

United States Renal Data System

National Institutes of Health
National Institute of Diabetes
and Digestive and Kidney Diseases
Division of Kidney, Urologic,
and Hematologic Diseases

Researcher's Guide to the USRDS Database



2011 ADR Edition

PREFACE

The Researcher's Guide is intended for investigators within and outside of the USRDS Coordinating Center who wish to undertake research projects using data from the USRDS database. The Guide places particular emphasis on the USRDS Standard Analysis Files (SAFs), the primary means by which USRDS data are available for use. The Researcher's Guide includes the information needed to select and use the appropriate SAFs for the intended project.

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Publications based upon USRDS data reported here or supplied upon request must include this citation 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.

In titles, the superscript number or letter refers to the chapter, the following number or letter identifies the figure or table, and the italicized roman numeral identifies the volume. Citations should separate chapter, number, and volume by periods — i.e., 3.1.ii refers to Chapter Three, Figure 1, Volume Two.

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INTRODUCTION

This Researcher's Guide to the USRDS Database is designed to assist those interested in using USRDS data to perform their own analyses. The following material is addressed:

- Getting Started. Examples of datasets and steps to help start constructing analyses.
- Section 1 ESRD Data Sources and the Database System. General descriptions of data available to the USRDS and the processes involved in their creation.
- Section 2 ESRD Patients. Methods used to define ESRD patients.
- Section 3 Treatment History. Methods used to create a treatment history for each patient.
- Section 4 Payer History. Methods for analyzing insurance payer information.
- Section 5 Transplant Process and Outcomes. Methods for analyzing transplant patient data.
- Section 6 Morbidity and Hospitalization. Methods for analyzing morbidity and hospitalization data.
- Section 7 Survival and Mortality. Methods for analyzing survival and mortality data.
- Section 8 Providers. Description of the Facility database, which contains data on US dialysis facilities.
- Section 9 Disease-Based Cohort. Description of the DM/CKD/CHF cohort finder files by year, using the 5% General Medicare Claims data and ESRD patient demographic information.

The appendices include:

- Data products and descriptions.
- Detailed discussion of the Medicare Claims.
- Statistical methods used by the USRDS.
- Data files available to researchers, with data dictionaries.
- Data formatting information.
- Lists of data forms available at www.usrds.org: CMS, UNOS, and CDC ESRD data forms; Special Study ESRD data forms; DMMS Waves I, II, III, IV, and FACS study forms.
- A glossary.

HISTORY OF THE USRDS

The first USRDS contract was awarded in 1988 to the Urban Institute in Washington, DC, which worked in conjunction with investigators at the University of Michigan at Ann Arbor. Under a new contract created in 1999, the USRDS was divided into a Coordinating Center (CC) and four Special Studies Centers (SSCs), each of which continues to operate under the direction of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH).

The CC and Cardiovascular SSC contracts were awarded in 1999 to the Minneapolis Medical Research Foundation, and are directed by Allan Collins MD and Charles Herzog MD, respectively. The Economic SSC was awarded to the University of Iowa under the direction of Lawrence Hunsicker MD. In 2000, the Nutrition SSC was awarded to the University of California at San Francisco, directed by Glenn Chertow MD, and the Rehabilitation SSC to Emory University, directed by Nancy Kutner PhD.

In early 2007, the CC and the SSCs entered a new seven-year contract period. The Cardiovascular, Nutrition, and Quality of Life/Rehabilitation SSCs remain as before, and the activities of the Economic SSC are included with those of the CC.

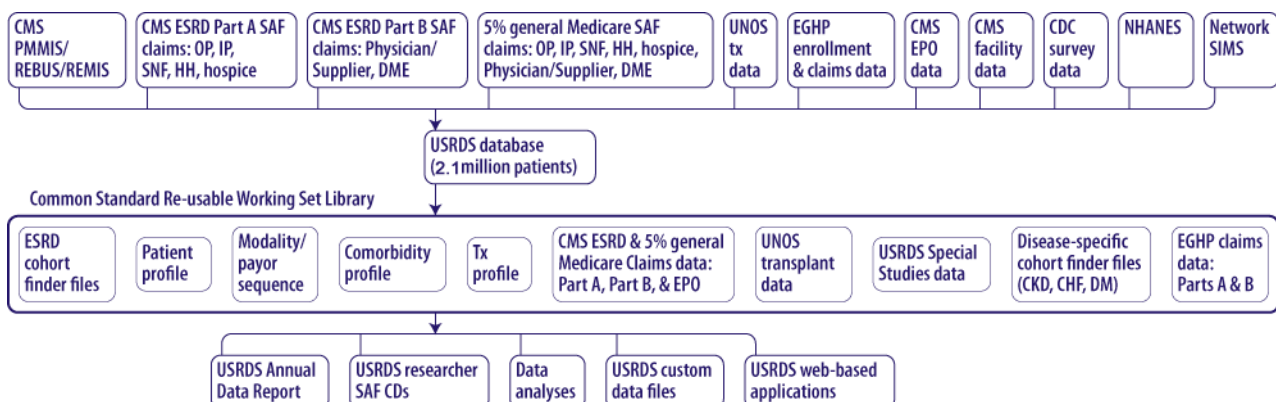
USRDS WEBSITE: WWW.USRDS.ORG

The USRDS website provides users with access to PDF files of the printed Annual Data Report (ADR), Excel files of the Reference Tables and the data underlying the graphs and state maps, and PowerPoint slides of USRDS presentations and ADR figures. Because of the size and complexity of the ADR files, downloading time for large portions of the book may be substantial.

RENDER

The USRDS Renal Data Extraction and Referencing (RENDER) System is an online data querying application accessible through the USRDS website, allowing access to a wealth of information regarding ESRD in the United States. It quickly returns an accurate table of data or an interactive map based on the user's query specifications. Tables can be copied into

Structure of the USRDS Database



a spreadsheet application on the user's computer for further manipulation and investigation, and map images can be copied or saved to local applications. A database file download of the mapped data, which can be opened or imported by most spreadsheet applications, is also available.

The RenDER System allows easy access to some of the most frequently requested data. While the ADR thoroughly covers many ESRD statistics, it cannot reasonably contain the more detailed tables often requested by researchers. RenDER allows users to "drill down" into the data behind many of the tables published in the ADR, allowing cross interactions among various demographic fields. For more information, visit <http://www.usrds.org> to access the RenDER tutorial.

WHAT'S NEW IN 2011

TXUNOS_KI/TXUNOS_KP FILES

Added 46 variables, see What's New 2011 text file on the Core SAF.

TXFUNOS_KI/TXFUNOS_KP FILES

Added 10 variables, see What's New 2011 text file on the Core SAF.

SECTION 11 - MEDICARE PRESCRIPTION DRUG

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Voluntary Prescription Drug Benefit Program (Part D). Effective January 1, 2006, Part D is an optional prescription drug benefit for individuals who are entitled to Medicare benefits under Part A or enrolled in Medicare benefits under Part B. The data from the first few months of 2006, when the benefit was very new, may not be complete, and should be interpreted with caution. See Section-11 for more information.

Year-to-Year Comparison of Number of Records in USRDS Standard Analysis Files (SAF)

SAF	2003	2004	2005	2006	2007	2008	2009	2010	2011
PATIENTS	1,367,309	1,516,251	1,600,693	1,698,706	1,801,298	1,910,161	2,024,425	2,138,876	2,260,986
RESIDENC	2,006,657	2,215,953	2,388,928	2,587,007	2,791,903	2,968,884	3,189,860	3,404,854	3,699,752
MEDEVID	669,587	786,297	896,447	1,164,686	1,147,657 [†]	1,265,566	1,385,589	1,505,285	1,630,270
RXHIST	9,745,224	10,630,350	10,733,455	11,658,208	12,533,612	13,532,743	11,626,297	11,741,390	12,392,072
FACILITY	51,038	55,547	60,138	64,870	69,764	74,831	80,071	85,572	91,332
TX	245,821	256,315	272,277	289,533	308,002	324,476	343,051	360,297	378,536
TXWAIT	243,651	313,446 [*]	347,564 [*]	378,262 [*]	405,165 [*]	437,256	474,348	513,028	546,239

^{*}TXWAIT is the total number of observations between Waitlist_ki and Waitlist_kp.

[†]MEDEVID is the total number of observations between Medevid95 and Medevid05.

Getting Started



INTRODUCTION

Work on a typical study consists of determining the study variables, selecting the variables from the datasets in which they are stored, merging the selected variables into one or more datasets for analysis, and finally performing the statistical analyses of the data. This section offers first-time users of the USRDS SAF datasets examples of this process.

All USRDS data are stored in SAS datasets that were created in the Windows environment and can be used only on the Windows operating system. Using the datasets on another computer platform requires moving and converting the data to SAS datasets for that platform. Using another data analysis system requires a conversion to a format compatible with that system.

The examples use basic SAS code. New SAS users should take classes, consult colleagues, or otherwise become familiar with the SAS system. Regardless of SAS experience, all users must know:

- The location of the SAS dataset.
- The location of the SAS catalog of FORMATS.

In the examples, the datasets and the FORMAT catalog are assumed to be in the same directory, namely, C:\SAF. Two SAS statements are needed to point to this information:

```
LIBNAME saf 'c:\saf'; * Directory location of the data;  
LIBNAME LIBRARY 'c:\saf'; * Directory location of format catalog;
```

Always assume that these two statements are required in all code. See *Data Formatting*, page 251, for additional information. The datasets and the format catalog may be in different directories.

BASIC SAS USE

The SAS CONTENTS procedure generates a list of all variables in the dataset and a label associated with each. The information in this label is usually an adequate indication of whether the variable will be of use; however, PROC CONTENTS is always the best method for obtaining the latest variable list, as last minute updates may not be reflected in the printed documentation. (See *Data Descriptions*, page 58.)

Note: In the following program examples, SAS keywords are in uppercase text. Datasets, comments, and variables in which SAS will perform operations are in lowercase text.

To determine the contents of the PATIENTS dataset, or any dataset, use the following code (remember the requirement of the two LIBNAMEs):

```
PROC CONTENTS DATA=saf.patients;  
  TITLE1 'DATASET: saf.patients';  
RUN;
```

To see what the data look like, use the SAS procedure PRINT to list all observations of the dataset.

```
PROC PRINT data=saf.patients;  
  TITLE1 'DATASET: saf.patients';  
RUN;
```

A dataset can have thousands of observations. To print the first 500, use the following code:

```
PROC PRINT DATA=saf.patients (OBS=500);  
  TITLE1 'DATASET: saf.patients';  
RUN;
```

To print a group of observations other than the first N observations, use the following code; this example prints observations 1500-2000, inclusive.

```
PROC PRINT DATA=saf.patients (FIRSTOBS=1500 OBS=2000);  
  TITLE1 'DATASET: saf.patients';  
RUN;
```

A dataset can contain hundreds of variables. Print selected variables using the 'VAR' statement:

```
PROC PRINT DATA=saf.patients (OBS=500);  
  VAR usrds_id sex race incyear;  
  TITLE1 'DATASET: saf.patients';  
RUN;
```

There are two parts to the 'data=' expression. The first is the directory location, defined by the LIBNAME, and the second is the dataset name. The first part (directory location) implies that the dataset is permanent. Later examples do not include

this part, and the datasets you create will disappear when you leave SAS. To permanently save a dataset, the first part of the expression must be included.

SAS FORMATS FOR USRDS DATA

Information in a dataset may be coded. Thus, the variable GENDER may have the values F, M, or U, where F is the coded value for female, M is the value for male, and U is the value for unknown. Using one character instead of several saves disk storage, but because the coded values are not always easy for users to understand, a format is assigned to translate them. Many variables have been assigned formats by the USRDS.

In each program, SAS must be told where these formats are. Assume that the format catalog is in the directory C:\SAF. Then the following SAS LIBNAME makes the formats accessible to your SAS programs.

```
LIBNAME LIBRARY 'c:\saf'; * Directory location of format catalog;
```

The SAS keyword LIBRARY must be used because it tells SAS to look for formats in the directory, C:\SAF. Other methods can accomplish this, but not as easily. To bypass the use of formats, use the following two SAS statements before running any SAS procedures:

```
LIBNAME LIBRARY;  
OPTIONS NOFMterr
```

Bypassing the use of formats allows you to see raw data instead of the formatted values, which may be useful when you need to write SAS IF statements to control the flow of your program in a SAS data step. See *Data Formatting* for a tabular list of the formats with their coded values.

COMMENT LINES

Comment lines in the SAS code look like this:

```
/* Comment line */  
* Comment line;
```

These refer to any descriptive comment. The use of comments is optional but strongly recommended.

THE SAF DIRECTORY

Throughout this section SAF has been used as the permanent SAS LIBNAME. It is assumed that all of the USRDS SAF datasets and catalogs have been placed in this directory. If the datasets have been placed in the WINDOWS directory C:\SAF, then the following SAS LIBNAME would point to the SAF datasets.

```
LIBNAME saf 'c:\saf';
```

Note: The datasets may be loaded into any directory, with the directory in the LIBNAME changed accordingly.

```
LIBNAME core_cd 'C:\USRDS\CORE_CD\SAF';  
LIBNAME hosp_cd 'C:\USRDS\HOSP_CD\SAF';  
LIBNAME in_cd 'C:\USRDS\IN\SAF';  
LIBNAME cpm_cd 'C:\USRDS\CPM\SAF';  
LIBNAME library 'C:\USRDS\CORE_CD\SAF';
```

EXAMPLES

EXAMPLE 1: INCIDENT COHORT

Create a patient cohort of incident patients from 1990 to 1999 to use in the examples that follow.

```
DATA inc90_99 (KEEP=usrds_id esrddate inc_year rxgroup);  
    SET core_cd.rxhist60;  
    BY usrds_id begdate;  
  
    FORMAT esrddate MMDDYY10.;
```

IF (FIRST.usrds_id) AND
(MDY(1,1,1990) <= begdate <= MDY(12,31,1999));

```
    esrddate = begdate;  
    inc_year = YEAR(esrddate);  
RUN;
```

```

PROC FREQ DATA=inc90_99;
TABLES inc_year;
TITLE 'Frequency Distribution of Incident Patients 1990 - 1999: Rxhist60 file';
RUN;

```

```

PROC FREQ DATA=inc90_99;
TABLE inc_year * rxgroup;
TITLE 'Frequency Distribution of Incident Patients 90-99 by Modality';
RUN;

```

EXAMPLE 2: INCIDENT PATIENTS DISTRIBUTION BY DEMOGRAPHIC DATA

```

PROC FREQ DATA=core_cd.patients;
TABLE incagec sex race disgrp;
WHERE (incyear = 1999);
TITLE 'Frequency Distribution of 1999 Incident Patients by Demographic Data';
RUN;

```

EXAMPLE 3: POINT PREVALENT COHORT

Create a patient cohort of point prevalent dialysis patients who were alive on January 1, 1999.

```

DATA pre_99 (KEEP=usrds_id rxgroup);
    SET core_cd.rxhist60;
        BY usrds_id begdate;

    IF (begdate <= MDY(1,1,1999)) AND
        ((enddate = .) OR (enddate >= MDY(1,1,1999))) AND
            (rxgroup NOT IN ('D' 'X')) THEN
        OUTPUT;
RUN;

PROC FREQ DATA=pre_99;
TABLE rxgroup;
TITLE 'Frequency Distribution of 1-1-99 Point Prevalent Patients by Modality';
RUN;

```

EXAMPLE 4: 1995 INCIDENT PATIENT SURVIVAL RATES (KAPLAN MEIER)

Calculate 5-year survival rates of 1995 incident dialysis patients using Kaplan Meier method.

```

DATA inc_95_s;
    MERGE inc90_99          (IN = x1)
          core_cd.patients (IN = x2 KEEP=usrds_id died tx1 date);
        BY usrds_id;

    IF x1 AND x2;

    * Extract only 1995 incident dialysis patients.;
    IF (inc_year = 1995) AND (rxgroup ^= 'T');

    * Calculate the survival time (in month) of each incident patient.;
    t = (MIN(died, tx1 date, MDY(12,31,1999)) - esrddate + 1) / 30.4375;
    IF (t < 0) THEN t = 0;

    * Determine whether the patient is censored.;
    c = (MIN(died, tx1 date, MDY(12,31,1999)) = died);
RUN;

```

```

PROC LIFETEST DATA=inc_95_s METHOD=KM NOTABLE PLOTS=(s) OUTSURV=surv95;
TIME t*c(0);
TITLE '1995 Incident Dialysis Patients 5-Year Survival Rates';
RUN;

```

EXAMPLE 5: MERGE WITH MEDICAL EVIDENCE FILE (CMS 2728)

Demonstrate a way to extract comorbid conditions for a pre-defined study cohort from the Medical Evidence file.

```

DATA medevid;
    SET core_cd.medevid (KEEP=usrds_id cancer cararr carfail
                        cva diabins diabprim dysrhyt hyper ihd
                        mi pulmon pvasc);
    BY usrds_id;

    IF (FIRST.usrds_id);
RUN;

DATA me_2728;
    MERGE medevid      (IN=x1)
          core_cd.patients (IN=x2 KEEP=usrds_id died tx1 date);
    BY usrds_id;

    IF x1 AND x2;
RUN;

DATA inc98_me;
    MERGE inc90_99 (IN=x1 WHERE=(inc_year = 1998))
          me_2728 (IN=x2);
    BY usrds_id;

    IF x1 AND x2;
RUN;

```

EXAMPLE 6 : 1998 INCIDENT PATIENT SURVIVAL RATES (KAPLAN MEIER)

Show a survival rate calculation stratified by patient comorbid condition.

```

DATA inc_98_s;
    SET inc98_me;
    BY usrds_id;

    IF (UPCASE(cancer) IN ('1' '2' 'Y' 'N'));

    IF (UPCASE(cancer) IN ('1' 'Y')) THEN
        can = 1;
    ELSE
        can = 0;

    * Calculate the survival time (in month) of each incident patient.;
    t = (MIN(died, MDY(12,31,1999)) - esrddate + 1) / 30.4375;
    IF (t < 0) THEN t = 0;

    * Determine whether the patient is censored.;
    c = (MIN(died, MDY(12,31,1999)) = died);
RUN;

PROC LIFETEST DATA=inc_98_s METHOD=KM NOTABLE PLOTS=(s) OUTSURV=surv98;
TIME t*c(0);
STRATA can;
TITLE '1998 Incident Dialysis Patients 2-Year Survival Rates by co-morbidity';

```

```
RUN;
```

EXAMPLE 7: WAITLIST ACCESS RATE

Determine waitlist access rate to December 31, 1999, of 1998 incident dialysis patients who were registered in the transplant waitlist.

```
DATA txwait;
    set core_cd.waitseq_ki core_cd.waitseq_kp;
run;

PROC SORT data=txwait;
    by usrds_id;
RUN;
```

```
DATA inc_98_w;
    MERGE inc98_me      (IN=x1)
          txwait (IN=x2 KEEP=usrds_id begin);
    BY usrds_id;

    IF x1;

    * Extract only 1998 incident dialysis patients.;
    IF (rxgroup ^= 'T');

    * Make sure all dialysis patients who were not put on the waitlist;
    * get to be censored at the end of follow-up period.;
    IF x1 AND ^x2 THEN begin = MDY(1,1,2000);

    * Calculate the waitlist access time (in month) of each incident patient.;
    t = (MIN(begin, died, MDY(12,31,1999)) - esrddate + 1) / 30.4375;
    IF (t < 0) THEN t = 0;

    * Determine whether the patient is censored.;
    c = (MIN(begin, died, MDY(12,31,1999)) = begin);
RUN;
```

```
PROC LIFETEST DATA=inc_98_w METHOD=KM NOTABLE PLOTS=(s) OUTSURV=wait98;
    TIME t*c(0);
    TITLE '1998 Incident Dialysis Patients Waitlist Access Rates';
RUN;
```

EXAMPLE 8 : TOTAL ADMISSION RATE

Create the patient driver for hospitalization rates, or use previously created file.

```
DATA driver;
    SET core_cd.patients (WHERE=(incyear=1998));

    sfu = first_se + 91;
    efu = MIN(died, first_se+455);

    IF (died NE .) AND (died < sfu) THEN DELETE;
    FORMAT sfu efu MMDDYY10.;
RUN;
```

```
PROC SORT DATA=driver;
    BY usrds_id;
RUN;
```

Link to hospitalization file; gather hospitalizations within period of interest (includes only patients with

hospitalizations).

```
PROC SQL;
    CREATE TABLE hospdat AS
    SELECT * FROM driver a, hosp_cd.hosp (KEEP=usrds_id clm_from clm_thru) b
    WHERE a.usrds_id=b.usrds_id AND a.sfu<=clm_thru AND a.efu>=b.clm_from;
QUIT;

PROC SORT DATA=hospdat;
    BY usrds_id clm_from clm_thru;
RUN;

DATA rate;
    SET hospdat;
        BY usrds_id;

    RETAIN n_hos n_adm exptime rt_adm;

    IF FIRST.usrds_id THEN
    DO;
        /* INITIALIZE RETAIN VARIABLES FOR EACH USRDS_ID */
        n_hos=0;
        n_adm=0;
        exptime=0;
        rt_adm=0;
    END;

    * FOR HOSPITALIZATIONS OVERLAPPING STUDY START ONLY COUNT;
    * HOSPITAL DAYS, NOT AS ADMISSION;
    IF (clm_from<sfu<=clm_thru) THEN n_hos=n_hos+(MIN(clm_thru,efu)-sfu+1);

    * IF WITHIN STUDY PERIOD COUNT DAYS (UP TO STUDY END) AND
    * ADMISSIONS;
    ELSE IF (sfu<=clm_from<=efu) THEN
    DO;
        n_hos=n_hos+(MIN(clm_thru,efu)-clm_from);
        n_adm=n_adm+1;
    END;

    IF LAST.usrds_id THEN
    DO;
        /* OUTPUT ONE RECORD PER USRDS_ID */
        exptime=(efu-sfu-n_hos)/365;
        IF exptime>0 then rt_adm=n_adm*1000/exptime;
        ELSE IF (exptime<0) THEN exptime=0;
        OUTPUT;
    END;
RUN;
```

Combine result with original incident sample to include patients without hospitalizations.

```
DATA rateall;
    MERGE driver (IN=x1) rate (IN=x2);
        BY usrds_id;

    IF x2=0 THEN
    DO;
        n_hos=0;
        n_adm=0;
        rt_adm=0;
        exptime=(efu-sfu+1)/365;
    END;
```

```

        IF x1 THEN OUTPUT;
    RUN;

```

Calculate mean admissions per 1000 patient-years by gender.

```

PROC TABULATE DATA=rateall;
VAR rt_adm;
CLASS sex;
WEIGHT exptime;
TABLE sex="rt_adm="*mean*f=8.1;
KEYLABEL mean=";
TITLE1 'Total Admission rates per 1,000 patient years';
RUN;

```

EXAMPLE 9: FIRST ADMISSION RATE

Using hospitalization data from above, calculate first hospitalization rates.

```

DATA frate;
    SET hospdat;
        BY usrds_id;

    RETAIN n_adm exptime rt_adm flag;

    IF FIRST.usrds_id THEN
    DO;                /* INITIALIZE RETAIN VARIABLES FOR EACH USRDS_ID */
        n_adm=0;
        exptime=0;
        rt_adm=0;
        flag=0;
    END;

    * FOR HOSPITALIZATIONS OVERLAPPING STUDY START SET EXPOSURE
    * TIME TO ZERO TO EXCLUDE FROM RATE;
    IF (clm_from<=sfu<=clm_thru) THEN
    DO;
        exptime=0;
        flag=1;
    END;

    * IF WITHIN STUDY PERIOD COUNT ADMISSION AND CALCULATE
    * EXPOSURE TIME;
    ELSE IF (sfu<clm_from<=efu) AND flag=0 THEN
    DO;
        exptime=(clm_from-sfu+1)/365;
        n_adm=n_adm+1;
        flag=1;
    END;

    IF LAST.usrds_id THEN /* OUTPUT ONE RECORD PER USRDS_ID */
    DO;
        IF exptime>0 then rt_fadm=n_adm*1000/exptime;
        OUTPUT;
    END;
RUN;

```

Combine result with original indicent sample to include patients without hospitalizations.

```

DATA frateall;
    MERGE driver (IN=x1) frate (IN=x2);

```

```

        BY usrds_id;

    IF x2=0 THEN
    DO;
        n_adm=0;
        rt_fadm=0;
        exptime=(efu-sfu+1)/365;
    END;
    IF x1 THEN OUTPUT;
RUN;

```

Calculate mean admissions per 1000 patient-years by gender.

```

PROC TABULATE DATA=frateall;
VAR rt_fadm;
CLASS sex;
WEIGHT exptime;
TABLE sex="*rt_fadm="*mean*f=8.1;
KEYLABEL mean=";
TITLE1 'First Admission rates per 1,000 patient years';
RUN;

```

EXAMPLE 10: CREATE A PATIENT COHORT OF 1998 MEDICARE INCIDENT PATIENTS

Create the 1998 incident patient file.

```

DATA inc_98;
    SET core_cd.patients (WHERE=(incyear=1998));
RUN;

```

Find Medicare payer status at first service date;

```

DATA first_payer;
    SET core_cd.payhist;
    BY usrds_id begdate;
    IF first.usrds_id;
RUN;

```

Combine payer information with original incident cohort and limit to patients with Medicare payers at first service date;

```

PROC SORT DATA=inc_98;
    BY usrds_id;
RUN;
DATA medicare_inc_98;
    MERGE inc_98    (IN=x1)
           first_payer (IN=x2 KEEP=usrds_id mcare payer dualelig);
    BY usrds_id;
    IF x1 AND mcare = 'Y';
RUN;

```


Sections 1-11



SECTION 1 • ESRD DATA AND THE USRDS DATABASE SYSTEM

The main objective of the USRDS CC is to use all relevant ESRD data to create an integrated and consistent database system for outcomes research. The CC database includes ESRD patient demographic and diagnosis data, biochemical values, dialysis claims, and information on treatment history, hospitalization events, and physician/supplier services.

DATA SOURCES

The data used by the USRDS CC originates from CMS, UNOS, the CDC, the ESRD Networks, and the USRDS special studies.

PMMIS/REBUS/REMIS DATABASE SYSTEM

The major source of ESRD patient information for the USRDS is the CMS Renal Beneficiary and Utilization System (REBUS), which was adopted in 1995 as the On-Line Transaction Processing (OLTP) system from its predecessor, the Program Management and Medical Information System (PMMIS) database. The PMMIS/REBUS database contains demographic, diagnosis, and treatment history information for all Medicare beneficiaries with ESRD. The database has been expanded to include non-Medicare patients, as discussed below.

Having advanced its database technology, CMS transformed the REBUS database into an Oracle relational database system, called the Renal Management Information System (REMIS), in the fall of 2003. This database included all patients who were alive and had ESRD as of January 1, 1995, or were incident after this date. This approach was adopted from the procedure used to create the Networks' Standard Information Management System (SIMS) database. However, because the REMIS system as it existed did not include legacy patients for longitudinal studies, CMS expanded it in the fall of 2004 to include all ESRD patients.

CMS regularly updates the PMMIS/REBUS/REMIS database, using the Medicare Enrollment Database (EDB), Medicare inpatient and outpatient claims, the UNOS transplant database, the ESRD Medical Evidence Report (CMS-2728) provided by the ESRD Networks, the ESRD Death Notification (CMS-2746) obtained from renal providers, and the ESRD Networks' SIMS database. CMS has established data integrity rules to ensure accurate identification of patients in the SIMS and CMS databases. Each ESRD patient (new and old) is identified with a unique patient identification number common to both databases, guaranteeing that data for all patients are consistently managed over time.

STANDARD INFORMATION MANAGEMENT SYSTEM (SIMS) DATABASE

The USRDS CC continues to collaborate with CMS and the ESRD Networks to address data-tracking issues related to non-Medicare ESRD patients. Working solely with data from the Medical Evidence Report, the CC could establish the first ESRD service data for these patients, but could not consistently generate a detailed treatment history. The integration of the SIMS event data into the CC database, however, allows for the examination of issues that arise in the non-Medicare ESRD population, such as the large and growing number of

lost-to-follow-up patients, and for the gathering of data on patients for whom no data were previously available on initial modality or death.

CMS MEDICAL EVIDENCE REPORT (FORM CMS-2728)

The CMS Medical Evidence Report is completed by the renal provider for each new ESRD patient, and is sent to CMS through the ESRD Networks. It establishes Medicare eligibility for individuals who previously were not Medicare beneficiaries, reclassifies previously eligible Medicare beneficiaries as ESRD patients, and provides demographic and diagnostic information for all new ESRD patients regardless of Medicare entitlement.

Before 1995, dialysis units and transplant centers were required to file the Medical Evidence Report only for Medicare-eligible patients. The form was revised in 1995, and providers were subsequently required to complete it for all new ESRD patients regardless of Medicare eligibility status. The 1995 revised form also included new fields for comorbid conditions, employment status, expanded race categories, ethnicity, and biochemical data at ESRD onset.

Only 1 Medical Evidence Report is expected for each ESRD patient for the entire ESRD treatment period; however, multiple forms may be filed for patients whose insurance eligibility changes due to therapy changes. For example, transplant patients with functioning grafts after 3 years lose Medicare benefits if ESRD was the sole qualification for Medicare eligibility. If such a patient experiences graft failure and returns to dialysis, a second Medical Evidence Report must be filed to reestablish Medicare eligibility. Dialysis patients who discontinue dialysis for more than 12 months also lose Medicare ESRD benefits. If such a patient returns to dialysis or undergoes kidney transplant, a second Medical Evidence Report must be filed to reestablish Medicare eligibility.

REVISED MEDICAL EVIDENCE REPORT (FORM CMS-2728)

Another revision of the Medical Evidence Report was introduced in May 2005. It includes new data collection methods and new variables. It allows users to specify whether the Medicare registration is initial (new ESRD patient), re-entitlement (reinstating Medicare entitlement after a lapse due to no claims being filed for 12 or more months or a functioning graft for 36 or more months), or supplemental (updating missing or incorrect information). This clarifies the intended use of the form without recourse to the "First Regular Dialysis Start Date," and helps chronicle the historical sequence of multiple forms for the same patient.

Multiple races can be specified. CMS provides a single variable containing a concatenated string representing all selected race codes with binary digits (0s and 1s). This string must be decoded to determine patient race (or races). Similar formatting requirements apply to information on comorbid conditions, medical coverage, and reasons for not informing patients of transplant options. Because the required programming is substantial, we include, for each of these 4 data categories, the original variable with the concatenated string and a new variable with the decoded values (i.e., information noted on form CMS-2728). However, the decoded multiple

race values must be presented as “Other” or “Multiple race” to maintain consistency with the legacy race information.

Data fields for nephrologist care, dietitian care, and access type were also added, with their respective time intervals relative to ESRD onset. Data on the laboratory values hematocrit, creatinine clearance, BUN, and urea clearance are no longer collected. Added laboratory values are HbA1c and lipid profiles (TC, LDL, and HDL cholesterol, and TG). Additional fields relate to whether patients were informed of transplant options and if not why not, and donor type. Comorbid conditions and primary diagnoses were also added. Please see “What’s New” (page 5) for a detailed description of new and dropped variables. Both the 2005 and 1995 versions of the form are provided in the USRDS Core SAF data set and are available for download in PDF format from the USRDS website: <http://www.usrds.org/reference.htm>.

CMS ESRD DEATH NOTIFICATION (FORM CMS-2746)

Like the Medical Evidence Report, the Death Notification form is data rich, and CMS requires renal providers to complete it. Providers usually have 45 days to report ESRD death events to their respective ESRD Networks, including information about place, time, and cause of death. Data are thus available to the USRDS CC for research on cause-specific mortality outcomes.

CMS MEDICARE ENROLLMENT DATABASE (EDB)

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

CMS PAID CLAIMS RECORDS

Inpatient transplant and outpatient dialysis claims records are sometimes used to identify new ESRD patients for whom no Medical Evidence Report has been filed. These patients are most likely to be non-Medicare patients or beneficiaries already receiving Medicare because of age or disability. They will eventually be entered into the PMMIS/REBUS database, and hence the USRDS database, through the claims records. For patients without Medical Evidence reports, these claims are the only reliable information from which to determine first ESRD service dates. These paid claims records, however, only supplement and do not replace other sources of information on incidence and prevalence. Bills for some Medicare-eligible patients may not be submitted to or paid by Medicare. These patients are MSP patients covered by private insurance, HMOs, Medicaid, or the Department of Veterans Affairs (DVA).

UNOS TRANSPLANT DATABASE

CMS began collecting data on all Medicare kidney transplants in the early 1980s. In 1988, UNOS was created to provide a national system for allocating donor organs and to maintain a centralized data depository for organ transplants. UNOS also began collecting data on all transplants. These two col-

lection efforts were consolidated in 1994, and UNOS became the sole source of data on transplant donors and recipients.

The CMS and UNOS transplant data files overlap for 1988–1993, and some patients with Medical Evidence Reports indicating 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:

- Before 1988, all transplant events found in CMS PMMIS/REBUS Transplant files are used.
- After 1994, all transplant events found in UNOS files are used.
- Between 1988 and 1993, all transplant events found in UNOS files are used, and additional transplant events from the CMS PMMIS/REBUS Transplant file are used only if they occur at least 30 days on either side of a previously accepted transplant event.
- Additionally, transplant events associated with reported incident transplant patients from the Medical Evidence Report are used if they occur at least 30 days on either side of a previously accepted transplant event.
- Each transplant event found in the Transplant file of the USRDS SAF Core CD is thus a unique event derived from the UNOS, CMS PMMIS/REBUS Transplant, and Medical Evidence record files.

CMS ESRD STANDARD ANALYTICAL FILES (SAFs)

The CMS 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 100% SAF claims:

- Inpatient
- Outpatient
- Skilled nursing facility (SNF)
- Home health agency (HHA)
- Hospice

For Part-B physician/supplier 100% SAF claims:

- Physician/supplier
- Durable medical equipment (DME)

CMS SAFs are updated each quarter through June of the next year, when the annual files are finalized. Datasets for the current year are created six months into the year and updated quarterly until finalized at 18 months, after which files are frozen and will not include late arriving claims. Annual files are thus approximately 98% complete. The USRDS 2010 ADR includes all claims up to December 31, 2008. Patient-specific demographic and diagnosis information, however, includes data as recent as October 2009.

CMS 5% GENERAL MEDICARE SAFS

The 5% general Medicare SAFs have the same structure and data elements as the ESRD 100% SAFs, but they were extracted from the general Medicare billing database as a random sample of 5% of the entire Medicare population. Because the sample is selected using the last two digits of patient Social Security Numbers, one should expect to see the same group of Medicare beneficiaries represented in the

5% SAFs each year, with exceptions for death, disenrollment, and new Medicare entitlements.

The USRDS CC uses these files to conduct studies on Healthy People 2010 objectives, comparing preventive care and other non-ESRD disease treatments in general Medicare and ESRD patients. In addition, these files are used to create DM/CKD/CHF cohort finder files.

CLINICAL PERFORMANCE MEASURES PROJECT (CPM)

CMS developed the ESRD CPM (formerly the ESRD Core Indicators Project) to collect information on the quality of care provided to dialysis patients. The data originate from surveys completed by primary care facilities, and focus on dialysis adequacy measures, anemia management, and vascular access use. Additional clinical parameters such as albumin are also available. These data have been collected annually since 1994, using a random sample of patients aged 18 years and older, alive and on dialysis at the end of each calendar year; on average, about 8500 in-center hemodialysis patients and 1500 peritoneal dialysis patients are surveyed each year. Data collection for all pediatric patients aged 12 to 17 years began in 2000, and in 2002 was expanded to all in-center hemodialysis patients aged younger than 18 years. Starting in 2005, all PD patients in the US have been sampled for the pediatric PD data collection. The USRDS CC, in collaboration with CMS, provides CPM/USRDS merged data to the general research community.

CMS DIALYSIS FACILITY COMPARE DATA

The USRDS uses the CMS Dialysis Facility Compare data to define chain and ownership information for each renal facility; before the 2003 ADR, similar data were extracted from the Independent Renal Facility Cost Report (CMS 265-94).

CMS ANNUAL FACILITY SURVEY (AFS)

In addition to the CMS ESRD databases, independent ESRD patient counts are available from the CMS Annual Facility Survey, which all Medicare-approved 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 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 used to complement the CMS patient-specific records.

CDC NATIONAL SURVEILLANCE DATA

From 1993-2002, the CDC used its 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. Because the CDC terminated this program in 2003, the last surveillance report is for 2002 data. The CDC did not conduct a survey in 1998.

DIALYSIS MORBIDITY AND MORTALITY STUDY (DMMS)

The DMMS was an observational study that collected data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance for a random sample of US dialysis patients, using dialysis records. Data were collected on 6000 ESRD patients in each of Waves I, III, and IV, and 4500 patients in Wave II, a total of 22,500 patients over three years. Waves I, III, and IV are each historical prospective studies in which data were collected for patients receiving in-center hemodialysis on December 31, 1993. Data were abstracted from patient medical records, and each patient was followed from December 31, 1993, through the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave II is a true prospective study of incident hemodialysis and peritoneal dialysis patients for 1996 and some incident patients entering the ESRD program in the first part of the 1997 calendar year.

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 ESRD onset before 1990. A total of 7096 patients from 523 dialysis units were included, the pre- and post-BUN values needed to calculate delivered dialysis dose were present for approximately 3300 patients. 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 this study were to:

- estimate the correlation of comorbidity and other factors present at ESRD onset with subsequent mortality and hospitalization rates, 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 for 5255 incident patients in 1986 and 1987 at 328 dialysis units nationwide.

PEDIATRIC GROWTH AND 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 prevalent in 1990 and born after December 31, 1970, were included in the study, a total of 3067 patients at 548 dialysis units.

CAPD AND 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 per dialysis unit. All units providing CAPD training participated in the study. The sample includes 3385 patients from 706 units.

USRDS DATABASE SYSTEM

The USRDS CC has developed a centralized ESRD patient database by integrating data from the above data sources and establishing methods to identify patients with ESRD. We use this database to update and maintain data on demographics, clinical measurements, biochemical lab test results, renal replacement therapy, treatment history, and all medical service events reported in the Medicare claims database. Through this patient-oriented database we attempt to define each individual ESRD patient through multiple stages of data cleaning, conversion, validation, and consolidation. Establishment of a universal patient identification system was critical to ensure that unique patient identification numbers are assigned to each ESRD patient at the time of ESRD initiation, to accurately track counts and rates of incident and prevalent cohorts over time.

In 1994, the USRDS CC introduced the Standard Analysis Files (SAFs)—not to be confused with the CMS Standard Analytical Files for Part A and Part B claims data—to help meet the ESRD data needs of a wide variety of research studies. These SAFs were subsequently enhanced to include not only ESRD clinical and claims data from CMS, but also transplant and wait list data from UNOS. All SAFs are sorted by the unique USRDS-specified patient identification number, and patient identifiers (name, address, SSN, HIC/BIC, etc.) are removed to protect patient confidentiality.

The CC also uses the USRDS ESRD database to generate data sets for the tables, graphs, and maps in the USRDS ADR.

The USRDS ESRD database is updated regularly with data obtained from the various data sources. The CC generally receives CMS SAF claims data, Facility Survey data, CDC Survey data, and UNOS transplant and wait-list data once a year, and REBUS and EDB data more frequently. These multiple updates allow the CC to assess growth of the ESRD population, the demographic distribution of ESRD patients, and changes in the percent of patients diagnosed with major diseases secondary to ESRD.

SECTION 2 • ESRD PATIENTS

ESRD is defined as chronic renal failure requiring renal replacement treatment—dialysis or transplant—to sustain life. It is not the same as acute renal failure, from which patients are expected to recover within weeks or months. A Medical Evidence Report must be completed immediately by renal providers for all ESRD patients to register them in the CMS ESRD database and to apply for Medicare eligibility if they were not previously eligible.

DATA SOURCES

To establish the incident and prevalent cohorts by year, modality, primary cause of renal failure, and other factors, patient demographic and clinical information is required, as is treatment history data. This information can be obtained from the USRDS Core CD with files “PATIENTS,” “MEDEVID,” “RXHIST,” “RXHIST60,” and “PAYHIST.”

FIRST ESRD SERVICE DATE

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 each new patient’s incident year 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 outcomes analyses. This rule allows each new ESRD patient to generate Medicare services despite potential delays in completing the Medicare eligibility application process, and it allows adequate time for patients to arrive at a stable and suitable dialytic treatment modality.

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 Report,
- the date of kidney transplant, as reported on a CMS or UNOS transplant form, a Medical Evidence Report, or a hospital inpatient claim, or
- the date of the first Medicare dialysis claim.

Most FSDs are derived from the Medical Evidence Report. In the absence of this form, the FSD is usually considered to be the date of the first Medicare dialysis claim or of transplant. 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 Report, the earliest claim date is used as the FSD.

IDENTIFYING ESRD PATIENTS

A person is identified as having ESRD when a physician certifies the disease on the Medical Evidence (ME) Report (form CMS-2728), or when other evidence of chronic dialysis or kidney transplant exists. Patients with acute kidney failure who are on dialysis for days or weeks, but who then recover kidney function, are excluded from the database if no ME forms are submitted for them. Patients who die soon after kidney failure without receiving dialysis are sometimes missed.

Starting with the 2007 ADR, FSDs for patients entering the ESRD program after December 31, 1994, are defined solely by the regular dialysis start date or the preemptive transplant date, whichever is earliest, on the ME form. This new method

of determining FSD was introduced to align more closely with methods used by CMS. After years of careful monitoring and repeated comparative analyses of the traditional USRDS method and the new ME method, the USRDS believes it is appropriate to apply the ME method to incident patients entering the ESRD program on or after January 1, 1995.

INCIDENCE AND PREVALENCE

Incidence is defined as the number of people in a population who are 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, used primarily throughout the ADR, as of December 31, and period prevalence for a calendar year. Annual period prevalent data thus include 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. Please refer to *Getting Started*, page 7, for further details about defining incident and prevalent patient cohorts using the USRDS SAFs.

The USRDS treats successful transplant as a therapy, not as recovery from ESRD. Patients who undergo transplant at the time of ESRD initiation are counted as incident patients, and those with functioning grafts as prevalent.

Because data are available only for patients whose ESRD therapy is reported to CMS, patients who die of ESRD before receiving treatment or whose therapy is not reported to CMS 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 CMS.

Point prevalence is useful in public health research because it measures the current burden of the disease on the health care delivery system. Period prevalence is appropriate for cost analysis because it indicates the total disease burden over the course of the year. The USRDS CC focuses primarily on ESRD incidence as the most useful measure for medical and epidemiological research that examines disease causality and its effect on various subpopulations.

MEDICARE AND 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 years and older
- Disabled
- Enrolled in the ESRD program
- Railroad Retirement Board (RRB)

Most ESRD patients are eligible to apply for Medicare as their primary insurance payer. However, some patients are not immediately eligible for Medicare primary payer coverage

because of their employment status and pre-existing primary insurance payers such as Employer Group Health Plans (EGHPs), the Department of Veteran Affairs, and private insurers. Typically, these patients wait 30-33 months before becoming eligible for Medicare as primary payer, and are not included in the EDB database during the waiting period. Some of these patients, particularly those who are new since 1995, have FSDs established by Medical Evidence Reports, but have no dialysis claims or hospitalization events in the CMS claims database to establish treatment history events. In the PMMIS/REBUS database, these patients are designated ZZ, or non-Medicare (the PMMIS/REBUS group assigns ZZ in the 2-character Beneficiary Identification Code field to identify all non-Medicare ESRD patients). CMS does not generally include these patients in the datasets released to researchers.

The USRDS recognizes that ZZ patients are ESRD patients and should therefore be included in patient counts for incidence, prevalence, and treatment modality. However, calculations of standardized mortality ratios (SMRs), standardized hospitalization ratios (SHRs), and standardized transplantation ratios (STRs) should not include these patients because of the small number of claims available in the first 30 to 33 months after first ESRD service. Furthermore, linking ZZ patients to their ESRD Death Notification (CMS 2746) or to the UNOS transplant data may be impossible; determining comorbid conditions or Part A and Part B services may also be impossible. Due to the limited availability of event data, event rates that include these patients must be assessed with caution.

SECTION 3 • TREATMENT HISTORY

The USRDS CC uses billing information from the CMS ESRD database to create a longitudinal history of ESRD treatment for each patient in the database. This history defines incident and prevalent cohorts and determines censoring points and outcomes for observational studies.

DATA SOURCES

The FSD is established by evaluating information from several sources. REBUS includes first ESRD service date from the Medical Evidence Report. The REBUS Quarterly Dialysis record summarizes dialysis billing information, and can also establish FSD if data are missing from other files. The UNOS transplant dataset provides FSD information for incident transplant patients. Data combined from these sources establish the first ESRD service date. Section 2 describes the decision algorithm used.

TREATMENT MODALITY CATEGORIES

Table 3.1 lists modality categories used by the USRDS. They can be described as detailed or general. For most analyses, the general categories, which combine detailed modality categories, are sufficient. A new modality/event (recovered renal function; RRF) was introduced in the 2007 ADR. RRF can be established only if it occurs within the first 180 days of FSD, and the RRF period persists for at least 90 days. The RRF modality (i.e., event) is similar to the lost-to-follow-up event in that patients with an RRF event will not be included in the prevalent populations for outcomes analyses. However,

as with lost-to-follow-up events, these patients remain in the modality sequence so subsequent renal failure episodes can be closely tracked in a timely manner.

Table 3.1. Treatment Modality Categories

Type	Detailed	General
1	Center HD	HD
2	Center Self HD	HD
3	HD Training	HD
4	Home HD	HD
5	CAPD	CAPD
6	CAPD Training	CAPD
7	CCPD	CCPD
8	CCPD Training	CCPD
9	Other PD	Unknown Dialysis
A	Uncertain Dialysis	Unknown Dialysis
T	Functioning Tx	Transplant
X	Lost to follow-up	Lost to follow-up
D	Death	Death
Z	Recovered Function	Recovered Function

HOW TREATMENT MODALITY IS DETERMINED

The treatment history files in the USRDS Core CD record the sequence of modalities for each patient. The variables included in these files are presented in Table 3.2. Each record in the file indicates a period of therapy with a given modality, and any change in provider or detailed modality results in a new record. Several data sources are used to determine the treatment history, including the Medical Evidence file, the Quarterly Dialysis file, the UNOS Transplant events file, and Medicare claims files.

Table 3.2 Treatment History SAF Variables

RXHIST Detailed Treatment History	
UID	USRDS Patient Identification
BEGDATE	Beginning date of a modality period
ENDDATE	Ending date of a modality period
BEGDAY	Start day of modality period (First Service Date = 1)
ENDDAY	End day of modality period (First Service Date = 1)
RXDETAIL	Detailed treatment modality for period
RXGROUP	Grouped treatment modality for period
PROVUSRD	USRDS assigned facility identification

Table 3.2 (continued)

RXHIST60 Condensed Treatment History	
UID	USRDS Patient Identification
BEGDATE	Beginning date of a modality period
ENDDATE	Ending date of a modality period
BEGDAY	Start day of modality period (First Service Date = 1)
ENDDAY	End day of modality period (First Service Date = 1)
RXGROUP	Grouped treatment modality for period

In constructing this treatment history file, these conventions are followed:

- The sequence always begins with the first ESRD service date and ends with the earliest of date of death or end of the period for which the data are complete. For the categories death, loss to follow-up, and functioning graft, the end date may be missing from a patient's last record. Dialysis categories always have an end date.
- Death is treated as the last event of the day, and is the absolute end point of the treatment history.
- If 2 dialysis billing periods overlap, the earlier is terminated at the start of the later. If a dialysis billing period is entirely contained within another billing period, the contained period is ignored.
- A functioning transplant is considered treatment, not recovery from ESRD.
- If a dialysis billing period overlaps a transplant date, the dialysis period is closed at the transplant date.
- If a graft failure is recorded in the database, but there are no subsequent records of dialysis or another transplant, a period of "unknown dialysis" is inserted. If no dialysis billing records or re-transplant appears within 1 year, the patient is designated lost to follow-up at the end of that year, and this status continues until dialysis or new transplant records appear.
- Once established, a modality is assumed to continue until a change in provider or detailed modality occurs. For dialysis patients, if no new dialysis billing data appear for 1 year, the patient is reclassified as lost to follow-up at the end of that 1-year period.
- A functioning graft is assumed to continue until an indication of graft failure or death appears, or evidence of regular or maintenance dialysis.

GRAFT FAILURE

The CC assumes that a graft failure date reported in the UNOS transplant follow-up file or the REBUS identification file is correct unless death or a new transplant occurs before this date. However, a graft failure date may be unrecorded in both files. In this case, the CC derives the graft failure date from the following sources:

- Date of death
- Date of subsequent transplant
- Date of return to regular dialysis, indicated by a continuous period of dialysis billing records covering a minimum of 60 days with at least 22 reported dialysis treatments
- Date of return to dialysis reported on the Medical Evidence Report, or the date of graft nephrectomy from the UNOS transplant follow-up record or a Medicare claim.
- If no failure date is available, then the earliest of the above dates is used as the graft failure date.

THE 60-DAY COLLAPSING RULE

The CC uses the convention that a dialysis modality must continue for at least 60 days to be considered stable. A transplant is considered a stable modality regardless of duration.

Because the dialysis treatment history is derived from the Medical Evidence Report, UNOS transplant events, and Medicare billing records, it includes intermixed and overlap-

ping details that are not required or are unsuitable for most analyses. A long period of CAPD, for example, may be interrupted by a short period of inpatient hemodialysis treatment, or a patient may go on vacation and receive dialysis from a different provider. By applying the 60-day rule, we collapse modality periods of less than 60 days, and periods that differ only by provider, giving a less complex treatment history for analyses that require less detail than is available in the detailed treatment history. For maximum flexibility, we provide two treatment history files, one with full detail (RXHIST), and one applying the 60-day collapsing rule (RXHIST60). Table 3.3 shows an example of how these two files differ. The 60-day file is constructed from the detailed file as follows:

- Consecutive records with the same modality group are collapsed into a single record. This removes changes of provider only and changes between detailed modalities within the same general modality group.
- Remaining modality periods, except functioning transplant, < 60 days are recoded as uncertain dialysis, and consecutive dialysis records labeled uncertain are combined.
- If a modality is interrupted by a different modality that lasts < 60 days (e.g., a period of peritoneal dialysis between two longer periods of hemodialysis), the short modality period is ignored and the longer modality extends over the entire period.

TABLE 3.3. DETAILED VS. CONDENSED TREATMENT HISTORY RXHIST

USRDS ID	BEGDATE	ENDDATE	RXDETAIL	PROVUSRD
900000001	1/1/91	1/31/91	Center HD	5
900000001	2/1/91	5/31/91	Center HD	7
900000001	6/1/91	6/31/91	CAPD training	14
900000001	7/1/91	1/31/92	CAPD	14
900000001	2/1/92	9/30/92	Center HD	5
900000001	10/1/92	10/15/92	CAPD	14
900000001	10/17/92	5/31/93	Center HD	5
900000001	6/1/93	7/15/93	Transplant	23
900000001	7/16/93	2/12/95	Center HD	5
900000001	2/13/95	1/31/96	Center self HD	5
900000001	2/1/96	2/29/96	HD training	5
900000001	3/1/96	2/12/97	Home HD	5
900000001	2/13/97		Death	

USRDS ID	BEGDATE	ENDDATE	RXGROUP
900000001	1/1/91	5/31/91	Hemodialysis ^a
900000001	6/1/91	1/31/92	CAPD ^b
900000001	2/1/92	5/31/93	Hemodialysis ^c
900000001	6/1/93	7/15/93	Transplant ^d
900000001	7/16/93	2/12/97	Hemodialysis ^e
900000001	2/13/97		Death

^aProvider change only.

^bSame modality category.

^cCAPD record only 15 days.

^dThe 60-day rule does not apply to transplants.

^eSame modality category.

DETERMINING LOST-TO-FOLLOW-UP PERIODS

The functioning transplant modality is assumed to continue until a graft failure occurs. A dialysis modality is assumed to continue for a maximum of 1 year in the absence of dialysis billing data or other confirmation of dialysis therapy. After 1 year with no dialysis billing data, the patient is classified as lost to follow-up until evidence of a new modality appears. Patients cannot be classified as lost to follow-up during the first 3 years of ESRD because Medicare may be secondary payer for up to 33 months. The dialysis billing data frequently contain gaps, as listed below.

- The first service date may be known from the Medical Evidence Report, but many ESRD patients are not Medicare eligible for 90 days, delaying billing data for modality determination.
- For patients who have medical insurance other than Medicare, Medicare is the secondary payer for up to 33 months. The first ESRD service date may be known from the Medical Evidence Report, but dialysis billing data are unavailable until Medicare becomes the primary payer.
- Some patients may recover enough renal function to discontinue dialysis, and the USRDS database contains no data for non-dialysis time periods.
- A patient may leave the country and become lost to follow up.
- A patient may die and the death data may not reach the USRDS.

- Self-dialysis treatments are billed by 2 methods, 1 of which may not be available in the CMS PMMIS/REBUS system, causing some home dialysis billing to be missed.
- Some dialysis bills for patients enrolled in Managed Care Organizations may be missed by the CMS billing system.
- Reporting, data entry, and clerical errors may obscure the first service date; for example, first-ever dialysis, not the start of maintenance dialysis, may be reported on the Medical Evidence Report.
- Errors in beneficiary identification may cause data for a single patient to be split between two patients or to be associated with the wrong patient.

DEFINING HOME HEMODIALYSIS PATIENTS

The 2006 ADR instituted an improved method for defining home hemodialysis patients. Previously, modality event data were taken from the SIMS event file only in the case of a gap or missing data in the USRDS Modality Sequence (i.e., Treatment History), which was constructed primarily from Medicare billing data and the REMIS database. However, after applying a series of systematic validation rounds to the SIMS database and examining the root causes of persistent under-counting of home hemodialysis patients, the CC concluded that SIMS event data should play a more prominent role. Thus, for the 2006 ADR, the CC incorporated all home hemodialysis events from SIMS data, with the billing data and the REMIS database, into the standard process of creating the final USRDS Modality Sequence. Subsequently, counts of incident and prevalent home hemodialysis patients rose substantially for all years reported in the 2006 ADR. In the event of data discrepancies, researchers should use home hemodialysis counts from the 2006 or later ADR.

SECTION 4 • PAYER HISTORY

The payer history file is similar to the treatment history file. CMS payer information is used to create a continuous sequential history of payers for each patient in the ESRD database, beginning with the first ESRD service date. Each patient's FSD in the payer history file is the same date reported in the treatment history file.

DATA SOURCES

The payer for any given time period is determined by evaluating several data sources. The CMS Enrollment DataBase (EDB) is used to determine Part A, Part B, Group Health Organization, MSP Primary Payer, Third Party Part A, and Third Party Part B payers. The CMS claims billing files provide dates of regular maintenance dialysis, used as an indicator of Medicare as primary payer. The "patients" file in the USRDS Core CD contains dates of death, used to help establish the end point of the payer sequence.

PAYER CATEGORIES

Table 4.1 shows the payer categories used by the USRDS and indicates whether a patient is considered a Medicare patient (yes or no), and whether the patient has dual Medicare/Medicaid eligibility for that payer time period (yes or no).

Table 4.1. Payer Categories

Code	Description	Medicare Patient	Mcare/Mcaid Dual Eligibility
MPAB	Medicare Primary, Part A and Part B	Y	Y or N
MPO	Medicare Primary, Other	Y	Y or N
MSP-EGHP	Medicare as Secondary Payer with EGHP	Y	N
MSP	Medicare as Secondary Payer	Y	N
HMO	Group Health Org.	Y	N
WAIT	90 Day Waiting Period	Y or N	Y or N
OTH	Other/Unknown	N	N

HOW THE PAYER CATEGORY IS DETERMINED

The payer history SAF in the USRDS Core CD records the sequence of payers for each patient. Table 4.2 shows the variables included in this file. Each record in the file represents a time period covered by a particular payer. Any change in payer, Medicare status, or dual eligibility status results in a new record.

Note that the "WAIT" status can be either Medicare or non-Medicare, depending on the Medicare status of the sequence following the "WAIT" period. This is a change from the payer history files for prior years, where each payer code corresponded to only one possible Medicare status.

TABLE 4.2 PAYER HISTORY SAF VARIABLES

Variable	Description
USRDS_ID	USRDS Patient Identification
BEGDATE	Beginning date of a payer period
ENDDATE	Ending date of a payer period
PAYER	Payer for the period
MCARE	Payer includes Medicare (Y/N)
DUALELIG	Payer includes Medicare and Medicaid (Y/N)

Because several data sources are used to determine payer history, more than one payer may be reported for any given time period. In constructing the history, the following conventions are followed:

- The sequence begins with the first ESRD service date. If the patient has died, the end date for the last patient record is the date of death. If the patient has not died, the end date is missing from the patient's last record.
- The expected ESRD entitlement date is defined as the remainder of the month of incidence, plus two full calendar months. If the payer on the first service date is unknown, the patient is assumed to be in the waiting period prior to entitlement, and the first payer is assigned to the value "WAIT". The "WAIT" period lasts until the expected entitlement date, or until another payer is identified. The Medicare status of the "WAIT" period is assumed to be the same as the Medicare status of the following period.
- If the reported end date for a payer is missing in the data source, the payer is assumed to continue sharing respon-

sibility through the date of death or through the period of available payer information, whichever comes first.

- If more than one payer is identified for a time period, precedence for assigning the payer for the sequence is as follows: HMO, Medicare Primary if indicated by the claims billing file, MSP, then Medicare Primary if indicated by the Enrollment Database. Note this is a change from prior years, where MSP was given precedence over other payers.
- If payer and dual eligibility status are the same in consecutive payer sequences, the sequences are collapsed into 1 time period, starting with the beginning date of the first and ending with the end date of the last.
- Unlike the treatment history file, the payer history file does not require a payer to continue for any specific time period to be considered stable, and all changes in payer are reported. At their discretion, users may apply additional rules to manage the payer history sequence.

GAPS IN THE PAYER HISTORY

Some patient payer histories include gaps with Other/Unknown as payer between sequences with identified payers. This might occur for several reasons, similar to the explanations for gaps in the treatment history:

- Some patients recover enough renal function to discontinue dialysis and the USRDS database may contain no payer information for non-dialysis time periods.
- Payer information for successful transplant patients may not be reported in the data sources because Medicare eligibility terminated after 3 years with a functioning graft.
- A patient may leave the country and become lost to follow-up.
- A patient may die and the death data may not reach the USRDS.
- CMS may not collect payer information.
- Reporting, data entry, and clerical errors may obscure the record of FSD and the corresponding payer.
- Errors in patient identification may cause data for a single patient to be split between two patients or to be associated with the wrong patient.

If a patient is alive but the last reported payer in the data sources ends on a date before the reported data extraction date, an additional payer sequence is created with Other/Unknown payer to extend the patient's payer history. Thus, only patients who have died have end dates in their last payer sequences, and the last end date is the date of death.

Some patients have no identified payers. Their payer histories are represented in the file as one payer sequence, starting at first ESRD service date, with missing end date and Other/Unknown payer.

SECTION 5 • TRANSPLANT PROCESS AND OUTCOMES

Transplant patients constitute a unique subset of the ESRD population and are often studied separately from dialysis patients. Researchers may wish to simply count the number of transplant events that meet certain criteria, or calculate transplant event rates and survival probabilities. Using the USRDS transplant data, researchers can obtain information on transplant events, such as donor and recipient characteristics, and on patient- and graft-related outcomes.

DATA SOURCES

Basic transplant variables are contained in the Transplant file on the Core CD. Transplant event data are combined from various sources including CMS (PMMIS/REBUS files) and UNOS. Before 1988, CMS was the primary source for all transplant event data. Between 1988 and 1993, both CMS and UNOS collected information regarding transplant events. Since 1994, UNOS has been the primary source for all transplant event data (see figure 5.1).

RECONCILIATION OF CMS AND UNOS EVENTS

The USRDS has implemented a decision algorithm that reconciles identical transplant events when multiple sources contain conflicting information.

- Before 1988, all transplant events found in CMS PMMIS/REBUS transplant files are used.
- After 1994, all transplant events found in the UNOS files are used.
- Between 1988 and 1993, all transplant events found in the UNOS files are used and additional transplant events from the CMS PMMIS/REBUS transplant file are used only if they occur at least 30 days on either side of a previously accepted transplant event.
- Additionally, transplant events associated with the report. Additionally, transplant events associated with the reported incident transplant patients in the Medical Evidence Report are used if they occur at least 30 days on either side of a previously accepted transplant event.
- Each transplant event found in the Transplant file of the Core CD is thus a unique event that the USRDS believes occurred after reviewing both UNOS and CMS PMMIS/REBUS Transplant and Medical Evidence record files.

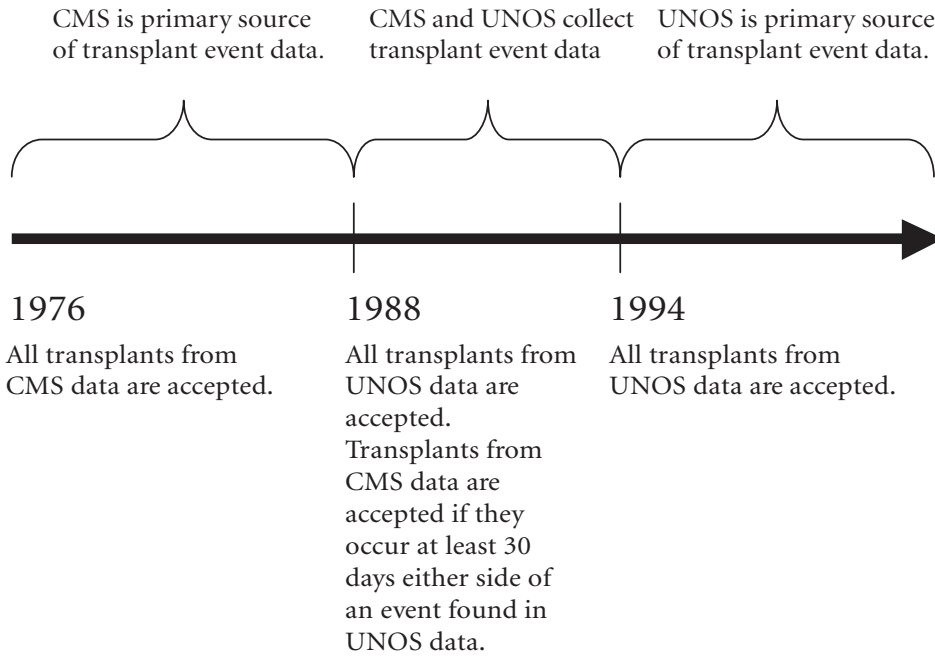
Table 5.2 details the various USRDS SAFs related to transplant. The transplant file on the Core CD contains transplant dates, basic descriptive data, and causes of graft failure, when known.

KIDNEY AND PANCREAS WAIT-ING LIST

The Core CD also contains four files with information on the kidney and simultaneous kidney-pancreas waiting list files from UNOS.

Most investigators are simply interested in the dates of listing at specific transplant centers. The WAITSEQ_KI and WAITSEQ_KP files contain entry and removal date sequences per patient per transplant center for the kidney alone and simultaneous kidney-pancreas waiting lists, respectively.

Figure 5.1 Source of Transplant Events in the USRDS Population



These records are collapsed from the raw UNOS waiting list files WAITLIST_KI and WAITLIST_KP. Both the raw UNOS waiting list files and the sequence files contain two patient identifiers, PID and USRDS_ID. ESRD patients included in the USRDS patient profile have a USRDS_ID. PID is the UNOS patient identifier and can be used to link the sequence files to the raw waiting list files.

Because the sequence files are collapsed versions of the waiting list files, investigators should use caution when linking back to the raw waiting list files to obtain information such as PRA values. Investigators will need to obtain all raw waiting list records and then make decisions as to which record contains the information most relevant to their needs. Some specific assumptions the CC used to collapse waiting list records are as follows:

- Candidates listed in error were removed (REMCODE=10).
- Patients with missing listing dates (EDATE=) were removed.
- Patients with listing and removal dates on the same date were removed.

- Transplant dates were taken from the USRDS Transplant file and not from the UNOS waiting list file. The transplant dates on the USRDS Transplant file are cleaned and reconciled with other sources of data, so these dates were used to ensure consistency. In the event that a patient not known to the USRDS received a transplant, the UNOS transplant date found in the raw waiting list file was used.
- Known transplant dates are used to truncate waiting periods at all centers at which a patient is currently listed. For example, if a patient underwent transplant but was not removed from a center’s waiting list, a removal date would be imputed on the transplant date. This is true for all centers at which a patient is listed.
- Patients with inactive waiting periods were removed; the waiting list sequence lists only active periods.
- Overlapping waiting periods at the same center were collapsed.

TRANSPLANT CD

To obtain additional data regarding transplant events, users need the Transplant CD, which contains detailed information,

Table 5.2 USRDS Transplant Files

File	Data Source	Contents	Years	CD
TX	Constructed by USRDS CC from UNOS, CMS PMMIS/REBUS, Transplant, Medical Evidence files	Identifying data on all known transplants	All	Core
WAITLIST_KI WAITSEQ_KI WAITLIST_KP WAITSEQ_KP	UNOS Transplant Waiting List	Waitlist periods on all patients from UNOS	1988+	Core
TXHCFA	CMS PMMIS/REBUS Transplant file	Details from CMS	1976-93	Tx
TXUNOS	UNOS Transplant file	Details from UNOS	1988+	Tx
TXFUHCFA	CMS PMMIS/REBUS Transplant follow-up file	Follow-up details, CMS	1988+	Tx
TXFUUNOS	UNOS Transplant follow-up file	Follow-up details, UNOS	1988+	Tx

in separate files, from CMS and UNOS. The Transplant file on the Core CD contains reconciled transplant event data from all available sources; as some researchers may find it beneficial to see the transplant data obtained from each source, data from each source are included.

Two transplant files contain data collected by CMS and UNOS on transplant follow-up visits. The follow-up records in SAF.TXFUHCFA and SAF.TXFUUNOS overlap in time, especially 1988 to 1993, and contain information collected during patient follow-up visits, which typically occur at 6 months, 1 year, and yearly thereafter. Before 2003, UNOS used 1 file to store kidney and kidney/pancreas recipient registration worksheet data and 1 file to store kidney and kidney/pancreas recipient follow-up worksheet data. Starting in 2003, UNOS separated these 2 recipient data groups. However, UNOS did not move the legacy kidney/pancreas recipient data into the respective new files. Users who need kidney/pancreas recipient longitudinal data should use TRR_ID and merge records from TXFUUNOS_KP with TXUNOS_KI and TXFUUNOS_KI to obtain all legacy kidney/pancreas records.

The TXIRUNOS and TXIFUNOS files contain information on immunosuppression treatment. Data in these files are from the Immunosuppression Treatment (TXIRUNOS) and Immunosuppression Treatment Followup (TXIFUNOS) forms. TXIRUNOS contains data on treatments at the time of transplant, and TXIFUNOS contains data on treatments updated at each followup visit if available.

Each file on the Transplant CD should be considered a separate analytical file. Attempting to combine information from various files involves reconciling information across files.

Starting in 2003, UNOS began to use the bitmask technique to maintain multiple values (i.e. selections/ choices) within 1 variable. This method applies to all multiple selection questions. Previously, UNOS used as many variables as needed to collect all possible answers for such questions. For example, for the question “Treatment: Other therapies,” UNOS used 3 variables, “PHOTOPH,” “PLASMA” and “LYMPHOID” with answer “Yes/No.” After 2003, UNOS combined these variables into a single variable, “THERAPIES,” for the same question, using bitmask technique.

The basic code values are value 1 = Photopheresis, value 2 = Plasmapheresis, value 4 = Total Lymphoid Irradiation (TLI). Value 3 represents the sum of values 1 and 2.; similarly value 5 implies that 1 and 4 are selected. To assist researchers in decrypting these multiple-selection/value variables, USRDS has identified all possible additive combinations of these bitmask-value variables and made them available as formats for researcher convenience.

Appendix F, Data Forms, lists the CMS and UNOS data collection forms, which are available at www.usrds.org. As a cross reference between the data file and the form, the SAS variable labels (shown in Appendix D, Data File Descriptions) indicate, whenever possible, the question number from the form. The label PM7694, for example, indicates that the variable can be found on the PMMIS from 1976 to 1994. If the question number on the form did not change over time, this number is also indicated in the label. PM819421b indicates question 21b on the PMMIS form collected between 1981 and 1994. Variables from the UNOS follow-up forms are labeled using section A-M, letters assigned by the CC because the form does not include question numbers. Table 5.3 gives details regarding these labels.

Most descriptive data on transplant events can be found in the Core CD’s Transplant file, which can be used to construct counts of various transplant-related events. Transplant rates can be constructed by combining transplant data with a patient treatment history file, RXHIST or RXHIST60; rates in the ADR are typically calculated using RXHIST60, the treatment history file with the 60-day rule built in. Transplant survival, both graft and patient, can be calculated using the transplant failure date found in the Transplant file and the date of death found in the PATIENT file.

SECTION 6 • MORBIDITY AND HOSPITALIZATION

Morbidity associated with ESRD can be determined from information on hospitalizations and acute events, documented in Medicare claims files through ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification) and CPT (Current Procedural Terminology) codes. The USRDS provides data on inpatient admissions, discharges,

Table 5.3 Variable Label Prefixes for Transplant CD SAFs

File	Variable Label Prefix	Definition
TXHCFA	TXPM7681	From CMS form, 1976-1981
	TXPM8194	From CMS form, 1981-1994
	TXPM7694	Appears on all CMS forms, 1976-1994
	TXPM819421b	CMS form, 1981-1994, question 21b
TXUNOS	TCR	Transplant Candidate Registration Form
	CDR	Cadaveric Donor Registration Form
	LDR	Living Donor Registration Form
	DH	Donor Histocompatibility Form
	RH	Recipient Histocompatibility Form
	KIR	Kidney Transplant Recipient Registration Form
	TCR55	Transplant Candidate Registration Form, question 55
TXFUHCFA	TFU	From CMS form before 1994
TXFUUNOS	UNOS A-M	UNOS form, sections A-M indicated by the USRDS CC

and diagnosis and procedure codes, which may be used to produce different types of hospitalization rates, such as first hospitalization, total admission, and hospital day rates.

DATA SOURCES

Inpatient hospitalization data, a subset of the data in the Institutional Claims file, are included in the HOSP data file. These data originate from the Part A institutional inpatient claims data and are supplemented by the REBUS inpatient data, as hospitalizations may appear in both sources or in one but not the other. The patient treatment history file (RXHIST or RXHIST60) provides the patient modality treatment history, which may be used to construct hospitalization rate data, while demographic data are obtained from the PATIENTS file.

CONTENTS OF THE HOSPITAL FILE

A complete list of variables in the HOSP file can be found in Appendix D, Data File Descriptions page 174. The following list outlines some of the key variables:

- HCFASAF: indicates the data source of the claim.
- CLM_FROM: provides the from date of service, indicating the admission date.
- CLM_THRU: provides the through date of service, indicating the date of discharge.
- HSDIAG1-HSDIAG10: provide up to 10 ICD-9-CM diagnosis codes.
- HSSURG1-HSSURG10: provide up to 10 ICD-9-CM procedure codes.
- DRG_CD: provides diagnostic-related group (DRG) codes, which categorize inpatient stays by ICD-9-CM diagnosis and procedure codes.
- PRIMDIAG: equals “YES” when HSDIAG1 provides the principal diagnosis code.

PREPARING INPATIENT CLAIMS DATA FOR USE

Preparing data for analyses requires that they be cleaned, with overlapping hospitalizations for the same patient combined. The principal diagnosis and procedure codes from the first of 2 overlapping hospitalizations should be retained, with the combined hospitalization extending from the first admission date to the last discharge date.

To create a dataset to calculate rates for period prevalent patient cohorts, attach data for hospitalizations occurring during the selected year by patient UID to a period prevalent cohort file for the year. In this way, all patients in the file, including those with multiple hospitalizations and those with none, are included in the rate calculation. Use data in which the 90-day rule defines patient start dates. The 90-day rule defines each patient start date as day 91 of ESRD. This avoids incomplete hospitalization data from center hemodialysis patients aged younger than 65 years and not disabled, who cannot bill Medicare until 90 days after first ESRD service date. To calculate rates by patient characteristics, demographic data may be attached to the dataset by patient UID from the PATIENTS file.

Because hospitalization data are incomplete for non-Medicare patients and for patients classified as Medicare secondary payer (MSP), these patients should be excluded,

thereby limiting their contribution to patient-years at risk. One method of MSP patient exclusion used in the ADR hospitalization rate calculation involves excluding dialysis patients who do not reach a certain level of Medicare paid dialysis bills. Dialysis patient start dates (January 1 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:

- Claims start date: the first day of the first month in which there is at least \$675 of Medicare paid dialysis claims.
- Claims end date: the end of a three-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 the claims start and end dates, that patient is excluded from the analysis for that year.

UNADJUSTED VS. STABILIZED HOSPITALIZATION RATES

Hospitalization rates may be computed as raw unadjusted rates or as model-based rates. Calculation of raw rates is fairly straightforward, but caution is needed when interpreting raw rates because they may be unstable for small patient groups. In the case of unstable raw rates, a pooled rate (comprising data from several combined years) or a model-based rate may be more appropriate.

Statistical modeling is used to produce stabilized rates, preventing instability of raw rates in groups with small sample sizes and few patient years at risk. Current USRDS methodology for computing total admission and hospital day rates uses a generalized linear model with log link and Poisson distribution. Calculation of raw rates is described below, and methods of calculating raw and model-based rates are described in further detail in Appendix C, Statistical Methods.

COMPUTATION OF UNADJUSTED RATES PER PATIENT-YEAR

Unadjusted first admission, total admission, and hospital day rates can be computed for period prevalent patients for selected years. For each year, the unadjusted rates can be calculated as total events divided by total time at risk. These rates can also be 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 events and the number of years at risk for each event are computed separately for each year and summed over the pooled years; rates are then computed by dividing the total admissions or days by the total time at risk. Rates may be expressed per patient-year or per 1000 patient-years at risk.

For patients in the all-dialysis, hemodialysis, and peritoneal dialysis categories, the period at risk for all hospitalization analyses is from January 1 or day 91 of ESRD until the earliest of death, 3 days before transplant, or December 31. The only modality change considered a censoring event is from dialysis to transplant. For dialysis patients in the all-ESRD category, in contrast, the analysis period for hospitalization is censored only at death or December 31; modality change is not a censoring event. For transplant patients in the all-ESRD and transplant categories, the analysis period is censored at the earliest of death, 3 years after the transplant date, or

December 31. Censoring transplant patients at 3 years after the date of transplant is necessary because Medicare eligibility may cease and hospitalization data may be incomplete.

If a hospitalization begins before January 1 or day 91 of ESRD and continues into the analysis year, the time at risk for first admission begins the day of discharge from this bridge hospitalization. Patients with bridge hospitalizations that span 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. Because hospitalized patients remain at risk for additional hospital days, rates for hospital days include hospital days in the time at risk. But because currently hospitalized patients are not at risk for additional admissions, hospital days for each year are subtracted from the time at risk for total admissions. For 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 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 1 day; hospitalizations with admission and discharge on the same day or with discharge the day after admission are counted as 1 day.

CAUSE-SPECIFIC UNADJUSTED RATES PER PATIENT-YEAR

Cause-specific hospitalization rates may be computed by counting only hospitalizations with selected principal ICD-9-CM diagnosis codes. In the denominator of the rate, computation of time at risk is similar to computation described above for total admission rates. However, in the numerator, only hospitalizations with specified principal diagnosis codes are counted in total cause-specific admissions. For example, principal ICD-9-CM diagnosis codes of 480-486 and 487.0 can be used for pneumonia.

UNADJUSTED RATES PER PATIENT

Rates of hospital days and total admissions may also be calculated per patient. For a selected year, the numerator remains the total number of events, and the denominator is the total number of period prevalent patients for the year. Rates per patient are susceptible to bias because they do not consider the actual length of time that a patient is at risk during the year. For example, a greater number of patients at risk for only a fraction of the year may produce smaller rates.

SECTION 7 • SURVIVAL AND MORTALITY

Survival and mortality analyses are often used to compare outcomes among treatment modalities, age groups, or races, or to evaluate outcome trends over time. Results can be reported for both incident and prevalent cohorts for the following

groups: all-ESRD patients, all dialysis patients, all hemodialysis patients, all peritoneal dialysis patients, all transplant patients, or all ESRD patients aged 65 years and over. Primary analyses include unadjusted survival probabilities using the Kaplan-Meier method, adjusted survival probabilities using the Cox regression model, unadjusted death rates by cause of death, adjusted death rates, and adjusted interval death rates.

DATA SOURCES

These survival and mortality analyses require patient demographic information such as age, gender, race, primary cause of ESRD, death date, and cause of death, and treatment modality history data, which can be obtained from the USRDS Core CD files PATIENTS and RXHIST or RXHIST60.

UNADJUSTED FIRST-YEAR SURVIVAL PROBABILITIES: INCIDENT PATIENTS

First-year survival probability is the probability of surviving from day 91 after onset of ESRD to one year plus 90 days (days 91 to 455). This 90-day delay is necessary because many patients aged younger than 65 years do not become eligible for Medicare for up to 90 days, and their data may be incomplete for this period. The survival probability can be estimated for patient characteristics including age on the first ESRD service date, race, gender, and primary cause of ESRD. Age, race, and primary cause of ESRD can be broken down into groups as needed. The Kaplan-Meier method for calculating unadjusted first-year survival probability is described in Appendix C, Statistical Methods.

ADJUSTED FIRST-YEAR SURVIVAL PROBABILITIES: INCIDENT PATIENTS

The adjusted first-year survival probability from day 91 can be estimated using the Cox regression model, and can be calculated for patient characteristics including age on first ESRD service date, race, gender, and primary cause of ESRD. Age, race, and primary cause of ESRD can be categorized into groups as needed. To avoid excessive imprecision of the estimated survival probabilities due to small cell sizes, these probabilities can be calculated using aggregate categories for age, gender, race, and primary cause of ESRD, with a probability calculated for groups defined by 1 of these variables adjusted for the remaining 3. Overall probabilities for all patients can be adjusted for each of the 4 variables. The Cox regression model for calculating adjusted first-year survival probability is described in Appendix C, Statistical Methods.

ADJUSTED FIRST-YEAR DEATH RATES: INCIDENT HEMODIALYSIS COHORTS

Adjusted first-year death rates for incident cohorts can be estimated using a Cox model. These death rates are presented using aggregate categories for age, gender, race, and primary cause of ESRD (diabetes, hypertension, glomerulonephritis, and other). A death rate estimated for one of these variables is adjusted for the remaining three; overall death rates for all patients are adjusted for each of the four variables. The

method for calculating these death rates is also described in Appendix C, Statistical Methods.

UNADJUSTED DEATH RATES: PERIOD PREVALENT COHORTS

Period prevalent cohorts include patients who are prevalent at a point in time (e.g., January 1, 2010) and those who become incident during a time period (e.g., 2010). The cohort thus includes patients who are alive and receiving 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 patients who reach day 91 of ESRD treatment during the year. Follow-up starts on January 1, 2010, for prevalent patients and day 91 after the first ESRD service date for incident patients, and is censored at transplant, death, or December 31. Because these calculations include only 1 year of follow-up, a prevalent patient who survives until the end of the year contributes 1 year at risk. Since the calculation for incident patients begins on day 91 of ESRD, most of these patients contribute less than 1 year; they contribute a full year only if day 91 of ESRD is January 1 and the patient survives until the end of the year.

For this cohort, deaths per 1000 patient-years at risk can be calculated using aggregate categories for age, gender, race, and primary cause of ESRD. The death rate for a specific primary cause of death is obtained by dividing the total deaths from the primary cause by total follow-up time. The sum of death rates for each specific cause is equal to the overall death rate of the cohort.

STABILIZED ANNUAL DEATH RATES FOR PREVALENT HEMODIALYSIS COHORTS

A statistical model is needed to obtain stable annual death rates for prevalent patients in each aggregate category of age, gender, and primary cause of ESRD. The USRDS currently uses a generalized mixed model with log link and Poisson distribution, as described in Appendix C, Statistical Methods. When calculating death rates for the 2010 cohort, for example, 1998 to 2010 patients, prevalent and incident, were used to improve the stability of rates. Follow-up time started on January 1 for prevalent patients and on day 91 after first ESRD service date for incident patients, and was censored at transplant, death, or December 31.

SECTION 8 • PROVIDERS

The Facility SAF file is constructed from data supplied by the CMS Annual Facility Survey, the CDC National Surveillance of Dialysis-Associated Diseases, and the CMS Dialysis Facility Compare database. Information is for dialysis facilities only and data are at the facility level; there are no individual patient-level data.

Construction of the Facility SAF is accomplished by merging the CMS Annual Survey data with the CDC National Surveillance of Dialysis-Associated Diseases survey data by provider number and year. All provider numbers in the Facility SAF file are assigned by the USRDS in an effort to ensure dialysis facility confidentiality; they are not the original provider numbers assigned by CMS.

Over time, dialysis facilities are purchased and sold. Thus, a facility may have the same provider number for several years, then be purchased by a different owner and receive a new provider number. The physical facility and location may be the same, and most staff may remain, but the provider number has changed. Linking the 2 numbers is not possible.

The Facility SAF contains Veterans Administration providers. BECAUSE THE USRDS REPLACED THE CMS PROVIDER NUMBER WITH A NEW PROVIDER NUMBER, THE NUMBERS CANNOT BE SEPARATED FROM THE PROVIDER LIST.

Researchers who wish to conduct patient-level studies incorporating the Facility SAF can link patient information from the Detailed Treatment History SAF (RXHIST), the Condensed Treatment History SAF (RXHIST60), or other SAFs with associated dialysis providers, to the Facility SAF via the USRDS provider number and year.

The Facility SAF file contains over 100 provider characteristics, including:

- Transplant counts
- Self-dialysis information
- HD, IPD, CAPD, and CCPD patient counts
- Number of in-center new dialysis patients at a facility
- Kidney sources
- Profit status, and hospital-based or freestanding status
- Chain affiliation
- Reuse practices

DATA SOURCES

The CMS Annual Facility Survey is obtained from the CMS End-Stage Renal Disease Public Use Files website. CMS Dialysis Facility Compare data are sent monthly from CMS. The CDC National Surveillance of Dialysis-Associated Diseases survey was requested from the CDC annually through 2002. A list of the CMS and CDC Surveys can be found in Appendix F, Data Forms. The forms are available at www.usrds.org. As the last CDC National Surveillance survey occurred in 2002, all data for CDC variables are missing after this date.

Provider Numbers Assigned by the USRDS

Each provider has been assigned an identification number by CMS. To conceal provider identity, the USRDS converts this number to an anonymous number.

Profit Status

The profit variable, NU_P_NP, has the values 'For-profit', 'Non-profit', and 'Unknown' (case sensitive).

The for-profit group consists of the facilities categorized on the CMS survey. They include individual-profit, partnership-profit, corporation-profit, or other-profit. Non-profit facilities are listed as individual-nonprofit, partnership-nonprofit, corporate-nonprofit, other-nonprofit, state-government non-federal, county-government non-federal, city government non-federal, city/county-government non-federal, hospital district/authority government non-federal, other-government non-federal, Veterans Administration Government Federal, Public Health Service Government Federal, military-government federal, or other-government federal. These 18 categories are designated by the variable TYPOWNER. The

2002 CMS Survey dropped this variable and it is missing in subsequent survey periods, starting with the 2004 SAF CDs. Profit status is now determined from CMS Dialysis Facility Compare data.

Chain Affiliation

The USRDS definition of a chain is 20 or more facilities in 2 or more states owned by the same corporation. The 2006 provider data consist of 9 chains based on the USRDS chain definition. The number of chains can vary from year to year depending on the change of facility ownership and new facilities. The chain variable, CHAIN_ID, contains a value identifying the chain ownership of the facility. A blank value for CHAIN_ID indicates that the facility has no chain affiliation.

Freestanding vs. Hospital-based Facility

A hospital-based dialysis facility is associated with a hospital; it can be located in the hospital or at a remote location. Freestanding dialysis facilities operate independently of a hospital.

A study analyzing freestanding vs. hospital-based units will include 3 groups: freestanding, hospital-based, and unknown. The variable NU_HBFS designates this status. The number 1 represents hospital-based and 2 represents freestanding. The unknown category will consist of any provider in the researcher's study not found in the Facility database, and must be assigned by the researcher; for example, mat set NU_HBFS=3 Unknown.

SECTION 9 • DISEASE-BASED COHORT (5% CKD COHORT FINDER FILES)

Due to growing concern about chronic diseases that affect ESRD patients, the USRDS has constructed a set of disease-based finder files to help researchers gain a better understanding of causes and effects of these illnesses and their associations to morbidity and mortality in patients with ESRD.

DATA SOURCES

To create the CKD cohort finder files by year, the CC uses 5% General Medicare Claims data (1992-2004) and ESRD patient demographic information. This information is available in the USRDS Core CD files "PATIENTS," "MEDEVID," "RXHIST," and "RXHIST60."

Each disease-based cohort finder file data set contains 3 basic data components, Patient Master File, Payer Sequence File, and a series of Comorbid Files. To illustrate the methodology used to ascertain patients with the specific disease of interest and the underlying data structure and file organization, below is a description of how the DM Cohort Finder File data set was created using the 5% General Medicare Claims data. The CKD Cohort Finder.

Patient Master File

For patients in this file, at least 1 DM ICD-9 diagnosis code (Table 9.1) was identified in the 5% IP, OP, HH, HS, SNF, and PB SAFs, with 1 record per patient. Definitions of the 2 key variables DM_xx (1-year entry period DM indicator) and

DM_xxyy (2-year entry period DM indicator) are defined as follows:

DM_xx = Y if a patient in year xx (e.g., DM_95 or DM_02)

- was Part A and Part B entitled and not enrolled in an HMO for the entire year (i.e., Payer_Seq_File);
- had any one DM ICD-9 diagnosis code from IP or HH or SNF, or any two DM ICD-9 diagnosis code combinations from PB or OP with different claim dates.

DM_xx = N otherwise.

DM_xxyy = Y if a patient in a two-year entry period (e.g., DM_9596, DM_9900, or DM_0102)

- was Part A and Part B entitled and not enrolled in an HMO for the entire two-year entry period (i.e., Payer_Seq_File),
- was alive and did not develop ESRD as of December 31 of the two-year entry period, and
- had any one DM ICD-9 diagnosis code from IP or HH or SNF, or any two DM ICD-9 diagnosis code combinations from PB or OP with different claim dates identified at any time during the two year entry period (either in one of the two years or across the two years).

DM_xxyy = N otherwise.

Patients with DM_95 = Y are a subset of patients in the 1995 comorbid file (Co_Morbid_95) in the 'Co-Morbid Files' data set; patients with DM_9900 = Y are a subset of the patients from the 1999 and 2000 comorbid files (Co_Morbid_99 and Co_Morbid_00) in the 'Co-Morbid Files' data set respectively.

Some patients in the Patient Master File may have all DM_xx = N and all DM_xxyy = N. This implies that these patients had at least 1 DM ICD-9 diagnosis code identified in the 1992 to 2004 5% IP, OP, HH, HS, SNF, and PB SAFs but did not meet the 1-year entry period and 2-year entry period DM eligibility criteria described above.

Each patient is identified by 2 patient identification numbers. One is FIVEP_ID, a unique patient ID in the 5% sample population and the primary linking key within the USRDS DM Cohort Finder data set. Each year, new FIVEP_ID numbers are generated only for new patients added to the 5% sample. All existing patients (repeated patients) are referenced with their previously assigned numbers. A second patient identification number, USRDS_ID, is the unique ID in the USRDS database system for identifying ESRD patients. Only patients with ESRD are assigned a valid USRDS_ID number. FIVEP_ID and USRDS_ID are not related.

Payer Sequence File

This file was created from the 5% Medicare denominator files and the IP, OP, HH, HS, SNF and PB SAFs. It contains Medicare coverage information for 5% patients with at least 1 DM ICD-9 diagnosis code identified through the 5% IP, OP, HH, HS, SNF, and PB SAFs. A patient might have 1 or many sequence records in which each record indicates different insurance coverage within a well-defined time period. There are 5 unique insurance types:

- A - Entitled with Part A only
- B - Entitled with Part B only

- AB - Entitled with Part A and Part B
- H - Enrolled in a Medicare HMO health plan
- N - Non-Medicare

The first record contains the earliest available date for coverage information in the 5% Medicare denominator files. The last record contains the last known available date (i.e., the most recent) for coverage information in the 5% Medicare denominator files. FIVEP_ID is the primary patient identification number.

Comorbid Files

The comorbid files are constructed from the 5% Medicare IP, OP, HH, HS, SNF, and PB SAFs and named individually by the respective calendar years. Each file contains all patients whose diabetes diagnosis was identified from the 5% Medicare IP, OP, HH, HS, SNF, and PB SAFs within that year (i.e., Co_Morbid_95 contains all patients whose DM comorbid events were identified from the 1995 5% Medicare Claims SAFs). However, patients were not necessarily required to be entitled to Parts A and B and not enrolled in an HMO for that entire year. A patient might have 1 or many records within a calendar year in which each record depicts 1 unique DM disease event. Records are considered duplicates if they are extracted from the same type of claim file with the same ICD-9 diagnosis code on the same date. These files do not include duplications. For example, each record in Co-Morbid_95 consists of 1 DM code per claim file per service date per unique patient in 1995. The combination of claim type, DM code, and service date for a patient establishes uniqueness in each comorbid file. FIVEP_ID is the primary patient identification number.

Table 9.1. ICD-9 Diagnosis Codes

Disease Codes
CKD 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.4, 271.4, 274.1 283.11 403.x1 404.x2 404.x3, 440.1, 42.1, 447.3, 572.4, 580-588, 591, 642.1, 646.2, 753.12-753.17, 753.19, 753.2, 794.4

SECTION 10 • COMPREHENSIVE DIALYSIS STUDY SAF FILES

The Comprehensive Dialysis Study (CDS) collected data on patient demographics, contact information, treatment, laboratory values, quality of life (QOL) survey interviews, and nutrition survey interviews for US dialysis patients who started treatment 2005-2007 at 335 randomly selected dialysis facilities. Patients were selected via a monthly REMIS/SIMS database custom extract process using the following criteria:

- Incident dialysis patients (age >= 18) who had survived for at least two months,
- No prior transplant,
- Dialyzed at one of the pre-determine 335 facilities

Over a period of 2 years, 11,292 patients were selected. Of these, 1677 consented and participated in the surveys or lab assays. The CDS SAF files contain the data for these patients. Of the 1677 patients, 1279 participated only in the QOL

survey; 364 participated in the QOL and nutrition surveys (231 with and 133 without lab data); 34 did not participate in either survey but provided lab data.

SAF files for the CDS dataset consist of:

- CDS Patient file. Contains 1 record for each of the 1677 patients. A patient record includes a unique identifier USRDS_ID (unique identifier used to cross reference to other USRDS SAF files), demographic data, and a patient category indicator (PAT_CAT_BL), which indicates baseline survey and lab participation status (QOL-only, QOL and nutrition w/lab data, QOL and nutrition w/o ab data, Lab data w/o survey).
- CDS QOL Baseline file. This file contains the Baseline QOL survey answer data and some derivative score data from QOL only and QOL/Nutrition participants.
- CDS Food Baseline file. This file contains the Baseline Nutrition survey answer data and data generated by “Block Dietary Data System” on QOL/Nutrition participants.
- CDS Lab file. This file contains up to 5 sets of lab data from a subset of QOL/Nutrition participants.
- CDS Dictionary. This file contains each CDS SAF file contents, variable’s format.

SECTION 11 • MEDICARE PRESCRIPTION DRUG

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social Security Act by establishing the Voluntary Prescription Drug Benefit Program (Part D). Effective January 1, 2006, Part D is an optional prescription drug benefit for individuals who are entitled to Medicare benefits under Part A or enrolled in Medicare benefits under Part B. The data from the first few months of 2006, while the benefit was very new, may not be complete, and should be interpreted with caution.

DATA SOURCES

The Part D data is obtained from CMS annually with USRDS provided Finder Files. The Part D data is divided into two separate files: an annual enrollment file containing monthly indicators of enrollment in Part D, and a prescription drug event file (PDE) containing details of prescriptions filled by Part D beneficiaries.

Part D Enrollment SAF

Since the Part D benefit is voluntary, not all Medicare beneficiaries are enrolled in Part D. The annual enrollment file contains 12 monthly indicators that detail whether the beneficiary is enrolled in Part D, and if so, what type of plan the beneficiary is enrolled in. There are also monthly indicators for dual eligibility (Medicare and Medicaid), monthly indicators for Retiree Drug Subsidy, and low income subsidy (LIS).

The variables PTD_CNTRCTID_01- PTD_CNTRCTID_12 indicate Part D enrollment as follows:

- H = Managed care organizations other than Regional Preferred Provider Organization
- R = Regional Preferred Provider Organization
- S = Stand-alone Prescription Drug Plan (PDP)

- E = Employer sponsored
- O = Not Medicare enrolled
- X = Medicare enrolled, but no Part D enrollment record
- N = Not Part D enrolled

Values of H,R, S, and E for these variables are generally considered to indicate Part D enrollment.

Low income subsidy status can be determined from the variables CST_SHR_GRP_CD_01- CST_SHR_GRP_CD_12. The values are

If beneficiary is Medicare enrolled and Part D enrolled

- 01 = 100% premium subsidy and no copayment
- 02 = 100% premium subsidy and low copayment
- 03 = 100% premium subsidy and high copayment
- 04 = LIS, 100% premium-subsidy and high copayment
- 05 = LIS, 100% premium-subsidy and 15% copayment
- 06 = LIS, 75% premium-subsidy and 15% copayment
- 07 = LIS, 50% premium-subsidy and 15% copayment
- 08 = LIS, 25% premium-subsidy and 15% copayment
- 09 = No premium subsidy or cost sharing

If beneficiary is Medicare enrolled and not Part D enrolled

- 10 = Not enrolled in Part D, but employer is entitled for RDS subsidy
- 11 = Creditable coverage but no RDS
- 12 = Not Part D enrolled, no creditable coverage, no RDS
- 13 = None of the above conditions has been met

Prescription Drug Event SAF

This SAF contains details on prescription drug utilization, including brand name, generic name, dosage form, drug strength, quantity dispensed, date of service, and total prescription cost. The variables in this SAF are listed in Table 10.2. More detailed information on the Part D benefit can be found at <http://www.cms.gov/PrescriptionDrugCovGenIn/>.