USRDS
UNITED STATES RENAL DATA SYSTEM

2015 USRDS Annual Data Report
Appendices

Glossary

Acute kidney injury (AKI) Also known as acute kidney failure or acute renal failure is a sudden decline in renal function triggered by any of a number of conditions such as shock, trauma, drug toxicity, acute glomerulonephritis, vasculitis, or obstruction to urine flow.

Acute myocardial infarction (AMI) An event causing death to a portion of the heart muscle due to lack of blood supply.

Adult polycystic kidney disease An inherited disease in which normal kidney tissue is replaced by multiple cysts.

Albumin/creatinine ratio (ACR) A screening test used to estimate the amount of albumin in a patients urine.

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 conversion of Angiotensin I to angiotensin II. Can delay progression of kidney disease in diabetics.

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

Arteriovenous fistula A type of vascular access used in hemodialysis patients, and created by the anastomosis of an artery and a 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 (e.g. saphenous vein) or a synthetic material.

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

Beta blockers Antihypertensive medications that block B-adrenergic receptors, thus interfering with the actions of endogenous catecholamines (epinephrine and norepinephrine), slowing the heart rate and reducing 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 (m2).

C-reactive protein A protein produced by the liver in response to infection or inflammation; 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 sudden complete cessation of cardiac activity.

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

Cardiomyopathy A general diagnostic term indicating a disease of the heart muscle.

Catastrophic coverage Health insurance to cover costs that exceed routine healthcare insurance benefits.

Dialysis 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) One of a number of classes of chronic progressive lung diseases .

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 impaired pumping of the heart and consequent 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 after initial benefits are exhausted, but preceding catastrophic coverage.

Creatinine A waste product of protein metabolism found in the urine. Blood creatinine concentration is an indirect measure of kidney function. Abnormally high creatinine levels indicate kidney failure or renal insufficiency.

Creatinine clearance A measure of kidney function.

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.

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) Any kidney donor over the age of age 60 years, or donors between the ages of 50 and 59 years with two of the following criteria: death by CVA, history or hypertension or creatinine at time of recovery (terminal creatinine) ≥ 1.5 mg/dL.

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) Rate in ml/min/1.73 m2 of the volume of plasma filtered by the kidney. Rates of filtration may be measured directly or estimated based on formulae that employ combinations of 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 percentage of hemoglobin-bound glucose in the bloodstream.

Health Maintenance Organization (HMO) An organization that provides or arranges managed care on a prepaid basis.

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 2020 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 transmitted through blood and body fluids; and Hepatitis C, also transmitted through blood and body fluids.

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. 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 A unitless number used to quantify clearance of small molecular weight substances (solutes) such as urea, where K = dialyzer clearance of urea, t = dialysis time and V = volume of distribution of urea, (approximately equal to the total body water). It reflects the degree of removal of these substances during dialysis treatment and is expressed by Kt/V per hemodialysis session or weekly Kt/V in the context of peritoneal dialysis.

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 Payer (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) in patients with impaired renal function using a single serum creatinine, age, sex and race.

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; using 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 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.

Peritoneal dialysis Dialysis in which fluid (dialysate) is introduced into the abdominal cavity and uremic toxins are removed by diffusion 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 OPTN 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). It included an operational interface to the SIMS Central Repository until 2012 at which point CROWNWeb replaced the functionality of SIMS.

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 expired on December 31, 2012.

SIMS CMS's Standard Information Management System (SIMS), which became operational at the beginning of 2000 and was replaced by CROWNWeb in 2012. 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 patient mortality rates for a selected group of patients by computing the ratio of the group's observed mortality rate to the expected mortality rate for the national ESRD population.

Standardized transplantation ratio (STR) Used to compare transplant rates for a subgroup of patients to national transplant rates, by computing the ratio of the group's observed transplant rate to the expected transplant rate for the national ESRD population.

Statins Medications that lower cholesterol through inhibition of the HMG CoA enzyme.

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. 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.

United Network for Organ Sharing (UNOS) A private, non-profit organization that holds the Organ Procurement and Transplantation Network contract to maintain the national organ transplant waiting lists and coordinates the matching and distribution of organs to patients awaiting transplant.

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

Vintage Time that a patient has had ESRD.

Waiting list A list of patients awaiting an organ transplant; maintained by the Organ Procurement and Transplantation Network (OPTN).

Some definitions from U.S. National Library of Medicine's Medical Dictionary: http://www.nlm.nih.gov/medlineplus/mplusdictionary.html

Abbreviations

A1c	glycosylated (hemoglobin)
AAPCC	Adjusted average per capita cost
ACE-I	angiotensin converting enzyme inhibitor
ACEI	angiotensin-converting enzyme inhibitor
ACR	albumin/creatinine ratio
ADL	activities of daily living
ADR	annual data report
AF	atrial fibrillation
AFIB	atrial fibrillation
AFS	Annual Facility Survey (CMS 2744)
AJKD	American Journal of Kidney Disease
AKI	acute kidney injury
AKI-D	acute kidney injury with dialysis
AMI	acute myocardial infarction
ANZDATA	Australia & New Zealand ESRD database
ARB	angiotensin receptor blocker
ASHD	atherosclerotic heart disease
AV	arteriovenous
BMI	body mass index
BUN	blood urea nitrogen
CABG	coronary artery bypass grafting
CAPD	continuous ambulatory peritoneal dialysis
CBC	complete blood count
CCPD	continuous cycler peritoneal dialysis
CDC	Centers for Disease Control and Prevention
CDM	Clinformatics DataMart
CDS	Comprehensive Dialysis Study
CES-D	Center for Epidemiologic Studies Depression Scale
CHF	congestive heart failure
CKD	chronic kidney disease
CKD-EPI	chronic kidney disease epidemiology calculation
CKO	cytokinin oxidase
CMS	Centers for Medicare & Medicaid Services
CMV	cytomegalovirus (antibody status)
COPD	chronic obstructive pulmonary disease
CORR	Canadian Organ Replacement Register
CPM	clinical performance measures
CPRA	calculated panel reactive bodies
CPT	current procedure and terminology
CrCl	creatinine clearance rate
CROWNWeb	Consolidated Renal Operations in a Web-based Network (CROWN) Data — data collection system for ESRD dialysis facilities mandated by CMS
CRT	cardiac resynchronization
CVA	cerebrovascular accident
CVD	cardiovascular disease
CVVHD	continuous venous-to-venous hemodialysis
CWF	common working file
DCD	donation after circulatory death
DCI	Dialysis Clinic Inc.
DFC	dialysis facility compare
DGF	delayed graft function
DHD	daily hemodialysis
DM	diabetes mellitus
DME	durable medical equipment
DMMS	Dialysis Morbidity and Mortality Study
DPO	darbepoetin alfa
DRG	diagnosis related group
DSA	Donation Service Area [or Disability Services Agency]
DUA	data use agreement
ECD	expanded criteria donor
EDB	Enrollment Database
eGFR	estimated glomerular filtration rate
EGHP	employer group health plan
EPO	erythropoietin
ESA	erythropoiesis stimulating agent
ESRD	end-stage renal disease
FSD	first service date
GFR	glomerular filtration rate
GLIMMIX	SAS procedure
GN	glomerulonephritis
HbA1c	glycosylated hemoglobin
HB	hospital-based (providers)
HCFA	Health Care Financing Administration (CMS before July 2001)
HCPCS	healthcare common procedure coding system
HD	hemodialysis

HDL	high density lipoprotein
HEDIS	Health Plan Employer Data Information Set
Hgb	hemoglobin
HF	heart failure
HHA	home health agency
HIC	health insurance claims
HIC/BIC	Health Insurance Claim/Beneficiary Identification Code
HIPAA	Health Insurance Portability and Accountability Act
HLA	Human Leukocyte antigen
HRSA	Health Resources and Services Administration
HS	hospice
HSA	Health Service Area
HTN	hypertension
ICD-9	International Classification of Diseases, 9th revision
ICD-9-CM	International Classification of Diseases, 9th revision, Clinical Modification
ICD	implantable cardioverter defibrillators
ICD/CRT-D	implantable cardioverter defibrillators/ cardiac resynchronization therapy with defibrillator devices
ICW	intracellular water
IHD	intermittent hemodialysis
IL2-RA	interleukin 2 receptor alpha
IP	inpatient
IPD	intermittent peritoneal dialysis
IRB	Institutional Review Board
ISHD	ischemic heart disease
IV	intravenous
KDIGO	Kidney Disease Improving Global Outcomes
KDOQI	Kidney Disease Outcomes Quality Initiative
LDL	low density lipoprotein
LDO	large dialysis organization
LIS	low income subsidy
MCBS	Medicare Current Beneficiary Survey
MDRD	Modification of Diet in Renal Disease
MI	myocardial infarction
MPP	Medicare as primary payer
MSP	Medicare as secondary payer
mTOR	mammalian (or mechanistic) target of rapamycin
NCHS	National Center for Health Statistics
NCQA	National Committee for Quality Assurance
NEJM	New England Journal of Medicine
NHANES	National Health and Nutrition
NHIS	National Health Interview Survey
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NKF	National Kidney Foundation
OMB	Office of Management and Budget
OOP	out-of-pocket
OP	outpatient
OPTN	Organ Procurement and Transplantation Network
PACE	programs of all-inclusive care for the elderly
PAD	peripheral arterial disease
PCI	percutaneous coronary interventions
PD	peritoneal dialysis
PDE	prescription drug event
PDP	prescription drug plan
PII	patient identifiable information
PMMIS	Program Medical Management and Information System
PPPM	per person per month
PPPY	per person per year
PPS	prospective payment system
PRA	panel reactive antibodies
pts	patients
PTLD	post-transplant lymphoproliferative disorder
PVD	peripheral vascular disease
QI	qualifying individuals
QMB	qualified Medicare beneficiaries
RBC	red blood cells
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
rhGH	recombinant DNA human growth hormone
RRB	Railroad Retirement Board
SAF	standard analysis file
SAS	Statistical Analysis System
SCA/VA	Sudden cardiac arrest and ventricular arrhythmias
SCD	sudden cardiac death
SCD	standard criteria donor
SDO	small dialysis organizations
SHR	standardized hospitalization ratio
SMR	standardized mortality ratio
SNF	skilled nursing facility
SSA	Social Security Administration
SSI	Supplemental Security Income

SSRI	selective serotonin reuptake inhibitor
ST-segment	EKG segment that follows the QRS complex and merges into the T wave
STR	standardized transplantation rate
STrR	standardized transfusion ratio
TBW	total body weight
THMS	Truven Health Market Scan
TIA	transient ischemic attack
TrOOP	true out-of-pocket costs
Tx	transplant
TZD	thiazolidinedione
UNOS	United Network for Organ Sharing
URR	urea reduction ratio
USRDS	United States Renal Data System
VA	vascular access
VAT	vascular access type
WHO	World Health Organization

Notes

USRDS Products and Services

Products and services provided by the USRDS to support the work of the renal community are detailed in Table A. The entire Annual Data Report (ADR) is available at www.USRDS.org, with PowerPoint slides of all figures and Excel files of the data behind the graphs, as well as PDF files of the Researcher's Guide. The site's RenDER system allows users to create customized data tables and regional maps.

Table a. USRDS Products and Services

Annual Data Report DVD
Annual Data Report DVD contains the text and graphics of the ADR, data tables, and PowerPoint slides, and is available from the USRDS Coordinating Center.
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 ADR figures and USRDS conference presentations; Excel files of table and figure data; 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 http://www.usrds.org/render/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 USRDS 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. Users must sign a Data Release Agreement with the NIDDK.
Merged data files: Merged files can be created by the Coordinating Center for a limited number of approved research projects. Users must sign a data release agreement with the NIDDK. Contact the USRDS Coordinating Center for more information.
Publications and 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 relevant journals.
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Data Requests

Making information on end-stage renal disease (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, and that require two hours or less of staff time, are fulfilled by the Coordinating Center without charge, usually within one week. However, more complex requests — requiring more than two hours of staff time — as well as requests for Standard Analysis Files (SAFs) and custom files, must be accompanied by a written proposal (see details below), and will be completed only upon written approval by the USRDS Project Officer.

Research Files

The Coordinating Center maintains a set of 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 required to use all of the other SAFs. Included are each patient's demographic information, payer 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 dataset. The Transplant dataset contains detailed transplant and transplant follow-up data collected by the Centers for Medicare & Medicaid Services (CMS) and the United Network for Organ Sharing (UNOS). Data on hospital inpatient stays are found on the Hospital dataset. All Medicare billing data are available by individual year (see Table B).

Table b. USRDS Standard Analysis Files

Standard Analysis Files	
Core dataset	Needed in order to use all other files.
Transplant dataset	Detailed transplant data from CMS and UNOS.
Hospital dataset	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	Survey information and laboratory values from the Comprehensive Dialysis Survey.
DMMS claims	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	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.
ESRD Medicare payment data	
Institutional claims	pre-1989 through 2012*
Physician/supplier claims	1991–2012
Part D Prescription Drug	2006–2012
CKD 5 Percent Medicare Sample Standard Analysis Files	
Patient cohort finder	
Hospital file	
Institutional claims	1992–2012
Physician/supplier claims	1992–2012
Part D	2006–2012
ESRD CPM Survey data	Includes 1994–2008 hemodialysis survey years and 1995–2008 peritoneal dialysis survey years
ESRD CPM/SAF linked files	Core, Hospital, Transplant
ESRD CPM Medicare participant institutional and physician/supplier claims	pre-1989 through 2011

Standard Analysis Files

SAF use is governed by the USRDS policy on data release for investigator-initiated research. Research proposals must be approved by a USRDS Project Officer, and institutions and researchers must sign the USRDS "Agreement for Release of Data," found later in these appendices.

Most SAFs provide patient-specific data and are considered limited datasets. 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. The agreement must be signed by the appropriate institutional authority responsible for IT and privacy security, then co-signed by the investigators/analysts as well to acknowledge their responsibility for protecting the privacy of this kind of individual patient data. 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 required for use of the Transplant, Hospital, or ESRD Medicare claims. Included files are as follows (also listed in Table C).

Patient

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

Residence

A longitudinal record of residence by ZIP code.

Payer History

Contains a new record for each patient at each change in insurance payer.

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; an expanded form was later implemented in 2005.

Transplant

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

Transplant Waiting 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 waiting-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 in the late 1980s to mid-1990s. 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, available from published sources 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 and 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 includes 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 patient incidents in 1986–1987 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, sex, 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 and Development

The objectives of the USRDS Pediatric Growth and Development Study were to establish a baseline for assessing the relationship 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.

Continuous Ambulatory Peritoneal Dialysis (CAPD) and 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 files. The first two are included on the Core SAF, and the remaining six are included in the Transplant SAF set.
- TX includes minimum details on all transplants from all sources
- TXWAIT contains one record for each patient in the USRDS database per waiting-list event
- TXHCFA includes transplant information collected by CMS's Program Management and Medical Information System (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 forms and institutional claims records indicate transplants not included in either file. To resolve conflicts among all 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 Medical Evidence form 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 dataset, 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 dataset 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 and Mortality Claims

This dataset 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 dataset contains Medicare claims for participants 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 are available as institutional and physician/supplier claim datasets for the ESRD population. Available years can be found in Table B.

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 Data Collection

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 health care 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 health care 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 can be found in Table B, or you may contact the USRDS Coordinating Center for further information.

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 payer sequence file, and a set of comorbidity files. We no longer produce datasets for diabetes and congestive heart failure 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. 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. The structure of the claims file is identical to the ESRD claims files and organized by calendar year. In addition, a pre-ESRD payer sequence is provided so researchers can determine Medicare enrollment for the periods prior to first ESRD service date. A listing of available files can be found in Table B.

Part D Data

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 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).

Table c. Contents of the USRDS Core Standard Analysis CD-ROM

File name Unit of observation and uses. This two-CD set is required 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.
Payer History One record for each period a patient is covered by one payer; each patient can have many records. The impact of insurance payers 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 Waiting 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 waiting 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.

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.

File Media and Formats

SAFs are provided on DVDs as SAS files. 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.

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 is included with the Core SAF DVD.

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 at the NIDDK to discuss requests before preparing a proposal. To request and use USRDS data files, investigators must provide the Project Officer with a detailed description of the proposed investigation (see Table 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.

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.

The investigator and the Coordinating Center will resolve any technical questions. The NIH will review the project for technical merit and for conformity with the Privacy Act. The Project Officer will notify the investigator(s) in writing of the outcome, and if the project is not approved, will discuss reasons for the decision. The Project Officer will send a copy of the approval letters to the Coordinating Center. The Coordinating Center will then 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 Project Officer prior to submission for publication to assure adherence to the Privacy Act. The Project Officer must respond within 30 days. If a report or article is determined not to adhere to the Privacy Act, it shall not be published until compliance is achieved. Assessment of compliance will not depend on the opinions and conclusions expressed by the investigators, nor will the Project Officer'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 Project Officer and the Coordinating Center.

Table d. 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 files.

I. Research topic title and submission date.
II. Background information.
III. Study design
    a. Objectives
    b. Hypothesis(es)
    c. Analytical methods.
IV. Data being requested:
    a. List of Standard Analytical Files needed (please specify years required); include brief justification for each dataset
    b. Description of data security: responsible party, computer access, etc.
    c. Time frame for the project
    d. 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 or waiver for all research proposals. IRB approval is not required from those requesting aggregate data.
VI. Agreement for Release of Data, signed by all researchers.
VII. Investigator information for principal investigator and coauthors, supply:
    a. Name
    b. Affiliation
    c. Business address
    d. Business phone number
    e. Business fax number
    f. Email address

Submit to

Kevin C. Abbott, MD, MPH
Director, Kidney and Urology Epidemiology
NIDDK
Room 621
6707 Democracy Blvd
Bethesda, Maryland 20892
301 594-7714
kevin.abbott@nih.gov

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

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

Project Title _____

In this agreement, "Requester Organization" means _____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center, will provide the Requester data extracted from the USRDS research database (the "Data"), via download or on CDs, DVDs, or other media type, which constitutes a Limited Dataset 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 Requester.

C. The Requester shall not use the Data to identify individual beneficiaries or individual providers on the files.

D. The Requester 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 files, except where a waiver of authorization has been approved by the Requester's IRB/Privacy Board and NIDDK.

E. The Requester 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 Requester shall not publish or otherwise disclose the Data in the files 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 Requester shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred. However, the

Requester may release Data to a contractor for purposes of data processing or storage if (1) the Requester specified in the research plan submitted to the USRDS Project Officer that Data would be released to the particular contractor, or the Requester 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 Requester 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 Resources, 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 these files except as necessary for the purpose authorized in this agreement. The Requester 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 (DUA) may be retained by the Requester until the date specified by the PO in the approval letter, at which time Requester 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 Requester 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 Requester 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.

Standard Analysis Files (SAFs) requested:

☐ Core
☐ Transplant
☐ Hospital
☐ CKD 5% Cohort Core
☐ CKD 5% Cohort Hospital
☐ CROWNWeb Clinical Data
☐ Dialysis Morbidity and Mortality Study (DMMS)
☐ Comprehensive Dialysis Study (CDS)
☐ Clinical Performance Measures
☐ Case Mix Adequacy (CMA)
☐ Active-Adipose Study (AAS)
☐ Medicare Claims Clinical Data

For the following SAFs, indicate the claim year(s) requested as well:

☐ Institutional Claims (pre-1989 through 2013 available) _____
☐ Physician/Supplier Claims (1991–2013 available) _____
☐ Part D (2006–2013 available) _____
☐ Pre-ESRD Institutional Claims (incident years 1993-2013) _____
☐ Pre-ESRD Physician/Supplier Claims (incident years 1993-2013) _____
☐ Pre-ESRD Part D (incident years 2006-2013) _____
☐ CKD 5% Institutional Claims (1992–2013 available) _____
☐ CKD 5% Physician/Supplier Claims (1992–2013 available) _____
☐ CKD 5% Part D (2006–2013 available) _____

Other:

☐ Provider Crosswalk
☐ Physician Crosswalk

_____

Requester Signature (for the Institutional Official for Data Assurance)

_____

Authorized Signatory (name, title & date)

_____

Requester Address

_____

Requester Telephone Number

Read and Acknowledged (for Primary Investigator and all co-investigators who will analyze data directly)

_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date

(attach additional signature pages as necessary)

USRDS Project Officer: Kevin C. Abbott, MD, NIDDK, NIH or Lawrence Y. C. Agodoa, MD, NIDDK, NIH

_____	_____
USRDS Project Officer Signature	Date

Checklist:
DID YOU REMEMBER TO SEND:

☐ Signed copy of your institutional IRB approval memo

☐ Copy of your project proposal in recommended format at http://www.usrds.org/2015/appx/3/1_Outline_for_research_proposals_using_USRDS_data.rtf

☐ Copy of this Data Use Agreement signed by your institutional official, PI, and all active participants.

Please note that any MODIFICATIONS or AMMENDMENTS, regardless of whether they require additional files, require a new IRB approval memo (1 above), copy of the original project proposal (2 above) with additional analyses/extractions highlighted, and a new signed Data Use Agreement (3).

Please send ALL documents (including the research protocol) in PDF format (please save the research protocol as PDF within Microsoft Word when you have completed it). AND consolidate all files into a single PDF file (using the "PDF Portfolio" feature in Adobe) when sending to the NIDDK.

03/09/2016 revision

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

Project Title _____

In this agreement, "Requester Organization" means _____

A. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), through the United States Renal Data System (USRDS) Coordinating Center, will provide the Requester data extracted from the USRDS research database (the "Data"), via download or on CDs, DVDs, or other media type. Prior to receiving USRDS data, the Requester will provide USRDS with a list of personally identifiable information (PII) so USRDS can report which of the Requester'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 Requester.
C. USRDS shall not use or disclose the Requester's data for any purpose other than to create the Data extracted from the USRDS database. In the event that the Requester's data is used or disclosed for any purpose other than that covered by this agreement, USRDS will notify the Requester immediately and agree to work with Requester to address the use or disclosure. The USRDS will destroy the Requester's dataset one year after the linkage is complete unless otherwise specified by the Requester in the research proposal.
D. The Requester 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 files, except where a waiver of authorization has been approved by the Requester's IRB/Privacy Board and NIDDK.
E. The Requester 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 Requester shall not publish or otherwise disclose the Data in the files 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 Requester shall not publish or otherwise disclose Data that identify individual providers or facilities, or from which such identities could be inferred. However, the Requester may release Data to a contractor for purposes of data processing or storage if (1) the Requester specified in the research plan submitted to the USRDS Project Officer that Data would be released to the particular contractor, or the Requester 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 Requester 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 Resources, 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 these files except as necessary for the purpose authorized in this agreement. The Requester 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 (DUA) may be retained by the Requester until the date specified by the PO in the approval letter, at which time Requester 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 Requester 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 Requester 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.

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☐ CROWNWeb Clinical Data
☐ Dialysis Morbidity and Mortality Study (DMMS)
☐ Comprehensive Dialysis Study (CDS)
☐ Clinical Performance Measures
☐ Case Mix Adequacy (CMA)
☐ Active-Adipose Study (AAS)
☐ Medicare Claims Clinical Data

For the following SAFs, indicate the claim year(s) requested as well:

☐ Institutional Claims (pre-1989 through 2013 available) _____
☐ Physician/Supplier Claims (1991–2013 available) _____
☐ Part D (2006–2013 available) _____
☐ Pre-ESRD Institutional Claims (incident years 1993-2013) _____
☐ Pre-ESRD Physician/Supplier Claims (incident years 1993-2013) _____
☐ Pre-ESRD Part D (incident years 2006-2013) _____
☐ CKD 5% Institutional Claims (1992–2013 available) _____
☐ CKD 5% Physician/Supplier Claims (1992–2013 available) _____
☐ CKD 5% Part D (2006–2013available) _____

Other:

☐ Provider Crosswalk
☐ Physician Crosswalk

IMPORTANT! Specify:

☐Data ONLY on matched patients ***OR***

☐Complete SAFs, including matched and unmatched patients

_____

Requester Signature (for the Institutional Official for Data Assurance)

_____

Authorized Signatory (name, title & date)

_____

Requester Address

_____
Requester Telephone Number

Read and Acknowledged (for Primary Investigator and all co-investigators who will analyze data directly)

_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date
_____	_____	_____
Investigator / Analyst signature	Name	Date

(attach additional signature pages as necessary)

USRDS Project Officer: Kevin C. Abbott, MD, NIDDK, NIH or Lawrence Y. C. Agodoa, MD, NIDDK, NIH

_____	_____
USRDS Project Officer Signature	Date

Checklist:
DID YOU REMEMBER TO SEND:

☐ Signed copy of your institutional IRB approval memo

☐ Copy of your project proposal in recommended format at http://www.usrds.org/2015/appx/3/2_Outline_for_research_proposals_using_merged_USRDS_data.rtf

☐ Copy of this Data Use Agreement signed by your institutional official, PI, and all active participants.

Please note that any MODIFICATIONS or AMMENDMENTS, regardless of whether they require additional files, require a new IRB approval memo (1 above), copy of the original project proposal (2 above) with additional analyses/extractions highlighted, and a new signed Data Use Agreement (3).

Please send ALL documents (including the research protocol) in PDF format (please save the research protocol as PDF within Microsoft Word when you have completed it). AND consolidate all files into a single PDF file (using the "PDF Portfolio" feature in Adobe) when sending to the NIDDK.

03/09/2016 revision

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT
MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS

Check one: ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name *(Last, First, Middle Initial)*

2. Medicare Claim Number

3. Social Security Number

4. Date of Birth ____/____/____ MM DD YYYY

5. Patient Mailing Address *(Include City, State and Zip)*

6. Phone Number ( )

7. Sex ☐ Male ☐ Female

8. Ethnicity ☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9)

9. Country/Area of Origin or Ancestry

10. Race *(Check all that apply)*
☐ White ☐ Asian
☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander*
☐ American Indian/Alaska Native
Print Name of Enrolled/Principal Tribe _____ *complete Item 9

11. Is patient applying for ESRD Medicare coverage?
☐ Yes ☐ No

12. Current Medical Coverage *(Check all that apply)*
☐ Medicaid ☐ Medicare ☐ Employer Group Health Insurance
☐ DVA ☐ Medicare Advantage ☐ Other ☐ None

13. Height
INCHES _____ OR
CENTIMETERS _____

14. Dry Weight
POUNDS _____ OR
KILOGRAMS _____

15. Primary Cause of Renal Failure *(Use code from back of form)*

16. Employment Status *(6 mos prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

17. Co-Morbid Conditions *(Check all that apply currently and/or during last 10 years)* *See instructions

a. ☐ Congestive heart failure
b. ☐ Atherosclerotic heart disease ASHD
c. ☐ Other cardiac disease
d. ☐ Cerebrovascular disease, CVA, TIA*
e. ☐ Peripheral vascular disease*
f. ☐ History of hypertension
g. ☐ Amputation
h. Diabetes, currently on insulin
i. ☐ Diabetes, on oral medications
j. ☐ Diabetes, without medications
k. ☐ Diabetic retinopathy
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Toxic nephropathy
p. ☐ Alcohol dependence
q. ☐ Drug dependence*
r. ☐ Inability to ambulate
s. ☐ Inability to transfer
t. ☐ Needs assistance with daily activities
u. ☐ Institutionalized
☐ 1. Assisted Living
☐ 2. Nursing Home
☐ 3. Other Institution
v. ☐ Non-renal congenital abnormality
w. ☐ None

18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
b. Was patient under care of a nephrologist?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
c. Was patient under care of kidney dietitian?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
d. What access was used on first outpatient dialysis:	☐ AVF	☐ Graft	☐ Catheter	☐ Other		
If not AVF, then: Is maturing AVF present?	☐ Yes	☐ No				
Is maturing graft present?	☐ Yes	☐ No				

19. Laboratory Values Within **45** Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	___ . ___		d. HbA1c	___ ___ . ___ %	
a.2. Serum Albumin Lower Limit	___ . ___		e. Lipid Profile TC	___ ___ ___	
a.3. Lab Method Used (BCG or BCP)			LDL	___ ___ ___	
b. Serum Creatinine (mg/dl)	___ ___ . ___		HDL	___ ___	
c. Hemoglobin (g/dl)	___ ___ . ___		TG	___ ___ ___ ___	

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility

21. Medicare Provider Number *(for item 20)*

22. Primary Dialysis Setting
☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

23. Primary Type of Dialysis
☐ Hemodialysis (Sessions per week____/hours per session____)
☐ CAPD ☐ CCPD ☐ Other

24. Date Regular Chronic Dialysis Began ____/____/____ MM DD YYYY

25. Date Patient Started Chronic Dialysis at Current Facility ____/____/____ MM DD YYYY

26. Has patient been informed of kidney transplant options?
☐ Yes ☐ No

27. If patient NOT informed of transplant options, please check all that apply:
☐ Medically unfit ☐ Patient declines information
☐ Unsuitable due to age ☐ Patient has not been assessed
☐ Psychologically unfit ☐ Other

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

28. Date of Transplant	29. Name of Transplant Hospital	30. Medicare Provider Number for Item 29
____/____/____ MM DD YYYY		

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

31. Enter Date	32. Name of Preparation Hospital	33. Medicare Provider number for Item 32
____/____/____ MM DD YYYY		

34. Current Status of Transplant *(if functioning, skip items 36 and 37)*	35. Type of Donor:
☐ Functioning ☐ Non-Functioning	☐ Deceased ☐ Living Related ☐ Living Unrelated
36. If Non-Functioning, Date of Return to Regular Dialysis ____/____/____ MM DD YYYY	37. Current Dialysis Treatment Site ☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

38. Name of Training Provider	39. Medicare Provider Number of Training Provider (for Item 38)
40. Date Training Began ____/____/____ MM DD YYYY	41. Type of Training ☐ Hemodialysis a. ☐ Home b. ☐ In Center ☐ CAPD ☐ CCPD ☐ Other
42. This Patient is Expected to Complete *(or has completed)* Training and will Self-dialyze on a Regular Basis. ☐ Yes ☐ No	43. Date When Patient Completed, or is Expected to Complete, Training ____/____/____ MM DD YYYY

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

44. Printed Name and Signature of Physician personally familiar with the patient's training	45. UPIN of Physician in Item 44
a.) Printed Name b.) Signature c.) Date ____/____/____ MM DD YYYY	

E. PHYSICIAN IDENTIFICATION

46. Attending Physician *(Print)*	47. Physician's Phone No. ( )	48. UPIN of Physician in Item 46

PHYSICIAN ATTESTATION

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

49. Attending Physician's Signature of Attestation *(Same as Item 46)*	50. Date ____/____/____ MM DD YYYY
51. Physician Recertification Signature	52. Date ____/____/____ MM DD YYYY

53. Remarks

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

54. Signature of Patient *(Signature by mark must be witnessed.)*	55. Date ____/____/____ MM DD YYYY

G. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the *Federal Register* notice cited above. You should be aware that P.L.100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 15. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **Code effective as of September 2003**.

DIABETES

25040	Diabetes with renal manifestations Type 2
25041	Diabetes with renal manifestations Type 1

GLOMERULONEPHRITIS

5829	Glomerulonephritis (GN) (histologically not examined)
5821	Focal glomerulosclerosis, focal sclerosing GN
5831	Membranous nephropathy
58321	Membranoproliferative GN type 1, diffuse MPGN
58322	Dense deposit disease, MPGN type 2
58381	IgA nephropathy, Berger's disease (proven by immunofluorescence)
58382	IgM nephropathy (proven by immunofluorescence)
5834	With lesion of rapidly progressive GN
5800	Post infectious GN, SBE
5820	Other proliferative GN

SECONDARY GN/VASCULITIS

7100	Lupus erythematosus, (SLE nephritis)
2870	Henoch-Schonlein syndrome
7101	Scleroderma
28311	Hemolytic uremic syndrome
4460	Polyarteritis
4464	Wegener's granulomatosis
58392	Nephropathy due to heroin abuse and related drugs
44620	Other Vasculitis and its derivatives
44621	Goodpasture's syndrome
58391	Secondary GN, other

INTERSTITIAL NEPHRITIS/PYELONEPHRITIS

9659	Analgesic abuse
5830	Radiation nephritis
9849	Lead nephropathy
5909	Nephropathy caused by other agents
27410	Gouty nephropathy
5920	Nephrolithiasis
5996	Acquired obstructive uropathy
5900	Chronic pyelonephritis, reflux nephropathy
58389	Chronic interstitial nephritis
58089	Acute interstitial nephritis
5929	Urolithiasis
27549	Other disorders of calcium metabolism

HYPERTENSION/LARGE VESSEL DISEASE

40391	Unspecified with renal failure
4401	Renal artery stenosis
59381	Renal artery occlusion
59383	Cholesterol emboli, renal emboli

CYSTIC/HEREDITARY/CONGENITAL DISEASES

75313	Polycystic kidneys, adult type (dominant)
75314	Polycystic, infantile (recessive)
75316	Medullary cystic disease, including nephronophthisis
7595	Tuberous sclerosis
7598	Hereditary nephritis, Alport's syndrome
2700	Cystinosis
2718	Primary oxalosis
2727	Fabry's disease
7533	Congenital nephrotic syndrome
5839	Drash syndrome, mesangial sclerosis
75321	Congenital obstruction of ureterpelvic junction
75322	Congenital obstruction of uretrovesical junction
75329	Other Congenital obstructive uropathy
7530	Renal hypoplasia, dysplasia, oligonephronia
75671	Prune belly syndrome
75989	Other (congenital malformation syndromes)

NEOPLASMS/TUMORS

1890	Renal tumor (malignant)
1899	Urinary tract tumor (malignant)
2230	Renal tumor (benign)
2239	Urinary tract tumor (benign)
23951	Renal tumor (unspecified)
23952	Urinary tract tumor (unspecified)
20280	Lymphoma of kidneys
20300	Multiple myeloma
20308	Other immuno proliferative neoplasms (including light chain nephropathy)
2773	Amyloidosis
99680	Complications of transplanted organ unspecified
99681	Complications of transplanted kidney
99682	Complications of transplanted liver
99683	Complications of transplanted heart
99684	Complications of transplanted lung
99685	Complications of transplanted bone marrow
99686	Complications of transplanted pancreas
99687	Complications of transplanted intestine
99689	Complications of other specified transplanted organ

MISCELLANEOUS CONDITIONS

28260	Sickle cell disease/anemia
28269	Sickle cell trait and other sickle cell (HbS/Hb other)
64620	Post partum renal failure
042	AIDS nephropathy
8660	Traumatic or surgical loss of kidney(s)
5724	Hepatorenal syndrome
5836	Tubular necrosis (no recovery)
59389	Other renal disorders
7999	Etiology uncertain

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0448

ESRD DEATH NOTIFICATION

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

1. Patient's Last Name	First	MI	2. Medicare Claim Number

3. Patient's Sex	4. Date of Birth	5. Social Security Number
a. ☐ Male b. ☐ Female	__ __ / __ __ / __ __ __ __ (Month / Day / Year)	

6. Patient's State of Residence	7. Place of Death	8. Date of Death
	a. ☐ Hospital c. ☐ Home e. ☐ Other b. ☐ Dialysis Unit d. ☐ Nursing Home	__ __ / __ __ / __ __ __ __ (Month / Day / Year)

9. Modality at Time of Death

a. ☐ Incenter Hemodialysis b. ☐ Home Hemodialysis c. ☐ CAPD d. ☐ CCPD e. ☐ Transplant f. ☐ Other

10. Provider Name and Address (Street)	11. Provider Number

Provider Address (City/State)

12. Causes of Death (enter codes from list on back of form)

a. Primary Cause _ _ _

b. Were there secondary causes?

☐ No

☐ Yes, specify: _ _ _ _ _ _ _ _ _ _ _ _

C. If cause is other (98) please specify:_____

13. Renal replacement therapy discontinued prior to death: ☐ Yes ☐ No

If yes, check one of the following:

a. ☐ Following HD and/or PD access failure
b. ☐ Following transplant failure
c. ☐ Following chronic failure to thrive
d. ☐ Following acute medical complication
e. ☐ Other
f. Date of last dialysis treatment __ __ / __ __ / __ __ __ __ (Month / Day / Year)

14. Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?

☐ Yes ☐ No

☐ Unknown ☐ Not Applicable

15. If deceased ever received a transplant:

a. Date of most recent transplant __ __ / __ __ / __ __ __ __ (Month / Day / Year) ☐ Unknown

b. Type of transplant received
☐ Living Related ☐ Living Unrelated ☐ Deceased ☐ Unknown

c. Was graft functioning (patient not on dialysis) at time of death?
☐ Yes ☐ No ☐ Unknown

d. Did transplant patient resume chronic maintenance dialysis prior to death?
☐ Yes ☐ No ☐ Unknown

16. Was patient receiving Hospice care prior to death?

☐ Yes ☐ No

☐ Unknown

17. Name of Physician (Please print complete name)	18. Signature of Person Completing This Form	Date

This report is required by law (42, U.S.C. 426; 20 CFR 405, Section 2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 U.S.C. 5520; 45 CFR Part 5a).

ESRD DEATH NOTIFICATION FORM
LIST OF CAUSES

CARDIAC
- 23 Myocardial infarction, acute
- 25 Pericarditis, incl. Cardiac tamponade
- 26 Atherosclerotic heart disease
- 27 Cardiomyopathy
- 28 Cardiac arrhythmia
- 29 Cardiac arrest, cause unknown
- 30 Valvular heart disease
- 31 Pulmonary edema due to exogenous fluid
- 32 Congestive Heart Failure

VASCULAR
- 35 Pulmonary embolus
- 36 Cerebrovascular accident including intracranial hemorrhage
- 37 Ischemic brain damage/Anoxic encephalopathy
- 38 Hemorrhage from transplant site
- 39 Hemorrhage from vascular access
- 40 Hemorrhage from dialysis circuit
- 41 Hemorrhage from ruptured vascular aneurysm
- 42 Hemorrhage from surgery (not 38, 39, or 41)
- 43 Other hemorrhage (not 38-42, 72)
- 44 Mesenteric infarction/ischemic bowel

INFECTION
- 33 Septicemia due to internal vascular access
- 34 Septicemia due to vascular access catheter
- 45 Peritoneal access infectious complication, bacterial
- 46 Peritoneal access infectious complication, fungal
- 47 Peritonitis (complication of peritoneal dialysis)
- 48 Central nervous system infection (brain abscess, meningitis, encephalitis, etc.)
- 51 Septicemia due to peripheral vascular disease, gangrene
- 52 Septicemia, other
- 61 Cardiac infection (endocarditis)
- 62 Pulmonary infection (pneumonia, influenza)
- 63 Abdominal infection (peritonitis (not comp of PD), perforated bowel, diverticular disease, gallbladder)
- 70 Genito-urinary infection (urinary tract infection, pyelonephritis, renal abscess)

LIVER DISEASE
- 64 Hepatitis B
- 71 Hepatitis C
- 65 Other viral hepatitis
- 66 Liver-drug toxicity
- 67 Cirrhosis
- 68 Polycystic liver disease
- 69 Liver failure, cause unknown or other

GASTRO-INTESTINAL
- 72 Gastro-intestinal hemorrhage
- 73 Pancreatitis
- 75 Perforation of peptic ulcer
- 76 Perforation of bowel (not 75)

METABOLIC
- 24 Hyperkalemia
- 77 Hypokalemia
- 78 Hypernatremia
- 79 Hyponatremia
- 100 Hypoglycemia
- 101 Hyperglycemia
- 102 Diabetic coma
- 95 Acidosis

ENDOCRINE
- 96 Adrenal insufficiency
- 97 Hypothyroidism
- 103 Hyperthyroidism

OTHER
- 80 Bone marrow depression
- 81 Cachexia/failure to thrive
- 82 Malignant disease, patient ever on Immunosuppressive therapy
- 83 Malignant disease (not 82)
- 84 Dementia, incl. dialysis dementia, Alzheimer's
- 85 Seizures
- 87 Chronic obstructive lung disease (COPD)
- 88 Complications of surgery
- 89 Air embolism
- 104 Withdrawal from dialysis/uremia
- 90 Accident related to treatment
- 91 Accident unrelated to treatment
- 92 Suicide
- 93 Drug overdose (street drugs)
- 94 Drug overdose (not 92 or 93)
- 98 Other cause of death
- 99 Unknown

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved
OMB No. 0938-0447

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM
ESRD FACILITY SURVEY (DIALYSIS UNITS ONLY)

FOR THE PERIOD

Facility Physical Address _____
(If different than mailing address) *Suite/Room* *Street* *City* *State/Zip Code*

Number of Dialysis Stations: _____ **Facility Telephone: (** **)** _____

Facility Ownership Type: ☐ **Profit** ☐ **Non-Profit**

Facility Local/National Affiliation/Chain Information _____
(i.e. Gambro, etc.)

Types of dialysis services offered:
☐ Incenter Hemodialysis ☐ Peritoneal Dialysis ☐ Home Hemodialysis Training

Does your facility offer a dialysis shift that starts at 5:00 p.m. or later?
☐ Yes ☐ No

DIALYSIS PATIENTS AND TREATMENTS

DIALYSIS PATIENTS

Patients Receiving Care Beginning of Survey Period		
Incenter	Home	Total Fields 01 thru 02
01	02	03

	Additions During Survey Period			
	Started for first time ever	Restarted	Transferred from other dialysis unit	Returned after transplantation
Incenter				
Home				
	04A 04B	05A 05B	06A 06B	07A 07B

Losses During Survey Period					
Deaths	Recovered kidney function	Received transplant	Transferred to other dialysis unit	Discontinued dialysis	Other (LTFU)
08A 08B	09A 09B	10A 10B	11A 11B	12A 12B	13A 13B

Patients Receiving Care at End of Survey Period											
Incenter Dialysis		Self-Dialysis Training				Total Incenter Dialysis	Home Dialysis				Total Home Dialysis
Hemo-Dialysis	Other	Hemo-Dialysis	CAPD	CCPD	Other	Fields 14 thru 19	Hemo-Dialysis	CAPD	CCPD	Other	Fields 21 thru 24
14	15	16	17	18	19	20	21	22	23	24	25

Total Patients
Fields 20 and 25
26

Patient Eligibility Status End of Survey Period		
Currently enrolled in Medicare	Medicare application pending	Non-Medicare
27	28	29

Hemodialysis Patients Dialyzing More Than 4 Times Per Week		
Setting	Day	Nocturnal
Incenter		
Home		
	30A 30B	31A 31B

Vocational Rehabilitation			
Patients aged 18 through 54	Patients receiving services from Voc Rehab	Patients Employed full-time or part-time	Patients attending school full-time or part-time
32	33	34	35

TREATMENT AND STAFFING

Incenter Dialysis Treatments (Include Training Treatments)	
Hemodialysis	Other
36	37

Staffing				
	Number of Staff		Number of Open Pos.	
Position	Full Time	Part Time	Full Time	Part Time
a. RNs				
b. LPN/LVNs				
c. PCTs				
d. APNs				
e. Dietitians				
f. Social Workers				
	38	39	40	41

COMPLETED BY (Name)	DATE	TITLE	TELEPHONE NO.

REMARKS REGARDING INFORMATION PROVIDED ON THIS SURVEY SHOULD BE ENTERED ON THE LAST PAGE OF THE SURVEY

This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).

Form Approved
OMB No. 0938-0447

END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM
ESRD FACILITY SURVEY (TRANSPLANT CENTERS ONLY)

FOR THE PERIOD

KIDNEY TRANSPLANTS PERFORMED

PATIENTS TRANSPLANTED AND DONOR TYPE

TO BE COMPLETED BY KIDNEY TRANSPLANT CENTERS ONLY

Patients who received transplant at this facility
42

Eligibility Status of Patients Transplanted at this Facility During the Survey Period			
Currently enrolled in Medicare	Medicare applica-tion pending	Non-Medicare	
		U.S. Res.	Other
43	44	45	46

Transplant Procedures Performed at This Facility			
Living Related Donor	Living Unrelated Donor	Deceased Donor	Total Fields 47 thru 49
47	48	49	50

Patients Awaiting Transplant	
Dialysis	Nondialysis
51	52

REMARKS/COMMENTS

COMPLETED BY (Name)	DATE	TITLE	TELEPHONE NO.

This report is required by law (42 USC 426; 42 CFR 405.2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 USC 5520; 45 CFR, Part 5a).

USRDS
UNITED STATES RENAL DATA SYSTEM

United States Renal Data System (USRDS)
International Data Collection Form

This form is designed to solicit information on the population of end-stage renal disease (ESRD) patients in your country. The information you provide will be returned to you along with comparable information from other countries participating in the voluntary effort.

If data are not available for all years, please include data for the most recent year(s). If you cannot provide data in the age categories listed, please provide the total numbers. The format has been created to more clearly separate incident and prevalent population counts from transplant counts.

A.1) Population: the population of your country for the years that ESRD data will be provided.

A.1) General population of the country/region										
Population: the population of your country for the years indicated or most recently available										
		Number by Sex		**Number of People by Age Category**						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

B.1) Incidence: the count of patients who start any form of renal replacement therapy during the year.

B.1) Incidence: Total ESRD (at day 1)										
Incidence: the count of patients who start any form of renal replacement therapy during the year. These are first-time patients only; patients who start dialysis after a failed transplant, for example, should not be included.										
		Number by Sex		**Number of People by Age Category**						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

B.2) The subset of total incident patients whose failure is due to diabetic nephropathy.

B.2) Incidence: Diabetics (at day 1)										
Indicate the subset of incident patients who started any form of renal replacement therapy during the year and their ESRD was due to diabetic nephropathy. Subtracting B2 from B1 should equal the total number of incident patients for all non-diabetic nephropathy causes.										
		Number by Sex		**Number of People by Age Category**						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.) Prevalence: the point prevalent count of patients at the end of the calendar year (December 31).

C.1) Prevalence: Total number of ESRD patients (all treatment categories) at the end of the year (December 31)

Please include all patients receiving either dialysis or living with a kidney transplant for ESRD treatment at end of year.

		Number by Sex		Number of People by Age Category						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.2) Prevalence: Total Number of ESRD patients with a functioning kidney transplant at the end of the year (December 31)

Please include all patients living with a functioning kidney transplant at end of the year for treatment of ESRD.

		Number by Sex		Number of People by Age Category						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.3) Prevalence: Total number of ESRD patients on dialysis at the end of the year (December 31)

Please list all patients receiving dialysis at end of year for ESRD therapy. C.2 and C.3 should sum to C.1 unless there are lost-to-follow-up patients. If there are lost-to-follow-up patients, please note this fact and whether these patients are captured in C.2.

		Number by Sex		Number of People by Age Category						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.4) Prevalence: Total number of ESRD patients on in-center hemodialysis at the end of the year (December 31)

Please include all patients treated with in-center hemodialysis for ESRD therapy at the end of each year.

		Number by Sex		Number of People by Age Category						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.5) Prevalence: Total number of ESRD patients on CAPD, APD, or IPD at the end of the year (December 31)

Please include all patients treated with continuous ambulatory peritoneal dialysis, automated peritoneal dialysis, or intermittent peritoneal dialysis for ESRD therapy at the end of each year.

		Number by Sex		Number of People by Age Category						
Country/Region	**Year**	**Female**	**Male**	**0-19**	**20-44**	**45-64**	**65-74**	**75+**	**Unknown**	**Total**
	2009									
	2010									
	2011									
	2012									
	2013									

C.6) Prevalence: Total number of ESRD patients on home hemodialysis at the end of the year (December 31)										
Please indicate all patients treated with home hemodialysis at the end of each year.										
		Number by Sex		Number of People by Age Category						
Country/Region	Year	Female	Male	0-19	20-44	45-64	65-74	75+	Unknown	Total
	2009									
	2010									
	2011									
	2012									
	2013									

D) Kidney transplant activity: This is meant to be a count of transplants, not transplanted patients. If a patient receives multiple transplants during the year, all should be counted. If you report only transplanted patients, please provide these numbers and note that they refer to patients. D1 (deceased donor [cadaveric] transplants), D2 (living donor transplants), and D3 (unknown donor type) should sum to the total number of transplants.

D.1) Transplant: Total number of deceased donor (cadaveric) transplants during the year										
Please indicate the total number of deceased donor (cadaveric) kidney transplantations performed during the year.										
		Number by Sex		Number of People by Age Category						
Country/Region	Year	Female	Male	0-19	20-44	45-64	65-74	75+	Unknown	Total
	2009									
	2010									
	2011									
	2012									
	2013									

D.2) Transplant: Total number of living donor transplants during the year										
Please indicate the total number of living donor kidney transplantations performed during the year.										
		Number by Sex		Number of People by Age Category						
Country/Region	Year	Female	Male	0-19	20-44	45-64	65-74	75+	Unknown	Total
	2009									
	2010									
	2011									
	2012									
	2013									

D.3) Transplant: Total number of transplants with unknown type of graft										
Indicate the total number of kidney transplantations performed during the year in which it was unknown whether the transplant was a deceased (cadaveric) or living donor kidney transplant.										
		Number by Sex		Number of People by Age Category						
Country/Region	Year	Female	Male	0-19	20-44	45-64	65-74	75+	Unknown	Total
	2009									
	2010									
	2011									
	2012									
	2013									