Appendices

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Appendix A · Analytical Methods

This Appendix describes the USRDS database and its standardized working datasets, specialized code definitions, and common data processing issues. It also details the statistical methods used to produce this 2000 Annual Data Report. The *Researcher's Guide to the USRDS Database*, published separately, provides additional detail about the USRD S Standard Analysis Files and the database.

DATA SOURCES

The USRDS maintains a stand-alone database that includes ESRD patient demographic and diagnosis data, biochemical data, dialysis claims, and information on treatment history, hospitalization events, and physician/supplier services.

REBUS/PMMIS database

The major source of ESRD patient information for the USRDS is the HCFA Renal Beneficiary and Utilization System (REBUS), which was adopted in 1995 as the On-Line Transaction Processing (OLTP) system from the previous Program Management and Medical Information System (PMMIS) database. The REBUS/PMMIS database contains demographic, diagnosis, and treatment history information for all Medicare beneficiaries with ESRD. The database has now also been expanded to include non-Medicare patients, a detailed discussion of whom is presented later in this Appendix.

HCFA regularly updates the REBUS/PMMIS database, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the United Network for Organ Sharing (UNOS) transplant database, ESRD Medical Evidence forms (2728) provided by the ESRD networks, and ESRD Death Notification forms (2746) obtained from renal providers.

HCFA Medicare Enrollment Database (EDB)

HCFA's Enrollment Database is the designated repository of all Medicare beneficiary enrollment and entitlement data, and provides current and historical information on beneficiary residence, Medicare as Secondary Payor (MSP) status, and Health Insurance Claim/Beneficiary Identification Code (HIC/BIC) cross-referencing.

HCFA paid claims records

Inpatient transplant and outpatient dialysis claims records are used to identify new ESRD patients for whom no Medical Evidence form has been filed. These patients, who are most likely to be non-Medicare patients or beneficiaries who develop ESRD while already on Medicare because of age or disability, will eventually be entered into the REBUS/PMMIS—and hence the USRDS—database through the claims records. For patients without Medical Evidence records these claims are the only reliable information from which to determine first service dates for ESRD. These paid claim records, however, are only a supplement to—not a replacement of—other sources of information on incidence and prevalence.

It is important to note that some Medicare-eligible patients may not have bills submitted to and paid by Medicare, including MSP patients covered through private insurance, HMOs, Medicaid, or the Department of Veterans Affairs (DVA).

UNOS transplant database

HCFA began collecting data on all Medicare kidney transplants in the early 1980s. In 1987, the United Network of Organ Sharing (UNOS) was created to provide a national system for allocating donor organs and to maintain a scientific registry on organ transplantation. UNOS also began collecting data on all transplants. These two collection efforts were consolidated in 1994, and UNOS became the single source of data on transplant donors and recipients.

The HCFA and UNOS transplant data files overlap for 1987–1993, and some Medical Evidence forms that indicate transplant as the initial modality are not included in either file. To resolve the conflicts among these three sources, the USRDS has adopted the following procedure:
- ♦ All UNOS transplants are accepted into the database.
- ♦ All HCFA transplants before 1987 are accepted.
- ♦ HCFA transplants from 1987 to 1993 are accepted if there is no UNOS transplant record for that patient within 30 days of the HCFA transplant.
- ♦ Transplants indicated on the Medical Evidence forms are accepted if there is no record of a transplant for that patient within 30 days of the date listed on the Medical Evidence form.

HCFA Standard Analytic Files (SAFs)

HCFA's SAFs contain data from final action claims, submitted by Medicare beneficiaries, in

which all adjustments have been resolved. For Part A institutional claims, the USRDS uses the following data:

- inpatient, 100% SAF
- outpatient, 100% SAF
- home health agency (HHA), 100% SAF
- hospice, 100% SAF
- skilled nursing facility (SNF), 100% SAF

For Part B physician/supplier claims:

- physician/supplier, 100% SAF
- durable medical equipment (DME), 100% SAF

The HCFA SAFs are updated each quarter through June of the following 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% complete. The USRDS 2000 Annual Data Report includes all claims up to December 31, 1998. Patient-specific demographic and diagnosis information, however, includes data as recent as May 2000.

Annual Facility Survey (AFS)

In addition to the HCFA ESRD databases, independent ESRD patient counts are available from HCFA's Annual Facility Survey, which all dialysis units and transplant centers are required to complete at the end of each calendar year. The AFS reports counts of patients being treated at the end of the year, new ESRD patients starting during the year, and patients who died during the year. Counts of both Medicare and non-Medicare end-of-year patients are included. While AFS files do not carry patient-specific demographic and diagnosis information, they do provide independent patient counts that are used to complement the HCFA patient-specific records.

CDC Surveillance

The Centers for Disease Control and Prevention use their National Surveillance of Dialysis-Associated Diseases in the United States to collect information from dialysis facilities on patient and staff counts, membrane types, reuse practices, water treatment methods, therapy types, vascular access use, antibiotic use, hepatitis vaccination and conversion rates (for both staff and patients), and the incidence of HIV, AIDS, and tuberculosis. None of the information is patient-specific; it is instead used to track trends in unit practices. Because the CDC did not conduct a survey in 1998, 1997 is the most recent year for which the USRDS can report surveillance data.

DATA MANAGEMENT & PREPARATION

The USRDS main computer system is a Compaq Alpha system consisting of one dual EV-4 (200 MHz) and two dual EV-6 (500 MHz) processor servers, with a total of 3.2 GB of RAM memory and one terabyte (1,000 gigabytes) of disk farms, all managed by three interconnecting clusters.

The new USRDS contractor uses the SAS database management system and development tools as its core database technology platform; this differs from the Oracle RDBMS system used by the previous contractor only in physical data allocation and management. All information in the earlier system has been integrated into the new database, and its continuity and completeness has been maintained.

Data loading & cleaning

All data files come to the USRDS in IBM 3480 cartridges with EBCDIC, ASCII, or SAS formats. Once loaded into the system, files are converted into SAS data sets for further processing, and a series of data verification steps is exercised to ensure data quality and integrity before updating the USRDS database system.

Database update

For this ADR, patient demographic and diagnosis data are updated through January 2000, and Medicare Part A and Part B claims are collected through December 31, 1998. While the USRDS has generally waited 15 months before reporting patient-specific data for a given time period, the new contractor intends to alleviate delays in processing data through the Medicare system by reporting updated information on its website (www.usrds.org) several times each year.

ESRD patient determination

A person is identified as having ESRD when a physician certifies the disease on a Medical Evidence form (HCFA 2728), or when there is other evidence that the person has received chronic dialysis or a kidney transplant. Patients who experience acute renal failure and are on dialysis for days or weeks, but who subsequently recover kidney function, are, as much as possible, excluded from the database. Patients who die soon after kidney failure without receiving dialysis treatment are occasionally missed.

The first ESRD service date (FSD) is the single most important data element in the USRDS database, and each patient must, at a minimum, have a valid FSD. This date is used to determine the incident year of each new patient and the first year in which the patient is counted as prevalent.

The date 90 days after the FSD is used as the starting point for most patient survival analyses.

The FSD is derived by taking the earliest of:
♦ the date of the start of dialysis for chronic renal failure, as reported on the Medical Evidence form,
♦ the date of a kidney transplant, as reported on a HCFA or UNOS transplant form, a Medical Evidence form, or a hospital inpatient claim,
♦ the date of the first Medicare outpatient dialysis claim.

Most FSDs are obtained from the Medical Evidence form. In the absence of this form, the date of the first Medicare dialysis claim usually supplies the FSD. In the few cases in which the date of the earliest dialysis claim is earlier than the first dialysis date reported on the Medical Evidence form, the earliest claim date is used as the FSD.

Medicare & non-Medicare ('ZZ') patients
Beneficiaries are enrolled in Medicare based on criteria defined in Title XVIII of the Social Security Act of 1965 and in subsequent amendments to the Act. A person in one of these four categories is eligible to apply for Medicare entitlement:
♦ aged 65 and over
♦ disabled
♦ ESRD program
♦ Railroad Retirement Board (RRB)

Most ESRD patients are eligible to apply for Medicare as their primary insurance payor. There are, however, some patients who are not immediately eligible for Medicare coverage because of their employment status and insurance benefits. These patients are usually covered by Employer Group Health Plans (EGHPs), and must wait 30 to 33 months before becoming eligible to have Medicare as their primary payor. They are therefore not in the EDB database during the waiting period. Some of these patients, particularly new patients since 1995, have FSDs established by Medical Evidence forms, but have no dialysis claims or hospitalization events in the HCFA claims database. In the REBUS/PMMIS database these patients are designated 'ZZ,' or non-Medicare (the REBUS/PMMIS group assigns 'ZZ' in the two-character Beneficiary Identification Code field to identify all non-Medicare ESRD patients). HCFA does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that 'ZZ' patients are true ESRD patients, and should therefore be included in patient counts for incidence, prevalence, and treatment modality. Calculations of standardized mortality ratios (SMRs), standardized hospital-ization ratios (SHRs), and standardized transplantation ratios (STRs), however, should not include these patients because of the small number of claims available in the first 30–33 months after their first ESRD service. Furthermore, 'ZZ' patients may or may not be able to be linked to their ESRD Death Notification forms (HCFA 2746) or to the UNOS transplant data, and it may be impossible to determine co-morbid conditions or Part A and Part B services. Because these data are limited, event rates that include these patients must be assessed with caution.

In order to duplicate the methods used by the previous USRDS contractor we have elected to include 'ZZ' patients in the mortality rate calculations for this report. We intend to collaborate with HCFA and other interested renal researchers to establish, for future reports, a consistent approach to managing the data for these patients.

The inclusion of non-Medicare patients is indicated in the figure captions or chapter discussions.

Lost-to-follow-up methodology
The USRDS draws on all available data to create a "treatment history" for each patient in the database, showing all modality events, their duration, and the renal providers involved in each patient's care.

Gaps frequently exist in the billing data upon which modality periods are based. When these gaps occur the convention used by the USRDS is to assume that a treatment modality continues until death or the next modality-determining event. A patient with a functioning transplant is assumed to be maintaining that transplant unless a transplant failure or death is encountered in the data. In the absence of death, dialysis claims, or other confirmation of a continuing modality, a dialysis modality, in contrast, is assumed to continue for only 365 days from the date of the last claim. After this period the patient is declared lost-to-follow-up until the occurrence of a dialysis claim or transplant event.

Lost-to-follow-up categorization cannot, however, begin until the end of the second year after first ESRD service; Medicare may be the secondary payor for up to the first 30 to 33 months of ESRD, which historically delays the appearance of Medicare dialysis claims. This 'first two-year rule' is particularly important for non-Medicare patients. Since it is now 30 to 33 months before these patients will have Medicare as their primary payor, some patients may be followed for up to two years with limited amounts of event or death

data. These patients contribute dialysis or transplant days to the denominator of rate calculations, but only questionable event data to the numerator of event rates. Non-Medicare patients who have been included in the database since 1995 therefore pose a significant challenge to the USRDS and HCFA, and methods of tracking these patients are currently being explored.

A number of factors can result in a lack of dialysis data and eventual reclassification of the patient as lost-to-follow-up:

- The patient may have recovered renal function and no longer have ESRD.
- The patient may have left the country.
- The patient's dialysis therapy may be covered by a payor other than Medicare, or the patient may have received a transplant not paid for by Medicare and not reported to UNOS.
- The patient may be enrolled in a Medicare HMO, so that Medicare claims for dialysis are not generated even though the patient is eligible for Medicare coverage.
- The patient's death may not have been reported to the Social Security Administration or to HCFA.

60-day rule
This rule requires that a treatment modality must continue for at least 60 days before it can be considered a primary or switched modality. It is used to construct a patient's treatment modality history, i.e. when creating the modality sequence file.

90-day rule
This rule defines each patient's start date, for data analyses, as day 91 of ESRD. Allowing outcomes to be compared among all ESRD patients at a stable and logical point in time, this rule is used primarily when calculating survival rates and comparing outcomes by modality at several points in time. Use of this rule overcomes the difficulties of examining data from the first three months of ESRD service, an unstable time for new patients as renal providers try to determine the best treatment modalities, and from center hemodialysis patients younger than 65 and not disabled, who cannot bill Medicare for their dialysis treatments and hospitalization until 90 days after the first ESRD service date (patients on peritoneal dialysis or with transplant as the first modality can bill immediately).

DATABASE DEFINITIONS
Modalities
Because different patient modality categories are used throughout the ADR, these categories are

defined in the methods sections for each chapter.

Primary cause of renal failure
Information on the primary cause of renal failure is obtained directly from the Medicare Evidence form. For the Annual Data Report these disease codes have been grouped into eight categories, with ICD-9-CM codes as follows:

- diabetes: 250.00 and 250.01
- hypertension: 403.9, 440.1, and 593.81
- glomerulonephritis: 580.0, 580.4, 582.0, 582.1, 582.9, 583.1, 583.2, 583.4, and 583.81
- cystic kidney: 753.13, 753.14, and 753.16
- other urologic: 223.0, 223.9, 590.0, 592.0, 592.9, and 599.6
- other cause: all other ICD-9-CM codes covered in the list of primary causes on the Medical Evidence form, with the exception of 799.9
- unknown cause: 799.9 and other ICD-9-CM codes not covered in the primary causes on the Medical Evidence form
- missing cause: no ICD-9-CM code listed

Race & ethnicity
Information on patient race and ethnicity is obtained from the Medical Evidence form, the HCFA Medicare Enrollment Database, and the REBUS identification file. Because they are addressed in separate questions on the Medical Evidence form, racial and ethnic categories can overlap; we have thus not included data on Hispanic background in most graphs and tables. Data on ethnicity is, however, included in Chapters One and Two and in many of the Reference Tables.

Because of the small number of ESRD patients of some races, we have concentrated throughout the ADR on white, black, Native American, and Asian patients. As the numbers of patients of other races increase, data on them will be presented in the ADR.

INCIDENCE & PREVALENCE ·
CHAPTER ONE & REFERENCE SECTIONS A & B
Incidence is the number of people in a population newly diagnosed with a disease in a given time period, typically a year. Prevalence is the number of people in a population who have the disease at a given point in time (point prevalence) or during a given time period (period prevalence). The USRDS generally reports point prevalence (the type of prevalence used primarily throughout the Annual Data Report) as of December 31st, while period prevalence is reported for a calendar year. Annual period prevalent data thus consist both of people who have the disease at the

end of the year and those who had the disease during the year and died before the year's end.

The USRDS treats successful transplantation as a therapy rather than as a "recovery" from ESRD. Patients with a functioning transplant are counted as prevalent patients.

Because data are available only for patients whose ESRD therapy is reported to HCFA, patients who die of ESRD before receiving treatment or whose therapy is not reported to HCFA are not included in the database. The terms incidence and prevalence are thus qualified as incidence and prevalence of reported ESRD. Some ESRD registries, such as the European Dialysis and Transplantation Association, use the term "acceptance into ESRD therapy." The USRDS, however, believes that "incidence of reported ESRD therapy" is more precise, because "acceptance" implies that remaining patients are rejected, when in fact they may simply not be identified as ESRD cases or may not be reported to HCFA.

As discussed earlier, patients are classified as lost-to-follow-up if they have had ESRD for at least two years but have had no reported dialysis, death, or transplant data for one year. Beginning with the 1992 Annual Data Report, patients classified as lost-to-follow-up are not included in the point prevalent counts; they are, however, reported separately in Table B.1 of the Reference Tables.

While point prevalence is a useful measure for public health research, since it measures the current burden of the disease on the health care delivery system, and period prevalence is appropriate for cost analysis, since it indicates the total disease burden over the course of the year, we have chosen to focus primarily on the incidence of ESRD, believing that it is the most useful measure for medical and epidemiological research that examines disease causality and its effect on different sub-populations.

The Reference Tables present parallel sets of counts and rates for incidence (Section A) and December 31st point prevalence (Section B). Section B also presents annual period prevalence counts and counts of lost-to-follow-up patients.

Incident data for Figure 1.1, a map of the odds ratio of developing ESRD, are obtained from HCFA, while population counts are obtained from the U.S. Census Bureau. A logistic regression is used to compare the incidence of ESRD by location, with ESRD (yes or no) as the dependent variable. Explanatory variables include in-

cident year, race (white and black), gender, age (20–44, 45–64, 65–74, and 75+), and location (50 states plus the District of Columbia).

Reference Section A

Because the U.S. population figures used for this report (presented in Reference Section L) include residents only of the 50 states and the District of Columbia, tables in this section focus on patients from these areas as well. The exceptions are Tabes A.1, A.2, A.11, A.12, and A.13–20, all of which present data specific to patients in Puerto Rico and the Territories, or include these patients in the patient population. Age is computed as of the beginning of ESRD therapy.

Reference Section B

These tables also focus on patients who are residents of the 50 states and the District of Columbia, with the exception of Table B.1 and B.5. Age is calculated as of July 1 for period prevalent (Table B.3), and December 31 in all other tables.

PATIENT CHARACTERISTICS · CHAPTER TWO & REFERENCE SECTION C

Data used in both Chapter Two and Reference Section C are obtained from the HCFA Medical Evidence Form (2728), which plays a central role in the USRDS database. This form is completed at the dialysis unit for each new ESRD patient treated at that unit and sent to HCFA through the regional ESRD Networks. It serves to establish Medicare eligibility for individuals who previously were not Medicare beneficiaries, reclassify previously eligible Medicare beneficiaries as ESRD patients, and provide demographic and diagnostic information on all new ESRD patients regardless of Medicare entitlement.

Before 1995 units were required to file the Medical Evidence form only for Medicare-eligible patients. With the adoption of the new form in 1995, however, dialysis providers are now required to complete the form for all new ESRD patients, regardless of Medicare eligibility status. The revision also contains new fields for comorbid conditions, employment status, race, ethnicity, and biochemical data at the start of ESRD.

This form is the only source of information about the cause of a patient's ESRD. Because the list of diseases was revised for the new form, the USRDS stores the codes reported on each version so that detail is not lost through trying to convert one set of codes to the other.

The data in Tables C.4 and on are restricted to patients for whom the first Medical Evidence

Form was filed within 12 months of the first service date; total patient counts for this group are listed in Table C.2.

TREATMENT MODALITIES · CHAPTER THREE & REFERENCE SECTION D

Chapter Three and the associated tables describe the treatment modalities of all known ESRD patients, both Medicare and non-Medicare, who are not classified as lost-to-follow-up. Tables D.9–11, however, contain data only on Medicare patients who have survived at least 90 days. The 60-day rule is used to identify a change in modality. (A detailed discussion of the lost-to-follow-up methodology, non-Medicare patients, and the 60-day rule is presented earlier in this Appendix.)

Treatment modalities are defined here as follows:

♦ center hemodialysis: hemodialysis treatment received at a dialysis center
♦ center self-hemodialysis: hemodialysis administered by the patient at a dialysis center; a category usually combined with center hemodialysis
♦ home hemodialysis: hemodialysis administered by the patient at home; cannot always be reliably identified in the database
♦ CAPD: continuous ambulatory peritoneal dialysis; usually combined with CCPD
♦ CCPD: continuous cycling peritoneal dialysis; usually combined with CAPD
♦ other peritoneal dialysis: primarily intermittent peritoneal dialysis (IPD), a small category except among very young children, and usually combined with unknown dialysis and uncertain dialysis to form an other/unknown dialysis category
♦ uncertain dialysis: a period in which the dialysis type is unknown or multiple modalities occur but none last 60 days; usually combined with other peritoneal dialysis (IPD) and unknown dialysis to form an other/unknown dialysis category
♦ unknown dialysis: a period in which the dialysis modality is not known (e.g., when dialysis sessions are performed in a hospital); usually combined with other peritoneal dialysis (IPD) and unknown dialysis to form an other/unknown dialysis category
♦ renal transplantation: a functioning graft from either a living donor (a blood relative or other living person) or a cadaveric donor
♦ death: a category not appearing in the year-end modality tables, which report only living patients, but used as an outcome, i.e., in tables showing living patients

followed for a period of time for their modality treatment history

The tables in Reference Section D are divided into three groups. The first group, Tables D.1–8 and D.14–17, provides counts and percentages of prevalent patients alive at the end of each year by treatment modality and demographic categories. Because these tables include both Medicare and non-Medicare patients, counts and percentages in the categories of unknown age, gender, race, primary cause of renal failure, network, and state are significantly higher. The totals by year are also higher than the point prevalent counts in Reference Section B, which include only U.S. residents and drop patients with missing birth dates. Age is computed as of December 31st.

The second group, Tables D.9–11, shows modality at 90 days and two years after first service for all incident Medicare patients beginning renal replacement therapy from 1994–1996. The 90-day rule is used to exclude patients who died during the first 90 days of ESRD, and age is computed as of the date of first ESRD service.

The third group, Tables D.12–13, presents counts of prevalent patients alive at the end of each year by ESRD exposure time and modality. Table D.12 shows counts by the number of years the patient has had ESRD, while Table D.13 shows counts by the number of years on the end-of-year treatment modality. For the duration of ESRD exposure, zero should be read as less than one year, one as at least one full year but less than two, and so on.

CLINICAL INDICATORS OF CARE · CHAPTER FOUR

Data underlying the figures in this chapter—new to this year's edition of the ADR—are obtained from several sources. The information used in Figures 4.1–4 is obtained from the HCFA 1999 ESRD Clinical Performance Measures Project (formerly the ESRD Core Indicators Project). Data on urea reduction ratios (URRs) in Figure 4.5 come from Part A institutional outpatient claims. Erythropoietin (EPO) dose information and hematocrit values in Figures 4.6–14 are obtained from EPO claims data, while in Figures 4.15–16 Part B physician/supplier claims data supply the CPT codes indicating the insertion of central venous accesses and simple fistulas.

Figure 4.5 illustrates the percent of 1998 prevalent hemodialysis patients with a median URR ≥65%, the target set by the Dialysis Outcomes Quality Initiative (DOQI). The range of each patient's URR is obtained from the "G" modifier attached to CPT code 90999 with revenue codes

821 or 825, and the median range includes all URR values from January 1st or day 91 of ESRD until the end of the year. When a patient has an even number of URR ranges, the two middle values are each given a weight of 0.5.

Figure 4.6 shows the average hematocrit for prevalent hemodialysis and peritoneal dialysis patients with EPO claims. Each patient's yearly mean hematocrit is calculated from claims dated from January 1st or day 91 of ESRD until the end of the year, and the average of these values for each year and dialysis group is computed. Figure 4.7 is an HSA-level map of the percent of prevalent dialysis patients with EPO claims who meet the DOQI target hematocrit of ≥33%. Multiple hematocrit measurements for 1998 are condensed into one mean hematocrit value per patient, and these values are used to determine the percent of patients meeting the DOQI target.

Figures 4.8–9 present data by race and modality for prevalent hemodialysis and peritoneal dialysis patients with EPO claims. Figure 4.8 displays the average EPO dose per administration, calculated as the total amount of EPO administered divided by the total number of administrations each year. EPO administration and dose information is again obtained from claims dated from January 1st or day 91 of ESRD until the end of the year. Figure 4.9 shows the percent of patients meeting the DOQI target hematocrit of ≥33%.

The HSA-level maps in Figures 4.12–14 display the mean EPO dose per kilogram of body weight for incident patients who have EPO claims and weight data. For each EPO administration occurring after day 91 of ESRD the EPO dose is divided by weight in kilograms, and the values of mean EPO dose per kg for each administration are then averaged across each HSA.

Figures 4.15–16 illustrate insertion rates per 1,000 patient years at risk for central venous accesses and simple fistulas in prevalent hemodialysis patients. Using the same method applied in the hospitalization analyses, dialysis patients failing to reach a certain level of Medicare paid dialysis bills are excluded from this analysis. And as in the economic analyses, patients are also excluded if they are classified as MSP, according to Part A and B claims data, in 1991, 1995, or 1998, the years analyzed. Part B physician/supplier claims data provide the CPT codes for these insertion rates; specific codes are listed in the figure captions. Duplicate occurrences of the same CPT code with the same first and last expense date on multiple lines of a claim are counted as one insertion, and

the time at risk is censored at modality change, loss-to-follow-up, death, or the end of the year.

MORBIDITY & HOSPITALIZATION · CHAPTER FIVE & REFERENCE SECTION E
Chapter Five

Methodologies used to create the figures in this chapter generally echo those used to create the tables in Reference Section E (described below). Inclusion and exclusion criteria are the same, as are the methods for computing hospitalization rates. Part A inpatient institutional claims are used for the analyses unless otherwise specified, and the methodologies for excluding MSP patients are applied here as well, as detailed in the discussion of Section E.

One exception is the practice in the reference tables of combining hospitalizations that occur with no days between discharge and the following admission into one hospitalization from the first admission date to the last discharge date. For Chapter Five, the only consecutive hospitalizations combined into one are those which overlap (approximately one percent of all hospitalizations in the database). In this case the principal diagnosis and procedure codes are retained from the first of the two overlapping hospitalizations, with the combined hospitalization extending from the first admission date to the last discharge date. An admission that occurs the same day or the day after a discharge is designated as a separate hospitalization with its own diagnosis and procedure codes.

Figures 5.1, 5.3, and 5.20 present rates per patient rather than rates per patient year at risk. Events per patient are counted for each year from January 1st or day 91 of ESRD until the date of censoring: the earliest of death, the end of the year, or three days prior to transplant for dialysis patients, and the earliest of death or the end of the year for transplant patients.

Data for the two graphs in Figure 5.2, and for related figures, are calculated using different methods. The graph of hospital days per patient year at risk includes only days within the analysis period, while the graph of hospital days per admission includes all days for hospitalizations in which the admissions occur within the analysis period, even days occurring after the period has ended. The number of days per admission in Figures 5.2 and 5.4 thus represents the mean length of stay per admission for hospitalizations beginning within the time at risk for the given year. The number of days per patient year at risk (Figures 5.2, 5.5–10, 5.14, and 5.17–19), however, in-

cludes only those hospital days that fall within the time at risk, regardless of the admission date.

Figures 5.5–10 present HSA-level data of the number of hospital days per year at risk for prevalent ESRD patients. While time at risk is censored here at death or the end of the year for the all-ESRD, diabetic, and non-diabetic patients, hemodialysis and peritoneal dialysis patients are also censored at three days prior to transplant in order to exclude transplant-related hospital days. The diabetic group consists of all ESRD patients for whom diabetes is stated as the cause of disease, while the non-diabetic groups contains all ESRD patients with a cause of disease that is unknown or other than diabetes. Those with a missing cause of disease are excluded from both the diabetic and non-diabetic groups.

Data from 1996 to 1998 are combined in Figures 5.11–14, which illustrate the mean number of hospital admissions and average length of stay per year at risk by gender and modality in combination with age, race, or diabetic status. Age is determined on January 1st of the year, and patients with a cause of disease that is unknown or other than diabetes are classified as non-diabetic. Patients with missing age, gender, race, or diabetic status, as well as patients with race other than white, black, Native American, or Asian, are excluded.

Data on the frequency of principal procedures and diagnoses (Figures 5.15–16) and on related hospital days (Figures 5.17–19) are obtained from Part A inpatient and outpatient institutional claims. Patients with missing values for gender, race, or cause of ESRD are excluded. The time at risk for each procedure is censored at the end of the year, death, or three days prior to transplant. As in the total admission rates presented in the hospitalization reference tables, inpatient rates are calculated by subtracting the days spent in the hospital for each procedure or diagnosis from the total time at risk for admission for that procedure or diagnosis.

Most of the principal procedure and diagnosis codes used in Figures 5.15–19 are listed in the figure captions. Infection (overall) is indicated by principal ICD-9-CM codes of 001–139, 254.1, 320–326, 331.81, 372–372.39, 382–382.4, 383.0, 386.33, 386.35, 388.60, 390–393, 394–398.99, 415–424, 429, 460–466, 472–474.0, 475–477.9, 478.22–478.24, 478.29, 480–491, 494, 510–511, 513.0, 518.6, 522.5, 522.7, 527.3, 528.3, 540–542, 566–567.9, 569.5, 572–572.2, 573.1–573.3, 575–575.12, 590–590.9, 595–595.4, 597–597.89, 599.0, 601–601.9, 604–604.9, 607.1, 611.0, 614–616.1, 616.3–616.4, 616.8, 670, 680–686.9, 706.0, 711–711.9, 730.3, 730.8–730.9, 996.6–996.69, 997.62, 998.5, 999.3, V01–V069, and V09.

Figure 5.20 shows the number of hospitalizations per patient for incident and prevalent transplant patients at various times following transplant. The time post-transplant is determined from the date of the patient's most recent transplant until January 1st of the year for prevalent patients, or, for incident patients, until day 91 of ESRD. Data is presented by year for 1991 to 1998, with the year representing the post-transplant year. A patient with a transplant on April 5, 1990, for example, is included in the <1 year group for 1991, in the 1 to <2 years group in 1992, and in the 2 to <3 years group in 1993. Because Medicare eligibility may be lost and hospitalization information may be incomplete, patients whose most recent transplant was three or more years ago are excluded from this analysis.

Figure 5.21 illustrates, by gender, the percent of ESRD patients developing new diagnoses. For a given year and diagnosis, a patient is included in the denominator if he or she is prevalent during the year and has not yet developed the diagnosis before January 1st or day 91 of ESRD. The first occurrence date for each diagnosis is obtained from Part A institutional inpatient and outpatient claims, REBUS inpatient data, and Part B physician supplier claims. Principal diagnosis codes are as follows:

♦ atherosclerotic heart disease: 410–414, V45.81, V45.82, and V81.0
♦ cardiomyopathy: 425
♦ cancer: 140–208, 230–234, and V10
♦ gastrointestinal disease: 456.0–456.2, 530.7, 531–534, 569.84–569.85, and 578
♦ congestive heart failure: 402.01, 402.11, 402.91, 425, and 428
♦ peripheral vascular disease: 440–444, 447, 451–453, and 557
♦ hepatitis: 573.1–573.3
♦ cerebrovascular accident/transient ischemic attack: 430–438

Reference Section E
The analyses in this section include non-Medicare as well as UNOS transplant patients. Hospitalization data is obtained from Part A institutional inpatient claims, and Tables H.38–39 also include REBUS hospitalization data.

Tables E.1–37 include dialysis and transplant patients who have been on their modality for at least 60 days, who have reached day 91 of ESRD by

the end of the year, and who are residents of the 50 states, the District of Columbia, Puerto Rico, or the Territories. Patients with AIDS as a primary or secondary cause of death, and patients with missing values for age or gender, are excluded. Age is classified on January 1st of each year. The non-diabetic category includes those with an unknown cause of ESRD or a cause other than diabetes; patients with missing cause of disease are included only in the marginals of the tables. Patients of races that are unknown, missing, or other than white, black, Native American, or Asian are also included only in the marginals.

Patients are classified by modality at the beginning of the year using the following categories:
- all-dialysis: patients on hemodialysis, CAPD/CCPD, or dialysis of an unknown type, as well as patients who have not been on one modality for the previous 60 days
- hemodialysis: patients who have been on hemodialysis for at least 60 days at the start of the period
- CAPD/CCPD: patients who have been on CAPD/CCPD for at least 60 days at the start of the period at risk
- all-ESRD: all patients

To limit the contribution of patient years at risk from patients who are classified as MSP, and who therefore have incomplete hospitalization data, dialysis patients failing to reach a certain level of Medicare paid dialysis bills are excluded from Tables E.1–37. Dialysis patient start dates (January 1st of the year for prevalent patients and day 91 of ESRD for incident patients) must fall between start and end dates based on Medicare paid dialysis claims, as follows:
- start date: 30 days after the first month in which there is at least $675 of Medicare paid dialysis claims
- end date: the end of a 3-month period in which there is less than $675 of paid claims in each month

If a patient's start date does not fall between these dates, he or she is excluded from the analysis for that year. This method is similar to that used in the economic analysis section, except that here the paid claims dates are analyzed only for the dialysis patient start date. The dialysis patient end date remains the earliest of death, three days prior to transplant, and December 31st of the year. This filter also excludes non-Medicare dialysis patients whose hospitalization data are incomplete.

MSP patients are also excluded from this dataset through use of an additional filter which uses Part A, Part B, and UNOS data to determine MSP status, and which is detailed in the discussion of the economic analyses later in this Appendix.

For patients in the all-dialysis, hemodialysis, and peritoneal dialysis categories, the period at risk for all hospitalization analyses is from January 1st or day 91 of ESRD until the earliest of death, three days prior to transplant, or December 31st. Modality change is considered a censoring event only in the case of a change from dialysis to transplant. For patients in the all-ESRD category, in contrast, the analysis period for hospitalization is censored only at death or December 31st of the year; modality change is not used as a censoring event.

In the case of a hospitalization that begins prior to January 1st or day 91 of ESRD and continues into the analysis year, the time at risk for first admission begins the day after discharge from this bridge hospitalization. Patients with a bridge hospitalization that spans the entire analysis period are excluded from the first admission rates.

Time at risk is calculated differently for length of stay and for total admissions. Since a hospitalized patient remains at risk for additional days in the hospital, rates for hospital days include hospital days in the time at risk. Since a currently hospitalized patient is not, however, at risk for additional admissions, hospital days for each year are subtracted from the time at risk for total admissions. In the case of hospitalizations in which admission occurs the same day as discharge, zero days are subtracted from the time at risk for total admissions. When bridge hospitalizations span the start of the analysis period, only the days within the period are subtracted from the time at risk for total admissions.

All admissions and hospital stay days that occur during the analysis period are included, respectively, in the total admissions and length of stay for each year. Admission for a hospitalization that occurs before and spans the start of the analysis period is excluded from the total admissions for that analysis period, and only the hospitalization days within the period are counted in the total days for length of stay rates. The minimum length of stay is one day, and hospitalizations with admission and discharge on the same day, as well as hospitalizations with discharge the day after admission, are both counted as one day.

In Tables E.1–37, overlapping hospitalizations and hospitalizations that occur with no days between discharge and the following admission are combined into one hospitalization that spans the first admission date to the last discharge date. This

follows the methodology of previous Annual Data Reports, allowing for comparison of the reference tables across years.

Tables E.38–39, in contrast, include all hospitalizations in the total discharges reported, and no overlapping or adjacent hospitalizations are combined. These tables present total hospital discharges by diagnostic related groups (DRGs), and include all discharges after the date of first ESRD service. No exclusions are made for patients who died of AIDS or for MSP status. The year represents the year in which the discharge occurred. Inpatient REBUS data is combined with Part A institutional inpatient claims data, and duplicate observations from both sources with identical hospitalization start dates, end dates, and DRG codes are omitted.

The methodology used in Tables E.1–12 for computing first admission rates utilizes a generalized mixed model. Smoothed rates are used to calculate the expected number of first hospitalizations, a number then used to obtain the standardized hospitalization ratios (SHRs) in Table E.13. These methods are described later in this Appendix.

The methods used to compute total admissions and days hospitalized are the same as those used in prior Annual Data Reports. As in the 1999 ADR, the total admission rate is expressed per 1,000 patient years at risk, while the rate of hospital days is given per patient year at risk. Data from 1996 to 1998 has been pooled to increase stability, but follow-up is for single calendar year periods using cohorts of patients alive at the beginning of each year. The number of hospital admissions and days, and the number of years at risk for each event, are computed separately for each year and summed over the three years; rates are then computed by dividing the total admissions or days by the total time at risk. A patient who is alive at the beginning of 1996, dies in 1998, and has two hospitalizations each year, for example, will contribute two and a fraction years at risk and six admissions.

The rates and standard errors for the all-ESRD group in Tables E.10–12, E.23–25, and E.35–37 differ considerably from those published previously. Table H.1S of the 1999 ADR, for instance, shows a total of 92,732 patient years at risk for all-dialysis patients, and 93,317 years at risk for all-ESRD patients. With both the addition of transplant patients and the omission of censoring at three days prior to transplant, it is unlikely that only 585 additional patient years at risk would be added to the all-ESRD group. It seems probable, then, that transplant patients were inadvertently omitted in the previous analyses.

PEDIATRIC ESRD · CHAPTER SIX
Information on pediatric patients is a subset of the ESRD patient data used throughout ADR; methods used to create most figures in this chapter are therefore the same as those described in the related chapter discussions. Methods unique to Chapter Six are described below.

The hospitalization data presented in Figures 6.28–37 contain information from Part A institutional inpatient claims, and include non-Medicare patients. As in the methods used for Chapter Five, two overlapping hospitalizations are combined into one, and an admission that occurs the same day or the day after a discharge is counted as a separate hospitalization. Patients with AIDS as a primary or secondary cause of death are excluded, as are patients classified as MSP according to paid dialysis claims, Part A claims, Part B claims, or UNOS data. Residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories are included. Age is classified on January 1st of the year, and patients with missing age information are excluded.

Figures 6.28–30 show cause-specific first hospitalization admission rates per 100 patient years at risk, by age, for prevalent pediatric dialysis, hemodialysis, and CAPD/CCPD patients, using combined data from 1996–1998. Time at risk is calculated from January 1st or day 91 of ESRD until the earliest of the first hospitalization, three days prior to transplant, death, or December 31st of the year. While the methodology used to calculate first-hospitalization rates generally follows that of Tables E.1–12, raw, cause-specific rates are presented here rather than the smoothed, overall first hospitalization rates provided in the tables. These rates are determined by classifying the first hospitalization according to its principal ICD-9-CM diagnosis or procedure code. Procedure codes used for overall cardiovascular and vascular access procedures, and diagnosis codes used for vascular access infection, infection (peritonitis), and catheter complications, are found in the captions of Figures 5.15–16. The diagnosis codes used for the overall infection category are listed in the discussion of Figures 5.15–19.

The methodology used to calculate inpatient admission rates in Figures 6.31–37 follows that used to calculate total admission rates in the hospitalization reference tables. Prior ESRD time is calculated as the time from the first ESRD service date until the first of the year for prevalent pa-

tients or day 91 of ESRD for incident patients. Patients with an invalid date of birth or missing gender information are excluded. Principal ICD-9-CM diagnosis codes used for overall infection are identical to those used in Figures 6.28–30, while the principal ICD-9-CM diagnosis codes for respiratory infection include 460–466, 472–474.0, 475–477.9, 478.22–478.24, 480–491, 494, 510–511, 513.0, and 518.6.

TRANSPLANTATION ·
CHAPTER SEVEN & REFERENCE SECTIONS F & G
Chapter Seven
In addition to the analyses conducted for the reference tables (discussed below), several additional methods are used for the figures in this chapter. All figures which present graft or patient survival estimates exclude non-Medicare patients (due to lack of follow-up information) and patients with first ESRD service dates prior to 1977.

Figures 7.1–4 present organ donation rates. The numerators include all transplant recipients aged <65 with known gender and who are white, black, Native American, or Asian. The denominators are obtained from the United States Census. Rates are calculated as the number of donated kidneys (excluding discarded organs) divided by the population, and multiplied by one million to yield donations per million population.

Figure 7.13 presents trends in the annual rate of graft loss, calculated from a Cox model and adjusted for age, gender, race, and primary diagnosis. Patient follow-up is censored at December 31, 1998. In estimating graft survival, death is considered a graft failure. Graft survival probabilities are standardized to the 1996 patient population, and the estimated percent graft failure is calculated as one minus the estimated graft survival probability for each year.

Figures 7.14–15 present the projected graft half-life for first transplants. Graft half-life is the time at which 50% of transplanted kidneys are still functioning, i.e., if 1,000 first transplants are performed in 1988, and 500 are still functioning 150 months (12.5 years) later, the half-life for the 1988 patient cohort is 150 months. Graft survival is calculated at 3, 12, 24, 36, and 60 months (survival for the most recent cohort group could not be estimated past 36 months); estimates are adjusted for age, gender, race, and primary diagnosis, and are standardized to 1996. Since the time to median graft survival has not yet been reached, a log linear extrapolation is used based on the log of the survival probabilities at 12 months and at the last follow-up (36 or 60 months).

Figure 7.16 presents trends, by race, in graft survival rates after first transplant; rates are adjusted for age, gender, and primary diagnosis, and standardized to 1996. The Kaplan-Meier method is used to create state maps of one-, two-, and five-year unadjusted graft survival rates (Figure 7.17). Patient survival rates, calculated using the same methods, are presented in Figures 7.18–19.

Figures 7.20–22 present counts of wait-listed patients; these counts are taken directly from the UNOS wait-list files.

Reference Section F
Transplant counts are presented in Tables F.1–22. All known transplant events are included here unless specified in the footnote, and all counts include non-Medicare patients.

Calculations of transplant rates per 100 patient years on dialysis begin in Table F.23, and include only those patients reaching day 91 of ESRD service. All hemodialysis patients, peritoneal dialysis (CAPD/CCPD) patients, and patients on an unknown form of dialysis are included, as are all non-Medicare patients. Patients who died of AIDS and patients whose age is unknown at transplant are excluded. A patient's dialysis days are counted from the beginning of the specified year, or day one of ESRD dialysis therapy if treatment begins mid-year, until transplant, death, or the end of the year, whichever comes first. Patients who are lost-to-follow-up in a given year are not censored at the lost-to-follow-up date, but are instead followed until the end of the calendar year. Transplant rates are calculated as the number of transplant events divided by the total number of dialysis patient years for each given year.

Table F.25, first transplant rates per 1,000 patient-years on dialysis, is calculated using a generalized mixed model to stabilize the rates (this model is detailed later in the Appendix).

Table F.35 displays standardized first transplant ratios by state and territory for 1996–1998. A state's observed first transplant rate is compared with the rate expected from national rates for patients with similar characteristics, with the 1998 prevalent cohort (Table F.25) used as a reference. The standardized first transplant ratio is calculated as the ratio of the observed number of first transplants in the state to the expected number.

Reference Section G
This section presents graft survival probabilities for various demographic groups and lengths of follow-up. Patients are followed from the date of

transplant to graft failure, death, or the end of the follow-up period (December 31, 1998); death in this analysis is considered a graft failure. Because a minimum of one year of follow-up is needed, 1997 is the most recent year reported.

To produce a standard patient cohort for the graft survival analyses, patients with unknown age, gender, or race are omitted. Unknown age is defined as a missing age at transplant, or an age that was calculated to be less than zero or greater than or equal to 100. Patients are also excluded if their first ESRD service date is prior to 1977. Non-Medicare patients are excluded from all tables in this section due to the lack of follow-up information; the renal transplant counts presented here differ, therefore, from those in Section F.

Unadjusted survival probabilities are estimated using the Kaplan-Meier method and Greenwood's formula, while adjusted probabilities are estimated using the Cox model. Probabilities are adjusted for age, gender, race, and primary diagnosis, standardized to 1996 patient characteristics, and expressed as percentages from 0 to 100.

SURVIVAL, MORTALITY, & CAUSES OF DEATH · CHAPTER EIGHT & REFERENCE SECTIONS H & I
Chapter Eight

Figures in this chapter are created using the same methodologies and patient populations used in constructing the related Reference Tables (described below); methods unique to the figures are discussed here.

EXPECTED REMAINING LIFETIMES

The expected remaining lifetime for a patient group is the average of the life expectancies for the patients within that group. Some patients in the cohort will live longer than, and some less than, the average. Although the average cannot be known until all the patients in the cohort have died, the expected remaining lifetime can be projected by assuming that patients in the cohort will die at the same rates as those observed among groups of recently prevalent ESRD patients.

For a subgroup of ESRD patients of a particular age, the expected remaining lifetime is calculated using a survival function, in turn calculated using the observed death rates. Let $r(A)$ denote the death rate for a 5-year age group, with A identifying one of the listed age ranges. Death rates for successive age intervals, $r(A)$, are plotted versus age, A, and the area under the curve up through age A is denoted by $R(A)$. The survival function, $S(A)$, at age A is the fraction of patients that would survive to age A in a hypothetical cohort sub-

jected to these death rates throughout their lifetimes. The survival function at age A is related to the death rates by the equation $S(A) = exp(-R(A))$, where "exp" denotes the exponential function. Among patients alive at age A, the fraction who survive for X more years is then $S_A(X) = S(A+X) / S(A)$. For a given starting age, the expected remaining lifetime is then equal to the area under the curve of $S_A(X)$ plotted versus X. Because few patients live beyond 100, this area is truncated at the upper age limit $A + X = 100$.

Table 8.1 reports expected remaining lifetimes by age, gender, race, and modality. These rates are calculated after excluding deaths due to AIDS, accidents ("accidents unrelated to treatment" on the ESRD Death Notification), and illegal drugs ("drug overdose (street drugs)"), so the lifetimes reported correspond to hypothetical populations in which these causes of death do not occur. Reference Tables H.3–4 and H.12–13 are used to make the calculations.

SURVIVAL CURVES & INTERVAL DEATH RATES

The Cox regression, used in Figures 8.11–15, is described later in this Appendix.

ASSOCIATION BETWEEN MORTALITY & HEMATOCRIT

Figures 8.16–18, each broken down by diabetic status, show the association of mortality and hematocrit level for the 1993–1996 cohorts of incident dialysis patients (8.16), incident hemodialysis patients (8.17), and incident CAPD/CCPD patients (8.18). The death rates in each graph are adjusted for patient characteristics, comorbidity, and disease severity. The overall death rate is the observed death rate.

The incident cohorts analyzed for these graphs are defined by the year (1993–1996) of first ESRD service. Excluded from the analysis are patients who are not U.S. citizens, incident patients who did not survive 90 days after the onset of ESRD, and patients with fewer than four hematocrit claims. All causes of death are included, and the cohorts are limited to dialysis patients.

For each incident cohort, data on patient characteristics, comorbidity, and disease severity are collected during the first six months (the entry period). Patients are followed until death, change of modality, transplant, loss-to-follow-up, or June 30, 1999, and are censored at change of modality, transplant, loss-to-follow-up, or June 30, 1999.

The survival probabilities used to calculate death rates in these graphs are estimated using a Cox model, described later in this Appendix. These

survival function estimates correspond to the means of the explanatory variables for each hematocrit and diabetic subgroup. Demographic characteristics include age, gender, and race, while comorbid conditions consist of atherosclerotic heart disease, congestive heart failure, peripheral vascular disease, cerebrovascular accident/transient ischemic attack, other cardiac disease, cancer, chronic obstructive pulmonary disease, and gastrointestinal disease. Severity of disease measures include the number of hospital days, blood transfusions, and vascular access procedures. Hematocrit levels during the entry period are grouped as <27%, 27 to <30%, 30 to <33%, 33 to <36%, and ≥36%.

ALL-CAUSE, INFECTIOUS, & CARDIAC DEATH RATES
The Cox regression and interval death rate estimation, used in Figures 8.19–21, are described in the statistical methods section of this Appendix.

Reference Section H
PATIENT POPULATION
Counts of deaths (H.1), adjusted death rates (H.2–16), standardized mortality ratios (SMRs, H.17), and cause-specific death rates (H.18–37) are reported for prevalent cohorts of 1996, 1997, and 1998. New to this Annual Data Report are tables of adjusted death rates by patient vintage, or prior ESRD time, calculated as the number of days from the first ESRD service date to the starting date (January 1st), divided by 365.25 (H.2S–16S). Also new are adjusted first-, second-, and third-year death rates for incident cohorts (H.38–40). Residents of the 50 states, the District of Columbia, Puerto Rico, and the Territories are included in each of these tables, as are all non-Medicare patients.

All causes of death are included in Tables H.1 and H.18–37; Tables H.2–16 and H.2S–16S exclude patients who died of AIDS. While patients who died of street drug overdoses or accidents unrelated to treatment are not counted in the death rates, their time at risk is counted until death.

Tables H.2–37 include both incident and prevalent patients, while Tables H.38–40 include incident patients only. As defined earlier, prevalent cohorts include those patients who are alive on renal replacement therapy at the beginning of the year and whose first service date is at least 90 days before the beginning of the year. Incident cohorts are limited to those patients who reach day 91 of ESRD treatment during the year. Because these calculations include only one-year of follow-up, a prevalent patient surviving until the end of the year contributes one year at risk, while a prevalent patient dying during the year contributes less than one year. Since the calculation for incident patients begins on day 91 of ESRD, most of these patients contribute less than one year at risk; a full year is contributed only if day 91 of ESRD is January 1st and the patient survives until the end of the year. Patients considered lost-to-follow-up at the beginning of the year are excluded from the analysis. The period at risk is not censored at the start of a lost-to-follow-up period, however; if a patient enters the lost-to-follow-up category during a calendar year, he or she remains in the death rate computation until the end of that year.

Patient cohort populations often overlap. Patients with a functioning transplant on the start day, for example, are included in the all-ESRD and all functioning transplant categories, while patients on dialysis are defined as both all-ESRD and all-dialysis. A patient in the all-dialysis category may also be reported in one of two subgroups—hemodialysis or CAPD/CCPD—if he or she has been on that modality for at least the previous 60 days. Dialysis patients who are not on hemodialysis or CAPD/CCPD, or who have been on that modality for less than 60 days, are included only in the all-ESRD and all-dialysis categories.

Both adjusted and unadjusted death rates are reported for the following groups (definitions are the same as those used in the hospitalization analyses; see the discussion of Section E):
- all-dialysis; if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
- hemodialysis; if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
- CAPD/CCPD; if a transplant occurs during or at the end of the year the period at risk is censored at the transplant date
- functioning transplant: patients with a functioning transplant at the start of the period and who have had the transplant for at least 60 days; the period at risk is censored only at the end of the year
- all-ESRD; the period at risk is censored only at the end of the year

METHODS
Generalized mixed models are used to calculate the smoothed rates in Tables H.2–16 and H.2S–16S; these methods are described later in this Appendix, as is the method used to calculate the standardized mortality ratios (SMRs) in Table H.17.

In Tables H.18–37 death rates are reported by primary cause of death among patients prevalent at

the beginning of, or incident (defined as 90 days following the start of ESRD) during 1996, 1997, and 1998. Subgroups are characterized by age, gender, race, and modality at the beginning of each cohort year for prevalent patients or at 90 days of ESRD for incident patients. Dialysis patients are censored at transplant or the end of the calendar year, while transplant patients and patients in the all-ESRD category are censored only at the end of the calendar year. The death rate in each subgroup for a specific primary cause of death is obtained by dividing the total deaths from the primary cause by the subgroup's total follow-up time. The sum of death rates for each specific cause in a subgroup, then, is equal to the overall death rate of that subgroup. Death rates for collapsed categories of death (table a.1) are presented in Tables H.18–32, while Tables H.33–36 list rates for each specific cause of death. Rates by cause of withdrawal are presented in Table H.37.

In Tables H.38–40 the adjusted first-, second-, and third-year death rates for incident cohorts—including all-dialysis, hemodialysis, CAPD/CCPD, and transplant patients—are computed from the Cox model, described later in this Appendix.

Reference Section I

PATIENT POPULATION

These tables, which include only incident cohorts, present patient counts, counts of first renal transplants, the mean and median time to first transplant from first ESRD service, and patient survival probabilities and standard errors. All causes of death are included, as are all non-Medicare patients and patients living in the 50 states, the District of Columbia, Puerto Rico, and the Territories. Patients with unknown gender or age, or whose age is listed as >110, are excluded from the patient cohorts.

Patient selection criteria are the same for both unadjusted and adjusted survival probabilities. All new ESRD patients with a first ESRD service date (for dialysis or transplant) between January 1, 1978, and December 31, 1997, are included in the analysis. These patients are followed until December 31, 1998, a maximum follow-up time of 15 years and a minimum of one year.

Results are reported for the following groups:
- ◆ all-ESRD: all ESRD patients beginning renal replacement therapy in a calendar year and surviving beyond day 90; patients are censored only at the end of follow-up

Collapsed categories	Individual categories
Acute myocardial infarction	Myocardial infarction, acute
Hyperkalemia	Hyperkalemia
Pericarditis	Pericarditis, including cardiac tamponade
Atherosclerotic heart disease	Atherosclerotic heart disease
Cardiomyopathy	Cardiomyopathy
Cardiac arrhythmia	Cardiac arrhythmia
Cardiac arrest	Cardiac arrest, cause unknown
Valvular heart disease	Valvular heart disease
Pulmonary edema	Pulmonary edema
Cerebrovascular disease	Cerebrovascular accident including intracranial hemorrhage Ischemic brain damage/anoxic encephalopathy
G. I. hemorrhage	Hemorrhage from transplant site; hemorrhage from vascular access; hemorrhage from dialysis circuit; hemorrhage from ruptured vascular aneurysm; hemorrhage from surgery; other hemorrhage
Septicemia	Septicemia, due to peritonitis; septicemia, due to peripheral vascular disease, gangrene; septicemia, other
Pulmonary infection	Pulmonary infection (bacterial); pulmonary infection (fungal); Pulmonary infection (other); tuberculosis
Viral infection	Viral infection, CMV; viral infection, other; Hepatitis B; other viral hepatitis
AIDS	AIDS
Other infection	Infection, other; fungal peritonitis
Cachexia	Cachexia
Malignant disease	Malignant disease, patient ever on immunosuppressive therapy Malignant disease
Other cause	Pulmonary embolus; mesenteric infarction/ischemic bowel; liver-drug toxicity; cirrhosis; polycystic liver disease; liver failure, cause unknown or other; pancreatitis; perforation of peptic ulcer; perforation of bowel; bone marrow depression; dementia, including dialysis dementia, Alzheimer's; seizures; diabetic coma, hyperglycemia, hypoglycemia; ohronic obstructive lung disease (COPD); complications of surgery; air embolism; accident related to treatment; accident unrelated to treatment; suicide; drug overdose (street drugs); drug overdose; other identified cause of death
Unknown cause	Unknown
Missing forms	Missing forms

Table a.1
Collapsed cause of death categories

♦ 65 and over at start of ESRD: all ESRD patients age 65 and over who begin renal replacement therapy in a calendar year; patients are grouped in two-year periods to increase cell size, and are censored only at the end of follow-up
♦ dialysis only: all ESRD patients starting renal replacement therapy in a calendar year, surviving beyond day 90, and not receiving a transplant by day 91; patients are censored at transplant or at the end of follow-up
♦ first renal transplant (cadaveric): patients receiving their first transplant in a calendar year and for whom the donor is cadaveric
♦ first renal transplant (living): patients receiving their first transplant in a calendar year and for whom the donor is living

In both transplant categories, patients for whom the donor type is other or unknown are excluded. The cohort is defined by the year of first transplant, regardless of the year of first ESRD service. These patients are followed from the date of transplant (the date at which age is computed), and are censored only at the end of follow-up.

METHODS

Unadjusted patient survival probabilities are estimated using the Kaplan-Meier method, while the Cox model is used for the adjusted probabilities. To avoid excessive imprecision of the estimated survival probabilities due to small cell sizes, adjusted survival probabilities are presented using aggregate categories for age, gender, race, and primary disease, and a probability presented for one of these variables is adjusted for the remaining three. Overall probabilities for all patients are adjusted for each of the four variables.

The one-year survival probability is the probability of surviving from day 91 to one year plus 90 days (days 91–455), while the two-year survival probability is the probability of surviving from day 91 to two years plus 90 days. This 90-day delay is necessary because many patients younger than 65 do not become eligible for Medicare for up to 90 days, and the database may not be complete during this time. The probabilities are expressed as percentages from 0 to 100.

PREVENTIVE HEALTH CARE MEASURES · CHAPTER NINE

This chapter—new to this edition of the Annual Data Report—contains data from the REBUS/ PMMIS database, HCFA's Standard Analytic Files (SAFs) and Annual Facility Survey, and the CDC National Surveillance of Dialysis-Associated Diseases. Because the CDC did not conduct a survey in 1998, data in some instances is reported only up to 1997.

Methods for determining screening rates for breast and cervical cancer, diabetic eye exams, and glycosylated hemoglobin testing (HbA1c) are taken directly from HEDIS® 2000 specifications (HEDIS® 2000 is a program of the National Committee for Quality Assurance, and is used to monitor the performance of managed health care plans). Because HEDIS® 2000 does not address screenings for prostate cancer or influenza vaccinations, algorithms for these analyses have been created by the USRDS. With the exception of influenza vaccination rates, screening rates are determined for both incident and prevalent ESRD patients.

Screening intervals for cervical and prostate cancer include the reporting year and the two prior years; for breast cancer, the reporting year and the prior year; for diabetic eye exams and glycosylated hemoglobin, the reporting year only; and for influenza vaccinations, September 1st through December 31st of the reporting year.

Patients with Medicare as a secondary payor or not eligible for Medicare are omitted from all analyses. With the exception of the Hepatitis C analysis, patients are also omitted who have a missing date of birth, who did not survive the entire reporting year, who were ESRD less than 90 days prior to January 1st of the reporting interval, and, for diabetic eye exams and glycosylated hemoglobin screening, who are non-diabetic.

In Figures 9.4–6, showing Hepatitis C diagnosis rates, patient years at risk are used for the denominator and are calculated from the start of the period (non-MSP prevalent patients), the first ESRD date (incident patients), or the date 30 days after the first month in which there is at least $675 of Medicare paid dialysis claims, whichever is latest. Patients are followed through death, transplant, loss-to-follow-up, or the end of the reporting period. Dialysis patients are censored at transplant; transplant patients, however, are not censored at a return to dialysis. ICD-9-CM diagnosis codes for Hepatitis C include 070.41, 070.44, 070.51, 070.54, and V02.62.

For the analysis of prostate cancer screening, patients are excluded if their claims contain any of the following ICD-9-CM procedure codes: 60.2, 60.21, 60.29, 60.3, 60.4, 60.5, or 60.62. Codes used

to identify patients who receive screening include CPT-4 codes of 52601, 52612, 52614, 55801, 55810, 55812, 55815, 55821, 55831, 55840, 55842, 55845, and 84153; revenue codes of 0300 or 0310, associated with an ICD-9-CM diagnosis code of 185 or 233.4; and ICD-9-CM procedure codes of 60.11, 60.12, 60.18, 87.92, and 91.39.

In Figure 9.12 the numerator includes all patients receiving an influenza vaccination in the last four months of 1998, while the denominator includes all prevalent patients. HCPCS codes used to identify patients who receive flu vaccinations include 90724 and G0008.

PROVIDER CHARACTERISTICS · CHAPTER TEN & REFERENCE SECTION J

This chapter contains data from HCFA's Annual Facility Survey, the CDC National Surveillance of Dialysis-Associated Diseases, and Freedom of Information Act requests regarding unit chain affiliation. Only facilities that have submitted both the HCFA and CDC surveys are reported. Because the CDC did not conduct a survey in 1998, data in some instances is reported only up to 1997.

For these analyses, a chain-affiliated unit is defined as one of a group of 20 or more freestanding dialysis units that are owned by a common party and that are located in more than one state.

ECONOMIC COSTS OF ESRD · CHAPTER ELEVEN & REFERENCE SECTION K
Chapter Eleven

Data in this chapter are calculated using several different analytical models, described here.

As-treated model

This model uses the same data sources and inclusion criteria as the intent-to-treat model described below. In the as-treated model, however, each modality change generates a new observation. Modality information is obtained from the USRDS database, and each patient is entered into the study with a particular modality. When a modality change is encountered, the beginning modality is censored at the change date, and a new observation with the new modality is created. In the case of changes involving only a new dialysis modality, the new modality must last at least 60 days in order to be counted (this rule is not applied for a change from dialysis to transplant). MSP status is determined in the same way used with the intent-to-treat model, and the same exclusions are applied.

HCFA model

This model, described in the HCFA research report on ESRD (1993–1995), is used for Tables 11.3–5. With this method patients are classified into four mutually exclusive treatment groups:

♦ dialysis: ESRD patients who are on dialysis for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled

♦ transplant: ESRD patients who have a kidney transplant during the calendar year

♦ functioning graft: ESRD patients who have a functioning kidney transplant for the entire calendar year, or for that part of the year in which they are alive, ESRD, and Medicare entitled

♦ graft failure: ESRD patients who have had a transplant, but returned to dialysis due to loss of graft function during the calendar year; patients with a graft failure and a transplant in the same calendar year are always classified in the transplant category

Patients are categorized as having Medicare as secondary payor on the basis of the "Primary payor amount" on Part A and Part B claims.

Six-month entry model

This model considers prevalent patients who survive on a given modality during the entry period (for these analyses, the first six months of 1998). Patients are characterized using Medicare claims data from the entry period, and costs are aggregated for the follow-up period (the last six months of 1998), with patients censored at modality change, death, loss-to-follow-up, or the end of the follow-up period (December 31, 1998). Patients who were MSP during 1998 are excluded.

Methods

Table p.1 in the Précis summarizes data on the costs of ESRD treatment. Total 1998 Medicare spending is calculated from the claims data, and includes all paid claims for ESRD patients in the USRDS database. Cost aggregation begins at the first ESRD service date for each patient. Total 1998 Medicare spending is inflated by two percent to account for incomplete claims, and HMO and organ acquisition costs are estimated with the same methods used in the 1999 ADR (149–150).

Non-Medicare spending by Employee Group Health Plans (EGHPs) is estimated by computing the per year at risk costs for EGHP and non-EGHP patients separately, then multiplying the difference by the EGHP years at risk for 1998. Patient obligations are estimated as 18% of the sum of Medicare payments, non-federal EGHP

costs, and patient obligations (1999 ADR, 149). Because non-Medicare patients are estimated to constitute 7% of all ESRD patients in the U.S. (1999 ADR, Table ES-1), costs are estimated as 7% of the total costs of Medicare patients.

Changes in Medicare spending from 1997 to 1998 are taken directly from Table K.1, without the two percent adjustment for late claims. Per patient year at risk figures are based on patients who were never MSP during the study period (Tables K.19–20), again using non-inflated results. The apparent decrease in per patient per year costs is likely artifactual, and due to the absence of late claims affecting the 1998 claims dataset. The range for inflation-adjusted costs is calculated using the overall Consumer Price Index (1.6%) as well as the Medical Consumer Price Index (3.4%). The year-at-risk figures for modality are taken directly from Table K.6; these figures include non-MSP patients only, and are not adjusted for late claims.

PMPM payments by hematocrit and URR are calculated using the six-month entry model. Data are obtained from outpatient dialysis claims, and only those patients with four or more EPO claims (Figures 11.6–7) or three or more claims with valid URR data (Figure 11.8) are included. The hematocrit range for each patient is based on the mean hematocrit for the six-month entry period, while the URR range is based on the median value from the same period. Claims are aggregated by month, and in the case of multiple claims per month only the last value of the month is used.

Figures 11.9–15 present trend data for vascular access payments from the physician/supplier claims file. Payments are aggregate totals for each calendar year 1991 to 1998. Place of service is determined from the Place of Service code included in the line item data, type of service is determined from the CPT code, and physician specialty is determined from the physician specialty code in the line item data. A patient growth line is included for comparison in Figures 11.12–15, and is constructed by normalizing each year's prevalent hemodialysis patient count to the count for 1991. Non-Medicare patients are excluded.

Information about the construction of other figures and tables is provided in the captions.

Reference Section K
MEDICARE CLAIMS DATA
The cost information in this section is derived from Medicare Part A and Part B (physician/supplier) claims data on the HCFA Standard Analysis Files, which are created annually six months

following the end of each calendar year. The data for 1994 to 1998 comprise approximately 28 million institutional claims (hospital inpatient and outpatient facilities, outpatient dialysis facilities, skilled nursing facilities, hospice facilities and home health agencies), as well as 213 million line items from physician/supplier claims. Claims data are obtained for all patient ID numbers in the USRDS database, and the Renal Beneficiary Utilization System (REBUS) is used to gather all HCFA ID numbers under which patients may have claims. The claims data are then merged with patient demographic data and modality information in the USRDS database.

The economic analysis for this reference section focuses on two amounts found in the claims data: the claim payment amount, which is the amount of payment made from the Medicare trust fund for the services covered by the claim record; and the pass-through per diem amount, which applies to inpatient claims and reimburses the provider for capital-related costs, direct medical education costs, and kidney acquisition costs. Chapter Eleven of the Annual Data Report includes another dollar amount called Medicare Allowable, defined here as the amount of allowed charges for the services covered by the claim record. For institutional claims, this amount is calculated as the sum of the amounts from the Medicare payment, coinsurance, deductible, and any payment provided by a payor other than Medicare. For physician/supplier claims, the Medicare Allowable amount is provided by HCFA as a separate data element.

PAYMENT CATEGORIES
The Medicare payments are broken down into several categories, as shown in Table a.2.

INTENT-TO-TREAT MODEL
In an intent-to-treat model patients are classified by their modality at the start of the analysis period, and retain that classification even after changes in modality. Aggregation of Medicare payments is done on an intent-to-treat basis, attributing all subsequent payments to the patient's initial modality, and calculating the payments per year at risk. Patients beginning on dialysis and later receiving a transplant are, however, exempt from this rule. These patients are censored at transplant, and entered again into the study as a new observation with transplant as the intent-to-treat modality.

Patients are classified in these tables into four intent-to-treat modality categories: hemodialysis, CAPD/CCPD, other dialysis, and transplant. The

"other dialysis" category includes cases in which the dialysis modality is unknown or is not hemodialysis or CAPD/CCPD, while the "transplant" category includes patients who have a functioning graft at the start of the period or who receive a transplant during the period. Some tables also include categories for all-dialysis (hemodialysis, CAPD/CCPD, and other dialysis) and all-ESRD (all-dialysis and transplant).

The study spans the five-years from January 1, 1994 to December 31, 1998, and ESRD patients prevalent on January 1, 1994 or incident at any time during the period are potentially eligible for inclusion. The study start date for a given patient is defined as the latest of the following:

♦ January 1, 1994
♦ thirty days after the first ESRD service date in the USRDS database for that patient
♦ for dialysis patients, 30 days after the first month in which dialysis payments exceed $675

Because it is impossible to characterize the total cost of their care, patients for whom Medicare is the secondary payor (MSP) at any time during the study period are excluded from the analysis. MSP status is determined using the same method as that described by HCFA in its ESRD research report (1993–1995). This method involves scanning the claims data for claims with a primary payor amount greater than zero, which confirms that a payor other than Medicare is paying for at least some of the care. Patients who have claims meeting this criterion in both Part A and Part B are considered to be MSP. Transplant patients are also considered MSP if UNOS data indicates that Medicare is the secondary payor.

Medicare payments are aggregated from the study start date until the earliest of death, transplant, loss-to-follow-up, or December 31, 1998. Dialysis patients are defined as lost-to-follow-up after a period of three consecutive months in which dialysis payments (institutional plus physician/supplier) fall below $675/month, and patients

Medicare payment categories	Basis for categorizing claim
Total	Sum of all payments
Total institutional	Sum of all institutional payments
Inpatient	Sum of all inpatient payments
Inpatient pass-throughs	Sum of all inpatient pass-throughs
Non-transplant inpatient	Source of claim is Inpatient SAF and DRG is not 302
Non-transplant inpatient pass-throughs	Source of claim is Inpatient SAF and DRG is not 302, calculated
Transplant inpatient	Source of claim is Inpatient SAF and DRG is 302
Transplant inpatient pass-throughs	Source of claim is Inpatient SAF and DRG is 302, calculated
Outpatient Institutional	Source of claim is Outpatient SAF, but has no dialysis revenue center code
Skilled Nursing Facility	Source of claim is Skilled Nursing SAF
Home Health Agency	Source of claim is Home Health SAF
Hospice	Source of claim is Hospice SAF
All Dialysis – Institutional	Sum of Hemodialysis, Peritoneal Dialysis, Other Dialysis Institutional
Hemodialysis – Institutional	Hemodialysis revenue center code
Peritoneal Dialysis – Institutional	Peritoneal dialysis revenue center code
Other Dialysis – Institutional	Other dialysis revenue center code
Total Physician/Supplier Dialysis	Sum of all physician/supplier payments
Total Physician/Supplier Dialysis	Sum of physician/supplier dialysis payments
Total Hemodialysis – Physician/Supplier	Sum of physician/supplier hemodialysis payments
Hemodialysis – Physician	Part B SAF, CPT code
Hemodialysis Home Supply	Part B SAF, HCPCS codes, service type code
Total PD – Physician/Supplier	Sum of physician/supplier peritoneal dialysis payments
PD – Physician	Part B SAF, CPT code
PD Home Supply	Part B SAF, HCPCS codes, service type code
Non-dialysis – Physician/Supplier	Sum of non-dialysis physician/supplier payments
Peritoneal dialysis catheter	Part B SAF, CPT code
Capitation	Part B SAF, CPT code, service type code
Vascular access	Part B SAF, CPT code
EPO	Part B SAF, HCPCS code
Iron	Part B SAF, HCPCS code
Transplant	Part B SAF, CPT code
Immunosuppressive	Part B SAF, HCPCS codes, service type code
Parenteral nutrition	Part B SAF, HCPCS code
Other surgical	Part B SAF, service type code
Other medical	Part B SAF, service type code
Transportation	Part B SAF, HCPCS code
Diagnostic lab/radiology	Part B SAF, CPT code, service type code
Durable medical equipment	Part B SAF, HCPCS codes, service type code
Other Physician/Supplier	Part B SAF, qualifies for no other category

Table a.2
Medicare categories of payment

incurring no Part A or Part B Medicare costs for the entire period are excluded. Medicare payment amounts are linearly prorated for claims that span the start or end date of the study.

In order to express the costs as dollars per year at risk (YAR), total costs during the follow-up period are divided by the length of the follow-up period. Costs per year at risk are calculated by patient category, and stratified by age, gender, race, modality, and diabetic status. Diabetic status is based on the primary disease causing ESRD, as recorded on the Medical Evidence form. A patient with a non-diabetic cause of renal failure may have diabetes, but the disease is not judged to be the cause of ESRD. Patient age is calculated at the study start date, and patients with a missing date of birth are excluded from the analysis.

INTERNATIONAL COMPARISONS · CHAPTER TWELVE

The international dialysis and transplant data for 1997 and 1998 have been collected and processed from the following countries using a data form designed by the USRDS: the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA), the Austria OEDTR, the Canadian Organ Replacement Registry (CORR), the Catalan Renal Registry, the Chilean Renal Registry, the Czech Society of Nephrology, Estonia Tallinn Pelguilinna Hospital, the Finnish Registry for Kidney Diseases, the German QuaSi-Niere, the Greek Hellenic Society of Nephrology, the Hungarian Transplant Registry, the Israeli Renal Registry, the Italian Registry of Dialysis and Transplantation, the Japanese Society of Dialysis Therapy, the Department of Nephrology of Sv. Kiril I Metodij University in Macedonia, St. Luke's Hospital in Malta, the Netherlands Dialysis Registry, the Norwegian National Hospital, the Polish Dialysis Registry, the Scottish Renal Registry, the Singapore Renal Registry, the Swedish Renal Registry, the United Kingdom Transplant Support Service Authority, the Uruguyan Renal Registry, and the USRDS. For all countries but the United States, data prior to 1997 are taken from 1993–1998 Annual Data Reports.

CENSUS POPULATION BASE · REFERENCE SECTION L

Census data in this section, which are used to calculate rates throughout the chapters and Reference Tables, are obtained from the United States Census Bureau. Updated population estimates are available at www.census.gov.

STATISTICAL METHODS
Kaplan-Meier—unadjusted survival probabilities

The Kaplan-Meier method and Greenwood's formula (Kalbfleisch JD, Prentice RL) are used to estimate unadjusted survival probabilities and standard errors in Chapters Six, Seven, and Eight, and Reference Sections I and G. Survival probabilities are expressed as percentages varying from 0 to 100, and estimated by patient age, gender, race, and primary diagnosis.

Cox regression—adjusted survival probabilities

Because of the different mix of patients each year, unadjusted survival probabilities may not be comparable across cohort years. Adjusted analyses, however, make results comparable by reporting probabilities that would have arisen had each incident cohort contained the same distribution of age, gender, race, and primary diagnosis as the reference population. Adjusted survival probabilities are reported in Reference Sections I and G, with incident year 1997 used as the reference cohort, and age, gender, race, and primary diagnosis used as adjusting risk factors. These probabilities are estimated using the Cox regression model (Kalbfleisch JD, Prentice RL). Data are reported separately for all new ESRD patients, new ESRD patients over age 65, and new dialysis, cadaveric transplant, and living donor transplant patients. Graft survival rates are also reported for cadaveric and living donor transplant patients.

For a given set of risk factors X, the adjusted survival probabilities are calculated as $S(t) = [S_0(t)]^{\exp(X'b)}$, where b is the set of estimated covariate effects of X from the Cox regression model, and $S_0(t)$ is the probability surviving to time t for the patients in the baseline population (i.e., the baseline survival probability with $X = 0$). The adjusted survival probabilities are calculated by applying the average age, the percentage of female patients, the percentage of patients in each race, and the percentage of diabetics from the 1997 reference cohort, as listed here:

	All ESRD (1997)	ESRD ≥ 65 (1996-97)	Dialysis (1997)	Transplant (1997)
Size (N)	75,958	75,115	74,249	10,497
Age (years)	60.1	74.1	60.6	43.9
Female (%)	46.9	48.6	47.0	40.4
Black (%)	30.6	23.1	31	24.3
Other Race (%)	7.1	5.9	7.2	6.9
Diabetic (%)	40.9	40.2	41.3	24.7

This process yields estimates of the survival probabilities that would have arisen in each year for "average" patients in the reference population. Since the probabilities in each table are adjusted to the same type of patients, any remaining differences among years are due to factors other than age, gender, race, and primary diagnosis.

Although the adjusted survival probabilities presented in the Annual Data Report can be com-

pared across years, they cannot be matched against results from previous data reports because the definition of the reference population differs for each publication. In addition, these results differ from unadjusted survival probabilities presented elsewhere in the Annual Data Report.

Interval death rates—from survival probabilities

Adjusted one-, two-, and three-to-five year interval death rates, reported for incident cohorts in Chapter Eight and in Tables H.38-40, are estimated from the adjusted survival probabilities at the start and end of the intervals. Such estimation is based on the assumption that the cumulative death rate is the negative natural log transformation of the survival probability. The interval death rate, assuming it is constant, is then estimated as the difference of cumulative death rates at the start and end of the interval divided by the length of the interval.

Similar to the adjusted survival probabilities, the adjusted interval death rates are comparable across years within this ADR. They cannot, however, be compared with previous Annual Data Reports, due to the different reference populations used for adjustment.

Generalized mixed model

The generalized mixed model with log link and Poisson error is used to calculate death rates, first admission (hospitalization) rates, and first transplant rates. While rates are reported only for 1998, three years of prevalent data (1996–1998) are used to improve the stability of the estimates.

Death rates are reported for patient subgroups defined by age (16 groups), gender, race (white, black, Native American, and Asian), and primary diagnosis (diabetes, hypertension, and other). Patients younger than 15 and patients with unknown diagnoses are designated as having a primary diagnosis of "other." First admission rates are reported for similar subgroups, although, under primary diagnosis, patients are classified as either diabetic or non-diabetic. Patients with unknown primary diagnoses or with diagnoses other than diabetes are categorized as non-diabetic. For both death and first admission rates, missing diagnoses and other races are included only in the margins of the tables, and patients with missing age or gender are excluded. Models for death rates are fit for all-dialysis, hemodialysis, CAPD/CCPD, transplant, and all-ESRD patients, while models for first admission rates are fit for all-dialysis, hemodialysis, peritoneal dialysis, and all-ESRD patients. First transplant rates are age-specific only.

The generalized mixed model, which considers both fixed and random effects, is implemented using the SAS macro GLIMMIX (SAS 1996). The Poisson rates for age, gender, race, and diagnosis are estimated using the equation Log (rate) = (fixed effects) + (random effect). Fixed effect variables include year, age, gender, race, and diagnosis, and all two-way interactions between age, gender, race, and diagnosis. Assumed to be independently and identically distributed with a normal distribution, the random effect is the four-way interaction between age, gender, race, and diagnosis. Similar models are fit to obtain marginal rates, i.e., to collapse over gender, the model is fit as above except that the main effect for gender and the two-way interactions including gender are not included, and the random effect is the three-way interaction between age, race, and diagnosis.

Standardized mortality ratio

The standardized mortality ratio (SMR) measures the mortality rate for a subgroup of patients relative to a reference rate.

In Table H.17, for example, SMRs are used to compare death rates for all prevalent dialysis patients in each state to the death rates for U.S. dialysis patients in the USRDS database from 1996 to 1998. The SMR accounts for the age, gender, race, and diabetic status of the prevalent dialysis patients in a population; in this case, the observed death rate in each state is compared to the rate predicted by national death rates for patients with similar characteristics. Mortality rates for the 1998 prevalent cohort (Tables H.2–16), which are adjusted for age, gender, race, and diabetic status, are used as the reference. The expected number of deaths in each stratum of the observed population is calculated by multiplying the stratum-specific standard rates by the length of the follow-up period at risk of the observed patients. The total expected number is then calculated by summing the expected numbers in each group, and the SMR is the ratio of the observed to the expected number of deaths. An SMR of 1.05 for a subgroup indicates that this group has a risk of death approximately five percent higher than that of the reference population.

Standardized first transplantation ratios (STRs) and first admission standardized hospitalization ratios (SHRs), calculated using similar methods, are reported in Tables F.35 and E.13.

Methods for adjusting rates

There are several rate adjustment methods, but only the direct method allows the rates to be com-

pared (Pickle LW, White AA). With this method the adjusted rate is derived by applying the observed category-specific rates to a single standard population, i.e. the adjusted rate is a weighted average of the observed category-specific rates, using as the weight the proportion of each category in the standard population. This method is used to produce some of the incident and prevalent rates in Reference Sections A and B.

Projection model

Projections to 2010 of patient counts (Figures 1.3, 3.3–4) and dollars of Medicare payment (Figure 11.1) are projected using the SAS "forecast" procedure (SAS 1993) on historical data from 1982 onward; this procedure includes extrapolative forecasting methods with time functions (year). We have applied the stepwise autoregressive method, which combines a time-trend regression with an autoregressive model. The number of point prevalent patients is projected using exponential smoothing and trends, a method that produces a time trend forecast allowing the most recent observations to be weighted more than the early observations (Montgomery DC, Johnson LA, Gardiner JS).

Projected values and confidence limits are graphically compared with historical values to examine the accuracy of the projections and to aid in the choice of appropriate models. Residuals from the projection models are examined for the accuracy of the projected values, and goodness-of-fit statistics are obtained.

Mapping methods

Mapping is an important tool for assessing environmental determinants and illustrating spatial patterns and temporal trends. Geographic resolution is enhanced by mapping on the level of small regions, but because this can increase data instability, smoothing methods are needed to stabilize the data. The methods described below have been used in the majority of maps presented in the Annual Data Report (some maps in Chapter One are unsmoothed in order to illustrate the impact of these smoothing methods on the data). Because the distribution of age, gender, and race in a population can affect ESRD incident and prevalent rates, we have also included maps that are adjusted for these variables as well as smoothed.

The majority of disease mapping within the ADR is by Health Service Area (HSA), an approach we have borrowed from the *Atlas of United States Mortality* (Centers for Disease Control and Prevention). Each HSA is a group of counties described by the CDC authors as "an area that is relatively self-contained with respect to hospital care." While these HSAs are defined in terms of access to general health care, the USRDS plans in the future to develop equivalent areas specific to the care of ESRD patients.

In many figures throughout the *Atlas,* data ranges have been standardized to invite comparison across years, modalities, or patient characteristics. In the remaining maps HSAs have been divided equally among five ranges to help readers more easily interpret the information. The mapping software used by the USRDS creates ranges in which the minimum value of one range is the same as the maximum value of the range below it; records containing this exact value are counted only in the higher range.

Throughout the ADR, data in maps and graphs are unadjusted unless noted. HSA-level information is mapped according to the patient's residence, and, because of area size and limitations in the mapping software, data for the District of Columbia, Puerto Rico, and the U.S. Territories are not included in the maps.

METHODS FOR SMOOTHING & ADJUSTING DATA
To smooth data we use both the weighted headbanging method (Tukey PA, Tukey JW; Mungiole M, Pickle LW, Simonson KH) and the Bayesian spatial model (Waller LA, Carlin BP, Xia H, Gelfand AE).

Weighted head-banging method
This method for smoothing data in maps uses weighted medians from geographical neighborhoods. The surrounding neighbors of a given region with value y (to be smoothed) are collected and paired so that they are located geographically in as straight a line as possible, with the region of interest located in the center. The weighted median l of the smaller values in all paired neighbors, and the weighted median u of the larger values, are defined (Mungiole M, Pickle LW, Simonson KH). If y is between l and u a new smoothed value for this region is assigned with value y; otherwise, it is assigned l or u or y, depending on their values and weights. This process is repeated iteratively until the differences between the new smoothed value and its previous value for all regions are within the pre-stated range. The population size of the corresponding region is used as the weight.

With the exception of those maps noted in the discussion of the Bayesian model, this method is used to smooth all maps in the ADR.

Bayesian spatial model

The Bayesian method is a statistical approach which uses the log linear model (Poisson regression model) to fit the incident counts of the regions. The relative risks for the regions follow the Conditional Autoregression (CAR) Normal distribution, and the precision of the relative risks has a Beta distribution (Waller LA, Carlin BP, Xia H, Gelfand AE). This model smoothes the incident counts by borrowing information for each HSA from its neighbors through the relationship defined by CAR; neighbors, in our definition, are HSAs that share a boundary. The exponential offsets in the model are the internally standardized incident counts. When obtaining the standardized incident count, we consider the differences among different age, gender, and race groups. The differences of relative risks are thus caused by the difference of regions (not including the population differences). Smoothed incident rates are obtained by dividing the predicted counts by the corresponding population sizes. If the exponential offsets are changed to the internally standardized incident counts without considering the differences among age, gender and race groups, and the estimated relative risks are kept unchanged, the predicted counts divided by the corresponding population sizes are the smoothed and adjusted incident rates. This method is used to smooth the data in Figures 1.6–9, 1.17, and 1.18.

MAPPING SOFTWARE

All maps were created using MapInfo® 5.5 (MapInfo Corporation, Troy NY).

MISCELLANEOUS
Special studies & data collection forms
Copies of the HCFA Medical Evidence form (2728) and Death Notification Form (2746); of the UNOS Transplant Candidate Registration Form, Kidney Transplant Recipient Registration Form, and Kidney Transplant Recipient Follow-up Form; and of forms used for data collection in past USRDS special studies, are available on the USRDS web site at www.usrds.org.

Captions
Figure captions in the ADR provide descriptions of patient cohorts and data adjustment, along with other general information regarding the figures, and should be read in conjunction with the explanations provided in this Appendix.

FUTURE DIRECTIONS OF THE USRDS
To improve and advance research on end-stage renal disease, the USRDS and its biostatistical team plan to investigate the following issues.

Adjusted survival probabilities
True survival probabilities change with time, in part due to changing cohort attributes. The ADR has traditionally reported adjusted survival probabilities in order to allow comparisons across years. The current method fits separate proportional hazards models to each year and adjusts the predicted survival probabilities using a reference population—for this book, the 1997 incident cohort, with age, gender, race, and primary diagnosis used as adjusting risk factors.

We are currently investigating an alternative approach that fits a single proportional hazards model to several years of data, stratifying on years. In its basic form, this method assumes that the effects of age, gender, race, and primary diagnosis are time constant, thus saving degrees of freedom and allowing stable estimation of survival probabilities for a finer grain of patient subgroups. This model can be generalized to include parametric or non-parametric time trends in covariate effects, approaches which will be investigated as well.

Annual death rates & standard errors
Multiple mixed-effect Poisson regression models are currently fitted to obtain estimated death rates and their standard errors (Reference Section H). In the future, however, we plan to use only one general model, which will be evaluated for its goodness-of-fit, and estimates for all tables will be obtained by appropriately collapsing the estimates based on the Poisson model. We will also investigate the bootstrap method as an alternative for obtaining standard errors. Due to the many possible crude approximations in the fitting of a mixed-effect Poisson model, current standard error estimates may not be accurate. The bootstrap method, a powerful and flexible approach, can take account of the effects of estimating the model parameters on assessment of the uncertainty in resulting estimates.

Spatial smoothing
High-resolution maps require smoothing in order to balance spatial focus with statistical stability. Because hierarchical models are more flexible and effective, the head-banging approach will be eliminated in future analyses, and the Bayesian hierarchical models adapted more fully to the needs of the USRDS. Developmental investigations will include the evaluation of candidate spatial correlation structures (appropriate spatial distance metamers, form of the correlation as a function of spatial distance), of covariates to be used as fixed-effects (for adjustment), and of predictive performance.

Informative censoring

When reported by dialysis modality, survival rates and probabilities may be influenced by informative censoring, i.e. the possibility that the competing risks of transplantation, changing modality, and becoming lost-to-follow-up may censor a patient before the outcome of interest is observed. This is a particularly notable issue when the time-specific death hazard is related to the time-specific censoring hazard, with the degree of impact depending on the strength of the relation. Peritoneal dialysis patients, for example, have a higher likelihood of being transplanted and of changing their dialysis modality than do hemodialysis patients. In an "on treatment" analysis, therefore, they are more likely to be censored before reaching the outcome of interest than hemodialysis patients. The USRDS plans to investigate this issue and the performance of state-of-the-art adjustment techniques (Robins) as they relate to the study of ESRD patients.

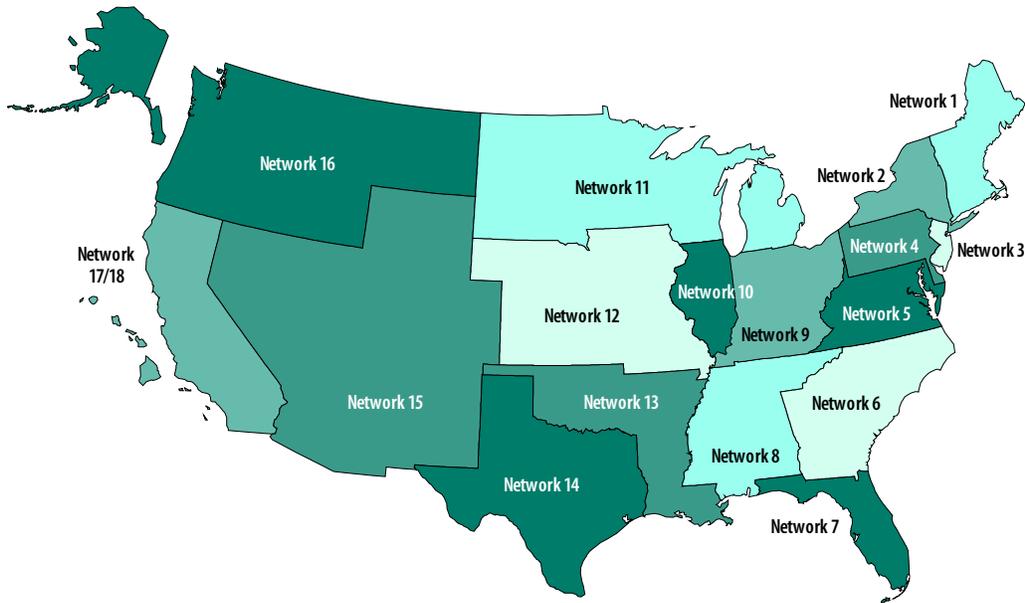### Non-Medicare ('ZZ') patients

As discussed at the beginning of this Appendix, the difficulties of identifying non-Medicare ('ZZ') patients lead to problems in calculating the actual number of patients with ESRD. Each non-Medicare patient is assigned a temporary Medicare Beneficiary Claim number (HIC/BIC) with 'ZZ' in the BIC field; this number is changed to a permanent HIC/BIC once the patient is eligible for Medicare entitlement. It is extremely important, therefore, for the USRDS to link all past services and new events so that records of these patients' medical and treatment history can be accurately maintained and tracked. We plan to collaborate with HCFA to create a consistent methodology for reconciling the records of all non-Medicare patients over the duration of their time on renal replacement therapy.

Dynamic web application

The USRDS currently maintains a Web site (www.usrds.org) with static pages of ESRD patient information that can be viewed and downloaded. To make this system more useful to researchers, and to allow users of the site immediate access to customized datasets, we are creating a dynamic query application system. The more interactive site will include a menu of data request services varying in complexity from overall patient counts to individual rates by state and network, and will include the most recent information available on ESRD patients, updated on a quarterly basis. The initial version of the site, scheduled for release in October 2000, will introduce the fundamental data elements and navigational structure, and it is hoped that the completed site will become a fundamental resource for publishing and sharing information on ESRD patients in the United States.

Appendix B · ESRD Network Definitions

Network 1 · Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

Network 2 · New York

Network 3 · New Jersey, Puerto Rico, Virgin Islands

Network 4 · Delaware, Pennsylvania

Network 5 · Maryland, Virginia, Washington D.C., West Virginia

Network 6 · Georgia, North Carolina, South Carolina

Network 7 · Florida

Network 8 · Alabama, Mississippi, Tennessee

Network 9 · Indiana, Kentucky, Ohio

Network 10 · Illinois

Network 11 · Michigan, Minnesota, North Dakota, South Dakota, Wisconsin

Network 12 · Iowa, Kansas, Missouri, Nebraska

Network 13 · Arkansas, Louisiana, Oklahoma

Network 14 · Texas

Network 15 · Arizona, Colorado, Nevada, New Mexico, Utah, Wyoming

Network 16 · Alaska, Idaho, Montana, Oregon, Washington

Network 17/18 · American Samoa, northern California, Guam, Hawaii, Southern California

Appendix B · ESRD Network Definitions

Network 1
Connecticut, Massachusetts, Maine, New
Hampshire, Rhode Island, Vermont

Network 2
New York

Network 3
New Jersey, Puerto Rico, Virgin Islands

Network 4
Delaware, Pennsylvania

Network 5
Maryland, Virginia, Washington D.C., West
Virginia

Network 6
Georgia, North Carolina, South Carolina

Network 7
Florida

Network 8
Alabama, Mississippi, Tennessee

Network 9
Indiana, Kentucky, Ohio

Network 10
Illinois

Network 11
Michigan, Minnesota, North Dakota, South
Dakota, Wisconsin

Network 12
Iowa, Kansas, Missouri, Nebraska

Network 13
Arkansas, Louisiana, Oklahoma

Network 14
Texas

Network 15
Arizona, Colorado, Nevada, New Mexico, Utah,
Wyoming

Network 16
Alaska, Idaho, Montana, Oregon, Washington

Network 17
American Samoa, northern California, Guam,
Hawaii

Network 18
Southern California
*Because of difficulties in identifying the network
of California patients, Networks 17 and 18 are
combined for the maps included in this ADR,
and are referred to as Network 17/18.*

Appendix C · Bibliography

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A complete and up-to-date list of references on subjects explored in the ADR is best found by using PubMed, the National Library of Medicine's online citation database, at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi.

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Appendix D · Glossary

Some of these definitions have been taken from *Dorland's Illustrated Medical Dictionary* and from the *On-line Medical Dictionary* (http://www.graylab.ac.uk/omd/index.html).

ABO blood group
The major human blood type system; important in the determination of blood donors and blood recipients.

Acquired immunodeficiency syndrome (AIDS)
An epidemic disease caused by the human immunodeficiency retrovirus that leads to immune system failure, infections, and severe weakening of the body.

Adjusted average per capita costs (AAPCC)
An estimate of how much Medicare will spend in a year for an average beneficiary.

Adult polycystic kidney disease (ADPKD)
An inherited disease in which the kidneys contain multiple cysts; can cause chronic renal failure.

Angioplasty
A procedure in which a balloon catheter is inserted into a blocked or narrowed vessel in order to re-open the vessel and allow normal flow through it.

Atherosclerotic heart disease (ASHD)
A disease of the arteries of the heart, characterized by a thickening and/or loss of elasticity of the arterial walls.

Blood urea nitrogen (BUN)
A by-product resulting from the break-down of amino acids and endogenous and injested protein.

Body mass index (BMI)
A measure of height to weight ratio. BMI = Weight (kg) / Height (M^2).

Conventional hemodialysis
Dialysis therapy using small surface area hemodialyzers that are made with conventional membranes and have low solute clearance and low fluid removal capabilities. This type of dialysis does not require the use of delivery systems with ultrafiltration control.

Coronary artery disease (CAD)
A disease that causes narrowing or occlusion of the arteries surrounding the heart.

Continuous ambulatory peritoneal dialysis (CAPD)
A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged by using gravity to fill and empty the cavity four to five times each day.

Continuous cycler-assisted peritoneal dialysis (CCPD)
A type of dialysis in which the abdominal cavity is filled and emptied of dialysate using an automated cycler machine.

Cancer
A disease that causes abnormal cell growth.

Cardiac arrest
A complete cessation of cardiac activity.

Cardiomyopathy
A general diagnostic term indicating a primary non-inflammatory disease of the heart muscle.

Cerebrovascular disease (CVD)
A disease that causes narrowing or occlusion of the arteries supplying the brain. Cerebral vascular accidents (CVA) and transient ischemic attacks (TIA) are two events that can result from this condition.

Common Working File (CWF) System
The Medicare Part A and Part B benefit coordination and claims validation system. Under the CWF, HCFA maintains both institutional and physician supplier claims-level data. CWF claims records are the data source for most claims and utilization files used by the USRDS.

Congestive heart failure (CHF)
A condition caused by ineffective pumping of the heart and subsequent fluid accumulation in the lungs.

Chronic obstructive pulmonary disease (COPD)
A progressive disease characterized by coughing, wheezing, or difficulty in breathing.

Clinical Performance Measures Project
Formerly the Core Indicator Project. A project cooperatively managed by HCFA and the ESRD Renal Networks that maintains a clinical database of key elements related to the quality of dialysis care. These elements are used as indicators in quality improvement initiatives.

Creatinine
A waste product of protein metabolism found in the urine and often used to evaluate kidney function. Abnormally high creatinine levels are seen in individuals with kidney failure or kidney insufficiency.

Creatinine clearance
Used as an indicator to predict the onset of uremia, which develops when the creatinine clearance falls below 10 ml/minute/1.73M^2.

Death Notification Form (HCFA-2746)
A form submitted following the death of an ESRD patient, and containing basic patient demographic information in addition to information on the primary cause of death.

Diabetes mellitus, insulin dependent
A condition in which insulin is necessary to regulate abnormally high levels of glucose (sugar) in the blood.

Diagnosis Related Groups (DRGs)
Used by Medicare to determine payment for inpatient hospital stays; based on diagnosis, age, gender, and complications.

Dialysis Outcomes Quality Initiative (DOQI)
Established in 1995 by the National Kidney Foundation to improve patient outcomes and survival by providing recommendations for optimal clinical practices in the areas of dialysis adequacy, vascular access, and anemia.

Dialysis and transplant center
A facility that combines the functions of a dialysis center and a transplant center.

End-stage renal disease (ESRD)
A condition in which an individual's kidney function is not adequate to support life.

Erythropoietin (EPO)
A hormone secreted chiefly by the adult kidney; acts on the bone marrow to stimulate red cell production.

Free-standing unit
A dialysis unit licensed to provide only outpatient and home maintenance dialysis; sometimes referred to as an independent unit.

Glomerular filtration rate (GFR)
The rate at which the kidneys remove waste products from the blood.

Health Care Financing Administration (HCFA)
The federal agency that administers the Medicare, Medicaid, and State Childrens' Health insurance programs.

Health Plan Employee Data Information Set (HEDIS® 3.0)
Established by the National Committee for Quality Assurance, HEDIS® 3.0 is a set of standardized performance measures established to aid consumers in the comparison of managed healthcare plans.

Hepatitis
An inflammation of the liver that may be caused by a viral infection, poisons, or the use of alcohol or other drugs. The disease takes on many forms which include Hepatitis A, a form of the virus usually transmitted by contaminated food or water; Hepatitis B, more serious than Hepatitis A and transmitted through blood and body fluids; Hepatitis C, also transmitted through blood and body fluids; and Hepatitis D, which causes symptoms only when an individual is already infected with the Hepatitis B virus.

High-efficiency dialysis
Dialysis therapy that is provided using hemodialyzers with larger surface areas than conventional hemodialyzers. Enhanced solute clearance is achieved through increased blood flow rates of 300 to 400 milliliters per minute, allowing treatment times to be reduced to approximately three hours.

High-flux dialysis
Dialysis therapy provided using hemodialyzers with synthetic membranes and large surface areas that, combined with high blood and dialysate flow rates, allow enhanced solute clearance and fluid removal. Delivery systems with ultrafiltration control are required for this therapy.

Hospital center unit
A dialysis unit located in or attached to a hospital and licensed to furnish inpatient and outpatient dialysis plus diagnostic, therapeutic and rehabilitative services.

Hospital facility unit
A dialysis unit attached to or located in a hospital and licensed to provide outpatient dialysis services directly to ESRD patients.

Incident patient
A patient starting renal replacement therapy for end-stage renal disease during the calendar year. This definition excludes persons with acute renal failure, persons with chronic renal failure who die before receiving treatment for ESRD, and persons whose ESRD treatments are not reported through HCFA.

Ischemic heart disease (ISHD)
A disease of the heart evidenced by a lowered oxygen supply to the heart tissue caused by occlusion or narrowing of the arteries supplying the heart muscle.

Kt/V
An indicator of the dose of dialysis received per treatment. Dose is calculated by multiplying the urea clearance (K) times the treatment duration (t) and dividing by the urea distribution (V). The urea distribution volume is approximately equal to the volume of total body water.

Medical Evidence Form (HCFA-2728)
A form which provides source data about ESRD patients, including information on patient demographics, primary cause of renal disease, comorbidity, laboratory values, dialysis treatment, transplant, dialysis training, employment status, and initial insurance coverage.

Myocardial infarction (MI)
An event which causes injury to the heart muscle, also called a heart attack.

National Claims History (NCH) 100% Nearline File
A file which contains all Common Working File (CWF) Part A (provider) and Part B (physician/ supplier) Medicare claims and adjusted claims information.

Period prevalent patient
A patient reported as receiving treatment for ESRD at some point during a period of time, usually six months or a year. Patients may die during the period or be point prevalent at the end of the period.

Peripheral vascular disease (PVD)
A progressive disease that causes narrowing or occlusion of the arteries supplying the extremities of the body.

Peritoneal dialysis
A type of dialysis in which fluid (dialysate) is introduced into the abdominal cavity and uremic toxins are removed across the peritoneum.

Point prevalent patient
A patient reported as receiving treatment for ESRD on a particular day of the calendar year (i.e. December 31st).

Program Medical Management and Information System for ESRD and Renal Beneficiary and Utilization System /Program. (PMMIS/REBUS)
The major source of data for the USRDS. This HCFA file incorporates data from the Medical Evidence Form (HCFA- 2728), the Death Notification Form (HCFA- 2746), the Medicare Enrollment Database, HCFA Paid Claims Records, and the UNOS Transplant Database.

Prevalent patient
A patient receiving renal replacement therapy or having a functioning kidney transplant (regardless of when the transplant was performed). This definition excludes persons with acute renal failure, persons with chronic renal failure who die before receiving treatment for ESRD, and persons whose ESRD treatments are not reported through HCFA.

Pyrogen
A substance which is bacterial in nature and capable of producing low grade fevers.

Pyrogen reaction
A condition in which a patient who was afebrile prior to dialysis experiences a low-grade fever during dialysis, caused by pyrogens in the dialysate fluid. The fever disappears after dialysis is over, distinguishing the reaction from an actual infection.

REMIS/PMMIS
HCFA's Renal Management Information System (REMIS)/Program Management and Medical Information System (PMMIS) is currently under development and is anticipated to replace the existing Renal Beneficiary and Utilization System (REBUS/PMMIS) in the summer of 2001. The first release, which will incorporate most of the capabilities, interfaces, and processes of the current system, will further support and improve

data collection, validation, and analysis, and will provide timely and accurate information to the ESRD Networks, dialysis facilities, transplant centers, and research organizations. This new system will significantly improve support for ESRD program analysis, policy development, and epidemiological research.

Renal network
Established in 1978 as a provider oversight system that assures ESRD patients are provided immediate access to treatment and that the care they receive meets the highest quality standards.

Reuse
A process through which a hemodialyzer is cleaned and disinfected, allowing it to be used multiple times on the same patient.

Reuse germicide
A chemical used during the reuse process to disinfect the hemodialyzer.

SIMS
HCFA's Standard Information Management System (SIMS), which became operational at the beginning of 2000, supports the HCFA reporting requirements and business processes of the ESRD Networks; provides communication and data exchange links among the Networks, HCFA and other segments of the renal community to support quality improvement activities relating to the treatment of ESRD; supplies standard core data functionality for previous Network data systems; and provides improved electronic communication capabilities, data standardization, and information management tools.

Standard Analytical Files (SAFs)
HCFA files which contain final action Medicare Part A claims data. SAFs are comprised of eight files: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and 5% Sample Beneficiary.

Standardized hospitalization ratio (SHR)
Used to compare hospitalization rates for a selected group of patients by computing the ratio of the group's observed hospitalization rate to the expected hospitalization rate for the national ESRD population.

Standardized mortality ratio (SMR)
Used to compare dialysis patient mortality rates from year to year. Mortality rates for a subgroup of patients are compared to a set of reference rates, with adjustments for age, race, gender, and diabetes as a cause of ESRD.

Standardized transplantation ratio (STR)
Used to compare the transplant rate of a subgroup of patients to the national transplant rate.

Transplant center
Ah ospital unit licensed to provide transplantation and other medical and surgical specialty services for the care of kidney transplant patients, including inpatient dialysis furnished directly or under arrangement.

United Network for Organ Sharing (UNOS)
A private, non-profit organization that maintains the organ transplant list for the nation and coordinates the matching and distribution of organs to patients awaiting transplant.

Urea reduction ration (URR)
A means of measuring dialysis dose by calculating the change in BUN over the course of a dialysis treatment. URR = (pre-dialysis – post-dialysis BUN) / pre-dialysis BUN * 100.

Valvular heart disease (VHD)
A condition in which a patient has one or more abnormal heart valves.

The VISION project
HCFA's Vital Information System to Improve Outcomes in Nephrology (VISION) will provide customized data entry and reporting for the nearly 3,700 U.S. dialysis facilities, and will capture and securely communicate ESRD patient and provider data collected via the HCFA-2728, HCFA-2746, HCFA-2744, HCFA-820 and HCFA-821 forms for subsequent electronic reporting to the ESRD Network Organizations and HCFA. This project is designed to meet the goals of the Hemodialysis Facilities of Achievement Project (FOA) as outlined in the Federal Register (April 29, 1997) and is further mandated by the Balanced Budget Act (BBA) of 1997 to be implemented by the beginning of the year 2001.

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Appendix F · USRDS Products & Services

Table f.1 describes the products and services provided by the USRDS to support ESRD research and the work of the renal community.

The entire ADR is available on the Internet at www.usrds.org; included on the site as well are color slides of figures, a PDF file of the *Researcher's Guide*, and USRDS contact information. In the future the site will allow users to create customized data sets and regional maps. Data on site use are presented in Figure f.1.

Dialysis unit-specific SMR/SHR reports

From 1996 through 1999 the USRDS produced more than 2,300 unit-specific reports each year, compiling information about the patients treated in each dialysis facility, and including Standardized Mortality Ratios (SMRs) and Standardized Hospitalization Ratios (SHRs). These reports are now being produced by the Kidney Epidemiology and Cost Center at the University of Michigan (www.med.umich.edu/kidney).

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 these requests can be answered by providing 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, 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.

DATA FILES AVAILABLE TO RESEARCHERS

The Coordinating Center maintains a set of Standard Analysis Files (SAFs) to meet diverse research needs and to provide easy access to the data used in the ADR. The SAFs were introduced in 1994, and at the same time NIDDK began awarding a new group of 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 files provided to researchers were custom files created for a specific research project. Since the introduction of the SAFs, however, custom files are generally limited to cases in which a researcher provides a file of patients to be matched with the USRDS database.

The Core SAF CD-ROM contains basic patient data and is needed in order to use any of the other SAFs. Included on this CD are each patient's treatment history, limited transplant data, and all data from the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFs need only this CD. Full transplant information is provided on a separate CD that contains detailed transplant and transplant follow-up data collected by HCFA and UNOS. Data on hospital

Figure f.1
Visits to the USRDS website
per week

Tracked since October 1999, the beginning of the transition period to the new USRDS contractor.
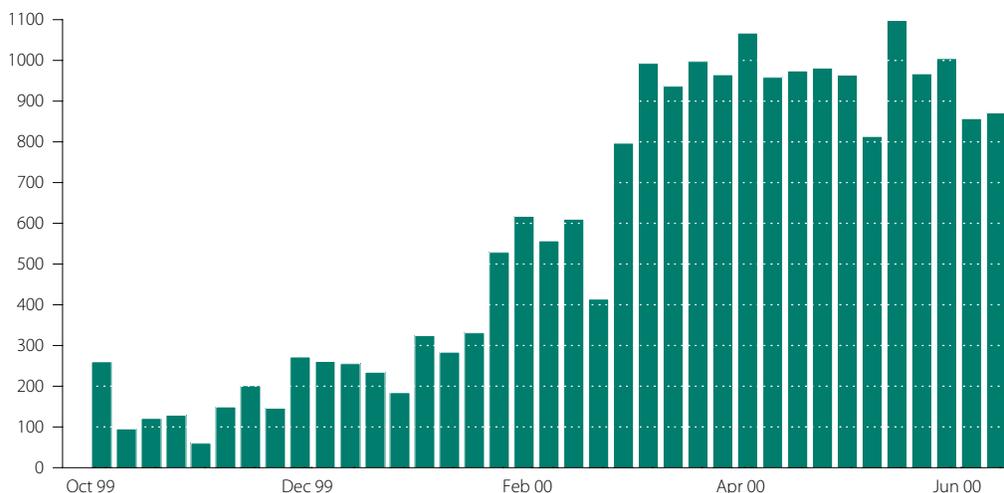
inpatient stays is found on the hospitalization CD, and Medicare payment data is available either in a full set or by individual year. See Table f.2.

STANDARD ANALYSIS FILES (SAFs)

The use of the SAFs is governed by the USRDS "Policy on Data Release for Investigator-Initiated Research," which appears later in this Appendix. A researcher's proposal must be approved by the USRDS Project Officer, and the researcher must sign the USRDS "Agreement for Release of Data" (see last page of Appendix). Prices for these files are listed in Table f.3.

Most SAFs provide patient-specific data. All patient identifiers (name, address, Social Security number, Medicare beneficiary ID, etc.) are removed from the files or are encrypted, but confidentiality of the data is still a serious concern. The "Agreement for Release of Data" therefore includes restrictions on the use and disposition of the SAFs. The SAFs do include an encrypted ID number to allow patient data from multiple SAFs to be merged when needed.

Core Standard Analysis File CD-ROM

The USRDS has carried out a number of Special Studies. Topics for these studies are approved by the NIDDK, with recommendations from HCFA, the USRDS Scientific Advisory Committee, the ESRD Networks, and the Renal Community Council. For each study, design and sampling plans were developed, samples were selected, and data collection forms and instructions were drafted, tested, and finalized. The main studies are summarized below and detailed in the *Researcher's Guide*.

This CD contains the most frequently used SAFs, including those from the USRDS Special Studies, and is needed for use of the Transplant CD, the Hospital CD, or any CD based on Medicare claims data. The files included on this Core CD are as follows (and are also listed in Table f.2):

PATIENT
Contains one record per patient in the USRDS database, and gives basic demographic and ESRD-related data.

RESIDENCE
Provides a longitudinal record, to ZIP code level, of each patient's place of residence.

Reports & guides	
Annual Data Reports	Available from the National Kidney and Urologic Diseases Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560, 301.654.4415, nkudic@info.niddk.nih.gov. Material from the ADR will also be published in the American Journal of Kidney Disease.
Researcher's Guide to the USRDS Database	Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files, and is the basic reference for researchers who use USRDS data files.
ADR CD-ROM	Contains the text and graphics of the ADR, supplementary data tables, color Powerpoint slides, and *The Researcher's Guide*.
Internet site: www.usrds.org	
	Contains PDF files of the chapters, reference tables, and Researcher's Guide; Powerpoint slides of Atlas figures and USRDS conference presentations; ASCII files of the data tables; notices regarding current news and analyses; links to related Internet sites; and email addresses for contacting the USRDS.
Requests for data	
2-hour data requests	Questions and data requests that are not answered directly by the ADR can be addressed to the Coordinating Center; those that require less than two hours of staff time to fulfill will be processed without charge.
Standard Analysis Files (SAFs)	These data files provide patient-specific data from the USRDS database to support ESRD research. An hourly rate of $72.70 will be assessed for time spent on the request, and users must sign a data release agreement with NIDDK.
Custom data files	Custom files can be created by the Coordinating Center for projects requiring data other than that provided in the Standard Analytical Files. An hourly rate of $72.70 will be assessed for time spent on the request, and users must sign a data release agreement with NIDDK.
Papers, abstracts, & publications	
	Most USRDS research studies result in published papers or presentations at professional meetings. Figures from presentations can be found on the website, while published abstracts and papers can be found in the relevant journals.

Table f.1
USRDS products & services
for ESRD researchers & the general renal community

Products are provided without charge except as noted.

TREATMENT HISTORY
Also referred to as the Modality Sequence file; contains a new record for each patient at each change in treatment modality or dialysis provider.

MEDICAL EVIDENCE
Contains full data from the 1995 version of the HCFA Chronic Renal Disease Medical Evidence Form (2728), the source of data about the primary disease causing renal failure and the start date of chronic renal dialysis. In April 1995 a new version of the form went into use that included data on comorbidity, employment status, lab values at start of dialysis, and Hispanic ethnicity.

TRANSPLANT
Contains basic data for all transplants, including graft failure date (detailed transplant data are contained on a separate CD).

TRANSPLANT WAITING LIST
Includes one record for each patient in the USRDS database who also can be identified in the UNOS transplant waiting list file, and contains only the date on which the patient was first placed on the waiting list. Because of the complexity and variability of the patterns of patient movement on and off the waiting list, we have not attempted to derive more complex indicators of transplant waiting list experience.

DIALYSIS MORBIDITY AND MORTALITY STUDY
The DMMS was an observational study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected for a random sample of U.S. dialysis patients, using dialysis records. Data was collected on 6,000 ESRD patients in each of Waves 1, 3, and 4 and 4,500 patients in Wave 2, a total of 22,500 patients over three years. Waves 1, 3, and 4 are each historical prospective studies in which data were collected for patients receiving in-center hemodialysis on December 31, 1993. Data were abstracted from the patient's medical record and the patient was followed from December 31, 1993 through the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996.

CASE MIX ADEQUACY STUDY
The objectives of the USRDS Case Mix Adequacy Study of Dialysis 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 at different dialysis doses
♦ assess how this relationship is affected by dialyzer reuse
♦ assess the impact of different dialysis membranes on patient morbidity and mortality

The study consisted of two groups of patients: an incident sample of ESRD patients who began hemodialysis during 1990, and a prevalent sample of hemodialysis patients with onset of ESRD prior to 1990. A total of 7,096 patients from 523 dialysis units were included, with approximately 3,300 patients having 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
The objectives of the USRDS Case Mix Severity Study were to
♦ estimate the correlation of comorbidity and other factors existing at the onset of ESRD to subsequent 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 using different treatment modalities
♦ compare relative mortality rates by treatment modality, adjusting for selected comorbid conditions and other factors

Data were collected on 5,255 patients incident in 1986–87 at 328 dialysis units nationwide.

PEDIATRIC GROWTH & DEVELOPMENT
The objectives of the USRDS Pediatric ESRD Growth and Development Study were to
♦ establish a baseline for assessing the relation of pediatric ESRD patient growth and sexual maturation to modality
♦ establish a prototype for the ongoing collection of pediatric data

All patients who were prevalent in 1990 and born after December 31, 1970 were included in the study, a total of 3,067 patients at 548 dialysis units.

CAPD & PERITONITIS STUDY
The USRDS CAPD and Peritonitis Rates 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, up to a maximum of 14 patients

File Name	Unit of Observation	Uses
Patient	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	Patient. One record for each period a patient spends on one modality.	Modality distribution and treatment patterns. Treatment modality at a point in time and changes in modality over time.
Medical Evidence	One record for each 2728 form filed.	Comorbid conditions, patient status at start of ESRD.
Transplant	Transplant. Can have multiple transplants for one patient.	Transplant and transplant outcome analyses.
Transplant Waiting List	One record for each patient ever on waiting list. Only data item is date first listed.	Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to waiting list.
Dialysis Mortality and Morbidity (DMMS) (USRDS Special Study)	Wave 1: 5,670 patients; Wave 2: 4,024 patients; Wave 3: 11,142 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.
Case Mix Adequacy (USRDS Special Study)	7,096 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values.
Case Mix Severity (USRDS Special Study)	5,255 patients.	Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values.
Pediatric Growth and Development (USRDS Special Study)	3,067 patients.	Growth, development, and other issues relating to pediatric ESRD Patients.
CAPD Peritonitis (USRDS Special Study)	3,385 patients.	CAPD and peritonitis.
Facility	One record for each year facility operated.	Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.
Facility Cost Reports	One record per facility per year (1993-1995 only).	Costs and staffing of dialysis facilities.
Dialyzers	Information on dialyzer characteristics; to be matched to patient dialyzer information in other files on CD	Relation of dialyzer characteristics to patient outcomes.
CLMCODES	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 the SAFs.	This is a SAS format library to format values of categorical variables.

Table f.2
Contents of the USRDS Core Standard Analysis File CD-ROM

This file is needed in order to use any of the other Standard Analysis Files. The data are provided on a single CD-ROM.

per dialysis unit. All units providing CAPD training participated in the study. The sample contains 3,385 patients from 706 units.

FACILITY
The HCFA ESRD Annual 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. Because of this link, geographic variables that could be used to identify facilities have been deleted. The survey period is January 1 through December 31.

FACILITY COST REPORTS
The HCFA hospital and independent facility cost reports for the years 1989–1995 are available as Standard Analysis Files. All geographic variables have been deleted in order to ensure confidentiality. The file may be linked with the Facility SAF

by using the USRDS provider ID; geographic analyses at less than a regional or ESRD Network level, however, are not possible. Because there has been minimal use of these files, data for additional years will be added only if there is sufficient demand.

DIALYZERS
The Case Mix Severity, Case Mix Adequacy, and DMMS Special Studies all collected information on the manufacturer and model of the dialyzer used for a patient at a specific time. The SAFs for these studies describe the dialyzer only through a code, which must be matched to information in the Dialyzer file to find the manufacture and model of the dialyzer along with characteristics such as membrane type and clearance. The data in this file come from published sources available at the time of the study. We believe these data

accurately represent the dialyzer characteristics, but they should be used with caution.

Transplant CD

Due to changes in data collection sources over the years, data pertaining to transplants are now presented in six separate SAFs. The first two files are included on the Core CD, and the remaining four are included on the separate Transplant CD.

- ♦ TX: includes minimum details about all transplants from all sources
- ♦ TXWAIT: contains one record for each patient in the USRDS database who also can be identified on the kidney transplant waiting list maintained by the United Network for Organ Sharing (UNOS); the only variables are the date of first listing and USRDS_ID
- ♦ TXHCFA: includes transplant details collected by HCFA's PMMIS system for 1976–93
- ♦ TXUNOS: includes transplant details collected by UNOS, currently the main source of transplant data for the USRDS, for the years since 1987
- ♦ TXFUHCFA: includes transplant follow-up reports collected by HCFA prior to 1988. Reports are completed at discharge, six months, each year post-transplant, and graft failure
- ♦ TXFUUNOS: includes transplant follow-up reports collected by UNOS since 1988.

The tables in Section F of the Reference Tables are produced primarily from the main and UNOS transplant files.

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

The HCFA and UNOS transplant data files overlap for 1987–1993, and some Medical Evidence Forms and institutional claims records indicate transplants that are not included in either the HCFA or the UNOS file. As reported in Appendix A, the following procedure is used to resolve the conflicts among the four sources and create the transplant SAF. All UNOS transplants are first accepted into the file, with all HCFA transplants prior to 1987 accepted next. HCFA transplants from 1987–1993 are then accepted if there is no transplant in the file for that patient within 30 days of the HCFA transplant (it is common for the transplant dates to differ by one day between these two sources). Finally, transplants indicated on the Medical Evidence 2728 Form are accepted if no transplant is listed for that patient within 30 days of the Medical Evidence transplant date.

Hospital CD

Hospitalization inpatient data from the USRDS database are a subset of the data in the Institutional Claims file. No payment or cost variables are included on this CD. This CD is for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays but who do not need payment data.

Dialysis Morbidity and Mortality CD

This CD contains files from the Dialysis Morbidity and Mortality Study and extracts data from all other SAFs for the patients in this study. All data on Medicare payments for these patients are included.

Case Mix Adequacy CD

This CD contains the Case Mix Adequacy Special Study file and extracts data from all other SAFs for the patients in this study. All data on Medicare payments for these patients are included. Along with analyses related to the study itself, this file is useful for developing analyses that will later be run on the full Medicare payments files.

CDs of Medicare payment data

Medicare payment data on institutional claims are available for pre-1989 through 1998, while data on physician/supplier claims are available for 1991 through 1998. These data sets can be purchased by year.

Institutional claims consist of all Part A claims (Inpatient, Outpatient, Skilled Nursing Facility, Home Health Agency, and Hospice) and some Part B claims, notably outpatient dialysis. All physician/supplier claims are Medicare Part B; these claims account for about 80 percent of the claims but only 20 percent of the dollars.

The structure and content of the two types of claims are different, as are the files derived from them. Institutional claims are provided in two file types: the Institutional Claims file, which indicates the type of claim, the dollar amounts, the type of dialysis involved (if any), and the dates of service; and the Institutional Claims Detail file, which contains details such as DRG codes, diagnoses, and procedures. Many analyses will 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.

Starting in 1999, we will add data for one year of claims with each annual update. To ensure that we have complete historical data for patients who have newly entered the database, we also will update the preceding four years for institutional claims and the preceding one year for physician/supplier claims. We will continue to evaluate how many prior years of claims should be updated each year. Note that the claims files contain all claims for a given patient, including claims for dates before the patient's first ESRD service date. This allows for at least a limited analysis of medical care in the pre-ESRD period.

File media and formats

The SAFs are provided on CD-ROM disks as SAS (Statistical Analysis System) files, and can be used directly by SAS on any 486 or Pentium PC with a CD-ROM reader.

A SAS format was chosen for the USRDS SAFs because it is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, from mainframes to PCs, and it is almost universally available on university computer systems. The USRDS SAFs take full advantage of the program's ability to incorporate a large amount of documentation into the file.

Researchers who require a different program format or a medium other than CD-ROM will need to arrange for the conversion themselves. The USRDS also may be able to convert files to alternative formats or media, but the cost will be substantially greater.

What is needed to use the SAFs
♦ Computer: A 486 or Pentium PC. The USRDS CC currently uses Pentium Pro 200s and Pentium II 450s. Smaller runs have been done on 486/100 PCs. The files can be converted to SAS transport format for use on any computer with access to SAS.
♦ CD-ROM drive: Any PC with a CD-ROM drive should be able to read the SAF CDs.
♦ Disk storage: Between 10 and 600 megabytes are needed for use of the Core CD,

Table f.3
Prices for USRDS Standard Analysis Files
on CD-ROM

Standard Analytical File CD-ROMs

CD	Description	CDs	Price
Core CD	The Core CD is needed in order to use any of the other CDs.	1	$500
Transplant CD	Detailed transplant data from HCFA and UNOS.	1	$100
Hospital CD	The Hospital CD is derived from the Institutional Claims and Institutional Claims Details CDs. It contains diagnosis and surgical procedure codes for each stay but does not include the cost data from the Institutional Claims records.	1	$100
DMMS claims CD set	The DMMS claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. The data from the Special Study data collection forms are included on the Core CD.	3	$300
Case Mix Adequacy claims CD	The Case Mix Adequacy Claims CD set contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Case Mix Adequacy Special Study. The data from the Special Study data collection forms are included	1	$100

Medicare payment data

Years	Institutional Claims			Physician/Supplier Claims	
	Claims CDs	Details CDs	Price	CDs	Price
Before 1989*	1	1	$200		
1989	1	1	$200		
1990	1	1	$200		
1991	1	2	$300	4	$400
1992	1	2	$300	4	$400
1993	1	2	$300	4	$400
1994	1	2	$300	5	$500
1995	1	3	$400	5	$500
1996	1	3	$400	6	$600
1997	1	3	$400	7	$700
1998	1	3	$400	7	$700

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

depending on the files being used. The data on each CD require from 550 to 650 megabytes of disk storage. Keep in mind that you will need space for temporary work files and for the files you create.

◆ Software: SAS. Files converted to SAS transport format can be used by SPSS.

◆ People with software experience: The SAF documentation provides some of the basics of loading the files into SAS and using them, but further work with the files requires SAS experience.

Cost
The price of the files covers the cost of reproducing and shipping the file and its documentation, the administrative cost of handling the sales, and the cost of technical support to researchers. Checks must be made payable to the *Minneapolis Medical Research Foundation.* These prices are subject to change.

Documentation
The *Researcher's Guide to the USRDS Database* provides most of the documentation of the SAFs. It includes a codebook of variables on the files, copies of the data collection forms used by the Special Studies, and a chapter on techniques for using the SAFs in SAS. Copies of the *Researcher's Guide* may be requested on the USRDS website or by phone.

ACKNOWLEDGMENT FOR USE OF USRDS DATA
Publications that use USRDS data should include an acknowledgment and the following 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 & PROCEDURE
Since the Standard Analysis Files and custom data files contain confidential, patient-specific data, release of these files requires the approval process described here. Investigators may contact the USRDS Project Officer at the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to discuss their requests before preparing a written proposal (see the list of USRDS contacts in the Forward). To request and use USRDS data files, investigators should do the following:

◆ Provide the USRDS Project Officer (PO) with a detailed description of the proposed investigation (see Table f.4). The project summary must include goals, background data, an in-depth description of the study design and analytic methodology, and resources available for completing the project, and may be the project description from a grant or other funding application. The proposed project must comply with the Privacy Act of 1974, and the project summary should provide enough information to enable assessment of compliance. Guidelines for adherence to the Privacy Act are contained in the USRDS "Agreement for Release of Data," provided at the end of this Appendix.

◆ Indicate which USRDS Standard Analysis Files will be needed. If the USRDS Standard Analysis Files cannot meet the requirements of the proposed research, the proposal must specify precisely which data

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Table f.4
Suggested outline for research proposals using USRDS data

I	Research topic title and submission date
II	Background information

III	Study design
	    Objectives
	    Hypothesis
	    Analytical methods

IV	Data being requested List Standard Analytical Files needed, or specify fields needed in custom data file

V	Investigator information
	For Principal Investigator and co-authors, supply:
	    Name
	    Affiliation
	    Address
	    Phone number
	    Fax number
	    Email address

Submit to:
Lawrence Y.C. Agodoa, M.D.
NIDDK
Democracy 2
6707 Democracy Blvd
Bethesda, MD 20892-5458
Phone 301.594.7717
Fax 301.480.3510
agodoal@extra.niddk.nih.gov

elements are needed, and investigators must budget for a substantially higher cost.

♦ If the project is approved, return a signed copy of the USRDS "Agreement for Release of Data" to the PO. The investigator and the 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 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 USRDS CC. The process of reviewing the data request, generating the data file, and releasing the data will take the CC approximately three months.

When both a copy of the signed "Agreement for Release of Data" and payment for the files have been received by the USRDS CC, the CC will prepare the files and documentation and will send them to the investigator.

Any reports or articles resulting from use of the USRDS data must be submitted to the PO prior to submission for publication for review 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 with the Act 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 the released data must contain the standard acknowledgement and disclaimer presented above. The investigator is re-

quested to send copies of all final publications resulting from this research to both the PO and the USRDS 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 investigator 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 the identity of individual patients, providers, or facilities from the data in the Standard Analysis Files, the data in these files are considered confidential. The USRDS "Agreement for Release of Data" contains a number of both 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 the Health Care Financing Administration.

Use of these data to identify and/or contact patients, facilities, or providers on the files is prohibited both 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, however, be provided under the USRDS contract, although USRDS CC personnel may participate in analyses funded by other sources.

Standard Analysis Files or other data files from USRDS Special Studies will become available one year after the data have been collected, edited, and entered into the database.

United States Renal Data System (USRDS)
Agreement for Release of Data

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. 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.   Authorized representatives of the PO and/or of HCFA will, upon request, be granted access to premises where data in this file are kept for the purpose of inspecting security procedures and arrangements.

_____

Recipient typed name, title, and organization

_____

Recipient telephone number

_____

Recipient signature & date

_____

Contractor typed name, title, and organization, as appropriate

_____

Contractor telephone number

_____

Contractor signature & date

Lawrence Y. C. Agodoa, M.D., NIDDK, NIH or
Camille A. Jones, M.D., NIDDK, NIH
USRDS Project Officer typed name & organization

_____

USRDS Project Officer signature & date

Revised June 1994