Medicare
End Stage Renal Disease Network Organizations Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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NEW/REVISED MATERIAL--*EFFECTIVE DATE:* January 2 , 2001

Foreword, List of Commonly Used Acronyms, and Glossary, changes the name of the component responsible for revising this manual, inserts additional acronyms, and defines additional terms in the glossary.

Section 100, Authority, changes a regulatory citation that was redesignated in the ***Federal Register*** effective on November 24, 1999, from 42 CFR Part 476 to the new 42 CFR Part 480.

Section 110, Purpose of ESRD Network Organizations, changes "Scope" of Work to "Statement" of Work.

Section 115, Requirements for ESRD Network Organizations, requires that at least one patient representative be included on your Network Council.

Section 120, Responsibilities of ESRD Network Organizations, changes "Renal Registry" to the "United States Renal Data System".

Section 130, Goals, requires that your national goals for the ESRD Network program in establishing and improving partnerships and cooperative activities include facilities, ESRD facility owners, professional groups, and patient organizations.

Section 135, Network Organization's Role in HCQIP, states that your role in HCQIP is to assist ESRD providers and facilities to assess and improve care provided to Medicare ESRD beneficiaries by conducting quality improvement projects.

Exhibit 2-1, Annual Report Format, clarifies that the facility offers dialysis shifts **beginning** at 5:00 P.M. or later.

Exhibit 2-2, Quarterly Progress and Status Report Format, describes the reporting format to use when completing your quarterly reports.

FOREWORD

Authority/Background

The Health Care Financing Administration (HCFA) contracts nationwide with End Stage Renal Disease (ESRD) Network Organizations (Networks) located in 18 geographically designated areas. The Networks were established for purposes of assuring effective and efficient administration of the benefits provided under the Social Security Act (the Act) for individuals with ESRD.

Title II of the Act grants individuals who are medically determined to have ESRD entitlement to Part A benefits and eligibility to enroll under Part B of title XVIII, subject to the deductible, premium, and coinsurance provisions of that title. Section 1881 of the Act provides the statutory authority for the broad objectives and operations of the ESRD program and the establishment of ESRD Network Organizations. Networks oversee the quality of care provided to Medicare ESRD patients in dialysis and transplant facilities as provided under the Act.

The legislative responsibilities of the Networks include identifying opportunities to improve health care related to the quality and appropriateness of patient care, assessing the appropriateness of patients for proposed treatment modalities, collecting, validating, and analyzing data for the preparation of reports, and assuring the maintenance of the United States Renal Data System (USRDS).

Activities, projects, and deliverables to be performed by the Networks as required by HCFA are contained in the Statement of Work (SOW), which is located in Section C of the contract. The SOW is amended, as necessary, to reflect statutory and programmatic changes. Occasionally, policy changes occur faster than we can update this manual. Therefore, if inconsistencies occur between the requirements of the SOW and this manual, the SOW requirements take precedence.

Purpose of the Network Manual

This manual provides detailed procedures and guidelines for Networks to use when performing activities outlined in the SOW.

Contents and Organization

This manual consists of parts and sections. The Table of Contents contains a list of each.

Relationship of the Network Manual to Other Manuals

This manual is primarily self-contained. However, there are a few cross-references to other HCFA publications. ESRD program-related information can also be found in the Hospital Manual (Pub. 10), Renal Dialysis Facility Manual (Pub. 29), Medicare Intermediary Manual (Pub. 13), Medicare Carriers Manual (Pub. 14), Coverage Issues Manual (Pub. 6), State Operations Manual (Pub. 7), and Regional Office Manual (Pub. 23).

Statutes and Regulations

Title XVIII of the Act is the statutory basis for the establishment of the ESRD Networks and is the foundation for all regulations that refer to Networks. Regulations contain interpretations and policies that expand on the statute and are formally approved and published by the Secretary of the Department of Health and Human Services. Regulations have the force and effect of law and are binding on all parties (whether or not they have been incorporated into manual instructions).

Acronyms

When a term is first used on the transmittal page, the Table of Contents, and/or the text of each part, it is followed by an acronym enclosed in parentheses (e.g., End Stage Renal Disease (ESRD)). A list of commonly used acronyms starts on page iv.

ESRD Network Organizations Manual Revisions

The Office of Clinical Standards and Quality (OCSQ) updates the Network Organizations Manual. When the Act is amended, regulations are implemented or policies are changed or clarified, this office amends corresponding instructions in the manual.

When OCSQ changes manual instructions, it issues a transmittal. Each transmittal includes a cover page(s) that is numbered sequentially. The transmittal also includes a summary of the changes made, the effective date of the changes, and the instructions for filing the replacement pages. The new or replacement pages are attached to the transmittal. New or revised text is highlighted by vertical lines in the left-hand margin as follows:

(Vertical line begins at this line where change begins.)
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxxxxxxxxxxxxxx(Vertical line ends at this line where change ends.)

Use of the Revision Transmittal Check Sheet

File transmittals in numerical order to avoid discarding a more recent page. Record receipt of the transmittal on the "Transmittal Check List." Some users retain the transmittal sheets since they explain the background and basis for the revisions.

Obtaining Copies of the Network Organizations Manual

OCSQ is responsible for updating the ESRD Network Organizations Manual as well as the manual distribution list. This list is used by HCFA to distribute new or revised manual transmittals to appropriate HCFA staff, contractors, and other involved government agencies and public organizations. Addressees appearing on this list automatically receive, free-of-charge, all new or revised transmittals of the manual as they are published.

To request any changes to this list, please contact OCSQ at:

Office of Clinical Standards and Quality
Attention: Quality Improvement Group
7500 Security Boulevard
Mailstop: S3-02-01
Baltimore, Maryland 21244-1850

Anyone not appearing on HCFA's Network Organizations Manual distribution list may receive copies of the manual, for a fee, by contacting the National Technical Information Service (NTIS) at:

U.S. Department of Commerce
National Technical Information Service
Subscription Department
5285 Port Royal Road
Springfield, Virginia 22161
1-800-553-6847

When contacting NTIS, be sure to refer to order number PB-94-956899 which identifies the ESRD Network Organizations Manual.

ESRD Manual HCFA-Pub. 81 can be downloaded from the internet at:

www.hcfa.gov/pubforms/pub_81.exe

The files downloaded from the internet recreate relatively complete versions of HCFA-Pub. 81. A few pages here and there that were never produced in Word 97 format (e.g., certain charts, graphs, diagrams) could not be included. Otherwise, every effort has been made to ensure the accuracy of these documents in electronic form. However, the paper version is considered the official version and takes precedence if any discrepancies occur.

List of Commonly Used Acronyms

AAKP	American Association of Kidney Patients
AHRQ	Agency for Healthcare Research and Quality
AKF	American Kidney Fund
ANNA	American Nephrology Nurses Association
BOD	Board of Directors
BUN	Blood Urea Nitrogen
CO	Central Office (HCFA)
CPM	Clinical Performance Measure
CQI	Continuous Quality Improvement
DVA	Department of Veterans Affairs
EC	Executive Committee of the Network
EDEES	ESRD Data Entry and Editing System (HCFA)
EPO	Erythropoietin
ESRD	End Stage Renal Disease
FPR	Final Project Report
HCFA	Health Care Financing Administration
HCQIP	Health Care Quality Improvement Program
HCT	Hematocrit
HD	Hemodialysis
HDC	HCFA Data Center
HIC	Health Insurance Claim
IMRP	Instruction Manual for Renal Providers
MRB	Medical Review Board
NC	Network Council
NCC	Network Coordinating Council
NIDDK	National Institute of Diabetes, and Digestive and Kidney Diseases
NIH	National Institutes of Health

List of Commonly Used Acronyms (Cont.)

NIP	National Improvement Project
NKF	National Kidney Foundation
NPP	Narrative Project Plan
NRAA	National Renal Administrators Association
OCSQ	Office of Clinical Standards and Quality
ODIE	Online Data Input and Edit
OGC	Office of General Counsel (HCFA)
OIC	Opportunity to Improve Care
OIG	Office of the Inspector General (HCFA)
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
OSCAR	Online Survey Certification and Reporting
PD	Peritoneal Dialysis
PID	Project Idea Document
PIP	Performance Improvement Plan
PMMIS	Program Management and Medical Information System
PO	Project Officer
PRO	Utilization and Quality Control Peer Review Organization
QA	Quality Assurance
QI	Quality Improvement
QIP	Quality Improvement Project
REBUS	Renal Beneficiary and Utilization System
REMIS	Renal Management Information System
RO	Regional Office (HCFA)
ROPO	Regional Office Project Officer
RPA	Renal Physicians Association
SA	State Agency/State Survey Agency

List of Commonly Used Acronyms (Cont.)

SIMS	Standard Information Management System
SOW	Statement of Work
SSA	Social Security Administration
SSN	Social Security Number
TQE	Total Quality Environment
UNOS	United Network for Organ Sharing
USRDS	United States Renal Data System
VISION	Vital Information System to Improve Outcomes in Nephrology

Glossary

Abstraction

Abstraction is the collection of information from the medical record via hardcopy or electronic instrument.

Albumin

One of a class of simple proteins in the blood. The level of albumin may reflect the amount of protein intake in food.

Algorithm

An algorithm is a rule or procedure containing conditional logic for solving a problem or accomplishing a task. Guideline algorithms concern rules for evaluating patient care against published guidelines. Criteria algorithms concern rules for evaluating criteria compliance. Algorithms may be expressed in written form, graphic outlines, diagrams, or flow charts that describe each step in the work or thought process.

Anemia

A condition occurring when the blood is deficient in red blood cells and/or hemoglobin which decreases the oxygen-carrying capacity of the blood.

Benchmark

A benchmark is sustained superior performance by a medical care provider which can be used as a reference to raise the mainstream of care for Medicare beneficiaries. The relative definition of superior will vary from situation to situation. In many instances, an appropriate benchmark would be a provider that appears in the top 10 percent of all providers for more than a year.

Blood Urea Nitrogen (BUN)

The term, blood urea nitrogen, refers to the substance urea, which is the major breakdown product of protein metabolism and is ordinarily removed by the kidneys. During kidney failure, urea accumulates in proportion to the degree of kidney failure and to the amount of protein breakdown. The symptoms of uremia correspond roughly to the amount of urea in the bloodstream.

Cadaveric Transplant

The surgical procedure of excising a kidney from a deceased individual and implanting it into a suitable recipient.

Carriers

Carriers are organizations/entities which contract with HCFA to process claims submitted by beneficiaries, physicians, suppliers, and other individuals/entities that are not associated with an institutional provider under the Part B program.

Case Mix

Case mix is the distribution of patients into categories reflecting differences in severity of illness or resource consumption.

Chronic Maintenance Dialysis

Dialysis that is regularly furnished to an ESRD patient in a hospital-based, independent (non-hospital-based), or home setting.

Clinical Performance Measure (CPM)

A clinical performance measure (CPM) is a method or instrument to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality.

Cohort

A population group that shares a common property, characteristic, or event, such as a year of birth or year of marriage. The most common one is the birth cohort, a group of individuals born within a defined time period, usually a calendar year or a 5-year interval.

Continuous Ambulatory Peritoneal Dialysis (CAPD)

A type of dialysis where the patient's peritoneal membrane is used as the dialyzer. The patient dialyzes at home, using special supplies, but without the need for a machine. (See Peritoneal Dialysis.)

Continuous Cycling Peritoneal Dialysis (CCPD)

A type of dialysis where the patient generally dialyzes at home and utilizes an automated peritoneal cycler for delivering dialysis exchanges. (See Peritoneal Dialysis.)

Continuous Peritoneal Dialysis

A regimen where peritoneal dialysate is present in the peritoneal cavity continuously 7 days per week. Short interruptions between infrequent exchanges do not disqualify the regime as continuous if the interruptions do not exceed 10 percent of the total dialysis time. (See Peritoneal Dialysis.)

Continuous Quality Improvement (CQI)

A process which continuously monitors program performance. When a quality problem is identified, CQI develops a revised approach to that problem and monitors implementation and success of the revised approach. The process includes involvement at all stages by all organizations which are affected by the problem and/or involved in implementing the revised approach.

Criteria

Expected levels of achievement or specifications against which performance can be assessed.

Department of Health and Human Services (DHHS)

DHHS administers many of the “social” programs at the Federal level dealing with the health and welfare of the citizens of the United States. It is the “parent” of the Health Care Financing Administration.

Dialysate

Dialysate or dialysate fluid is the solution used in dialysis to remove excess fluids and waste products from the blood.

Dialysis

Dialysis is a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semi-permeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

Dialysis Center (renal)

A hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis) furnished directly or under arrangement.

Dialysis Facility (renal)

A unit (hospital-based or free-standing) which is approved to furnish dialysis services directly to ESRD patients.

Dialysis Station

A portion of the dialysis patient treatment area which accommodates the equipment necessary to provide a hemodialysis or peritoneal dialysis treatment. This station must have sufficient area to house a chair or bed, the dialysis equipment, and emergency equipment if needed. Provision for privacy is ordinarily supplied by drapes or screens.

Durable Medical Equipment (DME)

DME are items covered under the Medicare program such as oxygen equipment, wheelchairs, and other medically necessary equipment prescribed by a physician for a patient’s in-home use.

End Stage Renal Disease (ESRD)

That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Eligibility Requirements

To qualify for Medicare under the renal provision, a person must have ESRD and either be entitled to a monthly insurance benefit under title II of the Act (or an annuity under the Railroad Retirement Act), be fully or currently insured under Social Security (railroad work may count), or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. An Application for Health Insurance Benefits Under Medicare For Individuals with Chronic Renal Disease, Form HCFA-43 (effective October 1, 1978), must be filed.

ESRD Facility

A facility which is approved to furnish at least one specific ESRD service. These services may be performed in a renal transplantation center, renal dialysis center, renal dialysis facility, self-dialysis unit, or special purpose renal dialysis facility.

ESRD Network

All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.

ESRD Network Organization

The administrative governing body of the ESRD Network and liaison to the Federal government.

ESRD Patient

A person with irreversible and permanent kidney failure who requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Service

The type of care or service furnished to an ESRD patient. Such types of care are: transplantation; dialysis; outpatient dialysis; staff-assisted dialysis; self-dialysis; home dialysis; and self-dialysis and home dialysis training.

Guidelines

Guidelines are systematically developed by appropriate groups to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances.

HCFA Agent

Any individual or organization, public or private, with whom HCFA has a contractual arrangement to contribute to or participate in the Medicare survey and certification process. The State survey agency is the most common example of a "HCFA agent," as established through the partnership role the State agency (SA) plays in the survey process under the provisions of §1864 of the Act. A private physician serving a contractual consultant role with the SA or the HCFA regional office as a part of a survey and certification activity is another example of a "HCFA agent."

HCFA-Directed Improvement Projects

A HCFA-directed improvement project is any project where HCFA specifies the subject, size, pace, data source, analytic techniques, educational intervention techniques, or impact measurement model. These projects may be developed by HCFA in consultation with the Networks, the health care community, and other interested groups.

Health Care Quality Improvement Program (HCQIP)

HCQIP is a program which supports the mission of the Health Care Financing Administration to assure health care security for beneficiaries. The mission of HCQIP is to promote the quality, effectiveness, and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to improving quality, monitoring and improving quality of care, communicating with beneficiaries and health care providers, practitioners, and plans to promote informed health choices, protecting beneficiaries from poor care, and strengthening the infrastructure.

Hematocrit

A measurement of red blood cell volume in the blood.

Hemodiafiltration (Also called high flux hemodiafiltration and double high flux hemodiafiltration.)

Simultaneous hemodialysis and hemofiltration which involves the removal of large volumes of fluid and fluid replacement to maintain hemodynamic stability. It requires use of ultra pure dialysate or intravenous fluid for volume replacement.

Hemodialysis

A method of dialysis in which blood from a patient's body is circulated through an external device or machine and then returned to the patient's bloodstream. Such an artificial kidney machine usually is designed to remove fluids and metabolic end products from the bloodstream by placing the blood in contact with a semi-permeable membrane which is bathed on the other side by an appropriate chemical solution referred to as dialysate.

Hemofiltration

Fluid removal.

Home Patients

Medically-able individuals who have their own dialysis equipment at home and, after proper training, perform their own dialysis treatment alone or with the assistance of a helper.

Improvement Plan

A plan for measurable process or outcome improvement. This plan is usually developed cooperatively by a provider and the Network. The plan must address how and when its results will be measured.

Incidence

The frequency of new occurrences of a condition within a defined time interval. The incidence rate is the number of new cases of specific disease divided by the number of people in a population over a specified period of time, usually one year.

Indicator

A key clinical value or quality characteristic used to measure, over time, the performance, processes, and outcomes of an organization or some component of health care delivery.

Intermediaries

Intermediaries are entities that contract with HCFA to perform Medicare administrative services for institutional providers (i.e., hospitals, SNFs, HHAs, and hospices) and all ESRD providers, and to determine and make Medicare payments for Part A or Part B benefits.

Intermittent Peritoneal Dialysis

An intermittent (periodic), supine regimen, which uses intermittent flow technique, automated, assisted manual, or manual method in dialysis sessions two to four times weekly.

Living Donor Kidney Transplant

The surgical procedure of excising a kidney from a living donor and implanting it into a suitable recipient.

Managed Care Organizations

Managed care organizations are entities that serve Medicare or Medicaid beneficiaries on a risk basis through a network of employed or affiliated providers.

Measurement

The systematic process of data collection, repeated over time or at a single point in time.

Medicare + Choice (M+C) Organization

An M+C organization is a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by HCFA as meeting the M+C contract requirements.

Medicare + Choice (M+C) Plan

An M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.

Medicare Handbook

The Medicare Handbook provides information on such things as how to file a claim and what type of care is covered under the Medicare program. This handbook is given to all beneficiaries when first enrolled in the program.

Modality

Methods of treatment for kidney failure/ESRD. Modality types include transplant, hemodialysis, and peritoneal dialysis.

Monitoring

A planned, systematic, and ongoing process to gather and organize data, and aggregate results in order to evaluate performance.

Morbidity

A diseased state, often used in the context of a "morbidity rate," i.e., the rate of disease or proportion of diseased people in a population. In common clinical usage, any disease state, including diagnoses and complications, is referred to as morbidity.

Morbidity Rate

The rate of illness in a population. The number of people ill during a time period divided by the number of people in the total population.

Mortality Rate

The death rate, often made explicit for a particular characteristic, e.g., gender, sex, or specific cause of death. Mortality rate contains three essential elements: (1) the number of people in a population group exposed to the risk of death (the denominator); (2) a time factor; and (3) the number of deaths occurring in the exposed population during a certain time period (the numerator).

National Improvement Projects

HCQIP projects developed by a group consisting of representatives of some or all of the following groups: HCFA, Public Health Service, Networks, renal provider, and consumer communities. The object is to use statistical analysis to identify better patterns of care and outcomes and to feed the results of that analysis back into the provider community to improve the quality of care provided to renal Medicare beneficiaries. Each project will have a particular clinical focus.

Organ

Organ means a human kidney, liver, heart, lung, or pancreas.

Organ Procurement

The process of acquiring donor kidneys in the ESRD program.

Organ Procurement Organization (OPO)

An organization that performs or coordinates the retrieval, preservation, and transportation of organs and maintains a system of locating prospective recipients for available organs.

Outcome

The result of performance (or nonperformance) of a function or process.

Outcome Indicator

An indicator that assesses what happens or does not happen to a patient following a process; agreed upon desired patient characteristics to be achieved; or undesired patient conditions to be avoided.

Part A of Medicare

Part A is the hospital insurance portion of Medicare. It was established by §1811 of title XVIII of the Social Security Act of 1965, as amended, and covers inpatient hospital care, skilled nursing facility care, some home health agency services, and hospice care.

Part B of Medicare

Part B is the supplementary or "physicians" insurance portion of Medicare. It was established by §1831 of title XVIII of the Social Security Act of 1965, as amended, and covers services of physicians/other suppliers, outpatient care, medical equipment and supplies, and other medical services not covered by the hospital insurance part of Medicare.

Pattern Analysis

The clinical and statistical analysis of data sets. Frequently used ESRD data sets include the PMMIS, USRDS, the core indicators, Network files, or HCFA analytic files.

Performance

The way in which an individual, group, or organization carries out or accomplishes its important functions or processes.

Performance Assessment

Involves analysis and interpretation of performance measurement data to transform it into useful information for purposes of continuous performance improvement.

Performance Measure

A gauge used to assess the performance of a process or function of any organization.

Peritoneal Dialysis

A procedure that introduces dialysate into the abdominal cavity to remove waste products through the peritoneum (a membrane which surrounds the intestines and other organs in the abdominal cavity). It functions in a manner similar to that of the artificial semi-permeable membrane in the hemodialysis machine. Three forms of peritoneal dialysis are continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis, and intermittent peritoneal dialysis.

Prevalence

The number of existing cases of a disease or condition in a given population at a specific time.

Process

A goal-directed, interrelated series of actions, events, mechanisms, or steps.

Process Improvement

A methodology utilized to make improvements to a process through the use of continuous quality improvement methods.

Process Indicator

A gauge that measures a goal-directed, interrelated series of actions, events, mechanisms, or steps.

Profiles

Data aggregated by specific time period (e.g., quarterly, annually) and target area (e.g., facility, State) for purposes of identifying patterns.

Program Management and Medical Information System (PMMIS)

An automated system of records that contains records primarily of current Medicare-eligible ESRD patients, but also maintains historical information on people no longer classified as ESRD patients because of death or successful transplantation or recovery of renal function. The PMMIS contains medical information on patients and the services that they received during the course of their therapy. In addition, it contains information on ESRD facilities and facility payment. Beginning January 1, 1995, the PMMIS collects information on all dialysis and kidney transplant patients.

Quality

Quality, as defined by the Institute of Medicine, is the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge.

Random Sample

A random sample is a group selected for study which is drawn at random from the universe of cases by a statistically valid method.

Regional Office (RO)

HCFA has 10 ROs that work closely together with Medicare contractors in their assigned geographical areas on a day-to-day basis. Four of these ROs monitor Network contractor performance, negotiate contractor budgets, distribute administrative monies to contractors, work with contractors when corrective actions are needed, and provide a variety of other liaison services to the contractors in their respective regions.

Rehabilitation (as distinguished from Vocational Rehabilitation)

A restorative process through which an individual with ESRD develops and maintains self-sufficient functioning consistent with his/her capability.

Renal Transplant Center

A hospital unit that is approved to furnish transplantation and other medical and surgical specialty services directly for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement.

Self-dialysis

Dialysis performed with little or no professional assistance (except in emergency situations), by an ESRD patient who has completed an appropriate course of training, in a dialysis facility or at home.

Staff-assisted Dialysis

Dialysis performed by the staff of the renal dialysis center or facility.

State Survey

Under §1864 of the Act, HCFA has entered into agreements with agencies of State governments, typically the agency that licenses health facilities within the State health departments, to conduct surveys of Medicare participating providers and suppliers for purposes of determining compliance with Medicare requirements for participation in the Medicare program.

Survey and Certification Process

The activity conducted by State survey agencies or other HCFA agents under the direction of HCFA and within the scope of applicable regulations and operating instructions and under the provisions of §1864 of the Act whereby surveyors determine compliance or noncompliance of Medicare providers and suppliers with applicable Medicare requirements for participation. The survey and certification process for each provider and supplier is outlined in detail in the State Operations and Regional Office Manuals published by HCFA.

Systematic

Pursuing a defined objective(s) in a planned, step-by-step manner.

Transient Patients

Patients who receive treatments on an episodic basis and are not a part of a facility's regular caseload (i.e., patients who have not been permanently transferred to a facility for ongoing treatments).

Transplant

The surgical procedure that involves removing a functional organ from either a deceased or living donor and implanting it in a patient needing a functional organ to replace their non-functional organ.

Vocational Rehabilitation (VR)

The process of facilitating an individual in the choice of or return to a suitable vocation. When necessary, assisting the patient to obtain training for such a vocation. Vocational rehabilitation can also mean preparing an individual regardless of age, status (whether U.S. citizen or immigrant), or physical condition (disability other than ESRD) to cope emotionally, psychologically, and physically with changing circumstances in life, including remaining at school or returning to school, work, or work equivalent (homemaker).

100. AUTHORITY

ESRD Network Organizations are governed by title XVIII of the Social Security Act (the Act), as amended, and by regulations contained in:

- 42 CFR 405.2100;
- 42 CFR 405.2110;
- 42 CFR 405.2112;
- 42 CFR 405.2113; and
- 42 CFR Part 480.

110. PURPOSE OF ESRD NETWORK ORGANIZATIONS

The Social Security Amendments of 1972 (PL 92-603) extended Medicare coverage to individuals with end stage renal disease (ESRD) who require either dialysis or transplantation to maintain life. At that time, the broad array of professionals and providers involved in the treatment of persons with ESRD indicated the need for a system to promote effective coordination of the ESRD program. The Federal Government believed that integration of hospitals and other health facilities into organized Networks was the most effective way to assure delivery of needed ESRD care. Therefore, proposed regulations were published on July 1, 1975. Final regulations, which included provisions for implementing ESRD Networks, were published on June 3, 1976.

Subsequently, the ESRD Amendments of 1978 (PL 95-292) amended title XVIII of the Act by adding §1881. Section 1881(c) of the Act statutorily authorized the establishment of ESRD network areas and Network Organizations. This amendment provided an approach for Network operation and performance as well as other quality assurance issues that relate to treatment of ESRD.

On July 1, 1988, HCFA awarded contracts to 18 geographically designated Network Organizations to administer the ESRD program. In 1989, HCFA developed a Statement of Work (SOW) for one-year extensions of existing contracts to provide for operation of the Networks as specified by §1881(c) of the Act. Also, in 1989, §1881(c) of the Act was amended by PL 100-239 to provide Networks both confidentiality in the medical review process and a limitation on liability. In 1990, HCFA competed two-year Network contracts, with a one-year renewal period. In July 1997, HCFA entered into one-year contracts with two option years with the ESRD Networks.

115. REQUIREMENTS FOR ESRD NETWORK ORGANIZATIONS

Final regulations issued on June 3, 1976 in 41 FR 22511 included provisions for creating ESRD Networks. (These regulations, with updates, are now found in 42 CFR 405, Subpart U.) These regulations required ESRD treatment facilities to join together into groups called Networks in order to promote a system of effective coordination. It was believed that an organized Network would assure coordinated patient referral, as well as access to resources. An organized network of facilities would permit the concentration of equipment and specially trained personnel in centers where they would be used efficiently to treat large numbers of patients.

In 1978, PL 95-292 amended title XVIII of the Act by adding §1881(c), which statutorily authorizes the establishment of ESRD network areas and Network Organizations to assure the effective and efficient administration of ESRD program benefits. This statute and regulations specify certain requirements. A Network Organization must:

o Establish a Network Council (NC) of renal dialysis and transplant facilities located in each area that includes at least one patient representative; and

o Establish a medical review board (MRB) that includes physicians, nurses, and social workers, engaged in treatment relating to ESRD, and at least one patient representative.

120. RESPONSIBILITIES OF ESRD NETWORK ORGANIZATIONS

The statute and regulations specify certain responsibilities. You are responsible for:

o Encouraging the use of those treatment settings most compatible with the successful rehabilitation of the patient;

o Encouraging the participation of patients, providers of services, and ESRD facilities in vocational rehabilitation programs;

o Developing criteria and standards relating to the quality and appropriateness of patient care;

o Evaluating procedures used by facilities and providers to assess the appropriateness of patient treatment;

o Implementing procedures for evaluating and resolving patient grievances;

o Conducting on-site reviews of facilities and providers, as necessary, utilizing standards of care established by your Network;

o Collecting, validating and analyzing data for the preparation of reports and assuring the maintenance of the United States Renal Data System;

o Identifying facilities not meeting Network goals, assisting facilities in developing appropriate plans for correction, and reporting to the Secretary on facilities and providers that are not providing appropriate medical care;

o Submitting an annual report to include:

- Your Network's goals, and activities conducted to meet your goals;

- Data on the comparative performance of facilities with respect to patients in self-care settings, transplantation and vocational rehabilitation programs;

- Identification of facilities that have failed to cooperate with your Network goals; and

- Recommendations for additional or alternative ESRD services for facilities in your Network area.

o Establishing a Network Council to include dialysis and transplant facilities in your Network area and a medical review board (MRB) to include at least one patient, physicians, nurses, and social workers.

You are also responsible for performing all other activities specified in the SOW, including any modifications, HCFA regulations and instructions, and relevant statutory provisions.

125. HEALTH CARE QUALITY IMPROVEMENT PROGRAM (HCQIP)

The mission of the HCQIP is to promote the quality, effectiveness, and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to monitoring and improving quality of care, communicating with beneficiaries and heath care providers in order to promote informed health choices, protecting beneficiaries from poor care, and strengthening the health care delivery system.

The Institute of Medicine defines quality as: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Using this definition, quality care under the HCQIP includes access to care, appropriateness of care, desired outcomes of care, and consumer satisfaction. By conducting the activities listed in your SOW and as outlined in this manual, you assist HCFA in achieving the mission of the HCQIP. The HCQIP supports the strategic goals of HCFA to assure health care security for Medicare beneficiaries. Health care security means:

- Access to quality health care;
- Protection of the rights and dignity of beneficiaries; and
- Dissemination of clear and useful information to beneficiaries and/or their representatives, facilities/providers, and practitioners to assist them in making health care decisions.

130. GOALS

The national goals of the ESRD Network program include the following:

- Improving the quality of health care services and quality of life for ESRD beneficiaries;
- Improving data reliability, validity, and reporting between ESRD providers/facilities, Networks, and HCFA (or other appropriate agency); and
- Establishing and improving partnerships and cooperative activities among and between the ESRD Networks, Peer Review Organizations (PROs), State survey agencies, ESRD providers/facilities, ESRD facility owners, professional groups, and patient organizations.

Achieve the above goals of the ESRD program by developing and conducting the activities and the work requirements as outlined in your SOW and this manual. In addition, establish measures to evaluate the effectiveness of the activities conducted to meet these goals.

135. NETWORK ORGANIZATION'S ROLE IN HCQIP

Your role in HCQIP is to assist ESRD providers and facilities to assess and improve the care provided to Medicare ESRD beneficiaries. Accomplish this by conducting quality improvement projects (QIPs) and activities, which support the HCQIP. Your quality improvement responsibilities include the following:

- Develop and conduct QIPs based on one or more of the established set of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, vascular access, or other CPMs developed or adopted by HCFA;

o Monitor, track, and disseminate regional (Network) and facility-specific (if available) clinical outcomes data (such as the CPM data) to identify opportunities to improve care within the Network area or within a specific facility; and

o Upon request and/or upon identifying poor performance or a specific need (either at the Network level or facility level based on the results of the annual CPM data collection, other more frequent data collection, or results of a site survey or other investigation), assist ESRD providers and facilities (either individually or in groups) in developing and implementing facility-specific quality improvement actions to improve their patient care processes and outcomes.

PART 2

ADMINISTRATION

Exhibits

EXHIBIT 2-1 (Cont.)

ANNUAL REPORT FORMAT

ESRD NETWORK_____ TABLE 8

VOCATIONAL REHABILITATION BY DIALYSIS FACILITY
PATIENTS AGED 18 - 55 AS OF DECEMBER 31, ____

PROVIDER	NUMBER OF PATIENTS AGED 18 - 55	REFERRALS TO VOC REHAB (1)	PATIENTS EMPLOYED OR ATTENDING SCHOOL FULL OR PART TIME (2)	OFFERS DIALYSIS SHIFT BEGINNING AT 5 PM OR LATER
LIST ALL FACILITIES				
TOTAL				

SOURCE OF INFORMATION:

DATE OF PREPARATION:

(1) Number of Patients (aged 18 - 55) who were referred to VR programs sponsored by the State or private agencies (or other programs if applicable), and

(2) Number of patients, aged 18 - 55, who were employed or attending school full-time or part-time during the reporting year regardless of the patient's State of residence (as reported by each dialysis facility in the network area).

The patient selection for this table shall be all dialysis patients between ages 18 - 55 receiving dialysis as of December 31 of the reporting year, as reported by each dialysis facility. Source of information should be based on data collected by the Network.

EXHIBIT 2-2

QUARTERLY PROGRESS AND STATUS REPORT FORMAT

The content of the quarterly report must include the following:

I. Quality Improvement

A. Narrative status of HCFA approved quality improvement project. Include the following information:

1. Name of project;

2. Primary contact at Network and phone number;

3. Report on progress made during quarter, comparing to the approved timeline;

4. Report on any problems in meeting approved timeline; and

5. Report on changes made to the originally approved QIP.

Attach a copy of any changes to timelines, data abstraction tools and new interventions, etc.

B. Narrative status of other quality management activities. Include the following information:

1. Description of activity;

2. Primary contact at Network and phone number;

3. If quality management activity was initiated in reporting quarter, provide the following information:

a. Purpose;

b. Objectives;

c. Methods (these could include proposed baseline measurement, sampling, data sources, data analysis, potential Network interventions and evaluation strategies); and

d. Timeline.

4. If activity was initiated in a prior quarter, provide the following information:

a. Progress of activity;

b. Changes in activity design from prior report period; and

c. Problems meeting original timeline.

C. Narrative on collaborations and other activities (e.g.,working with PROs and State agencies, other outside organizations, or Network MRBs).

II. Challenging Situations and Grievances

A. Narrative description of proactive activities (see §615).

B. Report on any complaints/concerns and grievances initiated in the reporting period, and provide update/status on current open caseload and any resolution/closure of caseload during reporting period. Provide the following information:

QUARTERLY PROGRESS AND STATUS REPORT FORMAT

1. Case number.

2. Open date.

3. Current status.

4. Area of concern (report using the following SIMS Contact Categories, i.e., formal grievance, beneficiary complaint, and facility concerns).

5. Type of contact/caller (e.g., beneficiary, facility staff, other, etc.).

6. Description: Be specific enough so that the PO understands the issue and concern. Do not provide patient or facility name.

7. Resolution: Provide information on the Network's action towards resolution or closure of this case.

8. Date closed.

C. Aggregate contact information for complaints/concerns and grievances (Contact Category and Classification of Complaints) by (1) total contacts for the reporting contract quarter (e.g., July, August, September; or October, November, December); and (2) total contacts for the current contract year to date (see Table 1 - Quarterly Reporting Format - Complaints/Concerns and Grievances).

III. Community Information and Resources

A. Provide narrative highlights of educational information provided, such as requests for:

1. QI information;

2. Data research information;

3. Grievance information;

4. Treatment options;

5. Transient patient/care;

6. Vocational rehabilitation information;

7. Reimbursement/financial issues; and

8. Miscellaneous requests.

B. Provide narrative highlights of technical assistance provided.

C. Provide the following information on the new ESRD Patient Packages:

1. The number of returns due to death of the beneficiary; and

2. The number of returns due to incorrect/change in address for the beneficiary.

QUARTERLY PROGRESS AND STATUS REPORT FORMAT

IV. Data

A. Number of 2728 forms processed in the reporting quarter

B. Number of 2746 forms processed in the reporting quarter

C. Number of inquiries from Medicare + Choice organizations regarding:

1. HCFA-2728 forms; and

2. Transplant status of beneficiaries.

D. HCFA Special Studies:

1. Provide narrative description of CPM activity.

2. Provide a narrative description of USRDS requests for information and your participation in the study.

3. Provide narrative on any other HCFA approved special studies.

E. SIMS issues

F. Other

V. General Administrative Information

A. Administrative Issues/Information

B. Other Information

1. Meeting schedule

a. Summary of meetings attended/held in the reporting quarter; and

b. Notice of meetings in the next quarter.

2. Potential quality of care problems that you have identified

3. Policy and/or concerns to be addressed by PO

4. Cost expenditure report, in following format:

a. Contract Award;

b. Contract Modification during the reporting quarter;

c. Quarterly Expenditures;

d. Percent Expended to Date; and

e. Amount of Award Remaining.

5. Additional information requested by PO.

Table 1 - Quarterly Reporting Format - Complaints/Concerns and Grievances

Contract Cycle: (1, 2, or 3)	**Reporting Quarter (Insert months covered during this period)**							
Contact Type (Categories of Complaint)	**Contact Categories (Areas of Concern)**						**Totals Current Contract Quarter**	**Totals Contract Year to Date**
	Formal Grievances	Beneficiary Complaints	Beneficiary Inquiries	Facility Concerns	Facility Inquiries	Other Concerns		
Physical Environment								
Staff Related								
Treatment Related/ Quality of Care								
Information								
Disruptive/Abusive Patient								
Patient Transfer/Discharge								
Professional Ethics								
Other								
Totals								