Products and services provided by the usrds to support the work of the renal community are detailed in table b.a. The entire adr is available at www.usrds.org, with powerpoint slides of all figures and excel files of the data behind the graphs; included as well are pdf files of the researcher's guide. The site's render system allows users to create customized data tables and regional maps. Data on website use are presented in figure b.1.

data requests

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

research files

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

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

The Core SAF set contains basic patient data, and is needed to use any of the other SAFS. Included are each patient's demographic information, payor and treatment history, limited transplant data, provider data, and data from many of the USRDS Special Studies. Approximately half of the researchers using the USRDS SAFS need only this data set. The Transplant data set contains detailed transplant and transplant follow-up data collected by CMS and UNOS. Data on hospital inpatient stays are found on the Hospital data set. All Medicare billing data are available by individual year (see Table b.c).

standard analysis files

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

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

CORE DATASET

The Core Standard Analysis Files contain the most frequently used data and are needed for use of the Transplant and Hospital datasets, or any data based on Medicare claims. Included files are as follows (also listed in Table b.b).

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

Residence A longitudinal record, to ZIP code, of residence.

Payor History Contains a new record for each patient at each change in insurance payor.

Treatment History/Modality Sequence Contains a new record for each patient at each change in modality or dialysis provider.

Medical Evidence Contains full data from the 1995 and 2005 versions of the CMS Medical Evidence form. In April 1995 a new version of the form went into use, with data on comorbidity, employment status, lab values at initiation, and Hispanic ethnicity.

Transplant Contains basic data for all transplants (reported by CMS and UNOS), including the date of graft failure (detailed transplant data are contained on a separate transplant data set).

Transplant Wait List Beginning with 2001 data (used in the 2002 ADR), this file has been updated to include basic patient demographic data and, from UNOS, all unique wait-list periods for each dialysis patient.

Facility Conducted annually, the CMS End-Stage Renal Disease Facility Survey is the source of data for the Facility SAF. Geographic variables that could identify facilities are deleted. The survey period is January 1 through December 31.

Facility Cost Reports CMS hospital and independent facility cost reports for 1989–1995 and 1989–1993, respectively, are available as SAFs. All geographic variables are deleted to ensure confidentiality. The files may be linked to the Facility SAF using the USRDS provider ID, though analyses at less than a regional or network level are not possible. Because these files are rarely used, additional data will be added only if there is sufficient demand.

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

DATA FROM SPECIAL STUDIES

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

Dialysis Morbidity & Mortality Study (DMMS) The DMMS was a USRDS Special Study in which data on demographics, comorbidity, laboratory values, treatment, socioeconomic factors, and insurance were collected, using dialysis records, for a random sample of U.S. patients. Waves 1, 3, and 4 are historical prospective studies on a total of 16,812 participants in which data were collected for patients on in-center hemodialysis on December 31, 1993. Data were abstracted from medical records, and patients were followed to the earliest of data abstraction, death, transplant, change in modality, or transfer to another facility. Wave 2 is a prospective study of incident hemodialysis and peritoneal dialysis patients for 1996 and early 1997 and included 4,024 participants. Case Mix Adequacy Study of Dialysis: The objectives of this USRDS Special Study were to establish the relationship between the dose of delivered dialysis therapy and mortality, determine the strength of this relationship when data are adjusted for comorbidity, assess how this relationship changes with dialysis dose, assess how this relationship is affected by dialyzer reuse, and examine the impact of different dialysis membranes on patient morbidity and mortality.

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

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

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

CAPD & Peritonitis Study The USRDS CAPD and Peritonitis Study examined the relation of peritonitis episodes in CAPD patients to connection device technology and other factors. The study population included all patients newly starting CAPD in the first six months of 1989, a maximum of 14 patients per dialysis unit. All units providing CAPD training participated in the study. The sample contains data on 3,385 patients from 706 units.

TRANSPLANT DATASET

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

TX includes minimum details on all transplants from all sources

- TXWAIT contains one record for each patient in the USRDS database per wait list event
- TXHCFA includes transplant information collected by CMS's PMMIS system prior to 1994
- TXUNOS includes transplant information collected since 1987 by UNOS, currently the main source of transplant data for the USRDS
- TXIRUNOS includes information on immunosuppressive drugs collected by UNOS at the time of transplantation events
- TXFUHCFA includes transplant follow-up reports collected by CMS prior to 1994; reports are completed at discharge, six months, each year post-transplant, and at graft failure
- TXFUUNOS includes transplant follow-up reports collected by UNOS since 1988
- TXIFUNOS includes information on immunosuppressive drugs, collected by UNOS at follow-up visits

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

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

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

a USRDS products & services

Reports & guides

Annual Data Reports Available from the National Kidney and Urologic Disease Information Clearinghouse, 3 Information Way, Bethesda, MD 20892-3560; 301.654.4415, nkudic@info.niddk.nih.gov. ADR material is also published in the American Journal of Kidney Diseases.

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

Researcher's Guide to the USRDS database

Provides a detailed description of the USRDS database and of the USRDS Standard Analysis Files; the basic reference for researchers who use USRDS data files.

www.usrds.org

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

RenDER

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

Requests for data

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

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

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

Merged data files Merged files can be created by the Coordinating Center for approved research projects. An hourly rate of $119.57 will be assessed for time spent on the request, and users must sign a data release agreement with the NIDDK. Contact the USRDS Coordinating Cener for more information.

Publications & presentations

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

Contact information

Data requests & publication orders USRDS Coordinating Center
914 South 8th Street, Suite S-206
Minneapolis, MN 55404
612.347.7776 or 1.888.99USRDS
Fax 612.347.5878
usrds@usrds.org

Data file contacts Shu-Cheng Chen, MS; schen@usrds.org
Beth Forrest, BBA; bforrest@usrds.org

b Contents of the USRDS Core Standard Analysis CD-ROM

File name unit of observation & uses. This two-CD set is needed in order to use any of the other Standard Analysis Files.

Patient one record for each ESRD patient. Incidence, prevalence, patient survival. Most other files will need to be linked to this file using the encrypted patient ID.

Residence for each patient, one record for each period in a different residence. Regional analyses.

Treatment History one record for each period a patient is on one modality. Modality distribution and treatment patterns.

Payor History one record for each period a patient is covered by one payor; each patient can have many records. The impact of insurance payors on clinical outcomes.

Medical Evidence one record for each 2728 form filed (1995 version). ESRD first service date, initial treatment modality, comorbid conditions, patient status at start of ESRD.

Transplant one record for each transplant event; patients can have multiple events. Transplant and transplant outcome analyses.

Transplant Wait List one or more records for each patient ever on list. Comparison of transplanted patients to dialysis patients who are transplant candidates. Patient selection to wait list.

Dialysis Morbidity and Mortality (DMMS; Special Study) Wave 1: 5,670 patients; Wave 2: 4,024 patients; Wave 3–4: 11,142 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory test values, nutrition, vascular access.

Case Mix Adequacy (Special Study) 7,096 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Case Mix Severity (Special Study) 5,255 patients. Comorbid conditions, adequacy of dialysis, dialysis prescription and other treatment parameters, laboratory values.

Pediatric Growth and Development (Special Study) 3,067 patients. Growth, development, and other issues relating to pediatric ESRD patients.

CAPD Peritonitis (Special Study) 3,385 patients. CAPD and peritonitis.

Facility one record for each year facility has operated. Merge with the treatment history, transplant, or annual summary SAFs for analyses involving provider characteristics by encrypted ID.

Facility Cost Reports one record per facility per year (1989–1995). Costs and staffing of dialysis facilities.

Dialyzers information on dialyzer characteristics; to be matched to patient dialyzer information in other files on CD. Relation of dialyzer characteristics to patient outcomes.

CLMCODES one record for each diagnosis, procedure, or HCPCS code appearing in claims files. Frequency of occurrence of each code. A starting point for analyses that will use diagnosis and procedure codes.

Formats.SC2 all USRDS-defined SAS formats used by SAFs. Format library used to format values of categorical variables.

are accepted if no transplant is listed for the patient within 30 days of the Medical Evidence transplant date.

HOSPITAL DATASET

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

COMPREHENSIVE DIALYSIS STUDY

This data set contains information from the Comprehensive Dialysis Study (CDS), a USRDS special data collection study to assess rehabilitation/quality of life and nutrition issues in incident dialysis patients. The study was conducted between 2005 and 2008. All 1,677 participants answered questions on physical activity level, health-related quality of life, and work/disability status during the first six months of after the initiation of ESRD therapy. In a subset of 400 participants, dietary intake and nutritional status were also assessed.

DIALYSIS MORBIDITY & MORTALITY CLAIMS

This data set contains Medicare claims for participants in the Dialysis Morbidity and Mortality Studies. Data are followed to the currently reported claims year.

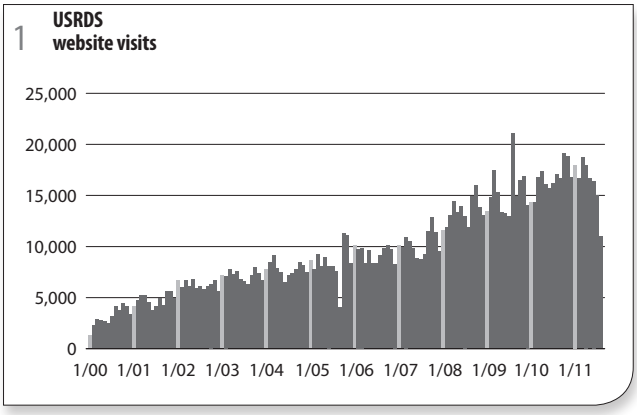
CASE MIX ADEQUACY CLAIMS

This data set contains Medicare claims for particiants in the Case Mix Adequacy Special Study. Medicare payment data for these patients are followed to the currently reported claims year.

MEDICARE PAYMENT DATA

Medicare payment data on institutional claims are available for pre-1989 through 2007, while data on physician/supplier claims are available for 1991–2007. The 2008 claims will be available, along with other updated USRDS SAFs, by the end of 2010.

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



CLINICAL PERFORMANCE MEASURES SURVEY

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

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

The USRDS Coordinating Center has made the CPM data available as SAFs. The dataset contains CPM data collected in surveys from 1994–2008. A listing of available files and the corresponding costs can be found in Table b.e, or you may contact the USRDS Coordinating Center for further information. For a detailed explanation of why there are no 2009 CPM form data available, please view the CPM 2010 Researcher's Guide on the USRDS website.

CKD 5 PERCENT GENERAL MEDICARE PAYMENT DATA

The CKD cohort datasets are built from the 5 percent general Medicare Claims SAFs, and contain a patient master file, a payor sequence file, and a set of comorbidity files. We no longer produce datasets for diabetes and CHF based on the 5 percent Medicare claims.

Separately, a 5 percent general Medicare Hospital SAF (inpatient, outpatient, skilled nursing facility, home health, hospice, Part B, and durable medical equipment) for the CKD cohort is also available for 1992–2008; 2009 claims will be available by the end of 2011. Data are derived from the IP claims SAF files. No payment or cost variables are included, so these data are for researchers who need data on hospital inpatient stays and on diagnoses and procedures for those stays, but do not need payment data.

PRE-ESRD MEDICARE CLAIMS

The pre-ESRD claims (also known as the back-casted claims) are a collection of Medicare institutional and physician/supplier billing records incurred prior to the onset of ESRD. Included in these claims are any and all claims available from Medicare for incident patients during their incident year and the two prior calendar years.

The USRDS has made the pre-ESRD data available as SAFs. This dataset includes Medicare claims of ESRD patients from incident years 1995–2008 with 2009 data available by the end of 2010. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payor sequence is provided so researchers can determine Medicare enrollment for the periods prior to first ESRD service date. A listing of available files and the corresponding costs can be found in Table b.e.

PART D DATA

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Title XVIII of the Social

c Prices for the USRDS Standard Analysis Files

Standard Analysis Files

Core dataset	$1,275	Needed in order to use the other files.
Transplant dataset	$500	Detailed transplant data from CMS and UNOS.
Hospital dataset	$500	Derived from the institutional claims; contains diagnosis and surgical procedure codes for each stay but does not include the cost data from the institutional claims records.
CDS survey dataset	$750	Survey information and laboratory values from the Comprehensive Dialysis Survey
DMMS claims	$500	Contains all of the Institutional and Physician/Supplier claims data for the patients in the USRDS Dialysis Morbidity and Mortality (DMMS) Special Study. Survey data are included in the Core dataset.
Case Mix Adequacy claims	$125	Contains all institutional and physician/supplier claims data for patients in the USRDS Case Mix Adequacy Special Study. Survey data are included in the Core dataset.

Pre-ESRD claims available for 1993 to 2010; price ranges from $200 to $800 per year and claim type. Prices subject to change.

ESRD Medicare payment data

	Institutional	Physician/ supplier	Part D
pre-1989	$250		
1989	$250		
1990	$250		
1991	$375	$500	
1992	$375	$500	
1993	$375	$500	
1994	$375	$625	
1995	$500	$625	
1996	$500	$750	
1997	$500	$875	
1998	$500	$875	
1999	$500	$875	
2000	$750	$875	
2001	$875	$875	
2002	$875	$1,000	
2003	$1,000	$1,125	
2004	$1,125	$1,125	
2005	$1,250	$1,250	
2006	$1,250	$1,250	$750
2007	$1,750	$1,375	$1,000
2008	$1,875	$1,500	$1,000
2009	$2,000	$1,625	$1,250
2010	$2,000	$1,750	$1,250

d Prices for the CKD 5 percent Medicare Sample Standard Analysis Files

Patient cohort finder $750 / Hospital file $250

	Institutional	Physician/ supplier		Institutional	Physician/ supplier	Part D
1992	$375	$375	2002	$500	$500	
1993	$375	$375	2003	$500	$500	
1994	$375	$375	2004	$500	$500	
1995	$375	$375	2005	$625	$625	
1996	$375	$500	2006	$750	$625	$350
1997	$375	$500	2007	$875	$625	$500
1998	$375	$500	2008	$1,000	$750	$500
1999	$500	$500	2009	$1,125	$875	$750
2000	$500	$500	2010	$1,125	$875	$750
2001	$500	$500				

e Prices for the ESRD CPM/USRDS files

ESRD CPM Survey data
Includes 1994–2008 hemodialysis survey years and 1995–2008 peritoneal dialysis survey years $1,250

ESRD CPM/SAF linked files

Core files	$500
Hospital	$200
Transplant	$200

ESRD CPM Medicare participant institutional & physician/supplier claims
are available for the years pre-1989 through 2010; $100–300 per year

f Outline for research proposals using USRDS data

A data request applies only to the project stated in the proposal; a new proposal must be submitted for each additional use of the data

I Research topic title and submission date.

II Background information.

III Study design: objectives, hypothesis(es), analytical methods.

IV Data being requested: 1) List of Standard Analysis Files needed (if multiple years, please specify), or data fields needed in custom data file. 2) Description of data security: responsible party, computer access, etc. 3) Time frame for the project. 4) Statement that data will be returned to the USRDS or destroyed at the end of the project.

V To address patient privacy issues, to be consistent with HIPAA policies, and to insure that researchers are adhering to local privacy standards as well as to USRDS and CMS privacy policies, the USRDS now requires IRB approval for all research proposals. IRB approval is not required from those requesting aggregate data.

VI Outline of estimated costs of requested data; source of funding.

VII Agreement for Release of Data, signed by all researchers.

VIII For Principal Investigator and co-authors, **required**:
Name
Affiliation
Business address
Business phone & fax
Email address

Submit to
Paul Eggers, PhD
NIDDK
6707 Democracy Blvd, Room 615
Bethesda, MD 20892-5458
Phone 301.594.8305
Fax 301.480.3510
eggersp@extra.niddk.nih.gov

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 be incomplete, and should be interpreted with caution.

The Part D data is obtained from CMS annually, with finder files provided by the USRDS. The Part D data are 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.

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

LINKAGES TO THE USRDS DATABASE

The USRDS does provide the service of linking population cohorts to the USRDS dataset to determine ESRD status and outcomes for epidemiological research. Please contact the USRDS Coordinating Center for more information on the application process and the costs for this service.

FILE MEDIA & FORMATS

SAFs are provided on DVDs as SAS files, and can be used by SAS on any 486 or Pentium PC with a DVD reader. The SAS format is widely used, easily transported, and largely self-documenting. SAS is a commercially available data management and statistical analysis software system that runs on most computers, and is almost universally available on university computer systems. The SAFs take full advantage of the program's ability to incorporate detailed documentation into the file. Researchers needing another format or medium must arrange for the conversion.

COSTS

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

DOCUMENTATION

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

data use acknowledgement

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

data release policy

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

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

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

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

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

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

caveats

This policy establishes conditions and procedures for the release of data from the USRDS, and is intended to ensure that data are made available to investigators in the pursuit of legitimate biomedical, cost-effectiveness, or other economic research.

The USRDS will not release data that identify individual patients, providers, or facilities. Since it might be possible, however, to infer identity from SAF data, these data are considered confidential. The USRDS "Agreement for Release of Data" contains a number of general and specific restrictions on the use of USRDS data, and investigators are expected to abide by these restrictions. If individually identifiable data are needed, the request should be submitted directly to CMS. Use of these data to identify and/or contact patients, facilities, or providers is prohibited by USRDS policy and by the Privacy Act of 1974.

The USRDS CC will provide data in on CD or DVD. Analytical services other than review of the proposal and preparation of the data file will not be provided under the USRDS contract, though CC personnel may participate in analyses funded by other sources.

Acute kidney injury (AKI) Also known as acute kidney failure or acute renal failure is a sudden decline in renal function triggered by a number of acute occurrences such as shock, trauma, drug toxicity, or kidney stones.

Acute myocardial infarction (AMI) An event causing injury to the heart muscle.

Adult polycystic kidney disease An inherited disease in which the kidneys contain multiple cysts.

Albumin/creatinine ratio (ACR) A screening test used to assess chronic conditions such as diabetes and hypertension that can put patients at risk for chronic kidney failure.

Anemia A condition marked by a reduced number of red cells in the bloodstream.

Angiography A radiographic procedure where a radio-opaque contrast material is injected into a blood vessel for the purpose of identifying its anatomy.

Angioplasty A procedure in which a balloon catheter is inserted into a blocked or narrowed vessel in order to reopen the vessel and allow normal blood flow.

Angiotensin converting enzyme (ACE) inhibitor An antihypertensive agent that inhibits the production of angiotensin II. Can delay progression to diabetes or kidney disease.

Angiotensin II receptor blocker (ARB) an antihypertensive agent that inhibits the actions of angiotensin II, a substance which causes narrowing of blood vessels.

Arteriovenous fistula A type of vascular access used in hemodialysis patients, and created by the anastomosis of the radial artery and the cephalic vein.

Arteriovenous graft A type of vascular access used in hemodialysis patients and created via a connection between an artery and vein using either a native vessel (saphenous vein) or a synthetic material such as Teflon.

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

Beta blockers Antihypertensive medications that block production of norepinephrine, slowing the heart rate and preventing the constriction of blood vessels.

Blood urea nitrogen (BUN) A by-product of the breakdown of amino acids and endogenous and ingested protein.

Body mass index (BMI) A measure of height to weight ratio: weight (kg)/height (m^2).

C-reactive protein A protein produced by the liver in response to infection or injury; high levels are associated with an increased risk of heart disease and stroke.

Calcium channel blockers Antihypertensive agents that work by blocking the access of calcium to muscle cells in artery walls.

Cardiac arrest A complete cessation of cardiac activity.

Cardiac resynchronization therapy defibrillator (CRT-D) A device designed to arrest the fibrillation of (heart muscle) by applying electric shock across the chest, thus depolarizing the heart cells and allowing normal rhythm to return.

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

Catastrophic coverage The interval following the coverage gap.

Catheter A vascular access used in hemodialysis patients, commonly implanted into the jugular or subclavian vein.

Centers for Disease Control & Prevention (CDC) The lead federal agency for protecting the health and safety of people at home and abroad; develops and applies programs designed to improve the health of the people of the United States.

Centers for Medicare and Medicaid Services (CMS) Formerly the Health Care Financing Administration (HCFA). Federal agency that administers the Medicare, Medicaid, and State Childrens' Health insurance programs.

Cerebrovascular accident (CVA) A general descriptor that encompasses such problems as stroke and cerebral hemorrhage.

Cerebrovascular disease A disease that causes narrowing or occlusion of the arteries supplying blood to the brain.

Chain provider A single business entity that at years end owns or operates 20 or more freestanding dialysis units. This definition applies to all chain affiliation references in the USRDS Annual Data Reports. An alternative definition from the Centers for Medicare and Medicaid Services can be found under "definitions" in the Health Care Provider/Supplier Application Form, CMS 855.

Chronic kidney disease (CKD) A condition in which there is a progressive loss of kidney function which over time may lead to end-stage renal disease.

Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) A method used to estimate glomerular filtration rate using a single serum creatinine. Yields a lower CKD prevalence than the Modification of Diet in Renal Disease (MDRD) Study equation.

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

Clinical Performance Measures (CPM) Project Formerly the Core Indicator Project. A project in which CMS and the ESRD networks cooperatively maintain a clinical database of key elements related to the quality of dialysis care. These elements are used as indicators in quality improvement initiatives.

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

Comprehensive Dialysis Study (CDS) A special data collection study that focuses on physical activity level, health-related quality of life, and work/disability status reported by patients who have recently started maintenance dialysis.

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

Continuous ambulatory peritoneal dialysis (CAPD) A type of dialysis in which dialysate is continuously present in the abdominal cavity. Fluid is exchanged using gravity to fill and empty the cavity 4–5 -times a day.

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

Coverage gap The interval following the initial coverage period, but preceding catastrophic coverage.

Creatinine A waste product of protein metabolism found in the urine; often used to evaluate kidney function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

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

Creditable coverage Prescription drug coverage that is actuarially equivalent to the standard Part D benefit, as defined annually by CMS. Beneficiaries with creditable coverage may forgo participation in Medicare Part D without having to pay increased monthly premiums upon future enrollment. Examples of creditable coverage include the Federal Employee Health Benefits Program, TRICARE, VA Health Care Benefits, State Pharmacy Assistance Programs (SPAPs), and private insurance that is eligible for the retiree drug subsidy. Private insurance for the working aged may or may not be creditable.

Cystatin-C equation A method which uses the laboratory marker cystatin-C for estimating glomerular filtration rate (GFR).

Darbepoetin alfa (DPO) One of a class of medications called erythropoietic proteins. Used to treat anemia in patient with serious kidney disease.

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

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

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

Employer group health plan (EGHP) A health plan of or contributed to by an employer, providing medical care directly or through other methods such as insurance or reimbursement to current or former employees, or to these employees and their families.

End-stage renal disease (ESRD) A condition in which a person's kidney function is inadequate to support life.

Erythropoiesis stimulating agent (ESA) Used to increase the production of red blood cells; includes erythropoietin (EPO) and darbepoetin alfa (DPO).

Erythropoietin (EPO) A hormone secreted chiefly by the adult kidney; acts on bone marrow to stimulate red cell production. Also produced in a formulated version to treat anemia.

ESRD Facility Survey Data for this survey are collected annually by CMS from all facilities certified to provide Medicare-covered renal dialysis and transplantation. The survey uses CMS form 2744, and encompasses the full calendar year. Geographic data are included to the level of facility ZIP code. Each record contains facility information and data on the number of patients served, dialysis treatments provided, and kidney transplants performed. The data include services to both Medicare and non-Medicare patients.

ESRD networks Regional organizations, established by law in 1978, contracted by CMS to perform quality oversight activities to assure the appropriateness of services and protection for dialysis patients.

Expanded criteria donors (ECDs) Older kidney donors or donors whose health issues in the past would have prevented their acceptance into the donor program.

Fills per person Each prescription drug purchase constitutes a fill. Fills per person are calculated from the quotient of cumulative fills in a population and the number of people in that population.

Glomerular filtration rate (eGFR) Estimated rate in ml/min/1.73 m^2 of the volume of plasma filtered by the kidney. Rates of filtration are based on an individual's age, gender, and height, and on levels of serum creatinine, blood urea nitrogen, and serum albumin. GFR is traditionally considered the best overall index to determine renal function.

Glycosylated hemoglobin (HbA1c) test Used to help determine how well a patient's diabetes is being controlled, this test measures the level of glucose-bound hemoglobin in the bloodstream.

Health Maintenance Organization (HMO) A competitive medical plan, such as Medicare+Choice, that has contracts with CMS on a prospective capitation payment basis for providing healthcare to Medicare beneficiaries.

Health Service Area (HSA) A group of counties described by the authors of the CDC Atlas of United States Mortality as "an area that is relatively self-contained with respect to hospital care."

Healthy People 2010 A national agenda for health promotion and disease prevention, with objectives and goals aimed at improving the health of the American people (www.health.gov/healthypeople).

Hemodialysis The process of removing toxins from the blood by diffusion through a semi-permeable membrane.

Hemoglobin Oxygen-carrying protein in the erythrocyte (red blood cell).

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

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

Implantable cardioverter defibrillator (ICD) An implantable device designed to arrest the fibrillation of (heart muscle) by applying electric shock thus depolarizing the heart cells and allowing normal rhythm to return.

Incident ESRD patient A patient starting renal replacement therapy for ESRD during a calendar year. Excludes patients with acute renal failure, those with chronic renal failure who die before starting ESRD treatment, and those whose treatments are not reported to CMS.

Incident population The people in a population who are newly diagnosed with a disease in a given time period, typically a year.

Independent unit A unit licensed to provide outpatient and home maintenance dialysis, and not affiliated with a chain.

Initial coverage period The interval following the deductible phase, but preceding the coverage gap.

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

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

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

Low income subsidy (LIS) For Medicare beneficiaries with limited income and/or assets, the costs of participation in Medicare Part D may be reduced by the LIS. Beneficiaries who are dually eligible for Medicare and Medicaid are automatically granted the LIS, while beneficiaries who are not dually eligible may apply for it. While the LIS may take eight different levels, with monthly premiums and copayments either eliminated or reduced, all dually eligible beneficiaries pay no monthly premiums.

Medical Evidence form (CMS-2728) A form which provides source data about ESRD patients, including information on demographics, primary cause of renal disease, comorbidity, biochemical data, dialysis treatment, transplant, dialysis training, employment status, initial insurance coverage, and first ESRD service date.

Medicare Advantage Part D plans (MA-PDs) Medicare Part D plans that are offered only to participants in Medicare Part C.

Medicare as Secondary Payor (MSP) patient A Medicare beneficiary with a health insurer other than Medicare (e.g. an Employer Group Health Plan) that has primary responsibility for payment of the beneficiary's medical bills.

Medicare Current Beneficiary Survey (MCBS) An ongoing national survey of aged, disabled, and institutionalized Medicare beneficiaries. Sponsored by the Centers for Medicare and Medicaid Services, and used to study the health status, health care use and expenditures, health insurance coverage, and socioeconomic and demographic characteristics of Medicare beneficiaries.

Microalbuminuria A condition in which small amounts of albumin are present in the urine; indicates early kidney damage.

Modality A method of treatment. Treatment for end-stage renal disease (ESRD) is comprised of three modalities: hemodialysis, peritoneal dialysis, and transplantation.

Modification of Diet in Renal Disease (MDRD) Study equation A method used to estimate glomerular filtration (GFR) using a single serum creatinine.

National Health and Nutrition Examination Survey (NHANES) A survey conducted by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention; uses home interviews and health tests to collect information on health and diet in the United States.

National Institutes of Health (NIH) The federal focal point for medical research in the U.S. and one of eight health agencies of the Public Health Services, which are part of the Department of Health and Human Services.

Organ Procurement and Transplantation Network (OPTN) The unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984. A private, non-profit organization administered by the United Network for Organ Sharing, under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services.

Part D Medicare coverage A U.S. government program which subsidizes the costs of medications for Medicare beneficiaries.

Percutaneous coronary intervention (PCI) A therapeutic procedure to treat the stenotic (narrowed) coronary arteries of the heart found in coronary heart disease. Commonly known as coronary angioplasty or simply angioplasty.

Period prevalent patient A patient receiving treatment for ESRD at some point during a period of time, usually six months or a year. Patients may die during the period or be point prevalent at the end of the period. Period prevalence is a useful measure for cost analysis, since it indicates total disease burden over the course of a year.

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

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

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

Program Medical Management and Information System for ESRD, and Renal Beneficiary and Utilization System (PMMIS/REBUS) The major source of data for the USRDS. This CMS file incorporates data from the Medical Evidence form (CMS 2728), the Death Notification form (CMS 2746), the Medicare Enrollment Database, CMS paid claims records, and the UNOS transplant database.

Prevalent ESRD patient A patient on renal replacement therapy or with a functioning kidney transplant (regardless of the transplant date). This definition excludes patients with acute renal failure, those with chronic renal failure who die before receiving treatment for ESRD, and those whose ESRD treatments are not reported to CMS.

Prevalent population The people in a population who have a disease at a given point in time (point prevalence) or during a given time period (period prevalence).

Proteinuria The existence of protein in the urine; indicative of kidney damage.

Recombinant human growth hormone (rhGH) Also called somatropin; a substance identical in its amino acid sequence to human growth hormone, and used to treat growth hormone deficiency.

REMIS CMS's Renal Management Information System (REMIS), which has replaced the Renal Beneficiary and Utilization System (REBUS). Includes an operational interface to the SIMS Central Repository.

Renin Inhibitors A class of drugs used to lower blood pressure by blocking the renin-angiotensin system which regulates blood volume and systemic vascular resistance.

Retiree drug subsidy (RDS) A program designed to encourage employers to continue to provide prescription drug coverage to retirees eligible for Medicare Part D. Under the program, employers received a tax-free rebate equal to 28 percent of covered prescription drug costs incurred by its retirees. The program is relatively simple to administer, but may ultimately be more costly than providing employees a type of Part D plan known as an "employer group waiver plan." Following passage of the Patient Protection and Affordable Care Act, the tax-free status of the subsidy is due to expire on December 31, 2012.

SIMS CMS's Standard Information Management System (SIMS), which became operational at the beginning of 2000. Supports CMS reporting requirements and the business processes of the ESRD networks; provides communication and data exchange links for the networks, CMS, and other parts of the renal community; supplies standard core data functionality for previous network data systems; and provides improved electronic communication capabilities, data standardization, and information management tools.

Standard Analysis Files (SAFs) CMS files containing final action Medicare inpatient/outpatient claims data: Inpatient, Outpatient, Home Health Agency, Hospice, Skilled Nursing Facility, Clinical Laboratory, Durable Medical Equipment, and 5 percent Sample Beneficiary.

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

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

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

Statins Medications that lower cholesterol through action on an enzyme in the liver.

Total days supply Each prescription drug is disbursed with sufficient quantity to administer for a set number of days, so long as instructions are followed (i.e., so long as adherence is perfect). The total days supplied is equal to the cumulative number of days supplied through all fills of a particular medication in a population.

Transient ischemic attacks (TIA) A temporary loss of neurological function caused by a brief period of inadequate blood supply in a portion of the brain supplied by the carotid or vertebral basilar arteries.

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

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

Vintage Time in years that a patient has had ESRD.

Wait list A list of patients awaiting an organ transplant; maintained by the United Network for Organ Sharing (UNOS).

Some of these definitions are obtained from the Mondofacto Medical Dictionary, found at www.mondofacto.com/dictionary.

abbreviations

A1c	glycosylated hemoglobin
AAPCC	average annual per capita cost
ACEI	angiotensin converting enzyme inhibitor
ACR	albumin/creatinine ratio
AKI	acute kidney injury
AKI-D	acute kidney injury with dialysis
AMI	acute myocardial infarction
ARB	angiotensin receptor blocker
ASHD	atherosclerotic heart disease
AV	arteriovenous
BMI	body mass index
BRFSS	Behavioral Risk Factor Surveillance System
BUN	blood urea nitrogen
CAPD	continuous ambulatory peritoneal dialysis
CCPD	continuous cycler peritoneal dialysis
CCR	creatinine clearance rate
CDC	Centers for Disease Control and Prevention
CDS	Comprehensive Dialysis Study
CHF	congestive heart failure
CK	cystic kidney disease
CKD	chronic kidney disease
CKD-EPI	Chronic Kidney Disease Epidemiology Collaboration
CMS	Centers for Medicare & Medicaid Services
COPD	chronic obstructive pulmonary disease
CPM	Clinical Performance Measures Project
CVA/TIA	cerebrovascular accident/transient ischemic attack
CPT	Current Procedure and Terminology
CRT-D	cardiac resynchronization therapy defibrillator
CVD	cerebrovascular disease
DCD	donation after cardiac death
DGF	delayed graft function
DM	diabetes, diabetic
DPO	darbepoetin alfa
DRG	diagnosis related group
ECD	expanded criteria donor
EGHP	employer group health plan
EPO	erythropoietin
ESA	erythropoiesis stimulating agent
ESRD	end-stage renal disease
eGFR	estimated glomerular filtration rate
GN	glomerulonephritis
HCPCS	healthcare common procedure coding system
HD	hemodialysis
HEDIS	Health Plan Employer Data Information Set
HMO	health maintenance organization
HSA	Health Service Area
HTN	hypertension
ICD	implantable cardioverter defibrillator
ICD-9-CM	International Classification of Diseases, 9th revision, Clinical Modification
IPD	intermittent peritoneal dialysis
ISHD	ischemic heart disease
KDOQI	Kidney Disease Outcomes Quality Initiative
LIS	low income subsidy
MCBS	Medicare Current Beneficiary Survey
MDRD	Modification of Diet in Renal Disease
ME	Medical Evidence form (2728)
MI	myocardial infarction
MPP	Medicare as primary payor
MSP	Medicare as secondary payor
NDC	National Drug Code
NDM	non-diabetic
NHANES	National Health and Nutrition Examination Survey
NKF	National Kidney Foundation
OPTN	Organ Procurement and Transplantation Network
PACE	programs of all-inclusive care for the elderly
PCI	percutaneous coronary intervention
PD	peritoneal dialysis
PPPM	per person per month
PPPY	per person per year
PAD	peripheral arterial disease
PVD	peripheral vascular disease
RDS	retiree drug subsidy
SCD	standard criteria donor
SHR	standardized hospitalization ratio
SMR	standardized mortality ratio
STR	standardized transplantation ratio
Tx	transplant
UNOS	United Network for Organ Sharing
WHO	World Health Organization

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

Project title _____

In this agreement, "Requestor Organization" means _____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Requestor with CDs, DVDs, or other media type containing the data extracted from the USRDS research database(the "Data"), which constitutes a Limited Data Set within the meaning of the HIPAA privacy regulations.

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

C. The Requestor shall not use the Data to identify individuals on the file.

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

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

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

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

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

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

I. No copies or derivatives shall be made of the data in this file except as necessary for the purpose authorized in this agreement. The Requestor shall keep an accurate written account of all such copies and derivative files, which will be furnished upon request to the PO. The USRDS data files covered in this data use agreement may be retained by the Requestor until the date specified by the PO in the approval letter, at which time Requestor may request renewal of this data use agreement to extend the retention period to comply with legal or institutional recordkeeping requirements or to maintain the integrity of the research or research publications. If at any time during the data retention period the DUA between USRDS and CMS is canceled, the Requestor will be contacted to destroy the files in their possession. At the completion of the activities in the research plan, the file(s) and any derivative files and copies shall be destroyed. At that time the Requestor will inform the USRDS and the PO in writing that the files have been destroyed.

J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the NIDDK and/or of CMS will, upon request, be granted access to premises where the Data are kept.

K. The following USRDS data file(s) is/are covered under this Agreement.

Name of Data file(s) requested (eg Core, Institutional claims, etc)	Year(s) if applicable

REQUESTOR SIGNATURE: _____

_____
Authorized signatory (name, title & date)

_____
Requestor address

_____
Requestor telephone number

READ AND ACKNOWLEDGED:

_____	_____
Investigator/Analyst signature	Print Investigator/Analyst name & date
_____	_____
Investigator/Analyst signature	Print Investigator/Analyst name & date
_____	_____
Investigator/Analyst signature	Print Investigator/Analyst name & date

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

_____
USRDS Project Officer signature & date

June 2012

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

Project title _____

In this agreement, "Requestor Organization" means _____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center (CC), will provide the Requestor CDs, DVDs or other media type containing data extracted from the USRDS research database. Prior to receiving USRDS data, the Requestor will provide USRDS with a list of personally identifiable information (PII) so USRDS can report which of the Requestor's subjects are in the USRDS end-stage renal disease (ESRD) data.

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

C. USRDS shall not use or disclose the Requestor's data for any purpose other than to create the data extracted from the USRDS database. In the event that the Requestor's data is used or disclosed for any purpose other than that covered by this agreement, USRDS will notify the Requestor immediately and agree to work with Requestor to address the use or disclosure. The USRDS will destroy the Requestor's data set one year after the linkage is complete unless otherwise specified by the Requestor in the research proposal.

D. The Requestor shall not combine or link the data provided with any other collection or source of information that may contain information specific to individuals on the file, except where a waiver of authorization has been approved by the Requestor's IRB/Privacy Board.

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

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

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

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

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

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J. For the purpose of inspecting security procedures and arrangements, authorized representatives of the NIDDK and/or of CMS will, upon request, be granted access to premises where the Data are kept.

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REQUESTOR SIGNATURE: _____

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Authorized signatory (name, title & date)

_____
Requestor address

_____
Requestor telephone number

READ AND ACKNOWLEDGED:

_____	_____
Requestor/investigator signature	Print name & date
_____	_____
Requestor/investigator signature	Print name & date
_____	_____
Requestor/investigator signature	Print name & date

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

_____
USRDS Project Officer signature & date

June 2012