

Attachment A

SECTION C - DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK

C.1. BACKGROUND

C.1.A. Contract Purpose

This 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 and comply with all Centers for Medicare & Medicaid Services (CMS) directives related to improving the quality of care of patients with ESRD through to the end of life.

Section 1881(c) of the Social Security Act, Sections 9335(d) through (h) of the Omnibus Budget Reconciliation Act of 1986, federal regulations, the *Medicare ESRD Network Organizations Manual*, and other CMS instructions provide additional details concerning Network functions, activities, and responsibilities.

A glossary of commonly used terms is contained in the *Medicare ESRD Network Organizations Manual*.

C.1.B. Statutory Mandate

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

- (A) “Encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs”;
- (B) “Developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and [developing] [N]etwork goals with respect to the placement of patients in home therapies, and in-center self-care settings and undergoing or preparing for transplantation”;
- (C) “Evaluating the procedure by which facilities and providers in the [N]etwork [area] assess the appropriateness of patients for proposed treatment modalities”;
- (D) “Implementing a procedure for evaluating and resolving patient grievances”;

- (E) “Conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the [Network] to assure proper medical care”;
- (F) “Collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) below and to assure the maintenance of the registry established under paragraph (7) of the Social Security Act at §1881(c)(7)”;
- (G) “Identifying facilities and providers that are not cooperating toward meeting [N]etwork goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care”;
- (H) “Submitting an annual report to the Secretary [through CMS] on July 1 of each year which shall include a full statement of the [N]etwork’s goals, data on the [N]etwork’s performance in meeting its goals [including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in home therapies, in-center self-care, and transplantation, encouraging participation in vocational rehabilitation programs, volunteerism, and self-sufficiency for increased quality of life], identification of those facilities that have consistently failed to cooperate with [N]etwork goals, and recommendations with respect to the need for additional or alternative services or facilities in the [N]etwork [area] in order to meet the [N]etwork goals, including self-dialysis training, transplantation, and organ procurement facilities.”

The Network shall carry out these legislative functions by conducting the tasks and activities described in this SOW to meet the strategic goals listed in Section C.1.C.

C.1.C. ESRD Network Program Strategic Goals

In accordance with the legislative mandate for the ESRD Network Program; to assist CMS in meeting agency goals (e.g., ensuring the right care for every person every time), and in keeping with sound medical practice, the strategic goals of the ESRD Network Program are to:

- Improve the quality and safety of dialysis-related services provided for individuals with ESRD.
- Improve the independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through support for transplantation, use of self-care modalities (e.g., peritoneal dialysis, home hemodialysis), and in-center self-care, as medically appropriate, through the end of life.
- Improve patient perception of care and experience of care, and resolve patients’ complaints and grievances.

- Improve collaboration with providers and facilities to ensure achievement of goals 1 through 3 through the most efficient and effective means possible, with recognition of the differences among providers (independent, hospital-based, member of a group, affiliate of an organization, etc.) and the associated possibilities/capabilities.
- Improve the collection, reliability, timeliness, and use of data to measure processes of care and outcomes; to maintain a patient registry; and to support the goals of the ESRD Network Program.

For the purposes of this contract, CMS uses the Institute of Medicine's (IOM) 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." Further, CMS defines rehabilitation for the purpose of this contract as restoring an individual to the maximum level of independence and quality of life that he or she can achieve. The Network shall achieve these goals through the development and implementation of the work requirements outlined in this SOW.

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

The Health Care Quality Improvement Program (HCQIP) supports achievement of the strategic goals of the ESRD Network Program by working to assure the IOM aims of patient-centered, effective, safe, efficient, equitable, and timely care. The Network, in conducting the activities listed in this SOW, assists CMS in achieving the strategic goals of the Program and the mission of the HCQIP.

Mission:

Specifically, the mission of the HCQIP is to ensure that care delivered to individuals with ESRD is:

Patient-centered: Care delivery and processes of care are focused on patient needs, concerns, values, and expressed priorities to empower the patient. Caregivers are empathic and care is provided in a compassionate, responsive manner.

Safe: Patients receive safe care in ESRD facilities and when appropriate, in-home settings. Systems of care are designed to allow staff to anticipate and prevent or minimize adverse events, learn from system failures, and seek system improvements. Caregivers are trained to recognize and anticipate errors and recover from them.

Effective: Caregivers use scientific knowledge, evidence-based guidelines, and best demonstrated practices to offer individuals with ESRD the best available care. Caregivers use this medical advice, and consider the individual preferences of patients, to derive effective care plans.

Efficient: National and local resources are used to deliver high quality care. Only those administrative and production costs that result in high quality care are included in program operation.

Equitable: Care provided to individuals with ESRD does not vary in quality because of personal characteristics or socioeconomic status.

Timely: ESRD providers/facilities have processes in place to measure and minimize unnecessary delay in provision of services; health care interventions occur neither too soon nor too late.

Expected Outcomes:

Implementation of the HCQIP will result in achievement of the Program’s strategic goals in such areas as:

1. **Measuring outcomes:** Outcomes that are achievable by patients and caregivers are monitored using valid, evidence-based measures of performance that are developed through broad consensus and have strong correlation to patient outcomes (e.g., quality of care, quality of life, hospitalization, mortality, perception of care, experience of care)
2. **Culture change:** Renal coalitions at the national and local level work together for the benefit of the patient, employing “spread” techniques to share and promote success. Individuals are informed, prepared, and involved in making choices as they move through the continuum of care from early ESRD to end of life. Patients and providers/facilities have a respectful relationship in which a patient’s informed choice is honored. An individual who progresses from CKD to ESRD receives appropriate care, with patient education and informed choice guiding appropriate renal replacement therapy. Preparation for renal replacement therapy includes timely vascular or peritoneal access, referral to transplant centers for evaluation, and discussion of all possible modalities with emphasis on home therapies and in-center self-care
3. **Process design:** The Network employs rapid-cycle improvement methods. Data elements are defined and data reports generated to assure high quality care. Redundant or unnecessary data elements are identified and eliminated. Providers are supported in efforts to incorporate information technology (recognizing differences in provider types, their capabilities, and possibilities that can be realized) to increase the efficiency, accuracy, and timeliness of data collection and reporting. The Network works with caregivers, facilities, and other representatives of the renal community in an inclusive and collaborative manner to support process improvements that help assure provision of quality care.

Reporting:

HCQIP results are publicly reported (as appropriate and permissible) to beneficiaries, and open communication occurs with providers/facilities in order to: promote informed health choices; protect individuals from poor care; and strengthen the health care delivery system.

C.2.A. Technical Requirements

The Network must have relevant knowledge and experience of both ESRD clinical issues and the CMS ESRD Network Program. The Network shall consider its experience and findings under any previous, relevant contract(s) in determining its approaches to fulfilling the contract requirements.

C.2.B. Contractual Requirements

Independently and not as an agent of the government, the Network shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the government, as needed to perform the requirements of this SOW.

C.2.C. Reporting Requirements

The Network shall submit reports and other documents as specified for the specific Task requirements of this SOW, the schedule of deliverables for this contract, and the appropriate portions of the *Medicare ESRD Network Organizations Manual*.

C.2 D. Confidentiality

The Network shall adhere to the confidentiality and disclosure requirements set forth in the most recent versions of the following:

- Section 1160 of the Social Security 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 this contract;
- The *Medicare ESRD Network Organizations Manual*;
- Other administrative directives;
- The *QNet System Security Policy Handbook*.

C.2.E. Information Collection/Survey Activities

Unless otherwise specified, a Network seeking to conduct surveys or collect data as a part of any of the Tasks included in this SOW shall do so only with pre-approval of the Project Officer and where appropriate the CMS Data Subcommittee, and in accordance with the Paperwork

Reduction Act, Chapter 9 of the *Medicare ESRD Network Organizations Manual*, and other administrative directives.

C.2.F. Institutional Review Board (IRB)

All projects and/or activities not specified or directed by CMS shall be evaluated by the Network's Medical Review Board (MRB) and reviewed by the Network's Project Officer using CMS-supplied guidance for compliance with Office for Human Research Protections (OHRP) regulations. If it is determined by the MRB and/or the Network's Project Officer that a project and/or activity requires Institutional Review Board (IRB) approval, the project and/or activity shall be submitted to the CMS entity that has jurisdiction for IRB review. If a specific MRB member is required to additionally submit the project and/or activity to his/her applicable IRB, that MRB member shall be responsible for seeking such approval. The cost of submitting the project and/or activity by a specific MRB member to the applicable IRB for review will be borne by the Network. Since it is not the purpose of ESRD Network to conduct research, CMS does not expect many projects and/or activities to require IRB approval. IRB processes shall be conducted in accordance with Code of Federal Regulations Title 45, Part 46.

C.3. TASKS

C.3.A. General Task Description

Under this contract, the Network shall be responsible for completing specific activities under each contract Task category.

- **Task 1 – Network Quality Improvement Program:** Quality Improvement Projects that are national, local, and facility/provider-specific.
- **Task 2 – Community Information and Resources:** Provision of educational information and technical assistance to patients, dialysis providers/facilities, and transplant facilities, coalition building activities, responsibilities in a disaster, and resolution of difficult situations, complaints, and grievances.
- **Task 3 – Administration:** Network administrative activities, including staffing and reporting, specifically mandated by statute or regulation and as directed by CMS.
- **Task 4 – Information Management:** System development and information management responsibilities applicable to all Network activities.
- **Task 5 – Special Projects:** Network-specific projects as directed or approved by CMS.

C.3.B. Task 1 Network Quality Improvement Program

In keeping with the ESRD Network Program strategic goals and the HCQIP mission, the Network shall assist ESRD providers/facilities in assessing and improving the care provided to all individuals with ESRD.

The Network Quality Improvement Program has four components:

1. Vascular Access (Fistula First) Quality Improvement Project (QIP);
2. Clinical Performance Measures (CPMs) Project;
3. Network-Specific Quality Improvement Projects (QIPs);
4. Facility-Specific Quality Assessment and Improvement Projects (QAIPs).

These projects shall be reflected in a comprehensive Quality Improvement Work Plan (QIWP) developed by the Network in conjunction with its MRB.

The Network's performance in any area of the Quality Improvement Program may be made public (e.g., through a Network Comparison Report) by CMS or its designee.

C.3.B.1.

Task 1.a. Vascular Access (Fistula First) Quality Improvement Project (QIP)

Vascular Access Measure

The Network shall implement quality improvement projects with dialysis providers/facilities in the area of vascular access as part of its Fistula First QIP.

Evaluation of performance for the Task 1.a. Vascular Access (Fistula First) QIP will be based on improvement in the Network-level rate of arteriovenous (AV) fistula use in prevalent patients. The CMS goal for the Medicare Program is that the percentage of prevalent patients using AV fistulas is at least 66%. To help reach the 66% AV fistula goal, CMS expects continual improvements by Networks in their fistula rates. Using the first calendar quarter data of each year as baseline, the Network shall reduce its quality deficit by 20% during this contract period unless the expected improvement is less than the floor of 1.0 percentage point or greater than the ceiling of 4.0 percentage points, at which point the floor or ceiling shall apply.

The quality deficit is defined as the difference between the baseline percentage and the Program goal of 66%.

The baseline percentage will be calculated based on data for all of the facilities/providers in the Network area from the January through March 2009 Fistula First Dashboard or another official CMS measurement system for vascular access. (See Chapter 5 of the *Medicare ESRD Network Organizations Manual* for additional details.) CMS reserves the right to change the methodology used to set Network targets in subsequent contract years based on evolving science, historical growth of fistula rates, and changes to practice patterns.

Evaluation of the contract-specified minimum threshold performance level for fistula use in prevalent patients will be based on the January through March 2009 Fistula First Dashboard or another official CMS measurement system for vascular access.

Facility Reporting

The Network shall support dialysis facilities in the submission of vascular access data (as defined by CMS) from 100% of applicable facilities (see Chapter 5 of the *Medicare ESRD Network Organizations Manual* for a list of exclusions) using the Fistula First data collection tool or another method(s) as provided by CMS. The Network shall be responsible for knowing fistula use rates in all facilities/providers and reporting to the Network's Project Officer if there is a concern with facility/provider reporting.

Educational/Technical Assistance

Educational/technical assistance shall be provided either on a Network-wide basis or for an identified need of a specific dialysis facility/provider. To establish a Network-wide need, an environmental scan shall be conducted prior to undertaking the educational or technical assistance activity. In the case of an individual dialysis facility/provider request, an organizational assessment of the facility/provider shall be conducted prior to the intervention.

Future Vascular Access Measure(s)

At such time that it is determined by CMS that there is an adequate mechanism, either through the Network or other means, to collect data necessary for tracking and monitoring performance, evaluation of Network performance shall also be based on the functionality and/or patency rate of AV fistulas in dialysis facilities in the Network area; the percentage of dialysis facility staff trained on cannulation, maintenance, and monitoring of AV fistulas; and/or another measure(s) that is scientifically based and that supports the National Vascular Access Breakthrough Initiative and/or any ESRD vascular access pay-for-performance program developed by CMS. CMS will notify the Network of the specific measurement and evaluation criteria. As part of this contract, as directed by CMS, the Network will be required to collect any data necessary to support such measurement and this revised data collection requirement will be accompanied by additional funding only if it is determined by CMS that this requirement will result in a significant increase in work effort.

Participation in National Vascular Access Breakthrough Initiative Coalition

The Network shall participate in Breakthrough Initiative Coalition meetings and actively engage with at least one subgroup of the Breakthrough Initiative Coalition. Active engagement, among

other activities, is defined as leading an activity, implementing an activity, measuring the results of an activity, providing supporting data for an activity, and/or working collaboratively on a joint project with another participant in the Breakthrough Coalition such as a Quality Improvement Organization (QIO).

Network Collaborations

The Network shall work with QIO(s) and other appropriate partners to:

1. Promote utilization of CMS-approved vascular access quality improvement tools and activities. This may include providing appropriate educational, promotional, and/or other communication resources not already available through the Network Coordinating Center.
2. Achieve ESRD treatment changes at system levels. This may include process improvements, e.g., adoption by hospitals of standards of care that promote use of AV fistulas and vessel mapping, evaluation, preservation.
3. Influence effective discharge planning to enable the earliest possible placement of an internal vascular access.
4. Conduct of quality improvement activities in the area of vascular access over the course of this contract does not exempt participation in, or conduct of, other quality improvement efforts as described in C.3.B.1. - Task 1.b.
5. Network activities in the area of vascular access (including efforts undertaken as part of the Breakthrough Initiative) must be reported in the Quarterly Progress and Status Report referenced in Section C.3.D. - Task 3.g.

Task 1.b. Clinical Performance Measures (CPMs) Project

The Network shall be responsible for monitoring and improving facility/provider performance on the ESRD CPM measures using the Electronic Laboratory Data Reports (ELab) or other data sources available to the Network.

Clinical Performance Measures (CPMs) Quality Improvement (QI) Activities

The primary use of the May 2009 Electronic Laboratory Data Reports (ELab) results by the Network will be to facilitate quality improvement among dialysis providers. The Network shall develop and conduct QIPs based on one or more of the established set of ESRD CPMs for adequacy of dialysis, anemia management, vascular access in the area of decreased catheter use and/monitoring for stenosis, or other CPM(s) developed or adopted by CMS not including measures related to increased use of fistulae. The QIP(s) shall be developed and implemented in conjunction with the Network's MRB.

ESRD Networks (NWs) will utilize the facility specific Electronic Laboratory Data Reports (ELab) for assessing the quality of care for hemodialysis patients. This effort provides a means for the reporting of facility-specific performance measures by capturing information related to the quality of care delivered. The NWs will continue to utilize the three CMS-published Dialysis Facility Compare results as a basis for quality improvement work. These results are based on data from multiple sources, including claims and SIMS. The three measures are standard mortality rate, dialysis adequacy, and anemia management.

Annually, the Network shall utilize the reported CPM and/or Electronic Laboratory Data Reports to:

1. Analyze practice patterns and processes and outcomes of care for the targeted patient population, both at a point in time and over a period time;
2. Analyze conformance to clinical practice guidelines both at a point in time and over a period of time;
3. Provide facilities/providers with information to stimulate improvement in patient care, through the provision of data describing practice patterns, processes, and outcomes for the targeted patient population.

As part of its Quality Improvement Work Plan (see Task 1.e.), the Network shall develop a plan for quality improvement activities based on one or more of the established set of CPMs for adequacy of dialysis, anemia management, or vascular access in the area of decreased catheter use and/monitoring for stenosis, or another CPM(s) developed or adopted by CMS not including measures related to increased use of fistulas. The choice of measure(s) shall be based on issues revealed by the CPM data for the CMS-selected patient sample. The CPM quality improvement activities shall be developed and implemented in conjunction with the Network's MRB.

Progress on CPM activities shall be reported to the Project Officer in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

Task 1.c. Network-Specific Quality Improvement Projects (QIPs)

The Network shall work with its MRB, Network Council, and Patient Advisory Committee and, as appropriate, with outside partners (e.g., QIO[s], provider and practitioner associations, beneficiary groups) to develop one or more specific QIPs that advance the purpose and strategic goals of the ESRD Network Program and are directly aligned with the areas of most need and potential impact for quality improvement within the Network area. These activities shall reflect identified Network-wide needs (such as variation in patient outcomes, practice patterns, and/or processes of care) or may be tailored to specific target areas, such as a geographic area, provider group, or domain of care.

The Network may undertake activities in the following areas that are pre-approved as Agency areas of priority, or may address other areas with prior approval from the Project Officer.

Pre-Approved Areas

1. Pre-approved areas for Network-Specific QIPs include:
2. Adequacy of Dialysis (in-center or home hemodialysis patients) CPMs I – III;
3. Adequacy of Dialysis (peritoneal dialysis patients) CPMs I - III;
4. Anemia Management CPMs I - III;
5. Vascular Access CPMs I – III;
6. Nutritional status;
7. Hemodialysis reuse, when applicable;
8. Patient experience of care;
9. Complaints/grievances;
10. Patient safety, e.g., medical injuries and/or medical errors;
11. Infection control;
12. Immunizations;
13. Bone disease;
14. Transplantation;
15. Measures/indicators to promote self-care (e.g., home therapies and/or in-center self-care);
16. Encouragement of vocational rehabilitation, volunteerism, and/or employment;
17. End-of-life care planning;
18. Mental health services/counseling.

Any data collection element and/or frequency outlined in the Network QIP that is not required in this SOW must be pre-approved by the Project Officer in accordance with CMS administrative guidelines (e.g., reviewed by the CMS Data Review Subcommittee when appropriate).

Progress on these activities shall be reported to the Project Officer in the Quarterly Progress and Status Report 15 working days after the beginning of each calendar quarter and to the CMS Central Office designee and the ESRD Networks Coordinating Center within two weeks after approval by the Project Officer referenced in Section C.3.D. - Task 3.g.

Task 1.d. Facility-Specific Quality Assessment and Improvement Projects (QAIPs)

Networks shall assist, as requested by facilities and/or CMS, in the development, implementation, maintenance and evaluation of an effective, data-driven, interdisciplinary Quality Assessment and Performance Improvement (QAPI) program in accordance with §494.110 of the Conditions for Coverage End-Stage Renal Disease Facilities: Final Rule. Facilities are expected to maintain an ongoing internal quality oversight program focusing on indicators related to improved health outcomes and prevention of medical errors.

The Network shall 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. Activities may be developed in collaboration with the Network MRB or Network Council, ESRD providers/facilities, ESRD facility owners, Large Dialysis Organizations, patient organizations, Medicare Advantage organizations, national and/or local renal-related professional organizations, QIO(s), State Survey Agency(ies), other ESRD Networks, or CMS. Any additional data collection element or frequency being considered for these activities that is not required in this SOW must be pre-approved by the Network's Project Officer and must be in accordance with other CMS administrative guidelines (e.g., reviewed by the CMS Data Review Subcommittee when appropriate).

The objectives of these activities are to assist in the facility-level development, implementation, maintenance, and evaluation of effective data-driven, interdisciplinary QAIPs that focus on improved processes of care and health outcomes.

Methods to achieve these objectives may include:

1. Fostering internal quality improvement at the facility level;
2. Providing technical assistance;
3. Providing education;
4. Encouraging and supporting focused local quality initiatives.

Progress on these projects shall be reported to the Quarterly Progress and Status Report referenced in Section C.3.D – Task 3.g.

Task 1.e. Quality Improvement Work Plan (QIWP)

The Network shall develop a Quality Improvement Work Plan (QIWP) in conjunction with the Network MRB. The initial QIWP shall include current CPM activities based upon CMS-approved CPM measures and/or lab data when applicable.

The QIWP shall address plans for achievement of all elements, as appropriate, of the Network's Quality Improvement Program, including measurement and re-measurement criteria for each activity. The QIWP shall be designed from available data sources (e.g., national reports, public use files, historical data, and complaints/grievances) in such a way as to allow for rapid cycle improvement. It shall also include processes to monitor Network resources through the Network's Internal Quality Improvement Program, to foster continuous quality improvement to improve timeliness, effectiveness, efficiency, and management control.

No later than 60 calendar days after the beginning of the contract period, unless otherwise directed by CMS, the Network shall submit an initial QIWP to the Project Officer for approval. Although CMS expects the Network to set quantitative outcome targets as a matter of good quality improvement practice, adherence to the QIWP and use of a process for rapid evaluation and adjustments, when indicated, will be a key part of the review of Task 1. Additional information related to Section C.3.B and C.3.B.1. is found in Chapter 5 of the *Medicare ESRD Network Organizations Manual*.

Any facility-specific quality improvement project that is not included in the QIWP for reasons such as duration will be reported upon in the appropriate Quarterly Progress and Status Report. Upon completion of the project, the Network shall submit a final status report to the Project Officer within 30 days. Any such activities shall also be reflected in the Annual Report.

No later than 60 working days after receipt of final CPM clinical data (or preliminary CPM data as directed by CMS), unless directed otherwise by CMS, the Network in conjunction with its MRB shall review and, as appropriate, modify the QIWP and submit the revised/modified QIWP to the Project Officer for approval.

The Network shall report on the status of its QIWP in the Quarterly Progress and Status Report referenced in Section C.3.D. - Task 3.g of this SOW.

Additional information related to Section C.3.B. and C.3.B.1. is found in Chapter 5 of the *Medicare ESRD Network Organizations Manual*.

C.3.C.

Task 2. Community Information and Resources

The Network shall work with providers/facilities and patients in its service area to improve the quality of care and 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:

1. Maintain an effective procedure for receiving, evaluating, resolving, and tracking patient grievances and complaints;
2. Maintain a national user-friendly, toll-free telephone number to facilitate communications with patients within the Network area;
3. Comply with laws that prohibit excluding or denying individuals with disabilities the opportunity to receive the same information and assistance provided to patients without disabilities; and
4. Specifically, maintain a Network Web site that is Section 508 compliant and follows CMS standards and guidelines.

Communication Requirements

Toll-free number: The Network's toll-free number shall be answered by a staff person during normal working hours. After hours, the system shall allow messages to be left. In accordance with requirements specified for Task 2.e, provisions should also be in place to ensure that a Network staff member is available in the event of an emergency or disaster.

Web site: The Network Web site shall include at least the following:

- A description of the Network grievance process;
- A list of the Network's goals;
- The Network's most recent Annual Report;
- A link to the Dialysis Facility Compare Web site (<http://www.medicare.gov/dialysis>);
- In the event of an emergency or disaster, the open and closed case status of facilities/providers and information to assist patients and providers.

The Network shall consult Chapters 6 and 7 of the *Medicare ESRD Network Organizations Manual* for additional information pertaining to SOW requirements under Task 2.

C.3.C.1.

Task 2.a. Provision of Education Information – New Patients

The Network shall make available a letter on Network stationary introducing the Network for duplication and distribution to new ESRD patients in the Network area. The letter shall be

provided to the Network Coordinating Center to distribute in the New ESRD Patient Orientation Package (NEPOP), with a copy to the Network's Project Officer when directed by CMS; and/or upon any changes to the letter's content (e.g., change in Network address or phone number).

The Network's letter of introduction shall include, at a minimum:

Information on the Network's grievance procedure;

1. The Network's toll-free number and Web site address; descriptions of services/assistance offered and quality improvement projects; and instructions on requesting and obtaining educational materials available through the Network including information on patient care, treatment options, and services;
2. Information about the function of State Survey Agencies, including the role of the State Survey Agency in receiving and investigating complaints and grievances. The letter must include addresses and phone numbers for the State Survey Agency(ies) in the Network area.

The Network shall investigate and resolve situations in which NEPOPs are undeliverable. The Network shall:

1. Determine whether the patient is deceased or is still alive and has a current address;
2. Provide the Network Coordinating Center with the patient's name and current address
3. Update the patient database in CMS' designated information system; and
4. Report monthly to the Network Coordinating Center the number of returns due to death and address changes;
 - Using an internal quality improvement process, track the error rate and set an acceptable target for distribution of the packet on initial mailing.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in Section C.3.D. - Task 3.g. of this SOW.

Task 2.b. Provision of Educational Information – Patients

The Network shall have a written plan for making informational materials available to patients in its service area and for annually informing patients how to contact the Network to obtain these materials.

The Network shall determine the most effective strategies for the distribution of informational materials, utilizing the basic principles of marketing and consumer engagement. The process for

distributing informational material shall be based on a thorough knowledge of the specific needs of the Network's ESRD patient population.

At a minimum, the Network shall make the following information available to patients through its informational materials:

1. The role of the ESRD Network;
2. The Network's process for receiving, reporting, resolving, and tracking patient complaints and grievances;
3. Treatment options and new ESRD technologies available to patients, with an emphasis on those that have been shown to support patient independence (e.g., transplantation, home therapies, in-center self-care);
4. Information to educate and encourage patients to achieve their maximum level of rehabilitation and to participate in activities that will improve their quality of life (e.g., vocational rehabilitation programs, volunteerism); contact information for state/regional vocational rehabilitation programs available in the Network area;
5. Information on vascular access procedures;
6. The Network's toll-free number;
7. The Network's Web site address;
8. Information on how to access and use the Dialysis Facility Compare Web site;
9. Information on the Network Patient Advisory Committee, including information on how to become a member of the committee;
10. Information on the importance of receiving immunizations (including hepatitis, pneumococcal, and influenza) and other information related to immunizations as directed by CMS;
11. Information on the benefits of the Medicare Prescription Drug Program (Medicare Part D) and on how to enroll, and any other guidance or materials related to this program of specific benefit to the individual with ESRD, as directed by CMS.

The Network shall use an internal quality improvement process (e.g., environmental scan or assessment) to determine the needs of its community for additional educational/informational materials. For each of the educational materials identified, the Network shall set a goal for distribution of the material, determine the most effective method of distribution, and evaluate the overall effectiveness.

In fulfilling this requirement, the Network shall utilize, to the extent possible and practical, information that is already available through CMS, CMS contractors (e.g., other Networks, the National Coordinating Center, QIOs), other federal agencies, renal partners (e.g., beneficiary representative groups and large provider groups/affiliations/corporations), and other sources as appropriate.

The Network shall distribute information through the most effective and efficient approaches possible (e.g., through meetings/training opportunities such as those sponsored by renal partners; through patient membership organizations; and in conjunction with other renal partners, such as other Networks, QIOs, and large provider groups/affiliations/corporations).

Where it is more efficient and effective to do so than to develop its own materials, the Network may subcontract with appropriate renal partners to fulfill some or all of these patient information requirements provided all contracting/subcontracting requirements are met.

The Network shall utilize the Patient Advisory Committee and Network Council where applicable in fulfilling these requirements.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in C.3.D – Task 3.g.

Task 2.c. Provision of Educational Information – Providers/Facilities

The Network shall make informational materials available to providers/facilities in its service area, accompanied by a directive on how to use the information in quality improvement activities and processes. The Network shall utilize its Patient Advisory Committee and Network Council, where applicable, in fulfilling these requirements, including in the development of materials.

The types of information/materials shall include the following, at a minimum:

- The Network's Annual Report, describing Network activities conducted to meet Network and ESRD Network Program goals, and the Network's plan for monitoring provider/facility compliance with these goals. The report may be provided in hard copy and/or on the Network's Web site;
- Regional and national patterns or profiles of care as provided in the Clinical Performance Measures Annual Report;
- Results of Network quality improvement projects;
- Information on the importance of immunizations (including hepatitis, pneumococcal, and influenza) and other information related to immunizations as directed by CMS;
- Other materials (such as journal articles or pertinent research information) that providers/facilities can use in their quality improvement programs;

- Information on how to access and use Medicare's Dialysis Facility Compare Web site and how to submit corrections to the Network on facility characteristics that are displayed in Dialysis Compare;
- Information on electronic submission of data (as it becomes available).

Additionally, the Network shall:

1. Conduct special mailings (up to two per year) as directed by CMS, duplicating materials as necessary for these mailings;
2. Print and distribute Dialysis Facility Reports annually or as directed by CMS. Within 30 days of receipt of the Dialysis Facility Reports for the dialysis facilities within the Network's service area, the Network shall print and provide copies of each facility's report to the Medical Director and the Unit Administrator, unless otherwise directed by CMS. A copy of the report may also be sent to corporate owners of a facility upon facility request. CMS, or its designee, shall provide the Network with instructions for preparing the notification to dialysis facilities. The notification shall include instructions on how a dialysis facility may provide comments to CMS (or its designee) regarding its updated measures data that are reported on the Dialysis Facility Compare Web site;
3. Distribute information regarding Food and Drug Administration alerts, dialysis recalls, etc., that affect dialysis facilities; and
4. Provide updated information to providers/facilities in its service area on the Network's role with respect to complaints/grievances and quality improvement with instructions to make the information available to patients or inform patients on how to contact the Network to obtain information.

In fulfilling this requirement, the Network shall utilize, to the extent possible and practical, information that is already available through CMS, CMS contractors (e.g., other Networks, the Network Coordinating Center, QIOs), other federal agencies, renal partners (e.g., beneficiary representative groups and large provider groups/affiliations/corporations) and other sources as appropriate.

The Network shall distribute information through the most effective and efficient approaches possible (e.g., through meetings/training opportunities such as those sponsored by renal partners; through patient organizations; and in conjunction with other renal partners, such as other Networks, QIOs, and large provider groups/affiliations/corporations).

Where it is more efficient and effective to do so than to develop its own materials, the Network may subcontract with appropriate renal partners to fulfill some or all of these provider information requirements provided all contracting/subcontracting requirements are met.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in C.3.D – Task 3.g.

Task 2.d. Provision of Technical Assistance

The Network shall provide technical assistance:

1. Upon request of a provider or patient;
2. Based upon identified opportunities to improve care;
3. When poor performance or problems are identified; and
4. As otherwise directed by CMS.

At least annually, the Network shall notify providers and patients in the Network area that it is available to provide technical assistance and referrals to appropriate resources.

In fulfilling these requirements, the Network shall conduct the following activities:

1. Assist patients seeking ESRD services in identifying available providers and/or facilities (including transient patients and during disaster situations);
2. Provide assistance to patients seeking ESRD services on how to use the Dialysis Facility Compare Web site;
3. Educate dialysis facility professional staff regarding the use of the information on Dialysis Facility Compare to assist patients in making choices about dialysis facilities, to allow patients to participate in decision-making regarding their treatment, and for other applicable uses per guidance set forth in the *Medicare ESRD Network Organizations Manual*;
4. Assist facilities in developing procedures to assess patients for placement in treatment modalities that improve independence, quality of life, and rehabilitation (to the extent possible) through transplantation, use of self-care modalities (e.g., peritoneal dialysis, home hemodialysis), and in-center self-care through to the end of life;
5. Provide learning activities for patients/providers regarding:
 1. Kidney transplantation;
 2. Home therapies;
 3. In-center self care;
 4. Immunizations;
 5. Importance of appropriate advance care planning;
6. Assist providers/facilities in developing processes for making appropriate and timely

kidney transplant referrals and addressing impediments to referrals and/or transplantation, as appropriate and feasible;

7. Assist providers/facilities in defining, establishing, and promoting rehabilitation goals and in referring suitable candidates to vocational rehabilitation programs or other programs or activities that enhance independence to the maximum extent possible and improve quality of life (e.g., volunteerism, education);
8. Assist providers/facilities in developing appropriate quality improvement plans if they are having difficulty in meeting Network goals, Medicare certification requirements, pay-for-performance program objectives, or other such requirements;
9. Assist providers/facilities in developing plans for local disasters (including emergencies such as floods, earthquakes, hurricanes);
10. Assist providers/facilities in developing mechanisms for assessing the health-related quality of life of patients; and
11. Assist providers/facilities in developing community and patient education programs.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in Section C.3.D – Task 3.g.

Task 2.e. Emergency/Disaster Preparedness and Response

The Network shall be responsible for the following activities related to natural, accidental or man-made emergency/disaster preparedness and response:

- Assist providers/facilities in developing plans for local emergencies/disasters as specified under Task 2.d. and in accordance with §494.100(c)(1)(vii) of the ESRD Conditions for Coverage ;
- Maintain a phone system to ensure that Network staff members can be contacted as necessitated by the emergency/disaster;
- When an emergency or disaster affects any portion of the Network's area, communicate with facilities to identify affected facilities. Networks should track availability of services and assist patients in identifying dialysis facilities that can provide ESRD services. The Network shall track and make available to the public the open and closed status of the facilities in the affected area. This information may be posted on the Network's Web site or a link may be provided to a central Web site, as available;
- Assist family members and treating facilities in locating displaced patients and exchanging critical medical information for those patients. In the event of an emergency or disaster, CMS will provide direction related to HIPAA regulations.

- If a family member is able to provide sufficient identification of the displaced patient, the Network shall give the family member contact information for the current treating facility, if known. If the current treating facility is able to provide sufficient identification of the displaced patient, the Network shall give the facility critical medical information, as available, and contact information for the dialysis facility where the patient was formerly treated;
- Organize or participate in national and/or regional calls with providers, emergency workers, and other essential persons to ensure coordination and that the needs of individuals with ESRD are being met;
- As directed by CMS, assist other Networks in carrying out contract requirements during the initial phase of an emergency and/or disaster and during the recovery phase;
- When an emergency or disaster affects any portion of the Network's area, the Network shall provide status updates via telephone or email to Project Officers and the Kidney Community Emergency Response Coalition.(KCER) Status updates should include an approximate number of impacted facilities; an approximate number of impacted patients; the priorities and concerns (e.g. lack of staff, utility outages, etc); and whether the Network needs Project Officer and/or KCER assistance.
- Establish a partner relationship with another Network to provide back-up assistance in the event of an emergency/disaster.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in Section C.3.D – Task 3.g.

Task 2.f. Coalition

The Network shall actively engage in efforts to support the development and/or maintenance of a strategic coalition within the renal community in the Network area through training and ongoing consultative support.

Specifically, the Network shall:

1. When a coalition does not already exist; identify a coalition focus, with PO approval, and recruit key partners, including some with which the Network does not conduct routine business;
2. Assemble and/or sustain an active coalition that conducts activities to support achievement of the ESRD Network Program strategic goals, the mission of the HCQIP, and/or Network quality improvement activities;

3. Support the establishment of a vision, mission, goal(s), and operating procedures as a joint agreement of coalition members;
4. Promote information exchange and collaboration among members aimed to enhance each other's capacity;
5. Ensure that agendas are established for coalition meetings and that meeting minutes are taken and distributed to coalition members;
6. Obtain PO approval prior to any changes in the coalition focus;
7. Work with any CMS-specified contractors in meeting these requirements.

The Network, through participation in training activities and practical experience, shall:

1. Build partnerships with new entities;
2. Expand and enhance existing partnerships;
3. Create greater ownership among coalition partners;
4. Utilize, within CMS conflict of interest guidelines, other available resources by having coalition partners bring resources to the table or identify others with resources;
5. Engage in innovative problem solving by collaborating with coalition partners on jointly shared problems.

The Network shall report on these activities, and on challenges faced in fulfilling the requirements of Task 2.f., in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

Task 2.g. Complaints and Grievances

The Network shall assume a proactive role in identifying, preventing, processing, and resolving complaints and grievances by:

1. Providing educational information to patients on their rights and the Network's role in handling complaints and grievances;
2. Making the Networks address and phone number available to facilities to ensure that facilities are in compliance with §494.70(c) of the ESRD Facilities Conditions for Coverage;
3. Implementing educational programs to assist facility staff in handling complaints and grievances, where appropriate;

4. Conducting trend analysis of reported situations to detect regional, corporate, local, or provider/facility-specific patterns of concern;
5. Developing Network-specific policies, procedures, and standards for receiving, processing, investigating, resolving, documenting, and reporting patient complaints and grievances, and dealing with facility concerns.

Specifically, the Network shall conduct the following activities:

1. Provide dialysis facilities/providers with resources and educational programs under the Decreasing Dialysis Patient-Provider Conflict Initiative;
2. Upon request, assist in the resolution of patient, provider, and/or facility complaints and grievances by providing education, facilitating solutions, and/or making referrals to address the issue(s) involved;
3. Describe in the CMS-designated system, in a narrative format, the Network's actions and interventions to resolve patient and provider/facility complaints/grievances. The report shall include:
 1. Information on the nature of complaints/ grievances;
 2. Actions taken to resolve these;
4. Provide aggregate, quantitative information on types of complaints, grievances, Involuntary Discharges, and patient/provider/facility inquiries/concerns;
5. Quarterly, at a minimum, analyze facility-specific and Network area data to identify patterns of concern at the facility or Network area level and opportunities for improvement;
6. Collect and categorize, as directed by CMS, inquiries, complaints, and grievance data using SIMS, or another mechanism(s) specified by CMS;
7. Work with, and implement activities to support, the CMS Ombudsman as directed by CMS; and provide aggregated data for the Ombudsman Report by February 1, 2009
8. Utilize complaint and grievance data to plan new training initiatives, provide facilities with feedback, and/or make recommendations to CMS for national training or policy changes;
9. Within 24 hours of receipt, refer serious complaints or grievances to the applicable State Survey Agency and/or QIO and the Network's Project Officer;
10. Upon request from CMS, assist the State Survey Agency with the investigation of a complaint or grievance.

11. Upon 30 day notification of patient's involuntary discharge from a facility) assist with any further investigation

The Network shall follow the guidance found in Chapter 7 of the *Medicare ESRD Network Organizations Manual*.

The Network shall, using an internal quality improvement process, evaluate the functioning of its complaint and grievance system and report findings to CMS.

The Network shall report on these activities in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

C.3.D.

Task 3. Administration

The Network shall:

1. Establish a corporate infrastructure to support its operations and to meet statutory requirements;
2. Establish an organizational structure that addresses staff reporting lines as well as a committee structure that supports the efficient and effective accomplishment of the requirements of this SOW;
3. Employ an adequate number of qualified administrative staff to manage the work of the contract and line staff to carry out the work; and
4. Establish required boards and committees; specify appropriate roles and functions for these entities; promulgate policies, procedures, and bylaws to govern these entities consistent with industry best practices and with ESRD regulations; and appropriately document meetings and actions for internal review and review by CMS upon request.

C.3.D.1.

Task 3.a. Organizational Structure

The Network's organizational structure shall include at a minimum the following:

1. **Board of Directors (BOD):** The BOD shall hold ultimate responsibility for the effective functioning of the Network, inclusive of the following : (1) responsibility for hiring the Executive Director and ongoing evaluation of the Executive Director's performance in meeting contract requirements and any additional deliverables (including undertaking personnel actions to correct situations in which the Executive Director is not

satisfactorily performing his/her duties); (2) responsibility for financial oversight and maintaining financial viability; and (3) responsibility for responding to direct CMS requests.

The BOD should: 1) adopt mechanisms to continuously infuse its deliberations with new and different perspectives; 2) adopt policies that will ensure a high level of representation of consumer and stakeholder interests; and 3) adopt reasonable performance standards for attendance and contributions by BOD members.

The BOD should be made up of representatives from the Network area, to include knowledgeable and influential physicians, nurses, social workers, dietitians, and other professionals and should include at least one patient representative, but preferably more than one. The BOD membership should reflect a policy that fosters diversity in terms of race/ethnicity, gender, stakeholder representation, and patient representation.

The BOD shall meet as necessary to ensure the successful operation of the Network (e.g., quarterly by teleconference or on-site).

2. **Network Council:** The Network Council shall meet as necessary, and serve as a liaison between its provider membership and the Network. The Network Council shall meet all the statutory requirements of Section 1881(c) of the Social Security Act.

The Network Council shall include renal dialysis and transplant facility/ providers located in the service area. Appointed Network Council Members should represent various geographic locations and types of providers/facilities in the Network area and the various types of professionals working for the providers/facilities in the area. In light of the ESRD Network's consumer protection responsibilities, strong consumer representation is essential. The Network Council must have at least one patient representative, and CMS encourages having more than one patient representative on the Council.

3. **Medical Review Board (MRB):** The MRB 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 ESRD treatment and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients. The MRB must meet the statutory requirements of Section 1881(c) of the Social Security Act.
4. **Patient Advisory Committee (PAC):** Each Network shall maintain an active Patient Advisory Committee (PAC) comprising patients who represent various regions of the service area to provide input to the Network and its Board on the concerns and needs of patients.

The Network shall conduct the PAC in a manner that values the time and efforts of the PAC members and shall be responsive to the insights offered. The PAC shall be represented on the Board of Directors.

When the Network determines it is appropriate and necessary, the Network shall compensate essential PAC member(s) (e.g., committee chairs) when their time and effort are significant, and, as appropriate, shall compensate committee members for travel expenses incurred for mandatory committee activities that assist the Network in meeting its goals.

Chapter 2 of the *Medicare ESRD Network Organizations Manual* provides additional information regarding the above bodies.

The Network may convene other committees or subcommittees as appropriate to meet contract requirements. Members should be selected to represent the diversity of the patient and practitioner community to the fullest extent possible.

Task 3.b. Network Staff

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

The Network shall employ an administrative staff that carries out the work requirements of this SOW. At a minimum, the full-time staff shall be composed of the following:

1. **Executive Director/Project Director:** responsible for the overall operation of the Network and for obtaining the staff and resources necessary to fulfill contract requirements. The Executive Director shall be appointed and evaluated on an ongoing basis by the BOD.
2. **Quality Improvement Manager/Quality Improvement Coordinator:** responsible for leading the development and implementation of the Network Quality Improvement Program. This position requires a professional with an advanced degree and/or extensive experience in the quality arena, with nephrology and dialysis experience strongly recommended.
3. **Data Manager:** responsible for overseeing the Network's data, including responsibility for data collection, validation, maintenance, and security.

Replacement of personnel in these positions must be done in accordance with Section G.8 – Key Personnel of this contract.

The Network shall also have available the following professional and technical expertise.

- **Patient Services Coordinator:** responsible for resolving patient and/or facility complaints and grievances, conducting training on managing difficult situations, and conflict resolution. This position requires an individual with a master's in social work or a comparably qualified individual (e.g., experienced nephrology nurse or counselor). If a

Network wants to hire an individual without these qualifications, or wants to retain current staff with proven capabilities but without these qualifications, it shall seek approval from its Project Officer for any such exceptions. Appropriate documentation and justification of the individual's abilities to meet requirements as indicated in Chapter 2 of the *Medicare ESRD Network Organizations Manual* would be required;

- **Community Outreach Coordinator:** responsible for partnership development, collaboration, and educational activities and for enhancing the community outreach and collaboration activities of the Network. This position requires an individual with education and/or experience in communications, materials development, and organizing volunteers. The individual in this position will plan and facilitate education, information dissemination, and training for ESRD professionals, patients, and family members and other members of the renal community. The Community Outreach Coordinator may work with consultants (e.g., Web, statistical) to provide support across Network program lines for improving the quality of care for patients through education, Web outreach, and coalition and partnership building;

Because this position provides support across Network program lines, the Network will determine whether the responsibilities are fulfilled through one dedicated part- or full-time position or shared among other positions. When possible, an individual with CKD/ESRD or who has personal, firsthand experience with a family member, spouse, or other significant individual with CKD/ESRD should receive preference for this position;

- Sufficient staff to conduct data-related activities as required by the SOW;
- Sufficient staff (including at least one registered nurse with nephrology experience) to conduct all activities and responsibilities in accordance with the SOW, Chapter 2 of the *ESRD Network Organizations Manual*, and other CMS directives;
- Sufficient staff to conduct the activities/responsibilities described in the *ESRD Network Administration and Disaster Recovery Handbook*, the *ESRD Infrastructure and Support Manual*, the *QNet System Security Policy Handbook*, the QualityNet Medicare ESRD Networks Business Continuity and Contingency Plan (BCCP) & Template, and other supporting documentation provided by CMS.

Task 3.c. Internal Quality Improvement (IQI) Program

The objectives of the IQI Program are to support and foster continuous quality improvement within Network processes to improve the timeliness, effectiveness, efficiency, and management control of Network activities.

1. The Network shall have a written IQI Plan that encompasses SOW activities that include, at a minimum, conducting quality improvement projects, evaluating and resolving ESRD grievances/complaints, conducting community education and resource

activities, collecting, analyzing, validating, and reporting data, performing administrative functions (including financial management), and conducting special studies.

2. The Network shall have an internal reporting system for all IQI activities, and shall make reports available to the MRB and CMS upon request for monitoring purposes.
3. The Network IQI Program shall have built-in processes for rapid identification and correction of problems.
4. The Network IQI Plan shall be submitted to the Project Officer for review no later than 60 days after the beginning of the contract year, unless otherwise directed by CMS. The Network shall supply IQI reports and analyses upon request by the Project Officer, to document the established processes and adherence to them and in response to problems that arise in performing contract requirements.

As appropriate, the Network shall report the status of and changes to its IQI Plan in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g of this SOW.

Task 3.d. CMS Meetings

Network staff (to be designated by the Executive Director except as directed by CMS) shall participate in CMS-sponsored/sanctioned meetings as follows:

The Executive Director, Quality Improvement Manager/Coordinator, Data Manager, and (as designated by the Executive Director or CMS) other appropriate staff are required to attend the CMS/Forum of ESRD Networks Annual Meeting unless exempted by prior approval of the Project Officer.

The Executive Director and (as designated by the Executive Director or CMS) other appropriate staff are required to attend the annual QualityNet Conference, unless otherwise directed by CMS.

Network Staff, inclusive of the Executive Director, should participate in conferences and meetings that support the overall mission of the national ESRD community as well as activities that support the Network's strategic plans and advance its goals. Chapter 2 of the *Medicare ESRD Network Organizations Manual* provides additional information regarding participation in CMS-sponsored/sanctioned meetings.

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

In addition to Task 1 – Quality Improvement Activities, as 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 QIO(s) to assist these organizations in improving the quality of care for individuals with ESRD. To this end, the Network shall:

Establish ongoing working relationships with the appropriate CMS Regional Office staff, including at a minimum the Regional Medical Director or the Division of Survey and Certification Branch Chief. These working relationships shall involve mutually agreeable communication structures and processes;

Establish an ongoing working relationship with each State Survey Agency in the Network's service area. This working relationship shall involve regularly scheduled meetings, a defined manner of communication, and establishment of mutually agreeable goals to help carry out each organization's legislative or regulatory responsibilities (as permitted by statute, regulations, or other CMS policy guidance);

Establish an ongoing mutually beneficial working relationship with each QIO in the Network's service area. This working relationship shall involve regularly scheduled meetings, a defined manner of communication, and establishment of mutually agreeable goals as well as sharing of information to assist QIO(s) in carrying out their legislative, regulatory, and/or contractual responsibilities (e.g., CKD initiatives) as permitted by statute, regulations, and CMS policy guidance.

The responsibilities of the ESRD Network with regard to these collaborations include, but are not limited to, the following:

1. Refer quality of care issues as appropriate;
2. Assist the State Survey Agency(cies) or QIO(s) in the investigation of quality of care issues, upon request, and with the approval of the Project Officer;
3. Conduct reviews as necessary (e.g., site visits, including sequential reviews of medical records);
4. Conduct cooperative state/Network evaluations of providers, where appropriate, in support of the sanction or alternative sanction process;
5. Provide technical assistance;
6. Report patterns of complaints and grievances to appropriate agencies and CMS;
7. Provide follow-up reports to agencies of any complaints/grievances referred to the Network;
8. Review follow-up reports from agencies to which the Network referred any complaints/grievances;
9. Coordinate and collaborate with State Survey Agency(ies) and QIO(s) with regard to quality improvement interventions for facilities/providers that fail to comply with the Conditions for Coverage;

10. Coordinate and collaborate with QIO(s) with regard to QI projects aimed at facilitating provision of CKD and ESRD care that is consistent with current professional knowledge and standards.

Collaborative activities with State Survey Agencies and QIOs are addressed in Chapter 2 of the *Medicare ESRD Network Organizations Manual*.

As appropriate, the Network shall report these activities in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

Task 3.f. Sanctions and Referrals

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

- 1.Recommending to CMS sanctions or alternative sanctions for facilities/providers that consistently fail to comply with Network goals and/or are not providing appropriate medical care;
- 2.Providing the necessary documentation, throughout the process, to support the recommendation and associated investigation;
- 3.Tracking and trending of dialysis facility data in such a manner that alerts the Network to facility non-compliance; and
- 4.Referring to the QIO or State Office of 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 or is involved in Medicare fraud.

Instructions for these responsibilities are contained in Chapter 10 of the *Medicare ESRD Network Organizations Manual*.

As appropriate, the Network shall report these activities in the Quarterly Progress and Status Report referenced in Section C.3. D – Task 3.f.

Task 3.g. Required Administrative Reports/Activities

The Network shall submit the following administrative reports/plans to its Project Officer:

1. **Quality Improvement Work Plan (QIWP):** The Network shall submit for approval to the Project Officer an initial QIWP developed in conjunction with the Network MRB. This plan, as described under Task 1.e., is due no later than 60 calendar days after the beginning of each contract year, unless otherwise directed by CMS. The QIWP shall address plans for achievement of all elements of the Network's Quality Improvement

Program, including measurement and re-measurement criteria for each activity. The QIWP shall be designed from available data sources (e.g., national reports, public use files, and data on complaints/grievances) in such a way as to allow for rapid cycle improvement.

2. **Internal Quality Improvement (IQI) Plan:** The Network shall submit for approval to the Project Officer an initial IQI Plan developed in conjunction with the Network BOD. This plan, as described in Task. 3.c., is due no later than 60 calendar days after the beginning of each contract year, unless otherwise directed by CMS. The IQI Plan shall use an improvement methodology that includes measurement and re-measurement criteria for each activity.
3. **Modified QIWP (CPM Focus Change/Update):** Within 60 working days of receipt of CPM clinical data, unless otherwise directed by CMS, the Network in conjunction with its MRB shall evaluate and modify, as appropriate, its QIWP and submit a modified Work Plan, with updated CPM goals and activities, to the Project Officer for approval.
4. **Quarterly Progress and Status Reports:** The Network shall submit a Quarterly Progress and Status Report to the Project Officer for approval 15 working days after the beginning of each calendar quarter and to the CMS Central Office designee and the ESRD Networks Coordinating Center within two weeks after approval by the Project Officer;
5. **Semi-Annual Cost Report:** The Network shall submit a semiannual report of operating costs, distinguishing between base contract and special project costs, which is due electronically to the Project Officer for approval and to the CMS Central Office designee no later than the close of business on the 15th working day of the second calendar month following the closing date of the cost reporting period covered, as specified in Section H.4 of the ESRD Network Contract;
6. **Annual Report:** The Network shall submit an Annual Report of Network Activities, a draft of which is due on May 15 and a final version shall be submitted to the Project Officer for approval by July 1 of each contract year, and to the CMS Central Office designee and the ESRD Networks Coordinating Center within two weeks after approval by the Project Officer. Within 90 calendar days after Project Officer approval, the Network shall post a copy of its report on its Web site and notify the Project Officer of the posting date. The Network shall include in the report:
 1. A description of the activities conducted to meet ESRD Network Program goals during the previous calendar year;
 2. An evaluation of the effectiveness of those activities in meeting the Network and CMS goals;

3. Data on the comparative performance of facilities/providers in identifying and placing suitable candidates in home therapies and in-center self-care, transplantation, and vocational rehabilitation programs and other activities that enhance quality of life (e.g., volunteering, education);
 4. Identification of those facilities that consistently failed to cooperate with Network goals or to follow the recommendations of the MRB;
 5. Any recommendations for additional or alternative ESRD facilities in the Network area;
1. **Business Continuity and Contingency Plan (BCCP):** Annually, on November 1, the Network shall provide to its Project Officer a written contingency plan detailing roles, responsibilities, and processes for recovering lost data and documentation of procedures for making and safeguarding backup copies of software, operating data, and user data, using the Business Continuity and Contingency Plan Template as referenced in Section C.3.E.1, Task 4.

Chapter 2 of the *Medicare ESRD Network Organizations Manual* gives instructions for the content and format of these reports.

As appropriate, the Network shall report these activities in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

C.3.E. Task 4 Information Management

The Network shall use an information system designated by CMS to collect and maintain data pertaining to the ESRD Network Organization Program. These data shall be used to fulfill Network contractual obligations.

The Network shall not develop software products for use by facilities or other Networks without written prior approval from CMS. In addition, no funds from this contract shall be used for data collection activities not specified in this contract without pre-approval from the Project Officer and in accordance with other CMS administrative guidance.

The Network shall consult Chapter 4 of the *Medicare ESRD Network Organizations Manual* for additional information pertaining to data requirements and the Network's responsibilities for processing/maintaining the required data.

Overall, the Network's responsibilities for information management and reporting within the CMS-designated information system are to:

1. Adhere to the policies and procedures outlined in Chapter 4 of the *Medicare ESRD Network Organizations Manual* and the most current versions of the following manuals, unless directed otherwise directed by CMS:

1. *ESRD Infrastructure and Support Manual*
2. *ESRD Networks Network Administration and Disaster Recovery Handbook*
3. *QNet System Security Policy Handbook*
4. *SIMS User Guides*
5. *VISION User Guide*
6. *Quality Net Exchange User Guide*
7. *Remedy AR System User Guide.*

These manuals delineate roles, responsibilities, and procedures for Network users and systems administrators, CMS personnel, and CMS supporting contractors in the maintenance of the Network IT infrastructure and information systems. These documents are available on a designated site(s) as specified by CMS;

2. Provide reliable and valid content for the development of business requirements for a national data system when directed by CMS;
3. Manage the collection, validation, storage, and use of data including data collected by the Network or provided by CMS;
4. Share appropriate data, as directed by CMS, with other Networks, the appropriate CMS Regional Office, the CMS Central Office, and the appropriate State Survey Agency;
5. Promote timely and accurate reporting of data by providers/facilities;
6. Maintain an ESRD patient and facility database and ensure the confidentiality, integrity, timeliness, accuracy, and security of the data;
7. Ensure that current patient events are reported to CMS in a timely way to allow for validation of appropriate enrollment into, and disenrollment from, the Medicare program for ESRD benefits;
8. At a minimum, on a quarterly basis, verify with dialysis facilities (using the standardized Network Patient Activity Report [NPAR]) patient event data.

Progress on these activities shall be reported to the Project Officer in the Quarterly Progress and Status Report referenced in Section C.3.D.–Task 3.g.

C.3.E.1.

Task 4.a. System Capacity

The Network shall maintain a system, as directed by CMS that provides the capacity to meet its contractual responsibilities for information management and reporting. The system, at a minimum, shall consist of the following:

- a. Secure IT system processes as defined by the *QNet System Security Policy Handbook*;
- b. Secure transmission methods for communicating with ESRD facilities, CMS Regional and Central Offices, and stakeholders;
- c. CMS-furnished hardware. See the list of approved hardware on a designated site(s) as specified by CMS;
- d. The Network shall not attach non-government servers, workstations, or any other peripheral devices to government-provided equipment and/or network systems. Exceptions to this policy, such as for printers or scanners, may be requested through the Standard Data Processing System (SDPS) Engineering Review Board process; requests for CMS-furnished hardware shall be initiated using the Remedy AR System software provided by CMS;
- e. CMS-approved statistical software for data analysis and profile analysis, including profiles of patients and facilities by county, to facilitate disaster planning and other studies. See the list of approved software—e.g., SAS, Crystal Reports, SPSS—available on a designated site(s) as specified by CMS;
- f. Policies, procedures, and processes for disaster recovery, including regularly scheduled backup of the databases and data system as outlined in the *ESRD Infrastructure and Support Manual*.

The Network shall maintain an accurate inventory of federally approved hardware and software through Remedy as directed by CMS subject to HHS-22 Request for Property Action.

Task 4.b. Database Management

The Network shall maintain a patient and provider database containing the mandatory data elements referenced in Chapter 4 of the *Medicare ESRD Network Organizations Manual*, in SIMS or another CMS-designated database.

The Network shall perform the following tasks related to its patient and provider data:

1. Maintain the completeness, timeliness, validity, and accuracy of these databases;
2. Continually update, in a timely manner, the database(s) with the data received from facilities/providers;
3. Research, resolve, and make necessary corrections, through a change reporting process approved by CMS (e.g., patient alerts/notifications, calls from/to the Data Quality Team), within 60 calendar days of notification to resolve discrepancies in the patient database to ensure the accuracy of data submitted for Dialysis Facility Compare and other purposes.

Chapter 4 of the *Medicare ESRD Network Organizations Manual* gives instructions for resolving data discrepancies;

4. Validate that automated replication of patient and provider data to the central repository is completed nightly;
5. Using an internal quality improvement process, develop, implement, and consistently evaluate for effectiveness internal policies and procedures to ensure the timeliness and accuracy of 2728 & 2746 data entered into the CMS-designated information system;
6. Perform data clean-up activities on a regular basis and other IT tasks as directed by CMS in support of a consolidated national database.

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

The Network shall obtain completed CMS ESRD forms from each ESRD facility/provider and/or corporate owner in the Network area either electronically or via hard copy. The Network will also collect all transmitted forms from non-Medicare Veterans Health Administration (VHA) facilities and voluntarily submitted forms from institutions such as prisons and nursing homes. Until electronic reporting becomes mandatory for all dialysis facilities, electronic submission of data will be on a voluntary basis. The Network shall be responsible for instructing and training facilities and/or entities that own those facilities on the proper procedures for electronic submission of ESRD forms. (See the *Medicare ESRD Network Organizations Manual* for information on training resources.)

The Network shall be responsible for authorizing access to the CMS-designated systems for the electronic transmission of ESRD forms. The Network shall enroll users in the CMS-designated system and shall keep the authorized user information up-to-date until the QualityNet Identity Provisioning System (QIPS) is implemented. Upon the implementation of the QIPS, the Network shall be responsible for the authentication of CROWNWeb Network users and facility level system administrators.

A. ESRD Forms

These forms contain patient-specific information necessary for the operation of the national ESRD Program. The CMS ESRD forms include the following:

1. CMS-2728-U3 - ESRD Medical Evidence Report Medicare Entitlement and/or Patient Registration (or computerized facility-generated medical evidence form) completed within 45 days of either:
 1. Start of a regular course of dialysis treatment; or
 2. Date of transplant.

Supplemental or re-entitlement enrollment as appropriate shall be documented by completing

the applicable sections of the CMS-2728-U3 Form within 45 days of:

1. Restarting dialysis after a one-year period of recovery of native kidney function;
 2. Restarting dialysis 36 months after a failed transplant;
 3. Changing from in-center dialysis to home dialysis, provided that the change occurred within the first three months of the first date of dialysis and initial form was submitted;
 4. Receiving a transplant within 90 days of a regular course of dialysis;
2. CMS-2744 - ESRD Facility Survey (completed annually);
 3. CMS-2746 - ESRD Death Notification Form or computerized facility-generated Death Notification Form (completed within 30 days of the date of death);
 4. CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually);
 5. CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually).

B. Processing Forms Data

The Network shall conduct activities to validate that the data required on these forms are collected completely and accurately in accordance with *Medicare ESRD Network Organizations Manual* instructions. Monitoring the accuracy and completeness of forms and validation of facility and patient data are critical in assuring the integrity of the patient tracking system. Similarly, the Network shall have a system in place that captures data forms on all incident cases, inclusive of a mechanism (e.g., missing forms report from and accretion report from SIMS) for cross-checking so the Network and/or facilities can detect unreported cases. Specifically, the Network shall:

1. 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) using a CMS-designated information system such as SIMS;
2. Review forms received for accuracy and completeness, and in consultation with the facility/provider, complete or correct forms with missing or inaccurate data (e.g., as identified in the reject report from SIMS);
3. Annually, validate 3% of the electronically submitted CMS-2728-U3 forms for patient and physician signatures. Results of this validation shall be reported in the Network's Annual Report and shall be available to CMS at any time upon request;
4. Replicate queued validated information on CMS-2728 and CMS-2746 forms no later than 15 working days from receipt at the Network;

5. Process the information on the CMS-2744 form via the CMS-designated information system(s) by the fifth working day in April, unless otherwise directed by CMS in a CROWN Memo;
6. Make corrections to the CMS-2744 form via the CMS-designated information system(s) by the third Friday in May, unless otherwise directed by CMS in a CROWN Memo;
7. Receive and process the CMS-820 and CMS-821 forms as required by the annual CPMs Project; Will need to know if CMS & VA will continue with MOU that indicates the VA will continue to send in hard copies of forms.
8. Maintain hard copies of completed ESRD forms that are entered into the CMS-designated database at the Network for at least two years.

Task 4.d. ESRD Forms Submission Compliance Rates

The Network, through the CMS-designated ESRD information system, shall track receipt of CMS-2728 and CMS-2746 forms from facilities/providers. The Network shall ensure that the forms are submitted on time and that all information in these mandatory fields were accurate.

To ensure compliance, the Network shall:

- Profile all facilities to determine their compliance rates for submitting timely, complete, and accurate CMS ESRD forms. Criteria for timeliness, completeness, and accuracy for each form type are found in Chapter 4 of the *Medicare ESRD Network Organizations Manual*;
- Maintain compliance rate information onsite and make it available at CMS' request;
- Document notification to noncompliant/delinquent facilities with unacceptable semiannual and/or annual compliance rates;
- Implement and document strategies/interventions employed to help facilities improve their performance and reach national compliance levels;
- Evaluate progress. If a facility/provider is not making a reasonable attempt to improve its performance, prepare and forward a sanction recommendation to the Project Officer following the instructions in Chapter 10 of the *Medicare ESRD Network Organizations Manual*.

The Network shall, semiannually and annually, report the number of facilities that failed to maintain a 90% compliance rate and identify strategies/interventions employed with non-compliant facilities in its Quarterly Progress and Status Report as follows:

1. Report by the 15th working day in October to the Project Officer the number of facilities that failed to maintain the semiannual compliance rate of 90%;
2. Report by the 15th working day in April the number of facilities that failed to maintain the annual compliance rate of 90%.

The ongoing progress of identified strategies/interventions shall be reported to the Project Officer in the Quarterly Progress and Status Report referenced in Section C.3.D–Task 3.g.

Task 4.e. Kidney Transplant Data

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

- a. Receive and process kidney transplant data through REMIS-to-SIMS notification and verify that the data are correctly displayed in the United Network for Organ Sharing (UNOS) system;
- b. Assist UNOS in obtaining delinquent kidney transplant registration and follow-up information;
- c. Report serious errors or discrepancies found in the UNOS data to CMS for follow-up with UNOS within 30 calendar days from the end of the quarter in which the transplant event occurred.

Task 4.f. Updating Status of Medicare ESRD Beneficiaries

The Network shall update patients' current status in the CMS-designated ESRD information system. Any changes to a patient's status shall be reflected as an event within 30 days of the Network receiving notification that a change in the patient's status has occurred. The Network shall:

1. Utilize the standardized monthly Patient Activity Report to collect patient event data from facilities;
2. Receive NPARs from the dialysis facilities on or before the 10th day of the following month;
3. Update the patient event data within 10 working days of receipt of the monthly NPAR.

When CMS is unable to resolve a patient's status through the Central Repository, a request for clarification will be sent to the Network. The Network shall investigate the status of the identified beneficiary and respond to CMS within 10 working days of receiving the request.

Instructions for the processing of these inquiries are found in Chapter 4 of the *Medicare ESRD Network Organizations Manual*.

Task 4.g. Coordination of Additional Renal-Related Information

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

1. Process CMS ESRD forms for Veterans Health Administration (VHA) dialysis patients from non-Medicare-approved VHA facilities, transplant centers, and other voluntarily submitted data from non-Medicare approved entities. Submission of data on ESRD patients to the Network by VHA non-Medicare-approved facilities is mandated by the VHA. This activity is part of the requirements for Task 4.c.;
2. Respond to selected inquiries from a CMS provided/approved list of Medicare Advantage organizations within the Network area regarding the status of CMS-2728-U3s filed with the Network, and/or the transplant status of ESRD Medicare beneficiaries who are enrolled by these Medicare Advantage organizations. Information to be provided includes current dialysis/transplant functional status, the first date of dialysis or the transplant date, and the approximate date the CMS-2728-U3 was submitted to CMS. The Network shall provide this information only for patients who have been on dialysis for at least four months and whose records are not retrievable through other CMS-provided electronic data sources;
3. Report the number and type of inquiries received in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

Task 4 h. Development and Testing of ESRD Network Data and Data Systems

The Network shall participate, as directed by CMS, in the following activities related to the successful development and implementation of a Web-based system to electronically collect and report ESRD administrative and clinical performance measurement data:

1. Participate in the development of business requirements, a data dictionary, and file specifications for ESRD data;
2. Review and provide comments on the ESRD Kidney Data Dictionary definitions, constraints, and valid values;
3. Review and provide comments on the business requirements and file specifications for the electronic data interchange (EDI) (batch) transmission of ESRD data;
4. Participate in testing ESRD information systems, software products, tools, data information sets, business requirements, and file specifications.

The Network shall be responsible for providing feedback in the form requested by CMS (in person, by telephone, or in writing) on a CMS-directed schedule.

As appropriate, the Network shall report these activities in the Quarterly Progress and Status Report referenced in Section C.3.D.—Task 3.g.

C.4. Task 5 Special Projects

Background

CMS reserves the right to direct the Network, or approve an application from the Network, to initiate a special project not currently defined under this SOW. The Network shall follow the guidance provided in C.2.F. regarding OHRP regulations in the development of special projects not currently defined under this SOW.

Task Description

A special project is defined as work that CMS directs a Network to perform, or work that a Network elects to perform with CMS approval, that is not currently defined in Tasks 1-4 of the SOW but falls within the scope of the contract. The term “special project” is interchangeable with the term “special work” and includes involvement in projects that CMS undertakes in agreement with other federal agencies (e.g., United States Renal Data Systems (USRDS), National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK]).

Evaluation

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

Network Resources to Support the United States Renal Data System (USRDS) and Special Study Centers

In addition, the Network shall support USRDS special project activities that are focused on identifying factors that can be used to improve patient care and outcomes, as directed by CMS. This requirement is 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.

CROWNWeb

CROWNWeb (CW) is the newest application in a suite of applications developed and maintained by CMS that make up the legislatively mandated ESRD Program Management and Medical Information System (PMMIS) that supports ESRD eligibility, reporting death data, payment and quality. CW has been developed to receive the administrative (e.g. SSA forms required to determine Medicare eligibility) and clinical data (e.g., performance measures that support Dialysis Facility (DF) Compare, Network quality improvement) that CMS currently accepts through a number of other methods many of which are done manually. This information

is required for Dialysis Facilities (DFs) to comply with the Medicare Conditions of Participation as well as feeds the Medicare Eligibility Data Base (EDB) on which CMS relies to make payments to DFs for services provided.

Task 5 A. Secure Participating Facilities

The Network must locate and enroll a total of 10 facilities comprised of five Large Dialysis Organizations (LDOs) and five Small Dialysis Organizations (SDOs) for Phase Two. If necessary, the NW must collaborate with another NW to make the participant selections. If the NW is unable to recruit dialysis facilities as described above, they must identify an alternative approved by CMS.

The 10 selected facilities must have completed the registration processes for QIPS (CROWNWeb User IDs/Password). LDO facilities must also have completed their Delegation of Authority forms.

Task 5 B. CROWNWeb Data

The purpose of this task is to verify that data is processed in SIMS and CROWNWeb in the same fashion. LDO facilities will enter the 2728 and 2746 data using the CROWNWeb single user interface (SUI). The Non-LDO facilities will enter all CROWNWeb administrative and clinical data via the SUI.

The Network must:

- Extract necessary information from CROWNWeb and enter the 2728, 2746 and events data into SIMS for the Non-LDO facilities.
- Provide to CMS, on a weekly basis, feedback on the completeness, accuracy, and timeliness of the data.
- Participate in weekly conference calls with CMS and other contractors to discuss status of project.
- Encourage their facilities to participate in the above mentioned weekly calls.
- Identify issues and respond by utilizing the helpdesk resource.
- Reinforce CROWNWeb training regarding appropriate entry of the necessary elements into CROWNWeb.
- Generate all available CROWNWeb reports and audit data.
- Review clinical data for face validity.
- Develop, implement, and evaluate internal Network processes for the validation of the timeliness, accuracy and validity of the CROWN WEB data submitted by the dialysis facilities.
- Evaluate the level of effort required by the NW to enter the CROWNWeb data into SIMS as we run parallel systems until full implementation of CROWNWeb.
- Evaluate the effectiveness of the CROWN Help Desk (HD) relative to the requirements of this special project.

Task 5 C. Recommendation

The Network must report weekly to CMS on each facility's performance. The report must include progress or lack of progress of their selected facilities in developing expertise with and the ability to independently use CROWNWeb. This weekly report must also include the number of NW hours needed to reinforce the CROWNWeb training, the number of NW hours needed to assist with data entry, and issues related to CROWNWeb reports, data, and connectivity. Specific content of the report may be altered as the project progresses and CMS will provide advance notice of any required changes to the report(s).

Task 5D. Project Management

Communication and project management will be coordinated by the selected Network. Meetings by telephone with the Government Task Leader, Project Officer, and all Task Leads will be conducted as necessary, with the expectation that frequent meetings may be needed initially. The selected NW will maintain and have available electronic summaries of these meetings including clearly documenting any identified problems, corrections made, and action items.

If a meeting requires the participation of more than one of the NWs, the above responsibilities will be rotated.

C.5. TRANSITION FROM INCUMBENT ESRD NETWORK TO SUCCESSOR ESRD NETWORK

General

During performance of this contract, should termination or non-renewal of an existing ESRD Network contract occur, CMS may require the successor ESRD Network to provide transition services beginning at the earliest mutually agreeable date. During this period, the incumbent ESRD Network shall work with the new ESRD Network, CMS staff, as well as other identified CMS contractors to ensure continued operation of the ESRD Program in the respective area.

Prior to the transition, the incumbent ESRD Network will be required, upon CMS request, to provide a Transition Plan. The Transition Plan will provide adequate coverage to ensure uninterrupted service to the ESRD Program. The incumbent Network will be responsible for effectively and efficiently administering the transition and ensuring that the elements of the plan are completed within a reasonable timeframe.

The successor ESRD Network shall cooperate fully with the incumbent ESRD Network, as directed by the Project Officer, to ensure that all services continue without interruption.

Contract Phase-Out Services

At the end of this contract, if a determination is made to terminate or not renew the incumbent ESRD Network's contract, the ESRD Network shall provide similar transition/phase-in/phase-out support to the successor ESRD Network selected by CMS (refer to Federal Acquisition Regulation 52.237-3 Continuity of Services) as defined in §1881(c)(1)(A)(ii)(I)and(II) of the Social Security Act.

Transition Plan

The Transition Plan shall provide detailed methods that will be used to ensure a smooth transition from the incumbent ESRD Network's operation to sole operation by the successor ESRD Network. At a minimum, the Transition Plan shall provide for the following:

A milestone chart detailing the timelines and stages of transition from the effective date of contract performance until the successor ESRD Network assumes sole responsibility for ESRD Network work in all contract tasks with a level of specificity to ensure continuity in all activities and beneficiary services;

An incumbent organizational chart that displays internal and external organizational relationships. The organizational chart shall identify the individuals (at all levels) who will be responsible for the transition and their respective roles and shall detail the lines of communication and how the ESRD Network will interface with CMS during this phase of contract performance;

A successor organizational chart that displays internal and external organizational relationships. The organizational chart shall identify the individuals (at all levels) who will be responsible for the transition and their respective roles and shall detail the lines of communication and how the ESRD Network will interface with CMS during this phase of contract performance;

Plans for communication and cooperation between the current and successor ESRD Networks. Transition services will include transfer of Government-Furnished Property (GFP) (e.g., hardware, software, records/data) from the incumbent ESRD Network to the successor ESRD Network, or to CMS, or another CMS contractor. CMS may elect to require the transition of GFP as follows:

- Prior to procurement of an asset, the ESRD Network shall propose a transition charge to be evaluated and negotiated by CMS.
- A successor ESRD Network to this contract, or CMS, will be afforded the opportunity to acquire ESRD Network assets at a reasonable transition charge.
 1. All existing assets shall remain installed and usable by CMS through the transition of assets or their replacement by the successor ESRD Network.

In the event a decision is made not to procure the assets, the ESRD Network has the responsibility to dispose of the assets as instructed by CMS.

C.6. INCORPORATION OF REPRESENTATIONS AND CERTIFICATIONS

The Contractor's representations and certifications, submitted in response to the solicitations in Section K, dated April 17, 2006, and revisions dated June 19, 2006, are hereby incorporated by reference and made a part hereof of this contract.