# ATTACHMENT B

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### C.1. BACKGROUND

### C.1.A. Statutory Mandate

The Statement of Work (SOW) delineates the activities to be conducted by each End Stage Renal Disease (ESRD) Network Organization (Network) to meet the requirements of section 1881(c) of the Social Security Act; the Centers for Medicare & Medicaid Services' (CMS); the Health Care Quality Improvement Program (HCQIP); and other directives related to improving the quality of care of patients with ESRD.

The statute, regulations, the ESRD Network Organizations Manual, and other CMS instructions provide additional detail concerning Network functions, activities, and responsibilities.

A glossary of commonly used terms is contained in the ESRD Network Organizations Manual referenced in section C.4.A.

### C.1.B. Network Functions

Sections 9335(d) through (h) of the Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) amended section 1881(c)(2) of the Social Security Act (the Act), which delineates Network functions listed below.

- Encourage participation in vocational rehabilitation programs and develop criteria and standards relating to this participation.

- Evaluate the procedures used by facilities and providers in the Network in assessing patients for placement in appropriate treatment modalities.

- Implement a procedure for evaluating and resolving patient grievances.

- Conduct onsite reviews of facilities and providers using standards of care established by the Network Organization to ensure proper medical care, as determined by a medical review board or the Secretary,

- Collect, analyze, and validate the data as are necessary to prepare the required annual report to the Secretary and to ensure the maintenance of a national ESRD registry.

- Identify facilities and providers that are consistently not cooperating toward meeting Network goals and assist the facilities and providers in

developing plans for correction as well as report to CMS on those facilities and providers that are not providing appropriate care.

- Submit an annual report to the Secretary by July 1 of each year.

The Networks carry out these legislative functions by conducting the tasks and activities described in this SOW to meet the goals listed in section C.1.C.

### C.1.C. Goals

The CMS goals for the ESRD Network program include the following:

- Improve the quality of health care services and quality of life for ESRD beneficiaries;

- Improve data reliability, validity, and reporting among ESRD providers/facilities, Networks and CMS (or other appropriate agency);

- Establish and improve partnerships and cooperative activities. These activities may include ESRD Networks, Quality Improvement Organizations (QIOs), State survey agencies, ESRD providers/facilities, Medicare + Choice (M+C) Organizations, ESRD facility owners, professional groups, and patient organizations.

- Support the marketing, deployment, and maintenance of CMS approved software (i.e., CROWN – Consolidated Renal Operations in a Web-enabled Network);

The Network shall achieve these goals through the development and implementation of the work requirements outlined in this SOW.

### C.1.D. The Health Care Quality Improvement Program (HCQIP)

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 monitoring and improving quality of care. The HCQIP's mission also includes communicating with beneficiaries and heath care providers in order to promote informed health choices, protect beneficiaries from poor care, and strengthen the health care delivery system.

The HCQIP supports the strategic goals of CMS 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, providers/facilities, and practitioners to assist them in making health care decisions.

For the purposes of this contract, we are using the Institute of Medicine's definition of quality, which is: "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.

The Network, in conducting the activities listed in this SOW, assists CMS in achieving the mission of the HCQIP.

### C.1.E. Contract Purpose

The purpose of this contract is to satisfy the requirements in Section 1881(c)(2) of the Act; CMS's HCQIP; and other directives related to monitoring, improving, and maintaining the quality of care provided to patients with ESRD.

### C.1.F. Technical Considerations

The contractors must have specialized understanding of both ESRD clinical issues and the CMS ESRD Networks Program. The contractors shall consider their experiences and the findings under previous Network contracts in determining their approaches to these contract requirements.

## C.2. REQUIREMENTS

### C.2.A. Contractual Requirements

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the activities/tasks outlined in this contract.

### C.2.B. Reporting Requirements

The Network contractor shall submit reports and other documents as specified in the specific Task requirements of this statement of work, the schedule of deliverables for this contract, and the appropriate portions of the ESRD Network Organizations Manual.

### C.2.C. Internal Quality Control

The objectives of the internal quality control (IQC) program are to support and foster continuous quality improvement within the Network in support of the Health Care Quality Improvement Program (HCQIP), and other SOW activities. The Network shall have a written IQC program that encompasses the major SOW activities that include, at a minimum, conducting quality improvement projects, evaluating and resolving ESRD grievances/complaints, conducting community information and resources activities, collecting, analyzing, validating, and reporting data, and performing administrative functions (including financial management). The Network shall have an internal reporting system on all major IQC activities, and shall make reports available for CMS monitoring purposes. The Network shall follow the IQC procedures contained in Chapter 2 of the ESRD Network Organizations Manual.

### C.2.D. Confidentiality

The Network contractor shall adhere to the confidentiality and disclosure requirements set forth in the following:

- Section 1160 of the Act;
- 42 CFR Part 480 of the Code of Federal Regulations;
- 45 CFR Parts 160 and 164 as they pertain to “oversight” agencies;
- Section H of the contract;
- The ESRD Network Organizations Manual; and
- Other administrative directives.

### C.2.E. Information Collection/Survey Activities

Networks seeking to conduct surveys as a part of any of the Tasks included in this SOW shall do so in accordance with the Paperwork Reduction Act, Chapter 9 of the ESRD Network Organizations Manual, and other administrative directives.

## C.3. TASKS

### C.3.A. General Guidelines

Under this contract, the Network shall be responsible for completing the specific Tasks under the contract task categories. Task 1 continues the Quality Improvement Projects including conducting activities to improve the rates of quality measures reported in the Annual CPM Report for its network area, and developing and updating its Plan for improving CPM performance in its Network

area. Task 2 includes the Network's provision of educational information and technical assistance, and its resolution of difficult situations, complaints and grievances. Task 3 covers Network administrative activities specifically mandated by statute or regulation. Task 4 includes system development and information management responsibilities applicable to all Network activities.

### C.3.B. Task 1. Quality Improvement

The Network is to assist ESRD providers in assessing and improving the care provided to Medicare ESRD beneficiaries. The Network shall accomplish this by:

- Establishing a Network quality improvement program which shall include quality improvement projects (QIPs);

- The collection, monitoring, and improvement of clinical performance measures (CPMs); and

- Conducting other quality improvement activities and information collection activities, as approved by CMS.

The Network's QI responsibilities shall include the following:

- Developing and conducting 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 CMS;

- Monitoring, tracking, and disseminating regional (Network) clinical outcomes data (such as the CPM data) to identify opportunities to improve care within the network area or within a specific facility; and

- Assisting 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, 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 Clinical Performance Measures data collection, other data reports, or results of a site survey or other investigation).

In the development of any quality improvement projects or activities, the question of meeting Office of Human Research Protection (OHRP) regulations may arise. All projects will be evaluated by the Network's Medical Review Board (MRB) and reviewed by the project officer using CMS supplied guidance for compliance with OHRP regulations. If it is determined by the MRB and/or the project officer that a project requires Institutional Review Board (IRB) approval, the project will be submitted to the CMS entity that has jurisdiction for IRB review. If a MRB

member is required to additionally submit the project to their local IRB, it will be the responsibility of that MRB member to seek such approvals. The cost of submitting the project for review will be borne by the Network. Since it is not the purpose of ESRD Networks to conduct research, CMS does not expect many projects to require IRB approval.

**C.3.B.1.**

**Task 1.a. CPM Quality Improvement Projects (QIP) - Performance-Based**

The Network shall develop and implement quality improvement projects with dialysis providers in the area of vascular access as part of the National Vascular Access Improvement Initiative for at least the first two years of the SOW. Project design and other implementation considerations will be developed in conjunction with dialysis providers and other stakeholders collaborating in the IHI-facilitated national "Fistula First" project on Vascular Access. Network participation and progress in the collaboration must be clearly reported/updated in the Quarterly Progress and Status Report referenced in section C.3.D. Task 3.c.

Evaluation of performance for the vascular access QIP will be based on improvements in Network-wide vascular access CPMs. Consistent with quality improvement practice, quantitative vascular access CPM improvement targets should be developed for each facility (as part of collaborative projects). CMS has developed network-wide vascular access improvement targets for prevalent patients. The absolute percentage of prevalent patients using AV fistula in your Network is required to increase _____ percent over the 2002 CDC data (reported in 2003) for AV fistula use in your Network.

Depending on Network-level progress, and the ability to assess such progress in a timely fashion, approval to move to a new CPM topic for the third year may be obtained from the Project Officer provided CMS elects to allow new QIP topics for the third year of this SOW.

As other CPM data collection modalities develop (e.g., VISION or other nationally standardized CPM collection methods) assessment of Network performance and project options may be adjusted to act on timelier, and/or more frequent data availability.

Additional project topics, assuming successful vascular access CPM performance targets are achieved, will not fall under the performance-based evaluation for a QIP and will not require a formal project plan other than reference to the existing plan created under C.3.B.1 - Task 1.b and terminating before the end of the SOW.

Conduct of the National Vascular Access Improvement Initiative over the course of the SOW, including the potential optional topic for year three, does not

preclude participation in, or conduct of, other quality improvement efforts as described in C.3.B.1. - Task 1.b.

**Task 1.b. Other CPM Quality Improvement Projects - Non-Performance Based**

Each Network shall develop a written plan that assesses the relative and historical performance of each CPM indicator (below) and prioritizes/plans/designs improvement activities, as resources allow. The plan must be submitted to the Project Officer no later than 60 days after CPM data is delivered to the Networks in each contract year after the SOW begins. Any additional data collection outlined in the Network's plan (elements and/or frequency) that is not required in the SOW must be approved by the Project Officer. These non-performance-based CPM QI projects should include quantitative targets, as with any quality improvement project. The timing of this plan (deliverable) is designed to allow assessment of the most current annual CPMs for each Network (available through annual CPM report - preliminary results). Annually this plan shall be reviewed and updated as needed by the Network and submitted to the Project Officer for approval within 60 days after CPM data is delivered to the Networks. Progress on these plans shall be reported to the Project Officer in the Quarterly Progress and Status Report referenced in section C.3.D. Task 3.c.

As other CPM/indicator data collection modalities (e.g., VISION or other nationally standardized CPM collection methods) become available this timeline may be adjusted to act on timelier, and/or more frequent data.

The annual Network evaluation process will contain a section that examines adherence to the approved plan. Although quantitative CPM outcome targets are set as a matter of good quality improvement practice, adherence to the CPM plan is the basis for successful review of Task 1.b.

Additional topics are limited to:

- Adequacy of Dialysis (in-center hemodialysis patients) CPMs I - V:
- Adequacy of Dialysis (peritoneal dialysis patients) CPMs I - III;
- Anemia Management CPMs I - III; and
- Other measures/indicators identified by CMS.

Other improvement activities may be developed:

- By the Network with its community; and/or

- In collaboration with others (Quality Improvement Organizations, State survey agencies, Medicare + Choice Organizations, national and/or local renal related organizations, providers, patients, other Networks and CMS when appropriate).

Additional information related to Section C.3.B, and C.3.B.1. can be found in Chapter 5 of the ESRD Manual.

**Task 1.c. Clinical Performance Measures (CPMs) Collection**

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. CPMs can be used for a variety of purposes such as tools to facilitate quality improvement activities, tools to allow for comparison of the quality of care delivered in similar or different settings, and/or tools to identify issues or sites that warrant more in depth evaluation. The primary use of CPMs by the Networks will be to facilitate quality improvement among dialysis providers.

Annually, the Network shall collect data on specific ESRD CPMs as described in the ESRD Network Organizations Manual instructions Chapter 5. CMS, working with the ESRD CPM Quality Improvement (QI) Committee (the committee is composed of both Network and renal community representatives) shall determine what CPMs to collect and what ESRD patient population(s) to target.

The work effort for this activity shall remain the same in each contract year. CMS may change or add additional CPMs; however, any changes in the CPMs will be made with input from the ESRD CPM QI Committee. Any changes in the CPMs will assume the same level of Network resources needed to conduct the activity described in Task 1.b.

The purposes of collecting data annually on the CPMs are to:

- Describe/analyze the practice patterns, processes (when able) and outcomes of care for the targeted patient population, both at a point in time and over time;

- Describe/analyze conformance to clinical practice guidelines both at a point in time and over time; and

- Provide the facilities/providers with information to stimulate improvement inpatient care, practice patterns, processes and outcomes for the targeted patient population.

Annually, the Network shall conduct the following activities involving CPMs:

- Collect data on specific measures by requesting the selected dialysis facilities to provide patient-specific data for a CMS selected sample of ESRD patients in the facilities. All collected data on the CMS selected patient sample must be transmitted to CMS or CMS' designee, using CMS' designated data entry program, within 90 calendar days after receipt of the CMS selected patient sample;

- Validate data from a five-percent hemodialysis patient random sample and a ten percent peritoneal dialysis patient random sample of the facility-abstracted data. CMS or CMS' designee shall draw the validation samples. All validated data must be transmitted to CMS or its designee, using the CMS designated data entry program, within 120 calendar days after receipt of the random validation sample; and

- Distribute or support the distribution, of the ESRD CPM Annual Report and/or tables to each provider/facility in its area.

The description of the sampling methodology; instructions for the data collection, validation of the CPMs, and the distribution of ESRD CPM Annual Report; and guidance for the establishing target performance levels for selected CPM indicators are listed in the ESRD Network Organizations Manual instructions Chapter 5.

**Task 1.d. Other Quality Improvement Activities**

The Network shall have and maintain the capacity to respond to local needs upon request by facilities or when poor performance/problems are identified in conjunction with the responsibilities set forth in section C.3.B. These other QI activities may differ from Network to Network depending upon local needs, variation in patient outcomes and practice patterns (processes of care). Other QI activities may be tailored to specific target areas, such as a geographic area, provider group (dialysis and/or transplant), or specific clinical domains. Other QI activities may be developed in collaboration with CMS, the QIO, or the Network Medical Review Board. Any additional data collection being considered for these activities (elements and/or frequency) that is not required in the SOW must be approved by the Project Officer. The objectives of these QI activities are to assist in the development of local (i.e., facilities, clinics, etc.) capacity to conduct internal quality improvement activities, which may include measurement and improvement of local/internal processes and outcomes of care. Methods to achieve may include:

- Fostering internal QI at the facility level;

- Providing technical assistance;

- Providing education; and

- Promoting and assisting facilities to conduct focused local QI initiatives.

The Network shall report the status of its other QI activities in the Quarterly Progress and Status Report referenced in section C.3.D. Task 3.c of this SOW. Any report or work product produced for other QI activity(ies) shall be submitted to the project officer within 30 days of its completion. CMS reserves the right to direct or redirect these activities.

### C.3.C. Task 2. Community Information and Resources

The Network is to assist providers and patients in its area to improve the quality of care and the quality of life of ESRD patients by providing informational material and technical assistance on ESRD related issues. In carrying out the activities under this task, the Network shall perform the following functions:

- Encourage participation in vocational rehabilitation programs and develop criteria and standards relating to this encouragement.

- Evaluate the procedures used by facilities and providers in the Network in assessing patients for placement in appropriate treatment modalities.

- Implement a procedure for evaluating and resolving patient grievances.

- Establish and/or maintain a national user-friendly toll-free number to facilitate communications with beneficiaries within its network area.

- Develop and/or maintain a web site that follows CMS standards and guidelines.

- Comply with laws that prohibit excluding or denying individuals with disabilities an opportunity to receive the same information and assistance it provides other beneficiaries.

The Network shall report on all Task 2 activities in its Quarterly Progress and Status Report as referenced in section C.3.D. Task 3.c.

**C.3.C.1.**

**Task 2.a. Provision of Educational Information – Provider/Facilities**

Annually the Network shall make available, at a minimum, the following informational materials to the providers/facilities in its Network area with a directive that each provider/facility make the information available to its patients or inform its patients on how to contact the Network organization to obtain the information.

- The Annual Report (either by hardcopy and/or referral to the Network's web site), which contains CMS and ESRD Network goals, the Network activities conducted to meet these goals, and the Network's plan for monitoring facility compliance with the goals;

- Regional and national patterns or profiles of care as provided in the Clinical Performance Measures Annual Report;

- Results of Network quality improvement projects;

- As directed, appropriate, and/or necessary (necessity would result from, for example, a substantive change to a grievance process that resulted in updated informational material on this process), the Network organization shall provide any updated information to providers/facilities in its network area with a directive that each provider/facility make the information available to its patients or inform its patients on how to contact the Network organization to obtain the information.

- Special mailings (up to two per year) as directed by CMS, including duplication of materials, as necessary;

- Annual printing and distribution of Dialysis Unit Specific Reports. Annually, within 30 days of receipt of the dialysis Unit Specific Report (by hard copy or electronic) produced by the University of Michigan Kidney Epidemiology and Cost Center (or other CMS designee) for the dialysis facilities within the Network's area, the Network shall print and distribute two copies of the facility's Report to the individual facilities, to the attention of the Medical Director and the Unit Administrator. Each facility shall only receive a copy of its own report.

- Annual notification of the updated Quality Measures for Dialysis Facility Compare. Annually, within 30 days of receipt of the dialysis Unit Specific Report (by hard copy or electronic) produced by the University of Michigan Kidney Epidemiology and Cost Center (or other CMS designee) or other report that describes the three updated quality measures to be posted on Medicare's Dialysis Facility Compare (DFC) web site for the dialysis facilities within the Network's area, the Network shall notify the applicable dialysis facility of its updated DFC quality measures. The notification shall also include instructions as to how the dialysis facilities can provide comments to CMS regarding its updated measures. CMS, or its designee, shall provide the Network with instructions for preparing the notification to the dialysis facilities.

- Other materials (such as journal articles or pertinent research information) that providers/facilities can use in their quality improvement programs; and

- Information on how to access and use Medicare's Dialysis Facility Compare (DFC) web site and how to submit corrections to the Network on its facility characteristics that are displayed on DFC.

The Network shall report on these activities in its Quarterly Progress and Status Report as referenced in section C.3.D. Task 3.c.

**Task 2.b. Provision of Educational Information – Patients**

Annually the Network shall make available, at a minimum, the following informational materials to its patients in its network area or inform its patients on how to contact the Network organization to obtain the information. The Network shall comply with laws that prohibit excluding or denying individuals with disabilities an opportunity to receive the same information and assistance it provides other beneficiaries. The types of information include:

- The Network's process for reporting and resolving patient grievances.
- Treatment options and new ESRD technologies available for patients.
- State/regional vocational rehabilitation programs available in the Network area.
- The Network's user-friendly toll-free number to facilitate communications with beneficiaries within its Network area (i.e., a staff person should be available to answer the phone during normal working hours or if a staff person is not available, the ability for a person to leave a message).
- The Network's web site that follows CMS standards and guidelines, which shall include at a minimum: Network grievance process, location of Network, toll-free number for patients to contact the Network, current completed Annual Report, Network goals, and a link to the Medicare.gov Dialysis Facility Compare web site**.**
- Information on how to access and use Medicare's Dialysis Facility Compare web site.

The Network shall report on these activities in its Quarterly Progress and Status Report.

**Task 2.c. Provision of Technical Assistance**

Annually, the Network shall notify its providers, facilities, and patients, that it is available to provide technical assistance, guidance, and/or referrals to appropriate resources upon request. At a minimum, the Network shall:

- Identify available providers and/or facilities to patients seeking ESRD services (including transient patients) and

  - refer those patients to the Medicare.gov Dialysis Facility Compare web site;

  - educate dialysis facility professional staff regarding the use of the information on Dialysis Facility Compare in assisting patients to make choices about dialysis facilities, to participate in decision making regarding their treatment, and other applicable uses per guidance set forth in the ESRD Network Organizations Manual; and

  - provide, upon request or inquiry, assistance in understanding the information provided on the Dialysis Compare page of the Medicare.gov web site per guidance set forth in the ESRD Network Organizations Manual.

- Assist providers/facilities in developing community and patient education programs;

- Promote patient education regarding kidney transplantation, and self-care home dialysis;

- Encourage and assist providers/facilities to do timely patient assessments thus promoting appropriate referrals for kidney transplant;

- Address impediments to referrals and/or transplantation, as appropriate and feasible;

- Assist providers/facilities in assessing the functional status of patients;

- Assist providers/facilities in defining or establishing rehabilitation goals for referring suitable candidates to vocational rehabilitation programs;

- Assist providers/facilities (that are having difficulty in meeting Network goals) in developing appropriate plans for correction; and

- Assist providers/facilities in developing local disaster plans that include planning for emergencies such as floods, earthquakes, hurricanes, etc.

The Network shall report on these activities in its Quarterly Progress and Status Report.

**Task 2.d. Resolution of Difficult Situations and Grievances**

The Network shall assume a proactive role in the prevention, facilitation, and resolution of complaints and grievances, including implementing educational programs that will assist facility staff in handling difficult situations. The Network shall also conduct trend analysis of reported situations to detect patterns of greater concern. Each Network shall be responsible for, but is not limited to, the following activities:

- Implement educational programs designed to provide facility staff with an understanding of the issues and skills to prevent, intervene, or mitigate difficult patient and/or facility situations;

- Upon request, assist in the resolution of patient, provider, and/or facility complaints, before they become formal grievances by providing education, and/or facilitating solutions, and/or making referrals, which address the issue(s) involved;

- Describe and report in the Quarterly Progress and Status Report, patient and facility concerns/grievances and Network actions and interventions in a narrative format;

- Annually, analyze facility-specific data to identify patterns of concern at the facility or Network level, and opportunities to improve;

- Implement interventions aimed at reducing grievances and/or the numbers of difficult situations;

- Collect and appropriately categorize inquiries/complaints/grievance data using SIMS; and

- Utilize grievance data to plan new training modules, provide facilities with feedback and/or make recommendations to CMS.

The Network shall follow the CMS national policy in the ESRD Network Organizations Manual instructions Chapter 7, for evaluating, resolving, and reporting patient grievances and facility concerns. The Network shall within 24 hours of receipt, refer immediate and serious grievances to the appropriate CMS regional office and State survey agency. On request from CMS, the Network shall assist the State survey agency with the investigation of a complaint.

The Network shall report on these activities in its Quarterly Progress and Status Report.

### C.3.D. Task 3. Administration

Each Network shall have an organizational structure, basic administrative staff, and infrastructure to support its operations to meet the statutory requirements, as

well as other work activities, set forth in this SOW. Each Network is required to establish various boards or committees, specify appropriate roles and functions for these entities, and provide minutes or documentation of committee meetings and actions.

**C.3.D.1.**

**Task 3.a. Organizational Structure**

Each Network's organizational structure shall include the following:

- Network Council that meets the statutory requirements of section 1881(c) of the Act. The Network Council shall be composed of renal providers in the network area, be representative of the geography and the types of providers/facilities in the entire network area and have at least one patient representative. The Network Council shall meet as necessary, and serve as a liaison between the provider membership and the Network.

- Board of Directors (BOD) composed of representatives from the network area including at least one patient representative. The BOD or Executive Committee (EC) shall meet as necessary (suggest quarterly by teleconference or onsite meeting) to ensure the successful operation of the Network. The BOD or EC shall be responsible for the performance of the Network's administrative staff in meeting contract deliverables and requirements, responding to CMS requests, and maintaining financial viability.

- Medical Review Board (MRB) or a committee that meets the statutory requirements of section 1881(c) of the Act to function as the medical review board. The committee (which shall be referred to as MRB in this SOW) shall be composed of at least one patient representative, and representatives from each of the professional disciplines (physician, registered nurse, social worker and dietitian) engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients.

- Other committees (or subcommittees) as appropriate to meet the requirements in the SOW. The committees shall be composed so as to represent the diversity of the patient and practitioner community to the fullest extent possible.

The ESRD Network Organizations Manual instructions Chapter 2 provide additional information regarding the above committees.

**Task 3.b. Network Staff**

Each Network organization shall have an administrative staff that carries out the work requirements of this SOW. At a minimum, the staff shall be composed of the following:

- Executive Director/Project Director responsible for the overall operation of the Network and obtaining the staff and resources necessary to conduct the contract;

- Quality Improvement Manager/Quality Improvement Coordinator responsible for coordinating the Network quality improvement activities.

Replacement of these positions must be done in accordance with section G.8 Key Personnel. The Network shall also have available the professional and technical expertise required to meet performance expectations described below.

- An individual responsible for data related activities (i.e., Data Manager, etc.);

- Sufficient support staff (including a registered nurse with nephrology experience) to conduct the activities and responsibilities in accordance with the SOW, Chapter 2 of the ESRD Network Organizations Manual instructions, and other CMS directives;

- A full time individual with a Masters in Social Work or an equally qualified individual (i.e., experienced nephrology nurse or counselor) responsible for resolving patient and/or facility complaints or grievances, and conducting educational training on managing difficult patients, and conflict resolution. If a Network is unable to find an individual with the above listed qualifications, or wants to retain current staff with proven capabilities, it shall seek approval from its Network Project Officer for these exceptions.

The responsibilities of the Network staff are discussed in Chapter 2 of the ESRD Network Organizations Manual instructions.

**Task 3.c. Required Administrative Reports/Activities**

The Network shall submit the following administrative reports to its project officer:

- Quarterly Progress and Status Reports of Network contractual activities, which are due fifteen working days after the beginning of each calendar quarter to the regional office project officers with a copy to CMS central office. The reports must be submitted electronically and by hard copy;

- Semi-annual report of Network operating costs, which are due electronically to the Network Project Officer and to CMS central office no later than the close of business on the fifteenth working day of the second

calendar month following the closing date of the cost reporting period it covers as specified in H.4.

- The final Annual Report of Network activities is due to the Network's Project Officer by July 1 of each contract year, and to CMS central office and the ESRD Network Coordinating Center within two weeks after approved by the Project Officer. Within 90 days after Project Officer's approval of the Network's Annual Report of Network activities, the Network shall place a copy of its report on its website and notify the Project Officer of the effective date. The Network shall include in the report:

  - The activities conducted to meet ESRD program goals during the previous calendar year;

  - An assessment as to whether those activities were effective in meeting the goals;

  - Data on the comparative performance of facilities/providers in identifying and placing suitable candidates in self-care settings, transplantation, and vocational rehabilitation programs

  - The identification of those facilities that consistently failed to cooperate with Network goals or to follow the recommendations of the medical review board; and

  - Any recommendations for additional or alternative ESRD facilities in the network area.

The Network shall perform the following administrative activities:

- The Network organization shall provide, for duplication and use by the contractor designated by CMS to distribute in the New ESRD Patient Orientation Package to new ESRD patients in its network area, a letter introducing the Network organization to the new patient. The letter shall be written on Network stationary and shall be provided to the Network Coordinating Center for the designated subcontractor to distribute in the ESRD new patient packages with a copy to the Network's project officer when:

  - Directed by CMS;

  - Requested by the designated contractor; and/or

  - Upon any changes to the letter's content information. The Network organization's letter of introduction shall include, at a minimum:

- ❖ Information on the Network's grievance procedure;

- ❖ Network specific information, including the Network organization's toll-free number, and a way to request/obtain additional educational materials on ESRD, patient care, treatment options, and services; and

- ❖ Information about the function of the State agencies, to include addresses and phone numbers of each SA in the Network contract area, and the fact that the SA receives and investigates complaints.

- The Network organization shall follow up on all returned mail for the Network Coordinating Center when New ESRD Patient Packages are undeliverable. The Network shall:

  - Determine whether the patient is deceased or is still alive and has a current address;

  - Provide the Network Coordinating Center with the patient's name and current address;

  - In cases where the patient is deceased, update its patient database to the Standard Information Management System (SIMS); and

  - Report monthly to the Network Coordinating Center the number of returns due to death and address changes.

The Network shall report on these activities in its Quarterly Progress and Status Report.

The ESRD Network Organizations Manual (Chapter 2) contains instructions for the content and format of these reports.

**Task 3.d. CMS Meetings**

Network staff (to be designated by the Network Executive Director or CMS) are to participate at CMS sponsored/sanctioned meetings when requested. Planned meetings include the CMS/Forum of ESRD Networks' Annual Meeting and the CMS Quality Net Conference.

**Task 3.e. Cooperative Activities with State Survey Agencies and Quality Improvement Organizations**

In addition to Task 1 Quality Improvement activities outlined in section C.3.B. of this SOW, the Network shall work with the appropriate CMS regional office(s), State survey agency(ies) and Quality Improvement Organization(s) (QIO) in other areas that shall assist each organization to improve the quality of care for ESRD patients. These activities can include, but are not limited to the following:

- Sharing information to assist the State survey agencies and/or QIOs in carrying out their legislative or regulatory responsibilities;

- Referring quality of care issues, as appropriate, and assisting the State survey agency or QIO in the investigation of quality of care issues, upon request. This may include:

  - Conducting reviews cooperatively (e.g., site visits, such as sequential reviews, as needed);

  - Conducting joint State/Network onsite visits only with the approval of CMS

  - Providing technical assistance;

  - Providing information regarding expected outcomes; and/or

  - Reporting patterns of complaints or grievances.

- Coordinating and collaborating with the State survey agency in regards to QI interventions when a provider is un-cooperative or unable to implement and maintain improvements whether in compliance with the conditions for coverage or in the provision of care that is consistent with current professional knowledge.

Suggestions for cooperative activities with the State survey agencies and QIOs are included in Chapter 2 of the ESRD Network Organizations Manual instructions.

**Task 3.f. Sanctions and Referrals**

The Network's responsibilities for alternative sanction recommendations and referrals include the following:

- Recommending to CMS alternative sanctions for providers/facilities that do not comply with Network goals and/or are not providing appropriate medical care.

- Referring to the QIO or the Office of the Inspector General information collected while conducting contract activities that indicates that a physician

may be failing to meet his/her obligation to provide quality care.

Instructions for these responsibilities are contained in Chapter 7 of the ESRD Network Organizations Manual instructions.

### Task 3.g. Network Resources to Support the United States Renal Data System (USRDS) and Special Study Centers

In addition to the Task 4 data activities/resources described in section C.3.E. that are conducted to support the ESRD Program Management and Medical Information System (PMMIS) database, which CMS provides to the USRDS, Network resources shall be available to support USRDS special study activities that are focused on identifying factors that can be used to improve patient care and outcomes.

Chapter 5 of the ESRD Network Organizations Manual instructions provides general instructions for the type of resources and activities the Network shall conduct to support the USRDS special study centers activities.

The Network shall report the status of its activities to support the USRDS in the Quarterly Progress and Status Report.

## C.3.E. Task 4. Information Management

This section contains the information management and reporting activities that the Network shall be required to perform. The Network shall be required to utilize the Standard Information Management System (SIMS) to support Network contractual requirements to CMS. The Networks will be required to utilize SIMS and the Quality Net Exchange to transmit and receive information electronically from CMS and the facilities. SIMS will be the primary source of information to support CMS ESRD benefit determinations. CMS will access SIMS patient and facility data through Renal Management Information System (REMIS). The Network shall be required to utilize REMIS as directed by CMS.

All work under this contract shall be performed using Government-furnished equipment only. Exceptions to this policy may be requested through the ERB process **for peripherals only (e.g. printers, scanners)**. Under no circumstances will Networks be allowed to attach non-Government servers or workstations to the Government equipment and/or network.

The Network's responsibilities for data processing, information management and reporting are to:

- Establish policies and procedures for maintaining CMS approved computer hardware and software and maintaining sufficient system capacity to carry out its contractual responsibilities;

- Effectively manage the collection, validation, storage and use of data; including data provided by CMS, for review, profiling, pattern analysis, and sharing appropriate data with the CMS RO and State survey agency for use in their ESRD Medicare survey and certification activities;

- Ensure timely and accurate reporting by the providers/facilities;

- Train facilities in the proper procedures for completing and transmitting forms electronically;

- Maintain an ESRD patient and facility database and ensure the confidentiality, integrity, and accuracy of the databases;

- Ensure the quality and accuracy of the SIMS database for inclusion in the ESRD Program Management and Medical Information System (PMMIS) and the United States Renal Data System (USRDS);

- Ensure current patient status is reported to CMS timely for appropriate enrollment and disenrollment into the Medicare program for ESRD benefits;

- At a minimum, on a quarterly basis, verify with dialysis facilities, patient event data maintained in SIMS; and

- At a minimum, on an annual basis, profile facilities based on glomerular filtration rates to ensure the appropriateness of renal replacement therapy. The results of this activity shall be reported in the Network's Annual Report and profile tables made available to CMS upon request.

Chapter 4 of the ESRD Network Organizations Manual instructions provides a summary of the data requirements in the SOW and the Network's responsibilities for processing/maintaining the data.

**C.3.E.1.**

**Task 4.a. System Capacity**

The Network shall maintain a system that provides the capacity to meet its contractual responsibilities for data collection, validation, entry, retrieval, profiling, analysis, reporting, and for electronic data interchange. The system, at a minimum, shall consist of the following:

- VISION software, SIMS software, and communication capability via Quality Net Exchange;

- Program documentation, for the entry and transmission of the CMS ESRD forms described in Task 4.c.;

- CMS approved software for the entry and transmission of clinical performance measures described in Task 1.c.;

- CMS approved hardware (HW) and software (SW) for transmitting and communicating with ESRD facilities and CMS Central and Regional Offices; **NOTE: Networks shall not develop Network software products for facility use without approval from CMS. In addition, no money from this contract shall be used for data collection activities not specifically specified in this contract unless approved by the project officer.**

- CMS approved statistical software for data analysis and profile analysis, including profiling patients and facilities by county, to facilitate disaster planning and other studies; and

- Provisions for disaster recovery including regularly scheduled backup of the databases and data system.

Any and all HW/SW necessary for the ESRD Network Organizations, SIMS, VISION, and other supporting systems as determined by CMS shall be purchased through the Quality Improvement Organization (QIO) Standard Data Processing System (SDPS) Contractor, the Iowa Foundation for Medical Care, Inc. (IFMC). Requests for HW/SW should be made using the Remedy AR System software provided by CMS. See the CROWN Website (http://www.cms.hhs.gov/esrd/) for a description of the SDPS ERB process. The Network shall maintain an accurate inventory of federally provided HW/SW as directed by CMS.

**Task 4.b. Database Management**

The Network shall maintain a patient database containing the mandatory data elements listed in the ESRD Network Organizations Manual instructions Chapter 4. The Network shall perform the following tasks related to its patient database:

- The Network shall continually update the local SIMS database and the SIMS central repository based on data received from the providers/facilities. Replication to the central repository shall be run nightly for all queued validated ready records based on a pre-determined schedule. CMS will access the SIMS central repository on a regularly scheduled basis to obtain an update of the Networks' patient data for REMIS.

- CMS may request each Network to submit its patient database (some or

all patients) to its designee for use in selecting patients for the annual CPM data collection effort. The patient database shall be due to CMS' designee within 30 calendar days of the request.

- The Networks are responsible for the validity and accuracy of the ESRD patient database. CMS may have additional or more current information on important patient data elements (e.g., beneficiary name, date of birth, Health Insurance Claim Number (HICN) and Beneficiary Identification Code (BIC)). The Networks will be responsible for resolving these discrepancies in their patient records.

- The Networks are responsible for providing accurate data to CMS. The Networks are required to run data clean up utilities supplied by the SIMS contractor on a regular basis or as directed by CMS.

- When requested, verify data and upload all corrections to provider data for the National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services directly to the Central Repository in the SIMS system.

- Through SIMS, the Network shall maintain an up-to-date facility database containing the mandatory data elements listed in the ESRD Network Organizations Manual. It is important to keep facility data current for the Dialysis Facility Compare Web Site maintained by CMS. The facility data is to be replicated to the Central Repository nightly.

### Task 4.c. Collection, Completion, Validation and Maintenance of CMS ESRD Forms

The Network shall obtain completed CMS ESRD forms from each ESRD provider/facility and/or corporate owner in the Network area either electronically or hardcopy. Until electronic reporting is mandatory from all dialysis facilities electronic submission of data will be on a voluntary basis. The Networks shall be responsible for marketing, instructing, and training the facilities and/or facility owner on the proper procedures for electronic submission. The Networks will be responsible for authorizing access to the Quality Net Exchange for the electronic transmission of ESRD Forms. The Network will also include all transmitted forms from the non-Medicare Veterans Health Administration (VHA) facilities, and voluntarily submitted forms from institutions such as prisons and nursing homes.

**ESRD Forms**

These forms contain patient specific information necessary for the operation of the national ESRD program. The CMS ESRD forms and their facility computer generated equivalents include the following:

- CMS-2728-U3 - ESRD Medical Evidence Report Medicare Entitlement

and/or Patient Registration (completed on each incident ESRD patient);

- CMS-2744 - ESRD Facility Survey (completed annually);

- CMS-2746 - ESRD Death Notification (or computerized facility generated Death Notification form) (completed within 30 days of the date of death);

- CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually on a sample of HD patients); and

- CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually on a sample of PD patients).

**Processing Forms Data**

Monitoring the accuracy and completeness of reports, and the validation of facility-level patient data are critical roles in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for cross-checking so Networks and/or facilities can query and detect unreported forms. As VISION is implemented, the activities specified below will need to be retained in a format that is consistent with migration from hardcopy to electronic reporting.

The Network shall conduct activities to ensure that the data required on the forms are collected, completed, and validated in accordance with the ESRD Network Organizations Manual instructions and the ESRD Program Instruction Manual for Renal Providers. The Networks shall replicate queued validated forms to the Central Repository nightly. CMS will access replicated forms from the Central Repository. These activities include the following:

Review forms data received for accuracy and completeness and return to the provider/facility (or otherwise query the provider/facility) for correction or completion of those forms with missing or inaccurate data.

Receive and process the ESRD Medical Evidence Report, Medicare Entitlement and/or Patient Registration form (CMS-2728-U3) and the ESRD Death Notification form (CMS-2746).

Replicate queued validated information on CMS-2728 and CMS-2746 forms via SIMS to the Central Repository.

Process the information on the CMS-2744 form via SIMS.

Complete corrections to the CMS-2744 form via SIMS by the third Friday in May.

Maintain a file of all CMS ESRD hardcopy forms that are entered at the Network for at least two years until electronic reporting through VISION is mandatory.

**Task 4.d. VISION Data Validation**

Annually, ESRD Networks shall validate 3 percent of patient and physician signatures on CMS 2728 forms received electronically through VISION. Results of this validation shall be reported in the Networks Annual Report.

**Task 4.e. Tracking System for ESRD Forms**

The Network, through SIMS, shall maintain a system to track receipt of CMS-2728 and CMS-2746 forms from the providers/facilities. The system shall ensure the forms are submitted timely and all mandatory data fields as listed in the ESRD Network Organizations Manual instructions Chapter 4 are completed and are accurate.

**Task 4.f. ESRD Forms Submission Compliance Rates**

Semi-annually, through SIMS, the Network shall profile the facilities to determine their compliance rates for submitting timely and complete/accurate CMS ESRD forms to the Network. Acceptable rates for timeliness, completeness and accuracy for each form type, as well as instructions for notifying those providers/facilities with unacceptable semi-annual compliance rates, are contained in the ESRD Network Organizations Manual instructions Chapter 4.

**Task 4.g. CMS ESRD Forms Data Discrepancies and Data Corrections**

After records are replicated to CMS Central Repository the mandatory data referenced in Task 4.c. will be subjected to edit checks. If discrepancies in the data are detected, notification will be transmitted to the Network for research and resolution. The Network shall resolve the data discrepancies and enter the corrections in the local SIMS database and replicate to the Central Repository, within 60 calendar days of notification. The ESRD Network Organizations Manual (Chapter 4) contains instructions for resolving the data discrepancies.

**Task 4.h. Renal Transplant Data**

The Network shall conduct the following tasks to obtain and process renal transplant data. The Network shall follow the instructions in the ESRD Network Organizations Manual instructions Chapter 4 for conducting the following tasks:

- Report kidney transplant and follow-up data through SIMS;
- Assist the United Network for Organ Sharing's (UNOS), the contractor for the Organ Procurement Transplant Network (OPTN) in obtaining renal

transplant registration and follow-up information; and

- Report serious errors or discrepancies found in the UNOS data to CMS for follow-up with UNOS.

**Task 4.i. Reporting on Renal Status of Medicare ESRD Beneficiaries**

It is the Network's responsibility to reflect current patient status within the SIMS central repository. A patient status is necessary to appropriately identify when Medicare benefits are to be terminated. Any changes to a patient status shall be reflected in SIMS within 30 days of a change in status. CMS may pull census data from SIMS quarterly during the year. This requires that the Network shall keep its patient database up-to-date.

For beneficiary status that CMS is unable to resolve through the SIMS central repository patient database, notice will be sent to the Network for clarification. The Network shall investigate the treatment status of the identified beneficiaries and respond to CMS within 10 working days of request. Instructions for the processing of these inquiries are contained in Chapter 4 of the ESRD Network Organizations Manual instructions.

**Task 4.j. Coordination of Additional Renal Related Information**

The Network shall perform the following tasks to coordinate the collection and reporting of additional information:

- Process CMS ESRD forms on Veterans Health Administration (VHA) dialysis patients from non-Medicare approved VHA facilities. The submission of data to the Network by VHA non-Medicare approved facilities on its ESRD patients is mandated by the VHA**.** These activities are part of the requirements reported in Task 4.c.

- Respond to selected inquiries from Network area Medicare+Choice (M+C) organizations regarding the status of CMS-2728s filed with the Network, and/or transplant status of ESRD Medicare beneficiaries who are members of the M+C organizations. Information to be provided includes the current dialysis/transplant functional status, the first date of dialysis or transplant date, and the approximate date the CMS-2728 was submitted to CMS. Selected inquiries are for those patients who have been on dialysis for at least four months and whose records are not retrievable through other CMS-provided electronic data sources. The Network shall report the number and type of inquiries received in the Quarterly Progress and Status Report referenced in Task 3.c.

## C.3.F. Task 5 Special Studies

1. Background

CMS reserves the right to direct the Network, or approve an application from the Network to initiate a special study not currently defined under this SOW.

2. Task Description

A special study is defined as work that CMS directs a Network to perform or work that a Network elects to perform with CMS approval which is not currently defined in Tasks 1-4 of the SOW, but falls within the scope of the contract. The term “special studies” is interchangeable with the terms “special projects” and “special work”.

3. Evaluation

All special studies approved under this task will be evaluated individually, based on study-specific evaluation criteria. The Network’s success or failure on a special study will not be factored into the evaluation of the Network’s work under Tasks 1-4.

## C.4. REFERENCES

### C.4.A. ESRD Network Organizations Manual

The ESRD Network Organizations Manual is hereby designated as reference material. The manual may be accessed on www.cms.hhs.gov/esrd.

### C.4.B. ESRD Program Instruction Manual for Renal Providers

The ESRD Program Instruction Manual for Renal Providers is hereby designated as reference material. The Contracting Officer will make the full text available upon request.