes the presence of structural or functional kidney damage over a minimum period of three months. Functional damage is often characterized by sustained reduction in estimated glomerular filtration rate (eGFR), persistent elevations in urinary albumin excretion or a combination thereof (KDIGO, 2012). The presence of a structural abnormality of the kidney also fulfills the criteria for CKD. Documentation of the presence of chronic structural or functional abnormalities of the kidney in medical claims may include traditional CKD codes or may only include a more precise structural or functional diagnosis. Consequently, a pediatric code set using ICD-9 and ICD-10 codes is utilized for Volume 1, Chapter 6: CKD among Children and Adolescents. Table 10.10 provides this set of CKDrelated ICD-9-CM and ICD-10-CM codes.

Condition name	ICD-9-CM codes	ICD-10-CM codes
Chronic kidney disease (CKD)	189.0, 250.4-250.43,255.13, 283.11, 285.21, 403, 404, 446.21, 446.4, 580.4, 556.9, 581-582, 583.81, 585-588, 590.01, 593.3, 593.5, 596.4, 593.71-597.73, 593.81, 753.0-753.36, 753.9, 756.71, 886.81, V10.52, V13.03, V42.0, V44.52, V45.11, V45.73	A02.25, A18.11, A36.84, A52.75, B52.0, B58.83, C64.1, C64.2, C64.9, C68.9, D30.0x, D41.0x- D41.2x, D59.3, E08.22, E08.29, E09.21, E09.22, E09.29, E10.21, E10.22, E10.29, E10.331, E10.339, E11.2x, E13.2x, E26.81, E31.21, E72.01, E72.03, E72.04, E72.53, E83.31, E85.8, I12.x, I13.0, I13.1x, I13.2, M10.3x, M13.722, M31.0, M3101, M31.31, M31.7, M31.7, M32.14, M32.15, M35.04, N01.x-N08.x, N11.0, B11.1, N11.8, N11.9, N13.1, N13.1x-N13.6, N13.70, N13.721, N13.729, N13.8-N13.9, N14.x, N15.0, N15.8, N15.9, N16, N17.x, N18.1-N18.5, N18.8, N18.9, N19, N25.xx, N26.1-N28.9, N31.2, N31.9, Q27.1, Q60.x-Q62.69, Q63-Q64.33, Q64.4-Q64.9, Q79.4, Q79.51, Q71.81, Q80.0, Q80.1, Q80.8, Q83.9, R94.4, Z85.520, Z85.528, Z87.441, Z90.5, Z93.52
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 or N18.6 with no CMS 2728 form
Stage unknown or unspecified	Patient has <u>no</u> claims with codes 585.1- 585.6 but has: 189.0, 250.4- 250.43,255.13, 283.11, 285.21, 403, 404, 446.21, 446.4, 580.4, 556.9, 581-582, 583.81, 586-588, 590.01, 593.3, 593.5, 596.4, 593.71-597.73, 593.81, 753.0- 753.36, 753.9, 756.71, 886.81, V10.52, V13.03, V42.0, V44.52, V45.11, V45.73	Patient has <u>no</u> claims with codes N18.1-N18.6 but has: A02.25, A18.11, A36.84, A52.75, B52.0, B58.83, C64.1, C64.2, C64.9, C68.9, D30.0x, D41.0x-D41.2x, D59.3, E08.22, E08.29, E09.21, E09.22, E09.29, E10.21, E10.22, E10.29, E10.331, E10.339, E11.2x, E13.2x, E26.81, E31.21, E72.01, E72.03, E72.04, E72.53, E83.31, E85.8, I12.x, I13.0, I13.1x, I13.2, M10.3x, M13.722, M31.0, M3101, M31.31, M31.7, M31.7, M32.14, M32.15, M35.04, N01.x-N08.x, N11.0, B11.1, N11.8, N11.9, N13.1, N13.1x-N13.6, N13.70, N13.721, N13.729, N13.8-N13.9, N14.x, N15.0, N15.8, N15.9, N16, N17.x, N18.8, N18.9, N19, N25.xx, N26.1-N28.9, N31.2, N31.9, Q27.1, Q60.x-Q62.69, Q63-Q64.33, Q64.4-Q64.9, Q79.4, Q79.51, Q71.81, Q80.0, Q80.1, Q80.8, Q83.9, R94.4, Z85.520, Z85.528, Z87.441, Z90.5, Z93.52

Table 10.10 ICD-9-CM and ICD-10-CM diagnosis codes used to define chronic kidney disease (CKD) in pediatric patients in Volume 1, Chapter 6 of the ADR

Source: ICD-9/10-CM, International Classification of Diseases, Ninth/Tenth Revision, Clinical Modification. Abbreviation: CKD, chronic kidney disease.

VOLUME 1: CKD ANALYTICAL METHODS

Tables 6.1 and 6.2 include point prevalent patients under 22 years old who survived all of the reported year (2016) and who did not have or develop ESRD during the reported year. Additionally, for the Optum Clinformatics[™] analysis, the plan member is required to be enrolled for the entire reported year.

Table 6.1 presents demographic and comorbidity characteristics of children and adolescents in the Optum Clinformatics[™] dataset. 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 as described in the <u>Identification of Major Comorbidities</u> section of this chapter by at least one inpatient or two outpatient medical claims during the reported year.

Table 6.2 presents the prevalence of coded CKD, DM, and CVD in Optum Clinformatics[™]. Table 6.2.a shows the sample counts and percent of all patients with the condition, for each condition separately. Table 6.2.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.

The hospitalization analyses follow a similar approach as the hospitalization section in <u>Volume 1</u>, <u>Chapter 3: Morbidity and Mortality</u>.

Table 6.3 and Figure 6.1 show adjusted all-cause admission rates for Optum Clinformatics[™] patients under 22 years old. Table 6.3 also shows the unadjusted rates. All Optum Clinformatics[™] patients in the cohort were under 22 years old, did not have ESRD on or before 1/1/2016, had plan enrollment for all of 2015, and were alive on January 1, 2016. Adjusted analysis is adjusted for age/sex/race. Rates presented by one factor were adjusted for the others. The standard cohort for Optum Clinformatics[™] analyses includes all patients in 2011.

Figure 6.2 shows adjusted, cause-specific admission rates for CKD Optum Clinformatics[™] patients under 22 years old. 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, however, those hospitalizations with the following diagnosis codes were reclassified from 'other cause' to cardiovascular:

Q20.3, Q21.0-Q21.3, Q22.1, Q22.2, Q23.1, Q13.3, Q24.5, Q24.8, Q24.9, Q25.9, Q26.1, R00.0, R01.0, R01.1, Z94.5

The 'other cause' of hospitalization is a residual category consisting of all hospitalizations other than those for cardiovascular or infectious conditions. Each cause is using an individual model adjusted for age/sex/race. Rates presented by one factor were adjusted for the others. The standard reference cohort for Optum Clinformatics[™] analyses includes all patients in 2011.

Figure 6.3 shows per person per year commercial spending (\$, in thousands) for Optum Clinformatics[™] patients under 22 years old by comparing CKD patients and non-CKD patients from 2006 to 2016. The analysis follows a similar approach as *Volume 1, Chapter 7: Health Care Expenditures for Persons with CKD*.

Chapter 7: Health Care Expenditures for Persons with CKD

Volume 1, <u>Chapter 7: Health Care Expenditures for</u> <u>Persons with CKD</u> used a cohort that continued the methodology introduced in the 2010 ADR, where 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 expenditures.

The data we received from the Optum Clinformatics[™] Data Mart this year included a complete refresh of all years from 2006 to 2016. This lead to changes in some of the trends using the

Optum cost data. Additionally, Optum added encounter claims. These are claims that the insurance company did not pay for outright but were bundled as part of a larger procedure, such as follow-up visits after surgery. While these claims may be useful for researchers studying surgeries who may want to track patients' adherence to the follow-up regimen, these claims are tricky for cost analysis. Since Optum sets a standard price for each CPT code/ICD procedure code, the encounter claims show a standard price even though the insurance company paid nothing. As we are interested in how much the payer spends on various patient groups, we limited the claims to those with a claim type of P for paid, whereas in the past, when there were no encounter claims, we summed all claims.

The same general point prevalent cohort was used to create all the Medicare tables and figures, and a similar cohort was created for the Optum Clinformatics[™] tables and figures. Each year's Medicare 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 oneyear 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. Perperson-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 Part A, B, and D expenditures. These were age-eligible patients who were continuously enrolled in Parts A and B, and not enrolled in a Medicare Advantage plan, for all of the previous year (year one). The Optum Clinformatics[™] data represents 100% of their beneficiaries, thus there was no need to weight the data to population totals.

Since the 2017 ADR, we no longer attribute only a fraction of claims that span the calendar year to each year. Instead, 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. With rows representing all combinations of the disease conditions of CKD, HF, and DM, Table 7.1 shows the total Medicare population aged 65 and older, total spending, per-patient per-year spending, the fraction of the total Medicare population with the given disease condition(s), and the fraction of total Medicare spending for the given disease condition(s). Table 7.2 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 7.3 and 7.4 show the same statistics for beneficiaries and members who were under the age of 65. Figure 7.1 shows the information in Table 7.1 graphically, along with the same information for the previous year.

Table 7.5 shows two years of per-person per-year spending for overall CKD (any stage) and by CKD stage for Medicare fee-for-service coverage, and Table 7.6 shows this data for Optum Clinformatics™ commercial insurance and Optum Clinformatics™ Medicare Advantage plans. Costs and conditions were determined as in Tables 7.1 and 7.2 and Figure 7.1, while race and sex were provided by the Master Beneficiary Summary File. Figure 7.2 displays this information graphically for four years. Table 7.7 shows data similar to Table 7.5, but for those with CKD and DM. Table 7.8 shows the same statistics as Table 7.7 but for Optum Clinformatics[™] Medicare Advantage and commercial insurance enrollees. Table 7.9 repeats Table 7.7, but for those with CKD and HF rather than DM. Table 7.10 presents the same results as Table 7.9,

but for the Optum Clinformatics[™] Medicare Advantage and commercial insurance enrollees.

The focus of Figures 7.3-7.6 is expenditure trends. Figure 7.3 shows the spending on fee-for-service Parts A, B, and D for all Medicare patients and for Medicare patients with CKD (7.3.a), patients with DM (7.3.b), and patients with HF (7.3.c). Figure 7.4 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 7.5 shows inpatient institutional costs by the cause of hospitalization, which was determined using the same methods as in Volume 1, Chapter 3: Morbidity and Mortality in Patients with CKD, using the codes displayed in Table 10.5. Figure 7.6 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). Figure 7.6.a shows Medicare feefor-service spending, 7.6.b shows Optum Clinformatics[™] commercial insurance plan members, and 7.6.c shows Optum Clinformatics[™] Medicare Advantage spending. Table 7.11 shows the overall percentage of CKD expenditures for Medicare, Medicare Advantage, and managed care beneficiaries aged 65 and older by CKD stage and year.

Chapter 8: Prescription Drug Coverage in Patients with CKD

Volume 1, <u>Chapter 8: Prescription Drug Coverage in</u> <u>Patients with CKD</u> describes prescription drug coverage and usage. Since the 2017 ADR, we show 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* <u>Comorbidities</u> section of this chapter and in 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 the chapter Prescription Drug Coverage in Patients with CKD 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 also differs from the sample used to describe General Medicare patients in Volume 2, Chapter 10: Prescription Drug Coverage in Patients with ESRD, which does not apply restrictions based on year-one Medicare participation.

In Volume 1, Chapter 8, 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 must have been 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 to enable CKD identification in the Medicare cohort, as diagnosis codes were only available for those with feefor-service Medicare. 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, Chapter 8 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 younger age groups.

Figures 8.1-8.3 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 "or" through "o8."

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 having a "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.

In prior deliveries of the Medicare 5% sample there was a variable called Creditable Coverage Switch with a value of "1", indicating another form of drug coverage that was at least as generous as the Part D benefit. For data year 2016 (used in the 2018 ADR), the Creditable Coverage Switch variable was no longer available on the files we received from the Chronic Conditions Warehouse, and it cannot be derived from other variables on the file. Figure 8.1 presents the distribution of sources of prescription drug coverage without the category of other creditable coverage for the General Medicare and CKD cohorts described above.

Table 8.1 shows the percent of beneficiaries with Part D coverage for the past six years in the General Medicare and CKD cohorts. Table 8.2 is an adaptation of data presented in the 2016 Medicare Outlook section of the <u>www.qimedicare.com</u> website and does not include USRDS analyses. Figure 8.2 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 (Figure 8.2.a) and CKD (Figure 8.2.b) cohorts, while Figure 8.3 shows the coverage categories by race groups (White, Black or African American, Asian, and Other.)

Table 8.3 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 8.1. Table 8.3 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 8.4 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 8.4 and Figure 8.5 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 8.4 shows the total Medicare Part D benefit expenditures and the per-person per-year spending 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 Volume 1, Chapter 7: Healthcare Expenditures for Persons with CKD, which show Medicare spending on Parts A and B benefits for those not in Medicare Advantage plans.

Figure 8.5.a shows spending and patient out-ofpocket costs 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. Figure 8.5.b breaks out these costs by whether the patient received any low income subsidies. Table 8.5.a shows PPPY spending by age, sex, and race for the General and CKD cohorts by feefor-service Medicare with LIS and fee-for-service Medicare without LIS. Table 8.5.b provides the same information for patients with Optum Clinformatics[™] Medicare Advantage plans and Optum Clinformatics[™] commercial insurance plans.

All drugs in the PDE file and Optum Clinformatics[™] PHARM_<YEAR> table were matched to a therapeutic category according to the American Hospital Formulary Service (AHFS) classification system. The Medicare cohort for Tables 8.6.a and 8.7.a was limited to those in the CKD cohort who had stand-alone Part D prescription drug coverage. Each therapeutic category in Tables 8.6-8.7 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 8.6 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-forservice Medicare (Table 8.6.a), Optum Clinformatics[™], Medicare Advantage (Table 8.6.b), and Optum Clinformatics[™] commercial insurance

(Table 8.6.c). Table 8.7 shows the top 15 drug classes ranked by spending. The column following the drug class shows the total amount spent by Medicare (Table 8.7.a), Optum Clinformatics[™] Medicare Advantage (Table 8.7.b), and Optum Clinformatics[™] commercial insurance (Table 8.7.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.

Since the 2017 ADR, the chapter Prescription Drug Coverage in Patients with CKD has shown data 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 used for Figures 8.6-8.7 was the same as the Medicare cohort used in Tables 8.6-8.7; 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 the patient having filled or refilled at least one prescription of a drug in the drug classes listed above. The state of residence was obtained from the Medicare Beneficiary Summary File. Figure 8.6 tabulates the use of NSAIDs (yes/no) by state, divides the states by quintiles, and shows the results in a map. Figure 8.7 does the same with the use of opiates.

The special focus of the 2018 ADR is antiviral medication use in the general Medicare population and the CKD population. Figure 8.8.a shows the prevalence of Human Immunodeficiency Virus (HIV) and Figure 8.8.b shows Hepatitis C virus (HCV) in patients with CKD. Diagnosis codes for HIV are 042 (ICD-9) and all of B20 (ICD-10). For HCV, the codes were 070.54 (ICD-9) and B18.2x (ICD-10) – all of the codes beginning with B18.2.

The antiviral class of drugs was defined as AHFS class o818. We focused on antiretrovirals (o81808), nucleosides and nucleotides (o818320), and protease inhibitors (o81840). Figure 8.9 shows the utilization of these drugs over time, and Figure 8.10 shows perpatient per-year spending on these drugs by the Medicare program.

Reference Tables

CKD REFERENCE TABLES

Downloadable CKD Reference Tables are found on this page: <u>https://www.usrds.org/reference.aspx</u>

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 ageeligible (aged 65 and older) cohort presented in Volume 1, Chapter 2: Identification and Care of Patients with CKD. 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 <u>Chapter 1: CKD in the General Population</u> section, above). For Table B.8, CKD was defined as an estimated glomerular filtration rate (eGFR) less than 60 ml/min/1.73m² (which identifies Stages 3 and 4) <u>or</u> urine albumin creatinine ratio (ACR) greater than 30 mg/g (which identifies Stages 1 and 2). We estimated eGFR 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) is defined as in *Volume 1, Chapter 1: CKD in the General Population*, and eGFR and ACR are described as in 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: HEALTHCARE EXPENDITURES

In Tables K.1–K.5 we present estimates of the perperson 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 <u>Chapter 7: Health Care</u> <u>Expenditures for Persons with CKD</u> section of this chapter. Reference Table K includes all adult patients aged 20 and older, while Volume 1, Chapter 7 presents these costs only for those age-eligible for Medicare (aged 65 or older).

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Notes