Because you open a door doesn’t mean there has to be a room
because there are windows doesn’t mean there’s an interior
doesn’t mean there’s a space where humans can live and die —
so far I’ve opened and shut countless doors, going out each one so I could come in through another
telling myself each time what a wonderful new world lies just beyond

Ryuichi Tamura, “Human House,” translated by Christopher Drake
In this appendix we describe the datasets and methods used for the CKD analyses in this volume. Appendix B includes information on all USRDS products and services. Data management and preparation, database definitions, and the data sources used for ESRD analyses are described in the appendix of Volume Two.

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

**CMS MEDICARE ENROLLMENT DATABASE**
CMS’s Enrollment Database (EDB) is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on residence, Medicare as secondary payer (MSP) and employee group health plan (EGHP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

**ESRD MEDICAL EVIDENCE FORM (CMS 2728)**
The ESRD Medical Evidence Form is used as the official form for registering individual patients at the onset of ESRD. This form must be submitted by dialysis or transplant providers within 45 days of ESRD initiation. The CMS, USRDS, and renal research communities rely on this form to ascertain basic patient demographic attributes, primary cause of renal failure, major comorbidities, and biochemical test results at the time of ESRD initiation.

The third major revision of the Medical Evidence Form was released in May, 2005. This latest revision was intended to remedy several shortcomings found in the 1995 form and its earlier version. Key additions target pre-ESRD care and vascular access use, and additional new fields collect information on HbA1c and lipid testing, on the frequency of hemodialysis sessions, and on whether patients are informed of their transplant options. This new form will help federal and private researchers gain better insights into the health and care of ESRD patients prior to their entry into the program.

**CMS 5 PERCENT STANDARD ANALYTICAL FILES (SAFs)**
These files contain billing data from final action claims, submitted by Medicare beneficiaries, in which all adjustments have been resolved. The claims data were selected randomly from the general Medicare claims (i.e. final action claims) using five combinations of the the last two digits of HIC (CMS Health Insurance Claims) Number: 05, 20, 45, 70, and 95. Since the same two-digit numbers are used each year to create the 5 percent general Medicare SAFs, one should expect to see the same beneficiaries in these annual datasets. These claims are categorized into the inpatient (IP), outpatient (OP), home health agency (HHA), hospice (HS), skilled nursing facility (SNF), physician/supplier (PB), and durable medical equipment (DME) SAFs.

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which they are not updated to include late arriving claims. Annual files are thus approximately 98 percent complete. The USRDS 2008 ADR includes all claims up to December 31, 2006.

**MEDICARE CURRENT BENEFICIARY SURVEY (MCBS)**
The Medicare Current Beneficiary Survey (MCBS) is a longitudinal survey of a nationally representative sample of aged, disabled, and institutionalized Medicare beneficiaries. MCBS contains information on the health status, health care use and expenditures, drug prescriptions, health insurance coverage, and socioeconomic and demographic characteristics of the entire spectrum of Medicare beneficiaries. The data is made available by CMS in two datasets: Access to Care (1992–2005) and Cost and Use (1992–2004).

MCBS began in fall 1991 to survey three times per calendar year (i.e. Winter, Summer and Fall), and later introduced a sample rotation scheme in the 1994 calendar year. Survey people are kept in the sample for 4 years, with approximately one third of them rolling off, and new people being added each fall to keep the overall sample size right around 12,000 each calendar year.

**THOMSON HEALTHCARE MARKETSCAN DATA**
The Thomson Healthcare, Inc. (MedStat) MarketScan Commercial Claims and Encounters Database includes specific health services records for employees and their dependents in a selection of large employers, health plans, and government and public organizations. The database is organized in nine files: Annual Enrollment Summary Table, Enrollment Detail Table, Inpatient Admissions Table, Inpatient Services Table, Outpatient Services Table, Outpatient Pharmaceutical Claims Table, Facility (Inpatient and Outpatient) Header Table, Aggregated Populations Table, and the RED BOOK (i.e. prescription drug information by National Drug Code). As would be expected, the strength of this database lies in the quality of its cost information, where claims data include actual paid dollars and net payments by the insurer.
The MarketScan database links billing and encounter data to detailed patient demographic and enrollment information across sites and types of providers, and over time from 1999 to 2006, and includes commercial health data from approximately 100 payers. About 80 percent of those covered are self-insured. Each year the database contains health data for about 10.5 million people. For details about the Medstat data, please visit www.usrsds.org.

INGENIX i3 DATA
The Ingenix i3 database is a commercial and non-capitated health plan database covering employees from multiple employers within a single insurer. Besides the usual service encounter and drug data, similar to that of the MarketScan database, this database also includes laboratory data, allowing for comparisons between claims-based and lab-based definitions of diseases. In order to protect the discount structure of its business, the billing data of this single insurer discloses only charged dollars without actual paid amounts or the portion paid by the insurer.

The Ingenix database links billing and encounter data to detailed demographic and enrollment information of individual employees from 2000 to 2006, and contains health data for about 14 millions people annually. For details about what is contained in the Ingenix i3 data, please visit our website at www.usrsds.org.

EGHP DATA
To examine the demographic segment not represented by Medicare, we use enrollment information to construct yearly cohorts of enrollees younger than 65. To ensure that we select enrollees with the potential to generate claims evidence appropriate to the demands of analytical methods, rules for inclusion also include 12 months of continuous coverage in a commercial fee-for-service plan, and, for medication analyses, continuous prescription drug coverage. Comorbidities are identified using claims. Patients with at least one inpatient claim or at least two outpatient claims during the period of interest and with a diagnosis code of a particular comorbidity are identified as having that comorbidity.

NATIONAL HEALTH & NUTRITION EXAMINATION SURVEY (NHANES)
NHANES is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). Begun in 1959, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III was conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2006 were nationally representative cross-sectional surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. Both surveys oversampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these subgroups.

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

ESRD COHORT IN THE EGHP POPULATION
Because the Medstat and Ingenix i3 databases do not provide identifiable data elements, we are unable to link them directly to the USRDS ESRD registry. To identify ESRD patients, we therefore use a process similar to that used in the registry. Transplant patients are identified by evidence of a kidney transplant procedure or an adverse graft event, and chronic dialysis patients by evidence of continuous history of dialysis therapy, with at least three consecutive months of dialysis service and with dialysis service claims in at least 70 percent of treatment months. Treatment months are defined by the period from the first dialysis claim to the earliest of kidney transplant, death, or end of enrollment. Both inpatient and outpatient claims are evaluated for evidence of dialysis service history.

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

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

Figures p.1–3 and Table p.a–b show the prevalence of CKD, ESRD, and other comorbidities in the Medicare, Medstat, Ingenix i3, and NHANES populations. The methods used for the Medicare, Medstat, and Ingenix i3 data are similar to those used for Figure 2.8, described later in this appendix. Methods used for the NHANES data are described in the section on Chapter One. The new ICD-9-CM codes for chronic kidney disease are as follows:

- 585.1: chronic kidney disease, Stage 1
- 585.2: chronic kidney disease, Stage 2 (mild)
- 585.3: chronic kidney disease, Stage 3 (moderate)
- 585.4: chronic kidney disease, Stage 4 (severe)
- 585.5: chronic kidney disease, Stage 5 (excludes 585.6: Stage 5, requiring chronic dialysis)
- 585.9: chronic kidney disease, unspecified

Figures p.4–5 and Table p.c compare the risk of hospitalization among patients with CKD, diabetes, and congestive heart failure within several datasets. Using the general Medicare 5 percent sample, the Medicare-only cohort includes patients age 66 and older on January 1, 2005, who are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during 2004. Patients enrolled in an HMO or Medicaid during 2004 are excluded. Patients are residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories. A dually-enrolled cohort follows the same description, but patients are also enrolled in Medicaid at any time during 2004. The Medstat employer group health plan (EGHP) and Ingenix i3 cohorts include patients age 50–64 on December 31, 2004, and require enrollment in a fee-for-service commercial health plan for the complete year in 2004. All cohorts exclude patients diagnosed with ESRD during 2004 and those with a bridge hospitalization spanning January 1, 2005, Comorbidity groups are mutually exclusive, and CKD, diabetes, and congestive heart failure are defined using the standard claims-based definition during 2004. Follow-up for the first hospital admission starts on January 1, 2005, and spans up to two years. Patients are censored at the earliest of ESRD initiation, end of payor coverage or plan enrollment, or December 31, 2006, and Medicare and dually-enrolled patients are also censored at death. The Cox proportional hazards model is used to generate hazard ratios for hospitalization among comorbidity groups. Analyses are adjusted for age and gender, and those for the Medicare only and dually-enrolled patients are also adjusted for race.

Table p.d shows the hazard ratio of death for Medicare-only, dually-enrolled, and Medstat populations. The method is similar to that used for Table 4.a, described later in this appendix. The Medicare-only cohort includes general Medicare patients entering Medicare before January 1, 2004, alive and age 66 or older on December 31. The dually-enrolled cohort is the same, but patients are enrolled in Medicare and Medicaid in 2004. Both Medicare and dually-enrolled patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the year are excluded. Medstat patients are enrolled in a fee-for-service plan for all of 2004, and are age 50–64; patients diagnosed with ESRD before or during 2004 are excluded. Patients are followed two years from January 1, 2005, to December 31, 2006. Medicare and dually-enrolled patients are censored at ESRD, while Medstat patients are censored at ESRD or the end of the plan.

Selected from Table p.d, Figures p.6–7 show the hazard ratio of death by comorbidity groups for Medicare only and dually-enrolled populations, respectively.

Figure p.8 shows trends in prescription medication use, by diabetic status, in the Medicare population. Data are obtained from Cost and Use data in the Medicare Current Beneficiary Survey (MCBS) — a national, continuous, multipurpose survey of older, disabled, and institutionalized beneficiaries. To ensure that we obtain information on all therapy received by each person during each study year, included patients are continuously enrolled in the Medicare inpatient/outpatient and physician/supplier program during the entire year, survive until the end of the year, have a completed survey, are not enrolled in a managed care organization, and do not have ESRD; they also reside in the 50 states or the District of Columbia and are community-dwelling respondents. Drug use information is obtained from the MCBS Cost and Use data file “Prescribed Medicine Events,” and SUDAAN (Research Triangle Institute, Research Triangle Park, NC) is used to analyze all data.

Figure p.9 illustrates trends in prescription medicine use by diabetic status, using 2001–2006 Medstat data. In each study cohort year, patients have both fee-for-service and drug insurance coverage for the entire study year. Patients with any evidence of ESRD are excluded. Figure p.10 presents equivalent trends, using 2001–2006 Ingenix i3 data. In each study cohort year, patients are enrolled for 12 continuous months, under commercial business coverage. Patients with any evidence of ESRD are excluded.

Methods for Figure p.11 and Table p.e are described in the section on Chapter Five, later in this appendix.

CKD in the NHANES population

Chapter One

DATABASE DESIGN, SETTING, AND STUDY PARTICIPANTS

Begun in 1960, the 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 Centers for Disease Control and Prevention. NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. NHANES III is conducted in two phases between 1988 and 1994. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. Both NHANES III and NHANES 1999–2006 were nationally representative cross-sectional health examination surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received

MEASUREMENTS

Age is defined as the participant’s age at the time of the household interview, and grouped into ages 20–39, 40–59 and 60 and older. Race/ethnicity is defined as non-Hispanic white, non-Hispanic black, and other, and ethnicity Hispanic (including Mexican-American and other Hispanic) and non-Hispanic only.

Obesity is defined as a BMI of 30 kg/m2 or above.

Participants with self-reported diabetes are those ever told by a doctor that they have diabetes or sugar diabetes (other than during pregnancy). In NHANES 1999–2006, participants answering “borderline” are classified as non-diabetic. Participants with self-reported congestive heart failure are those ever told by a doctor that they have congestive heart failure. And participants with self-reported cardiovascular disease are those with at least one of the following self-reported diseases: coronary heart disease, angina/angina pectoris, heart attack, congestive heart failure, or stroke.

Smokers are identified by an affirmative answer to the question: “Have you smoked at least 100 cigarettes during your entire life?” then further classified by their answer to the question: “Do you smoke cigarettes now?” Those with affirmative answers are classified as smokers; others are defined as non-smokers.

WHO anemia is defined as a hemoglobin < 13 g/dl in males and < 12 g/dl in females.

Self-reported hypertension is identified by an affirmative answer to the question: “Have you ever been told by a doctor that you had hypertension, also called high blood pressure?”

In NHANES 1999–2006, systolic blood pressure (SBP) / diastolic blood pressure (DBP) for each participant is calculated as mean of all measured SBPs / DBPs.

Microalbuminuria is defined by ratio of urinary albumin (mg/l) to urinary creatinine (mg/dl) (ACR). Participants with a valid ACR are classified as having microalbuminuria if the value is not less than 30 mg/g.

The glomerular filtration rate (ml/min/1.73 m2) is estimated by the MDRD method and based on standardized creatinine value for NHANES III and NHANES 1999–2000, 2001–2002, 2003–2004 and 2005–2006, separately, based on NCHS recommendations. The formula used to estimate the GFR is as follows (Levey et al.):

estimated GFR = 175 * (standardized serum creatinine in mg/dl)**(-1.154) * age**(-0.203) * (0.742 if female) * (1.212 if black)

CKD is defined as an eGFR less than 60 ml/min/1.73m2, or an eGFR ≥ 60 ml/min/1.73m2 in the presence of microalbuminuria. CKD stages are defined as follows: Stage 5, eGFR < 15; Stage 4, as 15 ≤ eGFR < 30; Stage 3, 30 ≤ eGFR < 60; Stage 2, eGFR ≥ 60 ≤ eGFR ≤ 89; and Stage 1, eGFR ≥ 90. These are the standard CKD definitions used in this chapter.

STATISTICAL ANALYSIS

To obtain national estimates of each statistic in these sample surveys, odds ratios, sampling weights, and survey design are implemented by SUDAAN (Research Triangle Institute, Research Triangle Park, NC). Standard errors are estimated using the Taylor Series Linearization method for NHANES III and NHANES 1999–2006.

Figure 1.7 presents a classification tree. To identify important risk factors for CKD, the tree is constructed using the recursive partition method with deviance as the measure of heterogeneity. The data are successively split along coordinate axes of the predictor variables so that at any node, the split which maximally distinguishes the response variable in the left and the right branches is selected. NHANES 1999–2004 and S-Plus software are used to construct it.

METABOLIC MARKERS

Table 1.g and Figure 1.14 present data on awareness, treatment, and control of various metabolic markers by CKD stage. Patients are classified as hypertensive if measured systolic blood pressure is ≥ 140 mmHg (≥ 130 mmHg for CKD or diabetic patients) or measured diastolic blood pressure is ≥ 90 mmHg (≥ 80 mmHg for CKD or diabetic patients), or if the patient self-reports currently taking a prescription to control hypertension. Patients are classified as being aware of hypertension if they self-report having been told they have high blood pressure, are classified as being treated for hypertension if they self-report currently taking a prescription to control hypertension, and are considered in control of hypertension if current blood pressure is < 140/<90 (<130/<80 for CKD or diabetic).

Control of hyperlipidemia, as displayed in Table 1.g and Figure 1.14, is assessed in a similar fashion. Hyperlipidemia is defined as a measured LDL cholesterol above the ATP III target range (≥160 mg/dl for patients with 0–1 risk factors, ≥190 mg/dl for patients with two or more risk factors, ≥190 mg/dl for patients with CHD and CHD risk equivalents). CKD is classified as a CHD risk equivalent. Awareness of hyperlipidemia is assessed by self-report of being told by a doctor that blood cholesterol level is high, and a patient is classified as being treated for hyperlipidemia if he or she self-reports currently taking a cholesterol medication or dieting to control cholesterol. Control is defined as meeting the ATP III LDL target for the appropriate risk category, as described above. Current control of HDL cholesterol and total cholesterol are also presented in Table 1.g: awareness and treatment, however, are not assessed, since LDL cholesterol is currently the recommended target of therapy.

Control of diabetes is presented in Table 1.g as well. Diabetic patients are identified by self-report, as described above. Control of diabetes is assessed as a glycohemoglobin (A1c) of <7 percent, as recommended by the American Diabetes Association.

CKD identified in the claims data

Chapter 1

Chapter 2 is described in the section on Chapter Five.

Figures 2.1–12 and Tables 2.a–d include patients from the 5 percent Medicare sample, age 65 and older, without ESRD, and who
survive all of 2006 with Medicare as primary payor (and are not enrolled in Medicare Advantage).

The Medstat (employer group health plan; EGHP) and Ingenix i3 cohorts are constructed in a similar fashion, but restricted to patients age 20–64, enrolled in a fee-for-service plan, and without ESRD. Diabetes, AMI, congestive heart failure, CVA/TIA, cancer, hypertension, and CKD are identified from claims diagnosis codes, including 585 for CKD. AMI is identified by ICD-9-CM diagnosis codes 410 and 412. Patients with at least one inpatient claim or at least two outpatient claims during 2006 and with the diagnosis code of a particular comorbidity are identified as having that comorbidity.

With the exception of Figures 2.6–7 and Table 2.c, CKD stages are identified by ICD-9-CM diagnosis codes 585.1–585.9. In Figures 2.6–7 and Table 2.c, CKD is defined as follows: Stage 5: eGFR $< 15$; Stage 4: $15 \leq$ eGFR $< 30$; Stage 3: $30 \leq$ eGFR $< 60$; stage 3-5: eGFR $< 60$.

Although ICD-9-CM code 585.6 indicates ESRD, the USRDS identifies ESRD patients through multiple methods, searching for dialysis claims over at least three consecutive months in the Medstat and Ingenix i3 databases, and identifying patients through the ESRD registry in the Medicare data. Such patients are excluded in the surveillance and analyses of CKD patients, and therefore a patient with a $585.6$ ICD-9-CM code (but not identified as having ESRD through USRDS methods) is considered to have code 585.5 — having Stage 5 CKD, but not yet requiring chronic dialysis.

The estimated glomerular filtration rate (eGFR) in Figure 2.6 is calculated using both the MDRD and Rule method, while the MDRD method is used in Figure 2.7 and Table 2.c. For Ingenix i3 patients, eGFR is calculated from the last serum creatinine value in 2006.

In Figure 2.13, the prevalence of cardiovascular disease (ASHD, CHF, CVA/TIA, arrhythmia, PVD, or other cardiac diseases, including valvular disease), diabetes mellitus, and hypertension are smoothed on eGFR, truncated at 15 and 150 ml/min/1.73 m². GFR is estimated by the Rule method, with serum creatinine equal to the mean of all such measurements collected during 2006.

**Morbidity & mortality**

**Chapter Three**

**HOSPITALIZATION**

Figures 3.1–5 compare all-cause hospital admission rates in CKD versus non-CKD patients using various patient cohorts: Medicare, dually-enrolled, Medstat, and Ingenix i3. The study design consists of a one-year period during which the cohort is defined, followed by the cohort year when follow-up for admissions begins on January 1. The Medicare cohort includes patients age 66 and older on January 1 of the follow-up year, who are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories, are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, are without HMO coverage, are without ESRD, and who survive the complete year prior to follow-up. Dually-enrolled patients include the subgroup of Medicare patients who are also enrolled in Medicaid any time during the prior year. The Medstat and Ingenix i3 groups include patients age 50–64 on December 31 of the prior year who remain without ESRD and enrolled in a fee-for-service commercial health plan during the prior year. Patients are followed for admissions from January 1 of the follow-up year, and are censored at ESRD initiation, end of plan coverage, or December 31, and Medicare and dually-enrolled patients are also censored at death. In these figures, CKD is defined by one or more inpatient

### Table 2.a CPT codes for vascular access & peritoneal dialysis access services

<table>
<thead>
<tr>
<th>Procedure</th>
<th>CPT Code(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemodialysis catheter placement</td>
<td>36061, 36419, 36823</td>
</tr>
<tr>
<td>Peritoneal dialysis catheter placement</td>
<td>49419.49d, 49420, 49421</td>
</tr>
<tr>
<td>Synthetic graft placement</td>
<td>36830</td>
</tr>
<tr>
<td>Fistula placement</td>
<td>36818, 36819, 36820, 36821, 36825</td>
</tr>
</tbody>
</table>

* Requires accompanying renal diagnosis code for inclusion.

### Table 2.b DRG & ICD-9-CM codes for vascular access & peritoneal dialysis access services

**DRG codes**
- 112 Percutaneous cardiovascular procedure
- 315 Other kidney and urinary tract procedure
- 433 Other OR procedure for injuries without complication
- 478 Other vascular procedure with complication
- 492 Complication of vascular device, implant, graft
- 499.61 Mechanical complication of vascular device, implant, graft
- 499.62 Infectious complication of vascular device, implant, graft
- 499.63 Other complication due to renal dialysis device, implant, graft
- 499.64 Fitting and adjustment of extracorporeal dialysis catheter
- 499.65 Replacement of peritoneal dialysis catheter

**ICD-9-CM codes**
- 39.42 Revision of arteriovenous shunt for renal dialysis
- 39.93 Placement of vessel-to-vessel cannula
- 996.11 Mechanical complication of vascular device, implant, graft
- 996.61 Infectious complication of vascular device, implant, graft
- 996.62 Other complication due to renal dialysis device, implant, graft
- 996.63 Other complication due to renal dialysis catheter
- 996.64 Fitting and adjustment of extracorporeal dialysis catheter
- 996.65 Replacement of peritoneal dialysis catheter

* DRG and procedure codes are used in conjunction to define inpatient pure vascular access events (both must be present)
* the presence of any of these diagnosis codes as the “Principal Diagnosis Code” is sufficient to define an inpatient pure vascular access or peritoneal dialysis access event
In Figure 3.1, CKD is defined during 2005 and the follow-up year is 2006; in Figures 3.2–5, the year indicates the follow-up year for admissions for the point prevalent cohort on January 1. Rates in Figure 3.1 are presented by age and adjusted for gender, since race is unavailable in the EGHP data. In Figures 3.2–5, for the Medicare and dually-enrolled groups, overall rates are adjusted for age, gender, and race, and rates by one factor are adjusted for the other two; for the Medstat and Ingenix i3 groups, overall rates are adjusted for age and gender, and rates by one factor are adjusted for the other one.

The reference cohort includes the 2005 Medicare cohort for the Medicare and dually-enrolled patients (Figures 3.2–3) and the 2005 cohort for the Medstat and Ingenix i3 patients (Figures 3.4–5). A different reference cohort is used in Figures 3.4–5 than in 3.2–3 due to adjustment for age and the different age inclusions among the data sources. For this reason, and because the availability of race data for adjustment only in 3.2–3, rates in 3.4–5 are not directly comparable to those in 3.2–3. The model-based adjustment method uses a Poisson model with data from the current and previous two years, with respective weights of 1, ¼, and ⅛. This method is described further in the description of Reference Section G in the appendix of Volume Two.

Figure 3.6 compares hospital admission rates among sources of CKD diagnoses in prevalent patients age 50–64 in the Ingenix i3 data. The study design and patient inclusions generally follow those of Figure 3.5, described above. This figure, however, includes only patients with at least one serum creatinine value during the year before follow-up, so as to calculate eGFR. For the CKD group identified from biochemical data, the MDRD equation is used to compute eGFR, and an eGFR <60 ml/min/1.73 m² defines CKD. One limitation of this application of the eGFR calculation is that race data are unavailable in the Ingenix i3 dataset; therefore, in the absence of race information, the eGFR equation assumes all patients are not African Americans. The “claims” CKD group uses the standard claims-based definition of CKD, as in Figures 3.1–5, while the “both” CKD group includes patients with both a biochemical and claims-based indication of CKD. Non-CKD is defined here as patients without either biochemical or claims-based evidence of CKD. Rates are adjusted for age and gender, and the 2005 Medstat cohort is used as the reference group.

Figures 3.7–15 present cause-specific hospital admission rates from various data sources. Medicare patients include point prevalent patients on January 1 of the year from the 5 percent general Medicare sample, continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, with no HMO coverage during the prior year. Included patients are age 66 and older on January 1 of the year. Dually-enrolled patients are also enrolled in Medicaid at any time during the prior year. The Medstat and Ingenix i3 cohorts include point prevalent patients on January 1 of the year who are age 50–64 on December 31 of the prior year. During the prior year, Medstat and Ingenix i3 patients are enrolled in a fee-for-service commercial health plan, respectively, and CKD is defined using claims. Patients diagnosed with ESRD prior to January 1 of the year are excluded, and patients are followed for admissions from January 1. Rates are adjusted for gender using the model-based adjustment method, with data from the current and previous two years and with the Medicare 2005 cohort as the reference. Cause-specific rates reflect hospital admissions for the purpose of the stated condition and are identified by the following principal ICD-9-CM diagnosis codes: CHF, 398.91, 402.x1, 404.x1, 404.x2, 422, 425, and 428; other ASHD (excludes AMI), 411 and 413–414; PVD, 440–444, 447, 451–453, and 557; CVA/TIA, 430–437; AMI, 410.x0 and 410.x1; dysrhythmia, 426–427; pneumonia, 480–486 and 487.0; bacteremia/septicemia, 038.0–038.9 and 790.7; urinary tract infection, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 616.1, 616.3–616.4, and 616.8.

MORTALITY

Figure 3.16 illustrates trends by CKD status, in all-cause mortality from 1994 through 2006 for Medicare and dually-enrolled patients. Patients are drawn from the Medicare 5 percent sample, and those in each cohort year are Medicare-eligible for the entire year prior to the cohort year, reside in the 50 states or the District of Columbia, and are without a diagnosis of ESRD in the year prior to the cohort year. Follow-up for the cohort year is from January 1 to December 31 of that year, with patients censored at the end of Medicare entitlement or the date of ESRD. Dually-enrolled patients are defined as eligible for both Medicare and Medicaid any time during the year prior to the cohort year. CKD is defined from claims in the year prior to the cohort year. Adjusted mortalities are calculated using generalized mixed models, and are adjusted for age, gender, and race. Medicare patients from 2005 are used as the reference cohort.

Table 3.a shows adjusted relative risks for death in 2000 and 2005. The cohorts include general Medicare patients entering Medicare before January 1 of each year, and alive and age 66 or older on December 31. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the period are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. CKD, diabetes, and CHF are defined during each period, and comorbidity groups are mutually exclusive. Patients are followed one year from January 1 until December 31 of next year, and are censored at ESRD. A proportional hazards model is used to obtain the relative risks, and covariates include age, gender, race, dually-enrolled status, and comorbidities. Reference groups are those age 65–69 at the beginning of each period, males, whites, and non-CKD, non-diabetic, and non-CHF patients. According to a previously validated method for using Medicare claims to identify diabetic patients, a patient is diabetic if, within a one-year observation period, he or she has an ICD-9-CM diagnosis.
code of diabetes on one or more inpatient/outpatient institutional claims (inpatient hospitalization, skilled nursing facility, or home health agency), or two or more institutional claims (outpatient) or physician/supplier claims. Using this methodology, we identify CKD patients with or without diabetes or CHF in each calendar year. Codes used to identify patients are as follows: CHF, 398.91, 422.xx, 425.x, 428.xx, 402.x1, 404.x1, 404.x3, V42.1; CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.x1, 404.x2, 404.x3, 784.59–784.61, 784.64, 784.65, 784.69, 784.72, 784.73, 784.78, 784.80, 784.81, 784.83, 784.91, 784.92, 93015–93018, and 93350 (CPT codes).

Figures 3.17–18 illustrate adjusted relative risks of death, by comorbidity groups, for Medicare-only and dually-enrolled patients, respectively, using the same method and cohort construction as described for Table 3.a. In Figure 3.17, however, patients enrolled in Medicaid during the period are excluded; Figure 3.18 includes only patients enrolled in both Medicare and Medicaid during the period.

DIAGNOSIS & TREATMENT OF CVD
Figures 3.19–27 describe the use of diagnostic tests and treatment for cardiovascular disease in Medicare patients with or without CKD, 1993 to 2005. Yearly prevalent CKD and non-CKD cohorts from 1992 to 2004 are identified from the Medicare database (5 percent sample), and include Medicare enrollees who are continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage, not enrolled in an HMO, not diagnosed with ESRD during each calendar year, and age 66 and older on January 1 of the following year. Cohorts are further limited to those residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories. CKD is identified using the method described for Table 3.a, above.

For analyses of trends in the 12-month cumulative percentage of patients receiving testing or treatment for cardiovascular disease during each year from 1993 to 2005, patients in each yearly cohort during 1992–2004 are followed from January 1 of the following year to the earliest of death, change of Medicare inpatient/outpatient and physician/supplier coverage enrollment status, enrollment in an HMO, or December 31 of the year. For evaluation of the 36-month cumulative percentage of patients receiving testing or treatment, patients in the yearly cohort of 1999, 2001, and 2003 are included and followed from January 1 of 2000, 2002, and 2004, respectively, to the earliest of death, change of Medicare inpatient/outpatient and physician/supplier enrollment status, enrollment in an HMO, or December 31 of 2002, 2004, and 2006, respectively.

The cumulative percentage of patients receiving diagnostic testing or treatment is calculated as the cumulative number receiving diagnostic tests or treatment divided by the total number at the beginning of follow-up. Different sources of information are used to identify tests and treatment. Echocardiograms, electrocardiograms (ECGs), and lipid testing are defined through CPT codes in physician/supplier claims. Implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy with defibrillator (CRT-D) are defined through ICD-9-CM procedure codes in inpatient/outpatient patient claims. And stress tests (including stress echocardiogram, stress nuclear test, and stress ECG), coronary angiography and/or catheterization, percutaneous coronary interventions (PCI), and coronary artery bypass graft surgery (CABG surgery) are defined through ICD-9-CM procedure codes in inpatient/outpatient claims and/or CPT codes in physician/supplier claims. Codes used to identify patients receiving these tests and treatment are as follows:

- Stress tests: 89.41–89.44 (ICD-9-CM procedure codes);
- Echocardiograms: 93000, 93005, 93010, 93012, 93014, 93224–93227, 93268, 93270–93272, and 93278 (CPT codes);
- Coronary angiography and/or catheterization: 37.22–37.23 and 88.53–88.57 (ICD-9-CM procedure codes); 93508, 93510, 93511, 93524, 93526, 93527, 93529, 93531–93533, 93539, 93540, 93543, 93545, and 93555 (CPT codes);

### Comparison of point & period prevalent methods for identifying CKD cohorts

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
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<tbody>
<tr>
<td>Jan. 1, Year 1</td>
<td>Dec. 31, Year 1</td>
</tr>
<tr>
<td>Survive all of Year 1</td>
<td>Enrolled all of Year 1</td>
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<tr>
<td>Have qualifying diagnosis during Year 1</td>
<td>Do not develop ESRD during Year 1</td>
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### Period prevalent

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
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<tbody>
<tr>
<td>Jan. 1, Year 1</td>
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<td>Enrolled all of Year 1</td>
</tr>
<tr>
<td>Have qualifying diagnosis during Year 1</td>
<td>Do not develop ESRD during Year 1</td>
</tr>
</tbody>
</table>

Censored at the earliest of death, change in enrollment status, development of ESRD, or end of Year 2

Year 2 is the analysis year
Those with “assistive devices” are those who have a durable medical equipment claim during 2005 for a cane (E01.00, E01.09), a walker (E01.30–E01.49), or a wheelchair (E09.50–E09.90, E10.50–E12.98, K00.01–K00.12, K00.14–K00.80). Comorbidities are identified from Medicare claims during 2005. Survival in Figure 3.33 begins on January 1, 2006, and is calculated as an unadjusted Kaplan-Meier survival curve.

Table 3.d illustrates the presence of a walking disability or assistive device in 2006 for only those without either one of them in 2005. Patients included are not required to survive for any length of time in 2006.

**Transition to ESRD**

**Chapter Four**

Figure 4.1 shows the likelihood of death vs. ESRD in the Medicare population. The cohort includes general Medicare patients entering Medicare before January 1, 2004, who are alive and age 66 or older on December 31. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the year are excluded, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories.

Patients are followed from January 1, 2005, until December 31, 2006, for the ESRD event or death. The Kaplan-Meier estimation method is used to calculate the likelihood. For the ESRD event, patients are censored at death; for death, patients are censored at ESRD. The likelihood of being alive is calculated by subtracting the likelihood of ESRD and that of death from one. CKD, diabetes, and CHF are defined using the same method described for Table 3.a, above.

Table 4.a shows predictors of ESRD, death, and the combined event for the Medicare-only patients, using a method similar to that described for Table 3.a. The cohort includes general Medicare patients entering Medicare before January 1, 2004, who are alive and age 66 or older on December 31. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the period are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, and those who enroll in Medicaid during 2005. Survival in Figure 3.33 begins on January 1, 2006, for the ESRD event or death. The Kaplan-Meier estimation method is used to calculate the likelihood. For the ESRD event, patients are censored at death; for death, patients are censored at ESRD. The likelihood of being alive is calculated by subtracting the likelihood of ESRD and that of death from one. CKD, diabetes, and CHF are defined using the same method described for Table 3.a, above.

WALKING DISABILITIES

Tables 3.b–c and Figures 3.33–34 present data on walking disability in 2005 CKD patients in the general Medicare population. A “walking disability” represents the presence of a Medicare claim during 2005 with an ICD-9-CM diagnosis code of 792.1 (abnormal gait), 792.2 (difficulty walking), V5.88 (history of fall), or for a specific type of fall: E88.01, E88.09, E88.42–46, E88.59, E88.88, E88.89. Those with “assistive devices” are those who have a durable medical equipment claim during 2005 for a cane (E01.00, E01.09), a walker (E01.30–E01.49), or a wheelchair (E09.50–E09.90, E10.50–E12.98, K00.01–K00.12, K00.14–K00.80). Comorbidities are identified from Medicare claims during 2005. Survival in Figure 3.33 begins on January 1, 2006, and is calculated as an unadjusted Kaplan-Meier survival curve.

Table 3.d illustrates the presence of a walking disability or assistive device in 2006 for only those without either one of them in 2005. Patients included are not required to survive for any length of time in 2006.

**Transition to ESRD**

**Chapter Four**

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Patients are followed from January 1, 2005, until December 31, 2006, for the ESRD event or death. The Kaplan-Meier estimation method is used to calculate the likelihood. For the ESRD event, patients are censored at death; for death, patients are censored at ESRD. The likelihood of being alive is calculated by subtracting the likelihood of ESRD and that of death from one. CKD, diabetes, and CHF are defined using the same method described for Table 3.a, above.

Table 4.a shows predictors of ESRD, death, and the combined event for the Medicare-only patients, using a method similar to that described for Table 3.a. The cohort includes general Medicare patients entering Medicare before January 1, 2004, who are alive and age 66 or older on December 31. Patients enrolled in an HMO, with Medicare as secondary payor, or diagnosed with ESRD during the period are excluded, as are patients not residing in the 50 states, the District of Columbia, Puerto Rico, or the Territories, and those who enroll in Medicaid during 2004. CKD, diabetes, and CHF are defined during each period, and comorbidity groups are mutually exclusive. Patients are followed two years from January 1, 2005 until December 31, 2006, for an ESRD event, death, or the combined event. For an ESRD event, patients are censored at death; for death, patients are censored at ESRD. A proportional hazard model is used to obtain the relative risks. Covariates include age, gender, race, and comorbidities. Reference groups are those age 65–69 at the beginning of each period, males, whites, and non-CKD, non-diabetic, and non-CHF patients.

Figures 4.2–3 show the probability of ESRD, death, or the combined event, by comorbidity, for Medicare-only and dually-enrolled populations, respectively. In Figure 4.2 the cohort includes general Medicare patients entering Medicare before January 1, 2001, who are age 66 or older on December 31. Patients enrolled in an HMO or with Medicare as secondary payor or diagnosed with ESRD dur-
ing the year are excluded, as are patients who do not reside in the 50 states, the District of Columbia, Puerto Rico, or the Territories, and those who enrolled in Medicaid in 2001. CKD, diabetes, and CHF are defined during 2001. Comorbidity groups are not mutually exclusive. Patients are followed from January 1, 2002, until December 31, 2006, for an ESRD event, death, or both. A Kaplan-Meier estimation method is used to calculate the probability. For an ESRD event, patients are censored at death; for death, patients are censored at ESRD. Figures 4.3 use the same method, but its cohort is limited to general Medicare patients enrolled in both Medicare and Medicaid during 2001.

Figures 4.4–5 show the probability of an ESRD, by comorbidity, for Medstat and Ingenix i3 populations, respectively, and use the same method described for Figure 4.2. The Medstat cohort includes those age 50–64 who are enrolled in a fee-for-service plan for all of 2001. The Ingenix i3 cohort includes those age 50–64, enrolled for all of 2001 under coverage with business type classified as commercial. In both populations, ESRD patients diagnosed before or during 2001 are excluded. Patients are censored at end of the plan, death, and end of 2006.

The cohort for Figure 4.6 consists of Medicare enrollees continuously enrolled in Medicare inpatient/outpatient and physician/supplier coverage in 2003–2004, identified as having CKD based on Medicare claims in 2003, not diagnosed with ESRD in 2003–2004, not enrolled in a health maintenance organization (HMO), age 65 or older on January 1, 2003, surviving through 2004, and residing in the 50 states, the District of Columbia, and the territories. Each individual is followed from January 1, 2005, to the earliest date of death, diagnosis of ESRD, change of Medicare enrollment (both parts), enrollment in an HMO, or December 31, 2006. Each individual is classified into one of three groups, according to outcome: 1) ESRD; patients who develop ESRD in 2005–2006; 2) death: patients who dying in 2005–2006 before developing ESRD; and 3) alive with CKD: patients alive with CKD on December 31, 2006, or who change Medicare inpatient/outpatient and physician/supplier enrollment status or enroll with an HMO in 2005–2006, and have not been diagnosed with ESRD. Comorbidities are defined based on the year prior to the outcome.

Figures 4.7–9, 4.11–16, and 4.31–34 include ESRD patients who are either MPP (Medicare) or eligible (Medstat, Ingenix i3) for two years prior to ESRD. Medicare patients include those age 65 or older at initiation. Comorbidities are identified during the two years prior to ESRD as one inpatient or two outpatient or Part B claims with a diagnosis for that comorbidity. Codes used to identify CKD, CHF, and ASHD are listed above in the discussion of Chapter Three. Cardiovascular disease represents a comorbidity of any of the following: ASHD, CHF, CVA/TIA, PVD, COPD or arrhythmia. Infections in Figures 4.10–13 represent an inpatient claim with a primary diagnosis of 001–139, 254.1, 320–326, 331.81, 372–372.39, 373.0–373.2, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 421–421.1, 422.0, 422.91–422.93, 460–466, 472–474.0, 475–476.1, 478.21–478.34, 478.29, 480–490, 491.1, 494, 500–515, 513.0, 518.6, 519.03, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.3, 572–572.3, 573.3–573.5, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 598, 599.0, 601–601.9, 604–604.9, 607.1, 607.2, 608.0, 608.4, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730–730.3, 730.8–730.9, 790.7–790.8, 966.60–966.69, 996.62, 998.5, or 999.1. Pneumonia (480–486 and 487.0) and bacteremia/septicaemia (038.0–038.8) are identified the same way. In Figures 4.14 and 4.16, a CKD claim represents a claim with a CKD diagnosis from any source (inpatient, outpatient, or Part B). Nephrologist claims in Figures 4.15–16 are identified from the physician specialty codes on Part B claims for Medicare patients, provider category codes on inpatient, outpatient, or Part B claims for Ingenix i3 data, and provider codes on inpatient and outpatient claims for Medstat data. Vascular access insertions are identified from codes as described in Tables a–b.

Figure 4.10 uses the same cohort as Figure 4.6, and infections represent inpatient stays with an infection as the primary diagnosis.

Figures 4.17–22 include incident ESRD patients in 2002, 2004, and 2006, and show the cumulative probability of testing during the 12 months before the first ESRD service date. Tests are identified from outpatient and physician/supplier claims during the year. Tests are identified as follows: parathyroid hormone testing, HCPCS code 83970; creatinine testing, HCPCS codes 80048, 80050, 80053, 80069, and 82565; lipid testing, HCPCS codes 80061, 82465, 83715, 83716, 83717, 83718, 83719, 83720,83721, and 84478; hemoglobin testing, HCPCS codes 85013, 85014, 85018, 85025, 85027, 80050, and 80055; and glycylated hemoglobin testing, HCPCS codes 83036 and 83037. The ESRD cohort includes patients age 67 and older; the Medstat cohort includes all ESRD patients with fee-for-service coverage during the study period, and the Ingenix i3 cohort includes all ESRD patients under coverage with business type classified as commercial.

Figures 4.23–30 include incident ESRD patients in 2002, 2004, and 2006, and show the cumulative probability of medication use during the 12 months before the ESRD start date. The cohorts here are the same as the Medstat and Ingenix i3 populations used in Figures 4.17–22.

**Costs of CKD**

**Chapter Five**

**POPOPULATIONS**

Figure 5.1 compares populations and costs for Medicare in 1996 and 2006, based on the 5 percent Medicare sample. Figure 5.2 — along with Figure 5.11 and Table p.e, in the Précis — compare costs for general Medicare and Medstat population. Figures 5.3–4, 5.8–9, and Table 5.3 compare costs for the general Medicare population, the Medicare dually-enrolled population (both based on the 5 percent Medicare sample) and the Medstat populations. Figure 2.1, in Chapter Two, compares Medicare, Medstat and Ingenix i3 data. These figures and tables are all based on the methodology described below.

**MEDICARE & DALLY-ENROLLED POPULATIONS**

The general Medicare population includes persons age 65 and older who survive all of year one, are continuously enrolled in Medi-
care inpatient/outpatient and physician/supplier coverage, are not enrolled in a managed care program (HMO), and do not have ESRD during year one. Costs for this portion of the cohort are aggregated for year two, with censoring at the earliest of death, development of ESRD, change in payor status, or the end of year two. In addition, the cohorts include those who survive at least three months during year two, are enrolled at least three months during the year in Medicare inpatient/outpatient and physician/supplier coverage, and are not enrolled in an HMO, and do not have ESRD during year two. Costs are also aggregated for year two for this portion of the cohort.

Important comorbidities (congestive heart failure (CHF), diabetes mellitus, and chronic kidney disease (CKD)) are determined for these cohorts from Medicare claims using a previously validated method. A patient is defined as having one of these comorbidities if, within the one year observation period (year one or year two), he or she has a qualifying ICD-9-CM diagnosis code on one or more institutional claims (inpatient, skilled nursing facility, or home health agency) or two or more outpatient claims and/or physician/supplier claims. Qualifying diagnosis codes are as follows: diabetes, 250.xx, 357.2, 362.xx and 366.41; CKD, 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1, 283.11, 403.xx, 404.xx, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; and CHF, 398.91, 422.xx, 425.x, 428.xx, 402.x1, 404.x1, 404.x2, 404.x3, 440.1, 442.1, 447.3, 572.4, 580–588, 591, 642.1, 646.2, 753.12–753.17, 753.19, 753.2, and 794.4; and CHF, 398.91, 422.xx, 425.x, 428.xx, 402.x1, 404.x1, 404.x2, 404.x3, and V42.1. Costs are presented for the 1992–1993 through 2005–2006 cohorts. The cost year is always year two of the cohort. The dually-enrolled population is a subset of these cohorts, meeting the above criteria and continuously enrolled in the Medicaid program for the cost year.

MEDSTAT POPULATION
The Medstat population includes persons age 50–64, and is constructed in the same fashion as described for the Medicare population, requiring continuous enrollment in a fee-for-service health plan. Patients identified as ESRD are excluded. The cohorts are from 1999–2000 to 2005–2006.

INGENIX i3 POPULATION
The Ingenix i3 population includes person age 50–64, and is constructed in the same fashion as described for Medicare and Medstat for 2005–2006. Since cost data are not available in the Ingenix i3 database, this cohort is included only in the population portion of Figure 2.1.

COST CATEGORIES
Costs are categorized in two ways. For Figures p.11 and 5.8–9, costs are defined by the type of claim: inpatient, outpatient, and physician/supplier. Medstat also has a separate claim set for drug claims, and these claims are included in the outpatient category. Costs are further broken down for Tables p.e and 5.a, using diagnosis related groupings (DRGs) for inpatient claims; revenue codes, current procedural terminology (CPT) and healthcare common procedure coding system (HCPCS) codes for outpatient claims; and CPT, HCPCS, provider specialty, and place of service codes for physician/supplier claims.

Figures 2.1 and 5.1–2 show total expenditures. For Medicare, the total cost aggregated from the 5 percent Medicare sample is multiplied by a factor of 20 to estimate total costs for Medicare.

Figures 5.11, 5.3–4, and 5.8–9, along with Tables p.e and 5.a, show per person per month costs.

Table 5.b–c present actual and predicted costs per person per month for CKD patients by diagnosis. Predicted costs are based on two methods: the adjusted average per capita cost (AAPCC) and the CMS Hierarchical Condition Category (HCC), using the 2007 CMS-HCC model software for Table 5.b and 2004–2006 CMS-HCC model software for Table 5.c (http://tinyurl.com/67s5me). Figures 5.10–11 present annualized actual Medicare costs and annualized predicted costs, respectively, based on the 2007 CMS-HCC model, for CKD patients by diagnosis. Figures 5.12–13 compare the predicted costs of the 2007 and 2004–2006 CMS-HCC models.

Populations in Table 5.b and Figures 5.10–11 include Medicare-eligible beneficiaries not enrolled in an HMO, without ESRD, and alive in 2005; patients are followed from January 1, 2006, to December 31, 2006, and censored at death. All diagnostic codes from Medicare claims in 2005 are collected from hospital inpatient, outpatient, and physician files. For each individual, the actual Medicare cost per person per month in 2006 is calculated by dividing the total Medicare payment in the calendar year by the total follow-up time, censoring at death in the same year. The annualized actual Medicare cost is calculated by multiplying per person per month costs by 12 months. And the predicted Medicare cost per person per month based on the AAPCC method is calculated by a base inpatient/outpatient and physician/supplier rate multiplied by a rescaling factor and a demographic factor, which is calculated based on age and gender (also at http://tinyurl.com/67s5me). The predicted Medicare cost per person per month based on the 2007 CMS-HCC model, in contrast, is calculated by a base inpatient/outpatient and physician/supplier rate multiplied by the corresponding rescaling factor and a risk factor. The inpatient/outpatient and physician/supplier rates and the rescaling factor for each county in 2006 are obtained from the same source as the 2007 CMS-HCC model software. Diagnoses for CKD, diabetes, and CHF are based on the CMS-HCC model, i.e., they are defined if there is any diagnosis code.
Products and services provided by the USRDS to support the work of the renal community are detailed in Table b.a. The entire ADR is available at wwwUSRDS, org, with PowerPoint slides of all figures and Excel files of the data behind the graphs; included as well are PDF files of the Researcher’s Guide. The site’s RenDER system allows users to create customized data sets and regional maps. Data on website use are presented in Figure b.1.

Data requests
Making information on ESRD available to the renal community is a primary objective of the USRDS, and we are committed to the timely fulfillment of data requests. In many cases requests can be answered through data published in the ADR or elsewhere. Requests for data not available in material published by the USRDS, but that require two hours or less of staff time, are fulfilled by the Coordinating Center without charge, usually within one week. More complex requests — requiring more than two hours of staff time — as well as requests for Standard Analysis Files and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the NIDDK Project Officer.

Research files
The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and provide easy access to data used in the ADR. The SAFs were introduced in 1994, as the NIDDK began awarding new grants focusing on research using the USRDS data. The result has been an annual increase in the number of files provided by the USRDS.

Prior to 1994 all researcher files were created for specific projects. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a patient finder file to be matched with the USRDS database. For more information on merged data requests, please contact the Coordinating Center at usrds@usrds.org.

The four-CD Core SAF set contains basic patient data, and is needed to use any of the other SAFs. Included are each patient’s demographic information, payer and treatment history, limited transplant data, provider data, and all data from the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this CD set. Full transplant information is provided on a separate CD that contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the hospitalization CD. All Medicare billing data are available by individual year (see Table b.c).

Standard Analysis Files
The use of Standard Analysis Files is governed by the USRDS policy on data release for investigator-initiated research, found later in these appendices. Research proposals must be approved by a USRDS Project Officer, and researchers must sign the USRDS “Agreement for Release of Data,” on the same page. File prices are listed in Table b.c.

Most SAFs provide patient-specific data. All patient identifiers are removed or encrypted, but data confidentiality remains a serious concern. The “Agreement for Release of Data” describes restrictions on SAF use and disposition. The SAFs include an encrypted ID number to allow patient data from multiple SAFs to be merged.

CORE CDS
The Core Standard Analysis File CDs contain the most frequently used SAFs, including those from the Special Studies, and are needed for use of the Transplant and Hospital CDs, or any CD based on Medicare claims data. Included files are as follows (also listed in Table b.b).

- **Patient** Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.
- **Residence** A longitudinal record, to ZIP code, of residence.
- **Payor History** Contains a new record for each patient at each change in insurance payor.
- **Medical Evidence** Contains full data from the 1995 version of the CMS Medical Evidence form. In April 1995 a new version of the form went into use, with data on comorbidity, employment status, lab values at initiation, and Hispanic ethnicity.
- **Transplant** Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant CD).
- **Transplant Wait List** Beginning with 2001 data (used in the 2002 ADR), this CD has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.
- **Facility** Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF, which can be linked to the Facility Cost Report files using the USRDS provider ID. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.
- **Facility Cost Reports** CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level.
are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.

Dialyzers The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies collected information on patient dialyzers. SAFs for these studies describe the dialyzer through a code, which must be matched to information in the Dialyzer file to find the maker and model along with characteristics such as membrane type and clearance. We believe that these data, from published sources available at the time of the study, accurately represent the dialyzer characteristics, but they should be used with caution.

DATA FROM SPECIAL STUDIES
Topics for USRDS Special Studies are approved by the NIDDK, with recommendations from CMS, the Scientific Advisory Committee, the ESRD networks, and the Renal Community Council. Design and sampling plans are developed, samples are selected, and data collection forms and instructions are drafted, tested, and finalized. The main studies to date are summarized below, and are detailed in the Researcher’s Guide.

Dialysis Morbidity & Mortality Study (DMMS) The DMMS was a USRDS Special Study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected, using dialysis records, for a random sample of U.S. patients. Waves 1, 3, and 4 are historical prospective studies in which data were collected for patients on in-center hemodialysis on December 31, 1993. Data were abstracted from medical records, and patients were followed to the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a prospective study of incident hemodialysis and peritoneal dialysis patients for 1996 and early 1997.

Case Mix Adequacy Study of Dialysis The objectives of this USRDS Special Study were to establish the relationship between the dose of delivered dialysis therapy and mortality, determine the strength of this relationship when data are adjusted for comorbidity, assess how this relationship changes with dialysis dose, assess how this relationship is affected by dialyzer reuse, and examine the impact of different dialysis membranes on patient morbidity and mortality.

The study consisted of two groups: an incident sample of ESRD patients who began hemodialysis in 1990, and a prevalent sample of hemodialysis patients whose ESRD began prior to 1990. A total of 7,096 patients from 523 dialysis units were included, with approximately 3,300 patients having both the pre- and post-BUN values needed to calculate delivered dialysis dose. Ninety-four percent of these cases were matched to the USRDS database. The ESRD networks collected these data in conjunction with their Medical Case Review data abstraction.

Case Mix Severity Study For this USRDS Special Study, data were collected on 5,255 patients incident in 1986–87 at 328 dialysis units nationwide. Objectives were to estimate the correlation of comorbidity and other factors existing at the onset of ESRD to mortality and hospitalization rates, while adjusting for age, gender, race, and primary diagnosis; evaluate possible associations of these factors with reported causes of death; assess the distribution of comorbidity and other factors among patients on different modalities; and compare relative mortality rates by treatment modality, adjusting for comorbid conditions and other factors.

Pediatric Growth & Development The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relation of patient growth and sexual maturation to modality, and establish a prototype for the ongoing collection of pediatric data. All patients prevalent in 1990 and born after December 31, 1970 were included in the study, a total of 3,067 patients at 548 units.

CAPD & Peritonitis Study The USRDS CAPD and Peritonitis Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors.

The study population included all patients newly starting CAPD in the first six months of 1989, a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains data on 3,385 patients from 706 units.

TRANSPLANT CDS
Due to changes in data collection sources over the years, data related to transplants are now presented in eight separate SAFs. The first two are included on the Core CD, and the remaining six are included on two separate Transplant CDs.

• TX includes minimum details about all transplants from all sources
• TXWAIT contains one record for each patient in the USRDS database per wait list event
• TXHICFA includes transplant information collected by CMS’s PMMIS system prior to 1994
• TXUNOS includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
• TXIRUNOS includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
• TXFUHCS includes transplant follow-up reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
• TXFUHCS includes transplant follow-up reports collected by UNOS since 1988
• TXFUNOS includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

Tables in Reference Sections E and F are produced primarily from the CMS and UNOS transplant files.

In July 1994, CMS and the Health Resources Services Administration (HRSA) consolidated transplant data into a single collection by UNOS under its HRSA contract. Expanded transplant data are shared among HRSA, CMS, and the NIH, and are thus available to the USRDS. This has resulted in the addition of data on a substantial number of non-Medicare transplant patients, including children.

CMS and UNOS transplant files overlap for 1988–1993, and some Medical Evidence (ME) forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among the sources and create the transplant SAF, all UNOS transplants are first accepted into the file, with all pre-1988 CMS transplants accepted next. CMS transplants from 1988–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the CMS transplant (it is common for dates between sources to differ by one day). Finally, transplants indicated on the ME form are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

HOSPITAL CDS
Hospitalization inpatient data are a subset of the data in the Institutional Claims file. No payment or cost variables are included on
The USRDS Renal Data Extraction and Referencing (RenDER) System is a tool used to extract and reference data from the USRDS database, which contains information on patients with end-stage renal disease (ESRD) in the United States. The system includes the Renal Data Extraction and Referencing system, which provides the ability to query and retrieve data from the USRDS database. The database includes various files that can be used for different types of analyses, such as standard analysis files, custom data files, and regional analyses.

Reports & guides
Annual Data Reports: Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.7776 or 1.888.99-USRDS; nkudic@info.niddk.nih.gov.

Annual Data Report CD: Contains the text and graphics of the ADR, data tables, PowerPoint slides, and the Researcher’s Guide.

Researcher’s Guide to the USRDS database: Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files; the basic reference for researchers who use USRDS data files.

www.usrds.org: Contains PDF files of the chapters, reference tables, and the Researcher’s Guide; PowerPoint slides of atlas figures and USRDS conference presentations; Excel files of the data tables; notices regarding current news and analyses; links to related Internet sites; and email addresses for contacting the USRDS.

RenDER: The USRDS Renal Data Extraction and Referencing (RenDER) System is a querying application that allows users to create data tables and interactive maps. It can be accessed at www.usrds.org/odr/render_home.asp following a short registration; a tutorial is also available on this site to help new users.

Requests for data:
Data requests: two-hour Questions and data requests that are not answered directly by the ADR can be addressed to the Coordinating Center; those that require more than two hours of staff time to fulfill will be processed without charge.

Data requests: more than two hours: Questions and data requests that require over two hours of staff time must be submitted in writing and approved by the NIDDK Project Officer. Fulfillment of these requests is subject to staff availability, and costs are assessed on a case-by-case basis.

Standard Analysis Files: SAFs provide patient-specific data from the USRDS to support ESRD research. A standard price list has been established for the files (Table b.c), and users must sign a Data Release Agreement with the NIDDK.

Custom data files: Custom files can be created by the Coordinating Center for projects requiring data other than those provided in the Standard Analysis Files. An hourly rate of $100 per hour will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK.

Publications & presentations:
Most USRDS research studies result in published papers or presentations at national meetings. Figures from abstracts and presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.

Contact information:
Data requests & publication orders: USRDS Coordinating Center 914 South 8th Street, Suite 5-206 Minneapolis, MN 55404 612.347.7776 or 1.888.99USRDS Fax 612.347.3878 www.usrds.org

Data file contact: Shu-Cheng Chen, MS, schen@usrds.org

Contents of the USRDS Core Standard Analysis CD-ROM:
- File name, unit of observation, & uses; this two-CD set is needed in order to use any of the other Standard Analysis Files.
- Patient: record for each ESRD patient Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.
- Residence: for each patient, one record for each period in a different residence. Regional analyses.
- Treatment History: one record for each period a patient is on one modality. Modality distribution and treatment patterns.
- Payor History: one record for each period a patient is covered by one payor; each patient can have many records. The impact of insurance payors on clinical outcomes.
- Medical Evidence: one record for each 2728 form filed (1995 version). ESRD first service date, initial treatment modality, comorbid conditions, patient status at start of ESRD.
- Transplant: one record for each transplant event; patients can have multiple events. Transplant and transplant outcome analyses.
- Transplant Wait List: one or more records for each patient ever on list. Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to wait list.
- Dialysis Morbidity and Mortality (DMMS; Special Study): Wave 1: 3,670 patients; Wave 2: 4,024 patients; Wave 3: 7,096 patients. Co-morbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.
- Case Mix Adequacy (Special Study): 7,096 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.
- Case Mix Severity (Special Study): 5,255 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.
- Pediatric Growth and Development (Special Study): 3,067 patients. Growth, development, and other issues relating to pediatric ESRD patients.
- CAPD Peritonitis (Special Study): 3,185 patients. CAPD and peritonitis.
- Facility: one record for each year facility has operated. Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.
- Dialyzers: information on dialyzer characteristics; to be matched to patient dialyzer information in other files on CD. Relation of dialyzer characteristics to patient outcomes.
- CLIMCODES: one record for each diagnosis, procedure, or HCPCS code appearing in claims files. Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.
- FORMATS.SC2: all USRDS-defined SAS formats used by SAFs. Format library used to format values of categorical variables.
The Clinical Performance Measures (CPM) data is a CMS project. This CD contains the Case Mix Adequacy Special Study file, and extracts data for the study patients from all CMS Medicare payment data. All data on Medicare payments for these patients are followed to the currently reported claims year.

**CASE MIX ADEQUACY CLAIMS CD**
This CD contains the Case Mix Adequacy Special Study file, and extracts data for the study patients from all CMS Medicare payment data. Medicare payment data for these patients are followed to the currently reported claims year. This file is useful for developing analyses to be run on full Medicare payment files.

**MEDICARE PAYMENT DATA CDS**
Medicare payment data on institutional claims are available for pre-1989 through 2005, while data on physician/supplier claims are available for 1991–2005. The 2005 claims will be available, along with other updated USRDS SAF CDs, by the end of 2007.

Institutional claims consist of all inpatient/outpatient claims (inpatient, outpatient, skilled nursing facility, home health agency, and hospice), including outpatient dialysis claims. Physician/supplier claims account for 80 percent of the claims but only 20 percent of the dollars. The structure and content of the two types of claims differ, as do the files derived from them. Institutional claims are provided in two types of files: the Institutional Claims file, indicating the type of claim, the dollar amounts, the DRG code, the type of dialysis involved (if any), and the dates of service; and the Institutional Claims Detail file, containing details such as diagnosis and procedure codes. Many analyses require only the Institutional Claims files. Physician/supplier claims are contained in one type of file with one record for each claim line-item. The file includes dollar amounts, dates of service, diagnosis and procedure codes, and type and place of service.

**CLINICAL PERFORMANCE MEASURES SURVEY CDS**
The Clinical Performance Measures (CPM) data is a CMS project developed to collect information on the quality of care provided to the ESRD dialysis population. The data originates from yearly surveys of approximately 10,000 people completed by the patients’ primary care facilities, and was formerly known as the ESRD Core Indicators Project. This project results in a rich source of detailed information, useful in analyses of healthcare delivery in a sample of the dialysis population.

To further expand the value and use of the CPM data, we have linked patient data from the USRDS SAFs, enabling complete claims extraction from the SAFs for all identified patients. The resulting claims history has been combined with the CPM data to form a complete mini-set of the USRDS data products with supporting files. This enables researchers to add patient-level laboratory and dialysis prescription detail to a broad range of healthcare service event data over many years.

The USRDS Coordinating Center has made the CPM data available as USRDS Standard Analysis Files (SAF). The dataset contains CPM data collected in surveys from 1994–2004. A listing of available files and the corresponding costs can be found in Table b.e, or you may contact the USRDS Coordinating Center for further information.

**DISEASE-BASED COHORT CDS & 5 PERCENT GENERAL MEDICARE PAYMENT DATA CDS**
Three disease-based cohort CD sets — for CKD, diabetes, and CHF — are built from the 5 percent general Medicare Claims SAFs. Each CD contains a patient master file, a payer sequence file, and a set of comorbidity files.

Separately, 5 percent general Medicare claims SAFs (IP, OP, SNF, HH, HS, PB, and DME) are also available for single or multiple years from 1992 to 2005. Data are derived from the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

**PRE-ESRD MEDICARE CLAIMS CDS**
The pre-ESRD claims (also known as “back-casted claims”) are a collection of Medicare Institutional (inpatient, outpatient, home health, hospice, and skilled nursing facility) and physician/supplier (Part B, durable medical equipment) billing records incurred prior to the onset of ESRD. Included in these claims are any and all claims available from Medicare for incident patients during their incident years and for the two calendar years prior to the incident year.

The USRDS has made the pre-ESRD data available as Standard Analysis Files (SAF). This dataset includes Medicare claims of ESRD patients from incident years 1995–2005. The structure of the claims file is identical to the ESRD claims files and organized by calen-
**Medicare payment data**

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<td>2006^</td>
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</table>

*files for years prior to 1989 include only hospital inpatient stays and quarterly summaries of outpatient dialysis; no cost data are included.

*prices subject to change.
The Researcher’s Guide to the USRDS Database provides most of the information about the United States Renal Data System (USRDS). The interpretation and use of the data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the USRDS “Agreement for Release of Data” contains a number of general guidelines for Privacy Act adherence. The data reported here have been supplied by the USRDS in accordance with the Privacy Act of 1974, and the summary should not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO’s approval indicate government endorsement of the investigator’s opinions and conclusions.

Caveats

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research. The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS “Agreement for Release of Data” contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in any of the usual media (tape, disk, or hard copy). Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.

**COSTS**

File prices cover file reproduction, documentation, administrative costs, and costs of technical support. Prices are subject to change.

**DOCUMENTATION**

The Researcher’s Guide to the USRDS Database provides most of the SAF documentation. It includes a codebook of variables, copies of data collection forms used by CMS, UNOS, and the USRDS Special Studies, and a chapter on using the SAFs in SAS. The guide may be downloaded from the USRDS website, and a copy on CD-ROM will be sent to researchers with the purchase of the SAFs.

**Data use acknowledgement**

Publications using USRDS data should include an acknowledgment and this notice: The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

**Data release policy**

Since the SAFs and custom data files contain confidential, patient-specific data, their release requires the approval process described here. Investigators may contact the USRDS Project Officer (PO) at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators must provide the PO with a detailed description of the proposed investigation (see Table b.d). The summary must include goals, background data, an in-depth description of study design and methodology, and resources available for completing the project, and may be the description from a grant proposal or other application. The project must comply with the Privacy Act of 1974, and the summary should provide enough information to enable assessment of compliance. Guidelines for Privacy Act adherence are found in the “Agreement for Release of Data,” later in the appendices. With your completed research proposal, please include a signed agreement for release of information from each investigator and analyst who will use the data files.

Investigators must also indicate needed USRDS SAFs by name. If these files cannot meet requirements of the proposed research, investigators must specify precisely which data elements are needed, and budget for a substantially higher cost.

The investigator and the Coordinating Center (CC) will resolve any technical questions. The investigator will arrange payment with the CC, and payment must be received before the files will be released. Checks must be made payable to the Minneapolis Medical Research Foundation.

The NIH will review the project for technical merit and for conformity with the Privacy Act. The PO will notify the investigator(s) in writing of the outcome, and if the project is not approved will discuss reasons for the decision. The PO will send a copy of the approval letters to the CC. When payment for the files has been received by the CC, the CC will prepare the files and documentation and send them to the investigator.

Any reports or articles resulting from use of USRDS data must be submitted to the PO prior to submission for publication to assure adherence to the Privacy Act. The PO must respond within 30 days. If a report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the PO’s approval indicate government endorsement of the investigator’s opinions and conclusions.

All publications using released data must contain the standard acknowledgement and disclaimer presented above. Investigators are requested to send copies of all final publications resulting from this research to both the PO and the CC.

**Caveats**

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research. The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS “Agreement for Release of Data” contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in any of the usual media (tape, disk, or hard copy). Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.
United States Renal Data System (USRDS)
Agreement for Release of Data

Project title

In this agreement, "Recipient" means

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Recipient with tapes, disks, and/or hard copies containing data extracted from the USRDS research database.

B. The sole purpose of providing the data is the conduct of legitimate and approved biomedical, cost-effectiveness, and/or other economic research by the Recipient.

C. The Recipient shall not use the data to identify individuals on the file.

D. The Recipient shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where written authorization has been obtained through the approval process.

E. The Recipient shall not use the data for purposes that are not related to biomedical research, cost-effectiveness, or other economic research. Purposes for which the data may not be used include, but are not limited to,
   • the identification and targeting of under- or over-served health service markets primarily for commercial benefit
   • the obtaining of information about providers or facilities for commercial benefit
   • insurance purposes such as redlining areas deemed to offer bad health insurance risks
   • adverse selection (e.g., identifying patients with high risk diagnoses)

Any use of the data for research not in the original proposal must be approved by the USRDS Project Officer (PO).

F. The Recipient shall not publish or otherwise disclose the data in the file to any person or organization unless the data have been aggregated (that is, combined into groupings of data such that the data are no longer specific to any individuals within each grouping), and no cells (aggregates of data) contain information on fewer than ten individuals or fewer than five providers or facilities. The Recipient shall not publish or otherwise disclose data that identify individual providers or facilities, or from which such identities could be inferred. However, the Recipient may release data to a contractor for purposes of data processing or storage if (1) the Recipient specified in the research plan submitted to the USRDS Project Officer that data would be released to the particular contractor, or the Recipient has obtained written authorization from the PO to release the data to such contractor, and (2) the contractor has signed a data release agreement with the PO.

G. A copy of any aggregation of data intended for publication shall be submitted to the PO for review for compliance with the confidentiality provisions of this agreement prior to submission for publication and, if not approved, shall not be published until compliance is achieved. The PO must respond within 30 days.

H. Appropriate administrative, technical, procedural, and physical safeguards shall be established by the Recipient to protect the confidentiality of the data and to prevent unauthorized access to it. The safeguards shall provide a level of security outlined in OMB Circular No. A-130, Appendix III — Security of Federal Automated Information System, which sets forth guidelines for security plans for automated information systems in Federal agencies.

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Recipient shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. The USRDS data files covered in this data use agreement may be retained by the Recipient until ________________. At the completion of the activities in the research plan, the file shall be returned to the USRDS CC at the Recipient’s expense, and any derivative files and copies shall be destroyed.

J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the PO and/or of CMS will, upon request, be granted access to premises where data in this file are kept.
Recipient typed name, title, & organization

Recipient telephone number

Recipient signature & date

Contractor typed name, title, & organization, as appropriate

Contractor telephone number

Contractor signature & date

Lawrence Y. C. Agodoa, MD, NIDDK, NIH or
Paul W. Eggers, PhD, NIDDK, NIH
USRDS Project Officer

USRDS Project Officer signature & date

May 2004