

ATTACHMENT B

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. BACKGROUND

C.1.A. Contract Purpose

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

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

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

C.1.B. 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 (the 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 network 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 network 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 organization 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 network 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; and,
- (H) Submitting an annual report to the Secretary [through CMS] on July 1 of each year which shall include a full statement of the network's goals, data on the network'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 network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

The Networks 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 transplantation, use of self-care modalities (e.g., peritoneal dialysis, home hemodialysis), in-center self-care, as medically appropriate, through the end of life.

- Improve patient perception of care and experience of care, and resolve patient’s complaints and grievances.
- Improve collaboration with providers to ensure achievement of the goals through the most efficient and effective means possible, with recognition of the differences among providers (e.g., 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; maintain Patient Registry; and to support the ESRD Network Program.

For the purposes of this contract, we are using 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, we are defining rehabilitation for the purpose of this contract as restoring an individual to the maximum level of independence and quality of life that an individual can achieve. The Networks 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) for the ESRD Network Program Mission

The HCQIP for the ESRD Network Program mission supports achievement of the strategic goals by assuring 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 and the mission of the HCQIP.

Mission:

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

- Patient Centered: Care delivery and processes of care are focused on patient needs, concerns, values, and expressed priorities to empower the patient. Care givers are empathetic and care is provided in a compassionate, responsive manner.
- Safe: Patients receive safe care in ESRD facilities and in home settings, when appropriate. Systems of care are designed to allow staff to anticipate and prevent, or minimize adverse events, learn from system

failures, and seek system improvements. Care givers trained to recognize and anticipate errors and recover from them.

- **Effective:** Care givers use scientific knowledge, evidence-based guidelines, and best demonstrated practices to offer individuals with ESRD the best available care. Care givers 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 an individual with ESRD does not vary in quality because of personal characteristics or socio-economic status.
- **Timely:** ESRD providers have processes in place to measure and minimize unnecessary delay in provision of services; healthcare interventions occur neither too soon nor too late.

Expected Outcomes:

Implementation of the HCQIP will result in achievement of the strategic goals as demonstrated in such areas as:

- **Measurable Outcomes:** Achievable by patients and caregivers using valid evidence-based measures of performance, developed through broad consensus, and that have strong correlation to patient outcomes (e.g., quality of care, quality of life, hospitalization, mortality, perception of care, and experience of care).
- **Cultural Change:** Renal coalitions at the national and local level work together for the benefit of the patient employing “spread” technique 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 have a respectful relationship where a patient’s informed choice is honored. An individual that progresses from CKD to ESRD receives appropriate care, with patient education and informed choice guiding appropriate renal replacement therapy (RRT). Preparation for RRT includes timely vascular or peritoneal access, referral to transplant centers for evaluation, and discussion of all possible modalities including emphasis on home therapies and in-center self-care.
- **Process Redesign:** Rapid cycle improvement is employed by the Networks. Data elements collected are defined and data reports

generated to assure high quality care. Redundant or unnecessary data elements are identified and eliminated. Information technology is used in partnership with providers (recognizing differences in provider types, their capabilities, and possibilities that can be realized) to increase efficiency, accuracy, and timeliness of data collection and reporting. ESRD Networks work with the caregivers, facilities, and other representatives of the renal community in an inclusive and collaborative manner to assure provision of quality care.

Reporting:

Results of the HCQIP program are publicly reported (as appropriate and permissible) to beneficiaries and open communications occurs with providers 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 Contractor must have relevant knowledge and experience of both ESRD clinical issues and the CMS ESRD Network Program. The Contractor shall consider its experience and findings under 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 Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the activities/tasks outlined in this contract.

C.2.C. Reporting Requirements

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

C.2 D. Confidentiality

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

- Section 1160 of the Act;
- 42 CFR Part 480 of the Code of Federal Regulations;

- 45 CFR Parts 160 and 164 as they pertain to “oversight” agencies;
- Section H of the contract;
- The Medicare ESRD Network Organizations Manual;
- Other administrative directives; and
- QNet System Security Policy Handbook (SSPH).

C.2.E. Information Collection/Survey Activities

A Network seeking to conduct surveys or collect data as a part of any of the Tasks included in this SOW, unless otherwise specified, shall do so 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 ESRD Network Organizations Manual, and other administrative directives.

C.3. TASKS

C.3.A. General Task Description

Under this contract, the Network shall be responsible for completing the specific Tasks under the contract task categories.

- Task 1 – Network Quality Improvement Program: contains Quality Improvement Projects that are national, local, and facility/provider specific.
- Task 2 – Community Information and Resources: includes the Network's provision of educational information (patients, facilities and providers) and technical assistance, coalition building activities, responsibilities in a disaster, and its resolution of difficult situations, complaints, and grievances.
- Task 3 – Administration: covers Network administrative activities, including staffing and reporting, specifically mandated by statute or regulation and as directed by CMS.
- Task 4 – Information Management: includes system development and information management responsibilities applicable to all Network activities.
- Task 5 – Special Projects: covers Network special studies as directed or approved by CMS.

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

Keeping with the ESRD Network Program strategic goals and HCQIP ESRD Network Program mission, the Network is to assist ESRD providers in assessing and improving the care provided to all individuals with ESRD. Program includes a vascular access quality improvement project, clinical performance measures (CPMs), Network specific quality improvement projects, and facility/provider specific initiatives reflected in a comprehensive Quality Improvement Work Plan all decided by the Network in conjunction with their Medical Review Board (MRB). The Network shall accomplish this by establishing a Network Quality Improvement Program. The Network's performance on any area of the Quality Improvement Program may be made public (e.g., Network Comparison Report) by CMS or its designee.

Vascular Access Quality Improvement Project (Fistula First):

- Quality improvement projects undertaken with dialysis providers and a National Breakthrough Initiative coalition in the area of vascular access, as required in Task 1.a.

Clinical Performance Measures (CPMs):

- Collection, analysis, improvement, and monitoring of ESRD Clinical Performance Measures (CPMs). As required in Task 1.b., Network shall develop and conduct Quality Improvement Projects (QIPs) based on one or more of the established set of CPM(s) for adequacy of dialysis, anemia management, or other CPM(s) developed or adopted by CMS. QIP(s) shall be developed and implemented in conjunction with the Network's Medical Review Board (MRB).

Network Specific Quality Improvement Projects (QIPs):

- Network specific QIP(s) that advance the purpose and strategic goals of the ESRD Network Program, as resources permit, and are directly aligned with the area of most need and potential impact to quality improvement within the Network area, in accordance with Task 1.c.

Facility Specific Quality Assessment and Improvement Projects (QAPIs):

- Assist ESRD providers and facilities (either individually or in groups) in the development and implementation of facility-specific, quality improvement activities to improve their patient care processes and outcomes. Networks shall perform this function upon request and/or upon identification of poor performance or a specific need (either at the Network level or facility level

based on the results of the annual CPM data collection, other data reports, analysis of complaint and/or grievance information, or results of a site survey, patient survey, or other investigation).

Institutional Review Board (IRB):

In the development of quality improvement projects or activities not specified or directed by CMS, the question of meeting Office of Human Research Protection (OHRP) regulations may arise. All projects not specified or directed by CMS will be evaluated by the MRB and reviewed by the Network's Project Officer using CMS supplied guidance for compliance with OHRP regulations. If it is determined by the MRB and/or the Network's Project Officer that a project requires Institutional Review Board (IRB) approval, the project will be submitted to the CMS entity that has jurisdiction for IRB review. If a specific MRB member is required to additionally submit the project to his/her local IRB, it will be the responsibility of that MRB member to seek such approvals. The cost of submitting the project for review will be borne by the Network. Since it is not the purpose of ESRD Networks to conduct research, CMS does not expect many projects to require IRB approval.

C.3.B.1.

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

Vascular Access Measure:

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

Evaluation of performance for the Task 1.a. Fistula First project will be based on improvements in Network level rates of arteriovenous (AV) fistula use in prevalent patients. The CMS goal for the Medicare Program is that percentage of prevalent patients using AV fistula is at least 66% by June 30, 2009.

In order to assist in the acknowledgement of this goal, CMS expects continual improvements by Networks in their fistula rates. To do this, CMS is setting Network-specific targets that aim to balance opportunity, attainability, and momentum. Using the third quarter of 2005 as baseline, each Network is expected to reduce its quality deficit by 20% during each contract year unless the number is less than the floor of 1 percentage point or greater than the ceiling of 4 percentage points, at which point the floor or ceiling would apply. This Network-specific expectation would apply both to all the facilities in their geographic area, but also specifically to the set of facilities not associated with a large dialysis organization (LDO). Based on evolving science, historical growth, and potential changes to practice patterns, CMS reserves the right to change the methodology used to set Network-specific targets in subsequent contract years.

The quality deficit is defined as the difference between the baseline percentage and the Program goal of 66%. The quality deficit's continuous scale, along with the floor (for momentum) and ceiling (for attainability), provide for a fair and sustained approach to improvement expectations that increase the likelihood that the health care system achieves a goal that is associated with more effective and efficient care for Medicare beneficiaries.

The three possible scenarios are exhibited below by example:

EXAMPLE 1: Expectation falls below the floor of one percentage point.

Network A has a baseline rate of 62%. Thus, the quality deficit is $66\% - 62\%$ or 4%. A 20% reduction in the quality deficit for the base year of the contract means Network A's expected improvement is 0.8 percentage points ($0.20 (20\%) \times 4$ (Network A's quality deficit)). In this case, the expected floor of 1 percentage point would apply to Network A both for all of its facilities and for the subset of its facilities not associated with an LDO.

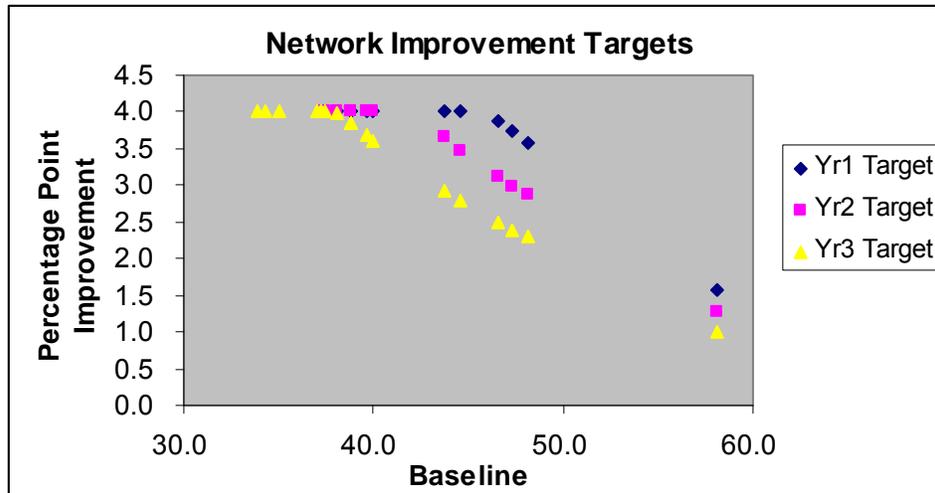
EXAMPLE 2: Expectation falls between the floor of one percentage point and the ceiling of four percentage points.

Network B has a baseline rate of 50%. Thus, the quality deficit is $66\% - 50\%$ or 16%. A 20% reduction in the quality deficit for the base year of the contract means Network B's expected improvement is 3.2 percentage points ($0.20 (20\%) \times 16$ (Network B's quality deficit)). In this case, neither the floor nor ceiling would apply. This improvement target of 3.2 percentage points would apply both for all of its facilities and for the subset of its facilities not associated with an LDO.

EXAMPLE 3: Expectation falls above the ceiling of four percentage points.

Network C has a baseline rate of 40%. Thus, the quality deficit is $66\% - 40\%$ or 26%. A 20% reduction in the quality deficit for the base year contract means Network C's expected improvement is 5.2 percentage points ($0.20 (20\%) \times 26$ (Network C's quality deficit)). In this case, the expected ceiling of 4 percentage points would apply to Network C both for all of its facilities and for the subset of its facilities not associated with an LDO.

The chart displays the expected improvement by Network over a three year period.



Evaluation of the contract specified minimum threshold performance level for fistula use in prevalent patients will be based on the January through March 2007 Fistula First Dashboard or other official CMS measurement system for vascular access.

Facility Reporting:

Networks shall collect aggregate vascular access data (as defined by CMS) from 100% of their facilities (not including those excluded due to obvious justifiable reasons for exclusion approved by the Project Officer, e.g., acute care hospitals, pediatric centers, facilities undergoing transition) using the FF data collection tool or other methods, as provided by CMS. Facility data will be reported electronically to CMS’s designated Information Technology Contractor(s) for those Large Dialysis Organizations (LDOs) associated facilities where the LDO agrees to participate and is capable of submitting data timely, accurately, and in the proper format. Networks are responsible for knowing fistula use rates in LDO facilities and reporting to the Network’s Project Officer if there is a concern with facility reporting whether LDO(s) are reporting electronically or not.

Educational/Technical Assistance:

Networks (as part of collaborative project with dialysis providers) shall undertake educational activities, and provide technical assistance, to enhance the facility’s fistula functionality and patency rate; including assisting facilities in training dialysis staff on proper cannulation, maintenance, and monitoring of AV fistulas.

Future Vascular Access Measure(s):

At such time that it is determined by CMS that there is a sufficient 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 Network area; the percentage of dialysis facility staff trained on cannulation, maintenance, and monitoring of AV fistulas; and/or other measure that is scientifically based and that supports the vascular access Breakthrough Initiative and/or any ESRD vascular access pay-for-performance program developed by CMS. CMS will notify Network regarding the specific measurement and evaluation criteria. As part of this contract, as directed by CMS, Network will be required to collect any data necessary (e.g. patient level vascular access data) to support such measurement. Addition of such measurement will only include additional funding if it is determined by CMS that the inclusion of such additional measurement, or revised data collection requirement, will result in a significant increase in work effort that is not currently part of this contract.

Participation In National Breakthrough Initiative:

In addition to Network directed activities, the Network is required to participate in Breakthrough Initiative coalition meetings and to actively engage in activities with at least one subgroup of the Breakthrough Initiative Coalition. Active engagement, among other activities, is considered to be leading an activity, implementing an activity, measuring 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:

Additionally, the Network will work with QIO(s), and other appropriate partners, to:

- Promote utilization of CMS-approved vascular access quality improvement programs, tools, and activities. This would include providing appropriate educational, promotional, and/or other communication resources needed, and not already available through the Network Coordinating Center.
- Achieve ESRD treatment changes at a system level; including process improvement so that hospitals adopt standards of care that promotes the use of AV fistulas such as vessel preservation, evaluation, and mapping (creation or referrals), and discharge planning.

Network activities in the area of vascular access (including efforts undertaken as part of the Breakthrough Initiative) must be clearly and timely reported in the Quarterly Progress and Status Report referenced in section C.3.D. - Task 3.g. Conduct of QI activities in the area of vascular access over the course of the SOW does not exempt participation in, or conduct of, other quality improvement efforts as described in C.3.B.1. - Task 1.b.

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

A Clinical Performance Measure (CPM) is an indicator to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality. CPM(s) can be used for a variety of purposes such as facilitation of quality improvement activities, comparisons of the quality of care delivered in similar or different settings, and identification of issues or areas that warrant more in depth evaluation.

Clinical Performance Measures:

The primary use of CPM(s) by the Networks will be to facilitate quality improvement among dialysis providers. Networks shall develop and conduct QIPs based on one or more of the established set of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, vascular access in the area of decreased catheter use and/monitoring for stenosis, or other CPM(s) developed or adopted by CMS not including increased use of fistulae. QIP(s) shall be developed and implemented in conjunction with the Network's Medical Review Board (MRB).

Annually, the Network shall collect data on specific ESRD CPM(s) as described in Chapter 5 of the Medicare ESRD Network Organizations Manual. CMS will work with the ESRD CPM Quality Improvement (QI) Committee (the committee is composed of both Network and renal community representatives) or other such work committee that is established for this purpose, and/or follow a recognized process based in scientific evidence to determine what CPM(s) to collect and what ESRD patient population(s) to target.

CMS may change, delete, or add CPM(s) (e.g. immunization, transplantation, renal related prescriptions, renal bone disease, and/or mineral metabolism); however, any changes in the CPM(s) will be made with input from the ESRD Networks. Network collection of additional CPM data collected in predominately the same manner will be considered part of the existing contract with the same level of CMS resources.

Clinical Performance Measures Reporting:

The purposes of collecting data annually on the CPM(s) are to:

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

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

Annually, the Network shall conduct the following activities involving CPM(s) data collection and analysis:

- Collect data, as directed by CMS, on specific measures by requesting the selected dialysis facilities to provide patient-specific data for a CMS selected sample of ESRD patients in the facilities. All collected data on the CMS selected patient sample must be transmitted to CMS or CMS' designee, using CMS' designated data entry program, or other procedure designated by CMS, within 90 calendar days after receipt of the final CMS selected patient sample, maintained by CMS, unless otherwise directed by CMS in the CPM timeline.
- Validate data for a hemodialysis patient random sample (as specified by CMS) and a ten percent peritoneal dialysis patient random sample of the facility-abstracted data or as directed by CMS. CMS or CMS' designee shall draw the validation samples. All validated data must be transmitted to CMS or its designee, using the CMS designated data entry program, or other procedure designated by CMS, within 120 calendar days after receipt of the random validation sample, unless otherwise directed by CMS in the CPM timeline maintained by CMS.
- Distribute or support the distribution of the ESRD CPM Annual Report and/or tables to each provider/facility in its area, if requested by CMS.

Chapter 5 of the Medicare ESRD Network Organization Manual describes the project, target population, sampling methodology, instructions for the data collection, validation procedures of the CPM(s), and the distribution requirements for the ESRD CPM Annual Report, and guidance for establishing target performance levels for selected CPM indicators. However, they are all subject to change as progress is made on electronic data collection of the ESRD Network Core Data Set elements (or other such project with similar purpose) and the Conditions for Coverage are finalized.

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

Network shall work with Medical Review Board, Network Council, Patient Advisory Committee and other partners, as appropriate (e.g., QIO(s), providers' affiliations and associations, beneficiary groups, etc.) to determine specific quality improvement projects, as resources permit, which 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 may differ from Network to Network, depending upon local needs, and variation in patient outcomes and practice patterns (processes of care). Other QI activities may be tailored to specific target areas, such as geographic area, provider group (dialysis), or other specific domains. Networks can undertake activities in areas that are pre-approved as Agency areas of priority, or with prior approval from Project Officer, including QIP undertaken with partners.

Any additional data collection outlined in the Network's plan (elements and/or frequency) that is not required in the SOW must be pre-approved by the Project Officer in accordance with other CMS administrative directives (e.g., Data Review Subcommittee). The timing of this plan (deliverable) is designed to allow assessment of the most current annual CPM(s) for each Network (available through annual CPM report - preliminary results). Progress on these plans shall be reported to the Project Officer in the Quarterly Progress and Status Report referenced in section C.3.D. - Task 3.g.

Pre-Approved Areas:

Pre-approved areas for Network Specific Quality Improvement Projects include:

- Adequacy of Dialysis (in-center or home hemodialysis patients) CPM(s) I – III;
- Adequacy of Dialysis (peritoneal dialysis patients) CPM(s) I - III;
- Anemia Management CPM(s) I - III;
- Vascular Access CPM(s) I – III;
- Nutritional Status;
- Hemodialysis reuse, if applicable;
- Patient experience of care;
- Complaints/Grievances;
- Patient Safety, which can include medical injuries, medical errors identification;
- Infection control;
- Immunizations;
- Bone disease;

- Transplantation;
- Measures/Indicators to Promote Self-Care Settings (e.g. home therapies) and/or In-Center Self- Care;
- Encourage vocational rehabilitation, volunteerism, and/or employment;
- End of Life care planning; and
- Mental Health Services/Counseling.

Prior Project Officer Approval Required:

With prior approval of Project Officer, Network may undertake other measures/indicators that support achievement of strategic goals and mission of the HQIP. This includes QIP(s) undertaken in conjunction with partners such as QIO(s) and beneficiary representative groups.

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

The Network shall have, and maintain, the capacity to respond to local needs upon request by facilities or when poor performance/problems are identified (e.g. complaints or grievances, clinical outcome data) in conjunction with the responsibilities set forth in section C.3.B. Activities may be developed in collaboration with CMS, the QIO State survey agencies, ESRD providers/facilities, Medicare Advantage Organizations, ESRD facility owners, national and/or local renal related professional organizations, Large Dialysis Organizations, patient organizations, other ESRD Networks, or the Network Medical Review Board and Network Council. Any additional data collection being considered for these activities (elements and/or frequency) that is not required in the SOW must be pre-approved by the Network's Project Officer and in accordance with other CMS administrative directives (e.g. Data Review Subcommittee). The objectives of these QI activities are to assist in the facility level development, implementation, maintenance, and evaluation of an effective data driven, interdisciplinary Quality Assessment and Performance Improvement (QAPI) program which focuses on indicators related to improved health outcomes.

Methods to achieve this may include:

- Fostering internal QI at the facility level;
- Providing technical assistance;

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

Task 1.e. General Requirements

Dissemination of Information:

The Network shall monitor, track, and disseminate regional provider and facility specific clinical outcomes data (such as the CPM data), and as otherwise directed or permitted by CMS, dialysis corporation specific clinical outcomes data, to identify opportunities to improve care within the network area or within a specific facility.

Quality Improvement Work Plan:

No later than 60 calendar days after the beginning of the contract year, unless directed by CMS, the Network shall submit for approval to the Project Officer an initial Quality Improvement Work Plan developed in conjunction with the Network Medical Review Board (MRB). The Quality Improvement Work Plan 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 Quality Improvement Work Plan shall be designed from available data sources (e.g. national reports, public use files, historical data, complaints/grievances, etc.) in such a way as to allow for rapid cycle improvement. It shall also contain the Network's Internal Quality Improvement Program developed to foster continuous quality improvement to improve timeliness, effectiveness, efficiency, and management control.

Although quantitative outcome targets are set as a matter of good quality improvement practice and expected, adherence to the Quality Improvement Work Plan and use of a process for rapid evaluation and adjustments, when indicated, is 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 Quality Improvement Work Plan because of reasons such as duration, the activity will be reported in the appropriate Quarterly Programs Status Report. Upon completion of the project, the final status report shall be submitted to the Project Officer within 30 days. Where appropriate, activity shall be reflected in Annual Report.

No later than 60 days after receipt of CPM clinical data, unless directed otherwise by CMS, each Network in conjunction with their MRB shall review, evaluate, and modify, as appropriate, the Quality Improvement Work Plan and submit the Work Plan to the Project Officer for approval.

The Network shall report the status of its other QI Work Plans in the Quarterly Progress and Status Report referenced in section C.3.D. - Task 3.g of this SOW. CMS reserves the right to direct or redirect these activities.

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

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

- Implement and/or maintain a procedure for receiving, evaluating, resolving and tracking patient grievances and complaints;
- Establish and/or maintain a national user-friendly, toll-free number to facilitate communications with patients within the network area;
- Develop and/or maintain a Network web site that follows CMS standards and guidelines; and
- Comply with laws that prohibit excluding or denying individuals with disabilities an opportunity to receive the same information and assistance provided to other patients without disabilities.

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

C.3.C.1. Task 2.a. Provision of Education Information – New Patients

The Network shall perform the following activities:

- The Network organization shall provide for duplication and use by the contractor designated by CMS to distribute the New ESRD Patient Orientation Package (NEPOP) to new ESRD patients in its Network area a letter introducing the Network organization to the new patient. The letter shall be written on Network stationary and shall be provided to the Network Coordinating Center, the designated subcontractor, to distribute in the new ESRD patient packages with a copy to the Network's Project Officer when:
 - Directed by CMS;
 - Requested by the designated contractor; and/or
 - Upon any changes to the letter's content information.

- The Network organization's letter of introduction shall include, at a minimum:
 - Information on the Network's grievance procedure;
 - Network specific information, including the Network organization's toll-free number, services and assistance offered, QI projects, and a way to request/obtain additional educational materials available through the Network, including information on patient care, treatment options, and services; and,
 - Information about the function of the State Survey Agencies (SSA) to include addresses and phone numbers of each SSA in the Network contract area, and the fact that the SSA receives and investigates complaints and grievances.

- The Network organization shall follow up on all returned mail for the Network Coordinating Center when New ESRD Patient Packages are undeliverable. The Network shall:
 - Determine whether the patient is deceased or is still alive and has a current address;
 - Provide the Network Coordinating Center with the patient's name and current address;
 - Update its patient database in CMS' designated information System; and,
 - Report monthly to the Network Coordinating Center the number of returns due to death and address changes.

Task 2.b. Provision of Educational Information – Patients

The Network shall make available, at a minimum, the following informational materials to its patients in its network area, and annually inform its patients on how to contact the Network to obtain the information. The types of information include:

- The role of the ESRD Network;
- The Network's process for receiving, reporting, resolving, and tracking patient complaints and grievances;

- Treatment options and new ESRD technologies available for patients with an emphasis on those that, based on sound medical practice, support independence through transplantation and self care in the best environment for the individual (e.g., home therapies, and in-center self-care);
- Information to educate and encourage patient use of those treatment setting most compatible with obtainment of the maximum rehabilitation achievable and participation in activities that will lead to the best possible quality of life, such as vocational rehabilitation programs, volunteerism, etc.;
- Information on vascular access procedures;
- State/regional vocational rehabilitation programs available in the Network's area;
- The Network's user-friendly toll-free number to facilitate communications with beneficiaries within its network area (i.e., a staff person should be available to answer the phone during normal working hours or if a staff person is not available, the ability for a person to leave a message) unless it is an emergency situation such as a disaster, in which case provisions should be in place to ensure Network staff member is available in accordance to requirements specified in Task 2.e.;
- The Network's web site that follows CMS standards and guidelines, which shall include at a minimum the Network grievance process, location of Network toll-free number for patients to contact the Network, current completed Annual Report, Network goals, a link to the Medicare.gov Dialysis Facility Compare (DFC) web site, and in emergencies (e.g., disaster response) the open and closed case status of facilities and emergency response information for providers and patients;
- Information on how to access and use Medicare's Dialysis Facility Compare (DFC) web site;
- Information on the Network Patient Advisory Committee including information on how to become a member of the committee (e.g., self-appointment, selection, etc.);
- Information on the importance of receiving immunizations (including hepatitis, pneumococcal, and influenza) and other information related to immunizations as directed by CMS; and,

- Information on the benefits of, and how to enroll in, the Medicare Prescription Program (Medicare Part D), and any guidance or material of specific benefit to the individual with ESRD, as directed by CMS.

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, QIO(s), etc.), other federal agencies, renal partners (e.g., beneficiary representative groups, provider organizations and corporations, etc.), and other sources as appropriate. Additionally, Networks 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, QIO(s), large provider groups/affiliations/corporations). Where it is more efficient and effective to do so, Networks can subcontract with appropriate renal partners to fulfill some or all of these patient information requirements provided all contracting/sub-contracting requirements are met. As appropriate and necessary, Networks may pay related travel expenses for critical speakers at training events, as resources permit, when all relevant federal requirements are met (e.g. conflict of interest, contracting). Further, Network shall utilize the Patient Advisory Committee and Network Council where applicable in fulfilling these requirements.

The Network shall report on these activities in its 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 available, at a minimum, the following informational materials to the providers/facilities in its network area with a directive that each provider/facility make the information available to its patients or inform its patients on how to contact the appropriate Network organization to obtain the information. Network shall utilize the Patient Advisory Committee and Network Council where applicable in fulfilling these requirements (e.g. development of material). Annually, the Network shall inform providers/facilities regarding the availability of the following informational materials, and how to contact the Network to obtain the information:

- The Annual Report (either by hardcopy and/or referral to the Network’s web site), which contains CMS and ESRD Network goals, the Network activities conducted to meet these goals, and the Network's plan for monitoring facility compliance with the goals;
- Regional and national patterns or profiles of care as provided in the Clinical Performance Measures Annual Report;

- Results of Network quality improvement projects;
- 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 (DFC) web site and how to submit corrections to the Network on its facility characteristics that are displayed on DFC; and,
- Information on the availability of VISION for electronic submission of data and other systems developed by CMS.

Additionally, the Network is required to:

- Conduct special mailings (up to two per year) as directed by CMS, including duplication of materials, as necessary;
- Print and distribute Dialysis Facility Reports annually or as directed by CMS. Within 30 days of receipt of the Dialysis Facility Report (produced by the University of Michigan Kidney Epidemiology and Cost Center or other CMS designee) for the dialysis facilities within the Network's area, the Network shall print and distribute two copies of the facility's Report to the individual facilities, to the attention of the Medical Director and the Unit Administrator, unless otherwise directed by CMS. Each facility shall only receive a copy of its own report. The notification shall also include instructions as to how the dialysis facilities can provide comments to CMS (or its designee) regarding its updated measures that are reported on Dialysis Facility Compare website. CMS, or its designee, shall provide the Network with instructions for preparing the notification to the dialysis facilities. Additionally, a copy of the report should be sent to national, corporate owners of a facility upon facility request;
- Distribute information regarding Federal Drug Administration (FDA) alerts, dialysis recalls, etc. that effect dialysis facilities; and,
- As directed, appropriate, and/or necessary (necessity would result from, for example, a substantive change to a grievance process that resulted in updated informational material on this process), the Network organization shall provide any updated information to providers/facilities in its network area with a directive that each provider/facility make the information available to its patients or inform its patients on how to contact the Network organization to obtain the information.

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, QIO(s), etc.), other federal agencies, renal partners (e.g., beneficiary representative groups, provider organizations and corporations, etc.), and other sources as appropriate. Additionally, Networks shall distribute information through the most effective and efficient approaches possible, (e.g., through provider affiliations and/or corporations; at training opportunities sponsored by renal partners; through professional associations; and, in conjunction with other renal partners and CMS contractors such as other Networks and QIO(s), etc.). As appropriate and necessary, Networks may pay related travel expenses for critical speakers at training events, as resources permit, when all relevant federal requirements are met (e.g. conflict of interest, contracting).

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

Task 2.d. Provision of Technical Assistance

Technical Assistance will be provided upon request of provider or patient, based on identified opportunities to improve care, when poor performance or problems are identified, or as otherwise directed by CMS. The Network shall conduct the following activities:

- Identify available providers and/or facilities for patients seeking ESRD services (including transient patients and during disaster situations);
- As appropriate, refer those patients seeking ESRD services to the Medicare.gov Dialysis Facility Compare (DFC) web site for additional information;
- Assist individuals with ESRD in understanding the information provided on the Dialysis Facility Compare page of the Medicare.gov web site per guidance set forth in the Medicare ESRD Network Organizations Manual;
- Educate dialysis facility professional staff regarding the use of the information on Dialysis Facility Compare (DFC) in assisting patients to make choices about dialysis facilities, to participate in decision making regarding their treatment, and other applicable uses per guidance set forth in the Medicare ESRD Network Organizations Manual;
- Assist facilities in developing procedures to assess patients for placement in treatment modalities that are consistent with sound medical practices that improve the 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;

- Provide education regarding kidney transplantation, home therapies, including in-center self care;
- Provide education regarding immunizations;
- Assist providers/facilities to make appropriate and timely kidney transplant referrals;
- Address impediments to referrals and/or transplantation, as appropriate and feasible;
- Provide education regarding the importance of appropriate advance care planning and, as approved or directed by CMS, assist in development of effective tools to encourage advance planning in these areas;
- Assist providers/facilities in defining, establishing, and promoting rehabilitation goals for referring suitable candidates to vocational rehabilitation programs and or such programs or activities that enhance independence (to the maximum extent possible) and a higher quality of life (e.g., volunteerism, education, etc.);
- Assist providers/facilities in developing appropriate quality improvement plans if they are having difficulty in meeting Network goals, Medicare certification requirements, or P4P program objective or other such requirements;
- Assist providers/facilities in developing plans for local disasters (including emergencies such as floods, earthquakes, hurricanes, etc.);
- Assist providers/facilities in development of mechanisms for assessing the health-related quality of life of patients; and,
- Assist providers/facilities in developing community and patient education programs.

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

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

Task 2.e. Emergency/Disaster Preparedness and Response

Networks shall be required to facilitate and assist providers/facilities in developing plans for local emergencies/disasters. The Network shall also maintain a phone system to ensure Network staff members can be contacted as necessitated by the emergency.

In the event of local disasters, the Network will track availability of services and assist patients in identifying dialysis facilities that can provide ESRD services. The Networks shall also track and make available to the public the open and closed status of the facilities in the effected area. In addition, as directed by CMS, the Network shall provide information to family members and treating facilities on where a patient previously/currently is receiving services to assist in location of individuals and the exchange of critical medical information.

As necessary, Networks shall 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 appropriate, Networks shall coordinate activities with providers and other emergency workers to ensure access to dialysis.

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 2.f. Coalition

The Strategic Partnership for Change (SPC) is an initiative to support strategic partnerships and coalitions among the renal community through national and local training, and on-going consultative support. The Network shall participate in, and actively engage in, all associated activities.

In addition, the Network will be responsible for assembling and/or sustaining an active coalition that conducts activities that supports achievement of the ESRD Network program strategic goals, mission of the HCQIP, and/or Network QI activities. Network shall submit any changes to the coalition focus to their PO for prior approval and must work with any CMS specified contractors to assist in meeting these requirements. As directed by CMS, Networks are required to assist other Networks in carrying out contract requirements during the initial phase of an emergency or disaster and during the recovery phase.

It is expected that by virtue of the Networks participation in training activities, and through practical experience, the Network shall be able to:

- Build partnerships with new entities;
- Expand and enhance existing partnerships;

- Create greater ownership by partners in coalition;
- Utilize other available resources by having coalition partners bring resources to the table or identify others with resources; and,
- Engage in innovative problem solving by collaborating with coalition partners on jointly shared problems.
- In fulfilling this requirement, it is expected that the Network shall: create a coalition that goes beyond just promoting information exchange, but also promotes collaboration among members defined as exchanges that aim to enhance the capacity of the other (i.e., Networks will try to enhance the QIO(s) achievement of their goals and the QIO(s) will try to enhance the Networks achievement of their goals);
- Have an established vision, mission, goal(s), and operating procedure(s) for the coalition, jointly agreed to by coalition members;
- Have an established agenda for coalition meetings, and that meeting minutes will be taken and distributed to coalition members;
- Identify and recruit key partners and engage in active participate in coalition activities. The Network shall identify needed resources in keeping with the vision, mission, and goals of the coalition when determining key partners. Key partners should go beyond those with which the Network conducts routine business;
- Expand available resources by having partners bring resources to the table and/or identify others with resources;
- Ensure resources outside of the Networks will be used to achieve coalition goals; and,
- Engage in collaborative problem solving of jointly shared problems, resulting in innovative solutions that lead to problem solving actions.

The Network will be responsible for recording activities, accomplishments, and challenges in the Quarterly Progress and Status Report referenced in Section C.3.D. – Task 3.g.

Task 2.g. Resolution of Complaints and Grievances

The Network shall assume a proactive role in the prevention, facilitation, and resolution of complaints and grievances, including implementing educational programs that will assist facility staff in handling difficult situations, where

appropriate. The Network shall also conduct trend analysis of reported situations to detect regional, local, or facility specific patterns of greater concern. Each Network shall be responsible for, but is not limited to, the following activities:

- Provide dialysis facilities with resources and educational programs under the Decreasing Dialysis Patient-Provider Conflict Initiative designed to provide facility staff with an understanding of the issues and skills to prevent, intervene, or mitigate difficult patient and/or facility situations;
- Upon request, assist in the resolution of patient, provider, and/or facility complaints and grievances, by providing education, and/or facilitating solutions, and/or making referrals, which address the issue(s) involved;
- Describe and report in the Quarterly Progress and Status Report, and upon CMS request, patient and facility complaints/grievances and Network actions and interventions. Unless otherwise specified by CMS, reporting shall include aggregate, quantitative information on type and quantity of complaints and grievances, average time period for handling complaints and grievances, and mode for handling from beginning to end of Network involvement. Additionally, report shall include, in narrative format, information on the nature of complaints and grievances, and actions taken to resolve complaints and grievances;
- At a minimum, annually, analyze facility-specific data to identify patterns of concern at the facility or Network level, and opportunities to improve;
- Implement interventions aimed at reducing grievances and/or the numbers of difficult situations;
- Collect and categorize, as directed by CMS, inquiries, complaints, and grievance data using SIMS, or other mechanism specified by CMS;
- Work with, and implement activities to support, the CMS Ombudsman, as directed by CMS; and,
- Utilize complaint and grievance data to plan new modular training initiatives, provide facilities with feedback, and/or make recommendations to CMS.

The Network shall follow the CMS national policy found in Chapter 7 of the Medicare ESRD Network Organizations Manual in developing Network specific policies, procedures, and standards for receiving, processing, investigating, resolving, documenting, and reporting patient complaints and grievances. In addition, the Network will develop a similar structure to deal with facility concerns. The Network is also expected to customize the complaint and grievance processes to be consistent with other business functions of the

Organization. The Network will, on a regular basis, evaluate the functioning of its complaint and grievance system and report findings to CMS in each Quarterly Report. The Network shall, within 24 hours of receipt, refer immediate and serious grievances to the appropriate and State survey agency. On request from CMS, the Network shall assist the State survey agency with the investigation of a complaint or grievance.

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

C.3.D. Task 3. Administration

Each Network shall have an organizational structure, basic administrative staff, and infrastructure to support its operations to meet the statutory requirements, as well as other work activities, set forth in this SOW. Each Network is required to establish various boards and committees, specify appropriate roles and functions for these entities, and take minutes or document committee meetings and actions for review by CMS upon request.

C.3.D.1.

Task 3.a. Organizational Structure

Each Network's organizational structure shall include the following:

- Network Council that meets the statutory requirements of section 1881(c) of the Act. The Network Council shall be composed of renal providers in the network area, be representative of the geography and the types of providers/facilities in the entire network area, and have at least one patient representative. The Network Council shall meet as necessary, and serve as a liaison between the provider membership and the Network.
- Board of Directors (BOD) composed of representatives from the network area including at least one patient representative (e.g., Patient Advisory Committee Chair), but preferably more than one (1), representing ESRD patients. The BOD shall meet as necessary (suggest quarterly by teleconference or onsite meeting) to ensure the successful operation of the Network. The BOD or EC shall be responsible for the performance of the Network's Executive Director in meeting contract deliverables and requirements (including undertaking personnel actions to correct situations where a Network staff member is not satisfactorily performing his/her duties), responding to CMS requests, and maintaining financial viability.
- Medical Review Board (MRB) or a committee that meets the statutory requirements of section 1881(c) of the Act to function as the Medical Review Board. The committee (which shall be referred to as MRB in this

SOW) shall be composed of at least one patient representative, and representatives from each of the professional disciplines (physician, registered nurse, social worker, and dietitian) engaged in treatment relating to ESRD and qualified to evaluate the quality and appropriateness of care delivered to ESRD patients.

- Patient Advisory Committee to facilitate and inform Networks regarding patient centered care. Each Network shall maintain an active Patient Advisory Committee comprised of patients that are representative of their region to provide input to the Network and its Board on the concerns and needs of patients. Network shall be responsive to the insight offered and shall conduct the Patient Advisory Committee in a manner that values the time and efforts of the Patient Advisory Committee members, including where feasible, representation on the Board of Directors. When the Network determines it is appropriate and necessary, the Network shall compensate essential committee member(s) (e.g., Committee Chair) when their time and effort is significant, and, where appropriate, for travel expenses incurred by committee members for mandatory Committee activities that assist in the goals of the Network.
- Other committees (or subcommittees) as appropriate to meet the requirements in the SOW. The committees shall be composed so as to represent the diversity of the patient and practitioner community to the fullest extent possible.

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

Task 3.b. Network Staff

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

- Executive Director/Project Director responsible for the overall operation of the Network and obtaining the staff and resources necessary to conduct the contract;
- Quality Improvement Manager/Quality Improvement Coordinator responsible for coordinating the Network quality improvement activities; and,
- Data Manager responsible for overseeing the Network data, including data collection, validation, maintenance, and security.

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

- Sufficient support staff to conduct the data related activities as required by the Network Statement of Work;
- Sufficient support staff (including a registered nurse with nephrology experience) to conduct the activities and responsibilities in accordance with the SOW, Chapter 2 of the ESRD Network Organizations Manual instructions, and other CMS directives;
- Sufficient support staff to conduct, understand and follow the activities/responsibilities described in the ESRD Network Administration and Disaster Recovery Handbook, QualityNet ESRD Networks Infrastructure Support Manual, QualityNet System Security Policies Handbook, QualityNet Medicare ESRD Networks Business Continuity and Contingency Plan (BCCP) & Template, and other supporting documentation provided by CMS.
- A full-time Patient Services Coordinator with a Masters in Social Work or an equally qualified individual (i.e., experienced nephrology nurse or counselor) responsible for resolving patient and/or facility complaints and grievances, conducting educational training on managing difficult situations, and conflict resolution. If a Network is unable to find an individual with the above listed qualifications, or wants to retain current staff with proven capabilities, it shall seek (with appropriate documentation and justification of the individual's abilities to meet requirements as indicated in Chapter 2 of the Medicare ESRD Network Organizations Manual) approval from its Project Officer for any such exceptions.
- A Community Outreach Coordinator who serves as a specialist in partnership, collaboration, and education, and who will be responsible for enhancing community outreach and collaboration activities of the Network. The individual in this position will plan and facilitate education, information dissemination and training for ESRD professionals, patients, and their family members and other members of the renal community, and will be the staff liaison lead to the Patient Advisory Committee. The Community Outreach Coordinator may work with consultants (e.g. website, statistical) and provide support across Network program lines to improve the quality of care for patients through education, web site outreach, and coalition and partnership building. To adequately perform these responsibilities, the individual must have related experience (e.g., in communications, material development, organizing volunteers) and where possible be a patient with CKD/ESRD, or have personal, first-hand experience with a family member, spouse, or other significant individual with CKD/ESRD.

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.

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

Task 3.c. Internal Quality Improvement Program

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

- 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.
- The Network shall have an internal reporting system for all IQI activities, and shall make reports available to the MRB and CMS for monitoring purposes.
- The Network IQI Program shall have built-in processes for rapid identification and correction of problems.
- The Network IQI Program shall be included in the Quality Improvement Work Plan to be submitted to the Project Officer no later than 60 days after the beginning of the contract year, as specified in Task 1.e.

Task 3.d. CMS Meetings

Network staff (to be designated by the Network Executive Director in the absence of CMS direction) shall participate in CMS sponsored/sanctioned meetings. The Network Executive Director, Quality Improvement Director, Data Manager and other appropriate staff, as designated by the Network Executive Director or CMS, are required to attend the CMS/Forum of ESRD Networks' Annual Meeting unless exempted by prior approval of Project Officer. The Network Executive Director, Data Manager, and other appropriate staff, as designated by the Network Executive Director or CMS, are required to attend the CMS QualityNet Conference.

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

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

- Sharing information to assist the State survey agency(ies) in carrying out their legislative or regulatory responsibilities (as permitted by statute, regulations, or other CMS policy guidance);
- Sharing information to assist QIO(s) in carrying out their legislative, regulatory, and/or contractual responsibilities (e.g., Chronic Kidney Disease initiatives) as permitted by statute, regulations, and CMS policy guidance. In carrying out this requirement, if the exchange of patient level data is involved, Network shall obtain prior approval of Project Officer, with review by the Data Review Committee;
- Referring quality of care issues, as appropriate, and assisting the State survey agency(ies) or QIO in the investigation of quality of care issues, upon request and with the approval of CMS Central Office. This may include:
 - Conducting reviews as necessary (e.g., site visits, such as sequential reviews of medical records, as needed);
 - Conducting cooperative state/Network evaluations of providers, where appropriate, in support of the sanction or alternative sanction process;
 - Providing technical assistance;
 - Providing information regarding expected outcomes;
 - Reporting patterns of complaints and grievances;
 - Providing follow-up reports to agencies of any complaints/grievances referred to the Network; and/or,
 - Reviewing follow-up reports from agencies to which the Network referred any complaints/grievances.
- Coordinating and collaborating with State survey agency(ies) and QIO(s) in regards to quality improvement interventions when a provider is unwilling or unable to implement and maintain improvements whether in compliance with the conditions for coverage for dialysis facilities or in the

provision of CKD and ESRD care that is consistent with current professional knowledge or standards.

- Coordinating and collaborating with QIO(s) in 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 the State survey agency(ies) and QIO(s) are included in Chapter 2 of the Medicare ESRD Network Organizations Manual.

As appropriate, the Networks 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 sanctions or alternative sanction recommendations and referrals include the following:

- Recommending to CMS sanctions or alternative sanctions for facilities/providers that do not comply with Network goals and/or are not providing appropriate medical care;
- Providing the necessary documentation to support the recommendation; and,
- Referring to the QIO or the State Office of the Inspector General information collected while conducting contract activities that indicates that a physician may be failing to meet his/her obligation to provide quality care or involved in Medicare fraud.

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

Task 3.g Required Administrative Reports/Activities

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

- As required in Task 1.e., no later than 60 calendar days after the beginning of the contract year, unless directed by CMS, the Network shall submit for approval to the Project Officer an initial Quality Improvement Work Plan developed in conjunction with the Network Medical Review Board (MRB). The Quality Improvement Work Plan 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 Quality Improvement Work Plan 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.

- Within 60 days of receipt of CPM clinical data, unless otherwise directed by CMS, each Network in conjunction with their MRB shall review, evaluate, and modify, as appropriate, the Quality Improvement Work Plan and submit the Work Plan to the Project Officer for approval.
- Quarterly Progress and Status Reports of Network contractual activities, which are due 15 working days after the beginning of each calendar quarter to the Network's Project Officer with a copy to CMS Central Office and the ESRD Networks Coordinating Center. These reports must be submitted electronically (attachments may be provided in hard copy if electronic transmission is not reasonably feasible);
- Semi-annual report of Network operating costs (with distinction between base contract and special project costs), which are due electronically to the Project Officer for approval and the CMS Central Office 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 H.4.
- A final Annual Report of Network Activities, which is due to the Project Officer for approval by July 1 of each contract year, and to the CMS Central Office and the ESRD Networks Coordinating Center within two weeks after approval by the Project Officer. Within 90 days after Project Officer's approval of the Network's Annual Report of Network Activities, the Network shall post a copy of its report on its website and notify the Project Officer of the posting date. The Network shall include in the report:
 - The activities conducted to meet ESRD program goals during the previous calendar year;
 - An assessment and relative measurable achievement as to whether those activities were effective in meeting the Network's goals;
 - 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 such programs that enhance quality of life (e.g., volunteerism, education);
 - Identification of those facilities that consistently failed to cooperate with Network goals or to follow the recommendations of the MRB;

- Any recommendations for additional or alternative ESRD facilities in the Network area; and
- Information specified elsewhere in Section C.3. of this Statement of Work.

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

Task 4. Information Management

This section contains the information management and reporting activities that the Network shall be required to perform. The Network shall be required to utilize an Information System designated by CMS to collect and maintain data pertaining to the ESRD program. This data is used to fulfill Network contractual obligations.

Networks shall not develop software products for use with facilities or use by other Networks without written prior approval by CMS. In addition, no money from this contract shall be used for data collection activities not specified in this contract unless pre-approved by the Project Officer and in accordance with other CMS administrative directives (e.g. Data Review Subcommittee).

The Network's responsibilities for information management and reporting within the CMS designated Information System(s) are to:

- Adhere to the policies and procedures outlined in the most current version of the ESRD Network Infrastructure Support Manual, the Information Technology Administration Manual, and the QualityNet System Security Policies Handbook issued by CMS at all times during the contract, unless directed otherwise by CMS. These manuals delineate the roles and responsibilities for ESRD Network users, systems administrators, CMS personnel, and CMS supporting contractors. These documents are available on <http://www.esource.net> (or other designated site specified by CMS);
- Effectively provide content for developing business file specifications when directed by CMS and manage the collection, validation, storage, and use of data; including data collected by the Networks or provided by CMS;
- Conduct, or work with CMS Contractor to conduct, reliability and validity studies of clinical data collection to ensure data collected are consistent with data in the patient's medical record, upon CMS request;

- Share appropriate data with the Network's CMS regional office, central office, and the appropriate State survey agency, as directed by CMS;
- Ensure timely and accurate reporting by the providers/facilities;
- Train facilities in the proper procedures for completing and transmitting forms electronically and/or manually;
- Maintain an ESRD patient and facility database and ensure the confidentiality, integrity, timeliness, accuracy, and security of the databases;
- Ensure current patient events are reported to CMS timely for appropriate enrollment into, and disenrollment from, the Medicare program for ESRD benefits; and
- At a minimum, on a quarterly basis, verify with dialysis facilities patient event data.

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

C.3.E.1.

Task 4.a. System Capacity

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

- CMS approved hardware (HW) and software (SW);
- Equipment for secure transmission and communicating with ESRD facilities and CMS central and regional offices, and other stakeholders;
- CMS approved statistical software for data analysis and profile analysis, including profiling patients and facilities by county, to facilitate disaster planning and other studies; and
- Provisions for disaster recovery including regularly scheduled backup of the databases and data system as outlined in the QualityNet ESRD Networks Infrastructure Support Manual.

All work under this contract shall be performed using Government-furnished equipment and software only. Exceptions to this policy, such as for peripherals

(e.g. printers, scanners), may be requested through QualityNet (QNet) Standard Data Processing System (SDPS) Engineering Review Board (ERB) process. Requests for HW/SW shall be initiated using the Remedy AR System software provided by CMS.

Under no circumstances will Networks be allowed to attach non-Government servers, workstations, or any other peripheral devices to Government equipment and/or network.

The Network shall maintain an accurate inventory of federally provided HW/SW through Remedy as directed by CMS.

Task 4.b. Database Management

The Network shall maintain a patient and provider database containing the mandatory data elements listed in Chapter 4 of the Medicare ESRD Network Organizations Manual. The Network shall perform the following tasks related to its patient and/or provider database:

- The Network is responsible for the completeness, timeliness, validity, and accuracy of the ESRD patient and provider database.
- The Network shall continually update, in a timely manner, the database and the data received from the facilities/providers or through a change-reporting process approved by CMS (e.g. Patient Alerts/Notifications, call from Data Quality Team). The Networks will be responsible for resolving, in a timely manner, all discrepancies in their patient or provider records as instructed by CMS.
- Replication to the Central Repository shall be performed nightly for all queued validated, ready records based on a pre-determined schedule. CMS will access the Network database as needed to obtain an update of the Networks' patient and/or provider data.
- The Networks shall be responsible for providing accurate data to CMS. The Networks shall perform data clean up activities on a regular basis and other IT tasks as directed by CMS in support of a consolidated National database (i.e., CROWN-Web).
- When requested, the Network shall review and verify provider data including but not limited to Medicare Dialysis Facility Compare, National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services, ESRD Provider Public Use File, and Annual Facility Survey.
- Through the CMS designated Information System, the Network shall maintain an up-to-date facility database containing the mandatory data

elements listed in the Medicare ESRD Network Organizations Manual. It is important to keep facility data current for the Medicare Dialysis Facility Compare Web Site maintained by CMS. The facility data is to be replicated to the Central Repository nightly.

- When not clearly directed by CMS, Networks shall develop and maintain policies and procedures to ensure the timeliness and accuracy for all data entered into CMS designated Information Systems.
- As directed by CMS, the Networks will work with CMS and CMS contractors to assist in the development of business rule file specifications for a tool for two-way communication between Networks, facilities, and CMS (e.g., SIMS and VISION/CROWN Web facilities).

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

The Network shall obtain completed CMS ESRD forms from each ESRD (if directed by CMS) facility/provider and/or corporate owner in the Network area either electronically or via hardcopy. 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 facility owners on the proper procedures for electronic submission of their CMS ESRD forms.

Training resources (e.g., Web-ex sessions, user documentation, and training materials) will be available upon request through CMS' designated Information Technology contractor(s). The Networks will be responsible for authorizing access to the CMS designated systems for the electronic transmission of ESRD Forms. The Networks shall enroll users in the CMS designated system and shall keep the authorized user information up to date. The Network will also include all transmitted forms from the non-Medicare Veterans Health Administration (VHA) facilities, and voluntarily submitted forms from institutions such as prisons and nursing homes.

ESRD Forms

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

- CMS-2728-U3 - ESRD Medical Evidence Report Medicare Entitlement and/or Patient Registration (or computerized facility generated Medical Evidence form) (completed within 45 days of either date of patient transplant or start of a regular course of dialysis and supplemental or re-entitlement forms, when necessary);

- CMS-2744 - ESRD Facility Survey (completed annually);
- CMS-2746 - ESRD Death Notification (or computerized facility generated Death Notification form) (completed within 30 days of the date of death);
- CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually); and
- CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually).

Processing Forms Data

The Network shall conduct activities to ensure that the data required on the forms are collected, completed, and validated in accordance with the Medicare ESRD Network Organizations Manual instructions and the ESRD Program Instruction Manual for Renal Providers. Monitoring the accuracy and completeness of forms and the validation of facility and patient data are critical in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for cross-checking so Networks and/or facilities can query and detect unreported forms. Related activities include the following:

- Review forms data received for accuracy and completeness and return to the facility/provider (or otherwise query the facility/provider) for correction or completion of those forms with missing or inaccurate data;
- Receive and process the ESRD Medical Evidence Report, Medicare Entitlement and/or Patient Registration form (CMS-2728-U3), and the ESRD Death Notification form (CMS-2746);
- Replicate queued validated information on CMS-2728 and CMS-2746 forms to the Central Repository no later than 15 working days from receipt;
- 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;
- Complete corrections to the CMS-2744 form via CMS-designated information system(s) by the third Friday in May, unless otherwise directed by CMS in a CROWN Memo;
- Receive and process the CMS-820 and CMS-821 forms as required by the annual CPM project; and

- Maintain a file of all CMS ESRD hardcopy forms that are entered into SIMS at the Network for at least two years until such time as electronic reporting becomes mandatory.

Task 4.d. Data Validation for Electronically Submitted Forms

Annually, ESRD Networks shall validate 3% of patient and physician signatures on CMS 2728 forms received electronically. Results of this validation shall be reported in the Networks Annual Report and shall be available to CMS at any time upon request.

Task 4.e. Tracking System for ESRD Forms

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

Task 4.f. ESRD Forms Submission Compliance Rates

Semi-annually, through the CMS-designated ESRD information system, the Network shall profile all facilities to determine their compliance rates for submitting timely, complete, and accurate CMS ESRD forms to the Network. Facilities are to be notified if they are below an 80% compliance rate during the January through June time period and all facilities below a 90% compliance rate for January through December will be notified of their rate. The Network maintains compliance rate information on site and makes it available at CMS request. Criteria for timeliness, completeness, and accuracy for each form type, as well as instructions for notifying those facilities/providers with unacceptable semi-annual and annual compliance rates, are contained in Chapter 4 of the Medicare ESRD Network Organizations Manual.

Further, the Network shall document its notification of the non-compliant/delinquent facilities with unacceptable semi-annual and/or annual compliance rates and also documents progressive strategies/interventions employed to help facilities improve their performance and reach national compliance levels. If a Network determines that a facility/provider is not making a reasonable attempt to improve its performance, following the application of progressive strategies/interventions, the Network shall prepare a sanction recommendation to the Regional Office following the instructions in Chapter 7 of the Medicare ESRD Network Organizations Manual.

The Network shall report by the 15th working day in October to the PO, the number of facilities that failed to maintain the semi-annual compliance rate of 80% as referenced in Task 4.f. Additionally, the Network shall report by the 15th working day in April the number of facilities that failed to maintain the annual compliance rate of 90% as referenced in Task 4.f.

The Network shall report in its Quarterly Progress and Status Report for the reporting period January–March the date the facilities in its Network area were notified of their annual compliance rates (January through December of the previous calendar year), identify the strategies/interventions employed for non-compliant facilities, and report the outcome of the strategies used to assist the facilities/providers to improve performance and reach national compliance levels in the Progress Report. The Network shall provide copy of the SIMS generated Annual CMS ESRD Form Compliance Rate Report that details those facilities that fell below the 90% annual compliance rate.

The Network shall report in its Quarterly Progress and Status Report for the reporting period July-September the date the facilities in its Network area were notified of their semi-annual compliance rates January - June of current calendar year, identify the strategies/interventions employed with non-compliant facilities/providers, and report the outcome of the strategies used to assist the facilities/providers to improve performance and reach national compliance levels. Included in the Progress Report, the Network shall provide copy of the SIMS-generated Semi-Annual CMS ESRD Forms Compliance Report that details those facilities that fall below the 80% semi-annual compliance rate.

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

Records replicated to the CMS Central Repository will be subject to edit checks. If any discrepancies are detected in the data provided by the Network, the Network will be informed via a change-reporting process approved by CMS (e.g., Patient Alerts/Notifications, call from Data Quality Team) and the Network shall research and resolve the discrepancy and make necessary corrections within 60 calendar days of notification. Chapter 4 of the Medicare ESRD Network Organizations Manual gives instructions for resolving data discrepancies.

As directed by CMS, the Network shall work with CMS (and CMS contractors) to establish parameters for new categories of data problems/anomalies.

Task 4.h. Renal Transplant Data

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

- Report kidney transplant data;
- Assist the United Network for Organ Sharing (UNOS), the contractor for the Organ Procurement Transplantation Network (OPTN), in obtaining delinquent renal transplant registration and follow-up information; and
- Report serious errors or discrepancies found in the UNOS data to CMS for follow-up with UNOS within 30 calendar days from the end of the quarter in which the transplant event occurred.

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

The Network is responsible for updating 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 change in status or within 10 working days of the Network receiving notification that a change in patient's status has occurred. The correct patient status is necessary to appropriately identify when Medicare benefits are to be terminated.

When CMS is unable to resolve a patient's status through the Central Repository, notice will be sent to the Network for clarification. The Network shall investigate the treatment status of the identified beneficiary(ies) and respond to CMS within 10 business 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.j. Coordination of Additional Renal Related Information

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

- Process CMS ESRD forms on VHA dialysis patients from non Medicare-approved VHA facilities. Submission of data to the Network by VHA non Medicare-approved facilities on its ESRD patients is mandated by the VHA. These activities are part of the requirements reported in Task 4.c.
- Respond to selected inquiries from a CMS provided/approved list of Medicare Advantage organizations within the Network area regarding the status of CMS-2728s filed with the Network, and/or transplant status of ESRD Medicare beneficiaries who are enrolled in these Medicare Advantage organizations. Information to be provided includes the current dialysis/transplant functional status, the first date of dialysis or transplant date, and the approximate date the CMS-2728 was submitted to CMS. Selected inquiries are for those patients who have been on dialysis for at least four months and whose records are not retrievable through other

CMS-provided electronic data sources. The Network shall report the number and type of inquiries received in the Quarterly Progress and Status Report referenced in Task 3.g.

Task 4 k. ESRD Network Core Data Set (Or Project Under Other Name with Similar Intent)

- The Network shall participate in defining elements to be included/excluded in the ESRD Network Core Data Set (or project of similar intent) and in the development of business file specification and implementation activities for the collection of data elements under the ESRD Network Core Data Set project (or project of similar intent). The Network shall test proposed definitions and/or business file specifications if requested by CMS.

Task 4.I. Electronic Collection of Information for Conditions for Coverage

- As directed by CMS, Network shall participate in discussion on how best to proceed with electronic data collection for fulfillment of the requirements under the Conditions for Coverage. Network responsibilities shall include assistance in defining the business file specifications for collection of elements electronically, and in testing the file specifications and if applicable, other software products.

Task 4.m. Testing

As directed by CMS, the Networks shall participate in testing ESRD information systems, software products, tools, business rules and file specifications. Networks shall be responsible for providing feedback in the form requested by CMS (orally or in writing) on a CMS-directed schedule.

Task 5 Special Projects

1. 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.3.B. regarding Office of Human Research Protection (OHRP) regulations in the development of special projects not currently defined under this SOW.

2. 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 which 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 those projects that CMS undertakes in agreement with other Federal agencies (e.g., United States Renal Data Systems (USRDS), and National Institute for Diabetes, Digestive and Kidney Diseases [NIDDK]).

3. 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.

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

In addition, the Networks 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.

ATTACHMENT D

SECTION F - DELIVERIES OR PERFORMANCE

F.1 PERIOD OF PERFORMANCE

The period of performance is:

Base Year: July 1, 2006 - June 30, 2007
 Option Year 1: July 1, 2007 - June 30, 2008
 Option Year 2: July 1, 2008 - June 30, 2009

F.2 OPTION TO EXTEND THE TERM OF THE CONTRACT (FP)

This contract may be extended for two (2) additional years at the option of the Government. In the event the Government intends to exercise an option year, no formal notification will be provided to the contractor; a unilateral modification will be issued.

F.3 SCHEDULE OF DELIVERABLES

The Network shall submit all required reports and deliverables in accordance with the following schedule **unless otherwise specified by CMS**.

Electronically = ELT Quantity = QTY
 Hard copy = HC

Item	Description	QTY/Recipients	Delivery
1.	The absolute percentage of prevalent patients using AV fistula increased _____% over the fourth quarter 2005 DASHBOARD data. CONTRACT SPECIALIST TO FILL IN BLANK	<i>1 HC or ELT to A</i>	March 31, 2007
2.	Network activities in VA and Breakthrough Initiative reported in the Quarterly QI Status Reports as specified in C.3.B.1 Task 1.a. and C.3.D.1 Task 3.g	1 ELT and HC to A 1 ELT and HC to B	15 working days after the beginning of each calendar quarter

3.	Quality Improvement Work Plan as specified in Section C.3.B.1. Task 1.e.	1 ELT and HC to A	60 calendar days after the beginning of the contract year, unless directed by CMS.
4.	QIP Work Plan reviewed, evaluated and modified as specified in Section C.3.B.1 Task 1.b.	1 HC or ELT to A	Within 60 working days after receipt of facility-specific CPM data.
5.	Network Specific QI Projects as specified in Section C.3.B.1 Task 1.c. and C.3.D.1 Task 3.g.	1 ELT and HC to A	15 working days after the beginning of each calendar quarter.
		1 ELT and HC to B	
6.	Clinical Performance Measures (CPMs) as specified in Task 1.b of C.3.B.1	1 ELT to J or CMS designee	Within 90 calendar days after receipt of patient data sample
7.	CPM Data Validation Sample as specified in Section C.3.B.1 task 1.b	1 ELT to J or CMS designee	Within 120 calendar days after receipt of validation sample
8.	Report on Facility Specific Quality Improvement Projects as specified in Task 1.e of C.3.B.1	1 ELT and HC to A	15 working days after the beginning of the appropriate calendar quarter
		1 ELT and HC to B	
9.	Report on work product of QI activity as specified in Section C.3.B.1 Task 1.d. and e.	1 HC to A	Within 30 days of completion

8.	Report on Educational Information, Technical Assistance Activities, and Resolution of Difficult Situations and Grievances as specified in Section C.3.C.1 Tasks 2.a, 2.b, 2.c, 2.d, and 2.g. and Section C.3.D.1 Task 3.g	1 ELT and HC to A	15 working days after the beginning of each calendar quarter
		1 ELT and HC to B	
9.	Report on Emergency/Disaster Preparedness and Response as specified in Section C.3.C.1 Task 2.e. and Section C.3.D. 1 Task 3.g	1 ELT and HC to A	15 working days after the beginning of each calendar quarter
		1 ELT and HC to B	
10.	Report on Coalition as specified in Section C.3.C.1 Task 2.f. and Section C.3.D.1 Task 3.g	1 ELT and HC to A	15 working days after the beginning of each calendar quarter
		1 ELT and HC to B	
11.	Report on Collaborative activities with State Survey Agencies and Quality Improvement Organizations as specified in Section C.3.D.1 Task 3.e and g.	1 ELT and HC to A	15 working days after the beginning of each calendar quarter
		1 ELT and HC to B	
12.	Quarterly Progress and Status Report on Network's activities as specified in Section C.3.D.1 Task 3.g.	1 ELT and HC to A	15 working days after the beginning of the calendar quarter
		1 ELT and HC to B	
		1 ELT to I	

13.	Annual Report of Network's Activities as specified in Section C.3.D.1 Task 3.g.	1 HC to A	Final due to the PO by July 1 of each contract year and to CMS CO and Coordinating Center within 2 weeks of approval by PO. Publication on web site within 90 days after approval by PO
		1 HC to B	
		1 ELT to I	
14.	Quarterly status reports of USRDS support activities as specified in Section C.3.D.1 Task 3.g	1 ELT and HC to A	15 working days after the beginning of the calendar quarter
		1 ELT and HC to B	
15.	Corrections to the National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services, Dialysis Facility Compare, and ESRD Provider Public Use File as specified in Section C.3.E.1 Task 4.b	1 ELT to F	Within 30 calendar days of CMS' request
16.	ESRD Facility Survey (CMS-2744) as specified in Section C.3.E.1 Task 4.c	1 ELT to F	5th working day of April
17.	ESRD Medical Evidence Reports (CMS-2728) as specified in Section C.3.E.1 Task 4 c	1 ELT to F	Daily or no later than 15 working days of receipt
18.	ESRD Death Notification (CMS-2746) as specified in Section C.3.E.1 Task 4.c	1 ELT to F	Daily or no later than 15 working days of receipt

19.	ESRD Facility Survey Corrections (CMS-2744) as specified in Section C.3.E.1 Task 4.c.	1 ELT to F	3 rd Friday in May
20.	ESRD Data Forms Submission Compliance Rates Notifications and Summaries as specified in Section C.3.E.1 Task 4.f	1 HC to A	15 th working day in October for Facilities that failed to maintain the semi-annual compliance rate of 80%
21.	ESRD Data Forms Submission Compliance Rates Notifications and Summaries as specified in Section C.3.E.1 Task 4.f	1 HC to A	15 th working day in April for Facilities that failed to maintain the annual compliance rate of 90%
22.	ESRD Forms Data Discrepancies and Corrections as specified in Section C.3.E.1 Task 4.g	1 ELT to F	Within 60 calendar days of notice.
23.	Notify CMS of Renal Transplants not reported as referenced in Section C.3.E.1 Task 4.h.	1 ELT to F	30 calendar days from the end of the quarter of the transplant event
24.	Current and/or changes to Patient Status of specific ESRD beneficiaries reflected as an event as referenced in Section C.3.E.1 Task 4.i	1 ELT to F	Within 30 days of status change or within 10 working days of receipt of the inquiries

25.	Provide written Contingency Plan detailing roles, responsibilities, process for recovering data and documented procedures for making and safeguarding backup copies of software, operating data, and user data (Business Continuity and Contingency Plan and Template) as referenced in Section C.3.E.1 Task 4	Maintained locally on-site and 1 HC to A	Sept. 1, 2006 and Annually thereafter. Submit complete replacement when changes and/or key personnel occur.
		1 CD to E	
26.	Record daily iterative and weekly full tape backup. Record off-site storage of back-ups and rotation. Back-up and Off-Site Storage Log (Appendix E of Business Continuity and Contingency Plan), as referenced in Section C.3.E.1 Task 4	Maintained locally on-site and 1 HC to A	Monthly review and as required when visited by external personnel.
		1 HC to E Upon request	
		1HC to E upon request	
27.	Complete Remedy ticket assignments within the designated timeframe as referenced in Section C.3.E.1 Task 4	Remedy AR System or as requested by CMS	As assigned to ESRD IT Representative through Remedy AR System
28.	Maintain systems and software to be in compliance with current standard configuration as referenced in Section C.3.E.1 Task 4.	As requested by CMS through Memorandums or Remedy AR System	As Released

29.	QNet System Security Policies Handbook (SSPH) Training and Training Log (Tab A) as referenced in Section C.3.E.1 Task 4	Maintained locally on site by the ESRD Security Point of Contact and 1 HC to A	Before an ESRD employee receives a User Account to access a QNet system/application and annually thereafter as specified by the CMS-OCSQ-ISG QNet Information System Security Officer. Monthly review and as required when visited by external personnel.
		1HC to E upon request	
30.	Signed QNet Security POC Site Compliance Letter as referenced in Section C.3.E.1 Task 4	Notarized letter provided to the CMS-OCSQ-ISG QNet Information Systems Security Officer and CMS Contract Specialist	Sept. 1, 2006 and Yearly thereafter as specified by the CMS-OCSQ-ISG QNet Information System Security Officer
31.	Sign in log for visitors as referenced in Section C.3.E.1 Task 4	Maintain locally on-site and 1 HC to A	As required when visited by external personnel
		1 HC to E upon request	
32.	List of current Active users accounts with access roles/privileges identified and a log of deactivated users as	Maintain locally on-site and 1 HC to A	As required when establishing or changing user access and when a user

	referenced in Section C.3.E.1 Task 4	1 HC to E upon request	leaves the organization. Monthly review as required and when visited by external personnel.
33.	Records of incident response (QualityNet Security Policies Handbook) as referenced in Section C.3.E.1 Task 4	Maintain locally on-site and 1 HC to A	Monthly review and as required when visited by external personnel. As required when a security incident occurs.
		1 HC to E	
34.	Update Remedy inventory for all procured and received IT equipment (hardware and software) as referenced in Section C.3.E.1 Task 4	Remedy AR System or as requested by CMS	As required, when hardware/software equipment is received
35.	HHS-22 submission as referenced in Section C.3.E.1 Task 4	1 HC to L	When hardware/software equipment is transferred and/or retired/disposed
36.	Subcontracting Report, SF-294, as specified in Section G.11 of the contract	1 HC to D	SF-294, semi-annually, 30 days after close of period
		1 HC to G1	
37.	Subcontracting Report, SF-295, as specified in Section G.11 of the contract	1 HC to G2	SF-295, annually, 30 days after close of period

38.	ESRD Network Semi-annual Cost Reports submitted electronically per Sections C.3.D.1 Task 3.c. & H.5	1 ELT to A 1 ELT to H	#1 due February 23, 2007 for reporting period July 1, 2006 through December 31, 2006. #2 due August 20, 2007 for reporting period January 1, 2007 through June 30, 2007. #3 due February 22, 2008 for reporting period July 1, 2007 through December 31, 2007.
			#4 due August 19, 2008 for reporting period January 1, 2008 through December 31, 2008. #5 due February 22, 2009 for reporting period July 1, 2008 through December 31, 2008. #6 due August 20, 2009 for reporting period January 1, 2009 through June 30, 2009.
39.	DHHS Form 565, Report of Accountable Property	1 HC to D	Annually - due October 31st
		1 HC to L	

RECIPIENT KEY:

- A.** CMS Regional Office Project Officer (Regions I, VI, VII, or X)
- B.** Centers for Medicare & Medicaid Services
Attention: Mary King
Office of Clinical Standards and Quality
Quality Improvement Group
Division of Quality Improvement Policy
for Chronic & Ambulatory Care
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone # (410) 786-9644
E-mail: mary.king@cms.hhs.gov
- C.** Centers for Medicare & Medicaid Services
ESRD Expenditure Monitoring Team
Attention: Rachel Nelson
Office of Clinical Standards and Quality
Quality Improvement Group, Division of Operations and Support
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone # (410) 786-1175
E-mail: Rnelson@cms.hhs.gov
- D.** Centers for Medicare & Medicaid Services
Attention: Dorothy Parker, Contract Specialist
OAGM, Medicare Contracts Group, Division of Quality Contracts
Mail Stop C2-21-15
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone # (410) 786-**5779**
E-mail: dparker2@cms.hhs.gov

- E.** Centers for Medicare & Medicaid Services
Attention: Michael Blake
CMS QualityNet Information Systems Officer
Office of Clinical Standards and Quality
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone # (410) 786-7240
E-mail: michael.blake@cms.hhs.gov
- F.** Electronically Replicated to the CMS Central Repository
- G1.** Small and Disadvantaged Business Utilization Specialist
OOM, AGG
Attention: **Sharon McKinney**
Centers for Medicare & Medicaid Services
Mail Stop C-2-21-15
7500 Security Boulevard
Baltimore, Maryland 21244-1850
Phone # (410) 786-5162
E-mail: Smckinney@cms.hhs.gov
- G2.** Attention: Linda Purnell
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200 Independence Avenue, SW
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Phone # (202) 690-7300
E-mail: Linda.Purnell@HHS.GOV
- H.** Electronically to esrdnwreports@cms.hhs.gov
- I.** Forum of ESRD Networks
Attention: Janet Crow, Administrator
1527 Huguenot Road
Midlothian, VA 23113
E-mail: jcrow@forum.esrd.net

J. Centers for Medicare & Medicaid Services
Attention: **Diane Frankenfield**
Office of Clinical Standards and Quality
Quality Measurement and Health Assessment Group
Division of Acute and Chronic Disease Management
Mail Stop S3-02-01
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K. Reserved

L. CMS Property Management Officer
Attention: Diane Jones
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Phone # (410) 786-3346
E-mail: Djones2@cms.hhs.gov

F.4 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

52.242-15 STOP WORK ORDER (AUG 1989)

F.5 ACCEPTANCE OF DELIVERABLES

All required contract deliverables shall be reviewed by the Project Officer to determine acceptance. The Project Officer will respond, in writing, within 45 days of receipt of any contract deliverable indicating if final acceptance has been granted. If deficiencies in Contractors' deliverable are identified, the Project Officer shall provide feedback to the Contractor prior to the 45-day timeframe for final acceptance. If the Contractor does not receive a written indication from the Project Officer within the 45 days, then the Contractor shall consider the deliverable to be accepted. **The Network is responsible for ensuring the Project Officer is in receipt of deliverables. Receipt can be acknowledged in any form of writing (mail or electronic). The 45-day timeframe begins on receipt of deliverable, not acknowledgment of receipt.**