STATEMENT OF WORK

SECTION C- DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. PURPOSE OF STATEMENT OF WORK (SOW)

The purpose of this Statement of Work (SOW) is to delineate tasks to be conducted by each End Stage Renal Disease (ESRD) Network Organization contractor in support of achieving national quality improvement goals and statutory requirements as set forth in Section 1881 of the Social Security Act and the Omnibus Budget Reconciliation Act of 1986. The term "Network" is used in this SOW to refer to the ESRD Network contractor, which shall be a QIO-like entity. The tasks described in this SOW are intended to align Network activities with the Department of Health and Human Services (HHS) National Quality Strategy (NQS), the HHS Secretary Priorities (the Opioid Crisis, Health Insurance Reform, Drug Pricing, Home ESRD Treatment Initiative (https://www.cms.gov/newsroom/press-releases/hhs-transform-care-delivery-patients-chronic-kidney-disease) and Value-Based Care) and the Centers for Medicare & Medicaid Services (CMS) goals that mirror the Secretary's priorities and other CMS priorities designed to result in improvements in the care of individuals with ESRD.

C.2. CONTRACT PERFORMANCE OBJECTIVES

This section outlines the role of the ESRD Network and how the NQS principles, HHS Secretary's priorities, and CMS goals should be applied to the ESRD SOW.

C.2.1.A. Priorities and Goals

The Network shall promote positive change relative to Secretary's priorities and CMS goals. The HHS Priorities are interpreted for purposes of this SOW as:

- **Priority 1: Opioid Crisis**
- **Priority 2: Health Insurance Reform**
- **Priority 3: Drug Pricing**
- **Priority 4: Value-Based Care**

The CMS Goals found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/CMS-RTC-Quality-Measurement-March-1-2019_508.pdf are interpreted for purposes of the SOW as:

- **Goal 1:** Empowering patients to make decisions about their health care
- **Goal 2:** Increasing state flexibility
- **Goal 3:** Developing innovative approaches to improving quality, accessibility & affordability
- **Goal 4:** Improving the customer experience

The quality improvement activities in the contract may incorporate one (1) or more of the Secretary's priorities. To substantively support these priorities and goals, the Network may need to deploy interventions that target patients, dialysis/transplant providers, other providers, and/or other stakeholders.

The Network shall incorporate a focus on disparities in conducting all of the activities outlined in this SOW. In each quality improvement activity (QIA), the Network shall analyze data and

implement interventions aimed at reducing disparities. All QIAs shall use innovative approaches and rapid cycle improvement that incorporate boundariliness, unconditional teamwork, are customer-focused and sustainable to achieve the strategic goals of the ESRD Network Program.

C.2.1.B CMS Roles

Contracting Officer's Representative (COR): an individual, designated and authorized in writing by the Contracting Officer to perform specific technical or administrative functions including acknowledgment, acceptance and/or approval of deliverables.

CMS Subject Matter Expert (CMS SME): an individual who may assist the COR. The CMS SME will assist the COR by:

- Providing comments on deliverables to the COR for incorporation into comment back to the Network
- Planning and convening workgroups, LAN calls, and CoP calls
- Attending monthly progress calls with the Network at the invitation of the COR

C.2.2.A Role of Network

The Networks are critical to achieving bold CMS goals for healthcare transformation and the aims of NQS, the HHS Secretary's priorities, and CMS goals.
The successful Networks shall be patient care navigators and lead transformation by:

- Serving as conveners, organizers, motivators, and change agents;
- Leveraging technology to provide outreach and education;
- Serving as partners in quality improvement with patients, practitioners, healthcare providers, other healthcare organizations, and other stakeholders;
- Securing commitments to create collaborative relationships with other stakeholders and partners
- Achieving and measuring changes at the patient level through data collection, analysis, and monitoring for improvement;
- Disseminating and spreading best practices including those relating to clinical care, quality improvement techniques, and data collection through information exchange; and
- Participating in the development of a CMS national framework for providing emergency preparedness services for the ESRD community.

The Network is uniquely positioned to ensure full participation of the ESRD community in achieving the aims of the NQS, HHS Priorities, and CMS Goals. Therefore, this SOW emphasizes:

- Network relationship with ESRD patients
    - Ensuring representation of ESRD patients in shared decision making related to ESRD care in order to promote person-centeredness and family engagement
    - Protecting ESRD patients' access to and quality of dialysis care, especially among vulnerable populations

- Network relationship with ESRD facilities
    - Identifying opportunities for quality improvement at the individual facility level and providing technical assistance
    - Promoting all modalities of care, including home modalities and transplantation, as appropriate, to promote patient independence and improve clinical outcomes
    - Facilitating processes to promote coordination between care settings
    - Ensuring accurate, complete, consistent, and timely data collection, analysis, and reporting by facilities in accordance with national standards and the ESRD Quality Incentive Program (QIP). This also includes the submission of Master Account Holder information for all new facilities to the ESRD Network.
- Coordination and sharing across 18 Networks
    - Using standardized procedures to collect data and address grievances to promote consistency across Networks
    - Collaborating to share information, such as data on patient migration, across Networks to promote care coordination
    - Coordinating with regional Quality Innovation Network-Quality Improvement Organizations (QIN-QIO), Clinician Quality Improvement Contractors (CQIC) and Hospital Improvement Innovation Networks (HIIN), as well as other recognized subject matter experts in the quality improvement field.
    - Sharing information to promote care coordination for ESRD patients
    - Sharing best practices to improve quality of care for ESRD patients, including Network involvement in Learning and Action Networks (LANs)
- Network acting on behalf of CMS
    - Conveying information from CMS to facilities on HHS and CMS goals, strategies, policies, procedures, and initiatives, including the ESRD QIP
    - Maintaining integrity of information and tone of messaging consistent with CMS expectations for entities acting on behalf of the agency
    - Interpreting and conveying to CMS or its designee information relevant to the ESRD healthcare system to assist with monitoring and evaluation of policy and program impacts, including the effects of the ESRD QIP.

C.2.2.B. Network Activities:
The Network staff shall continue several specific functions through the base and four (4) option years (OYs) of the contract. The Network shall conduct patient engagement activities through the Patient and Family Centered Care (C.3.21.) and Patient Experience of Care (C.3.22) sections

of the contract. These activities shall include, but shall not be limited to:

1) Selection of a diverse group of 15 Patient Subject Matter Experts (SME), and integration of these individuals into, all of the quality improvement activities (QIAs);
2) Conduct Patient Engagement at the Facility Level;
3) Processing of grievances and access-to-care issues;

A major function of the Networks shall be to conduct a number of QIAs.

With COR/CMS ESRD Team Lead approval, Networks may initiate local, needs-based QIAs, aside from those listed in this contract. The Network shall provide the COR/CMS ESRD Team Lead with the Full QIA Form (J-7 Quality Improvement Activities) for Network proposed QIAs by January 31st of each contract year and once approved submit updates to the COR by the 2nd business day of each quarter.

Unless otherwise specified, evaluation for each of the contract specific QIA shall be based on achievement of results reported in the October Dashboard. Beginning in option year 2 for option year 3 and in option year 3 for option year 4, the Network shall revise the QIA plan using the QIA Short Form (Attachment J-7), re-assess the participants in the QIAs, and identify potential new facilities or populations to replace those that have achieved success (i.e., those that have achieved the QIA goal) by October 31st (this is not required for option year 4). This will support the Network incorporating rapid cycle improvements from the current contract year into the QIA plan and provide a more seamless transition between contract years.

Additionally, the Network shall conduct all SOW-required activities to support CMS-designated data systems (e.g. CROWNWeb, National Healthcare Safety Network (NHSN), and Patient Contact Utility) and utilize such systems to support the patient services and quality improvement functions of this contract.

C.3. GENERAL REQUIREMENTS

C.3.1. Compliance

The Network shall comply with all requirements outlined in this SOW, all additional instructions from CMS, and all relevant statutory and regulatory requirements.

C.3.2. Independence

The Network, acting independently and not as an agent of the federal government, shall furnish the necessary personnel, materials, services, facilities, and supplies (except as otherwise specified in the contract) and otherwise do all things necessary for, or incident to, the performance of work as set forth by this SOW.

C.3.3. Organizational Structure

The ESRD Network shall establish an organizational structure that supports the Network's operations and meets all statutory requirements. The corporate structure shall include at minimum a Network Council, Corporate Governing Body (CGB) (e.g., Board of Directors), Medical Review Board (MRB), and Patient Advisory Committee. The Patient Advisory Committee may be comprised in part or whole by the 15 patient SMEs denoted in section C.3.21.

The Network shall have a designated Executive Director. The Network shall provide an updated listing of Network Council members, CGB members, and MRB members to the COR by the last business day of December of the base contract year and within 10 days of any changes. The Network shall continue to provide a list of PAC members annually at the same time SMEs are selected by December 15th of each option year. The Executive Director shall devote sufficient time to the Network to ensure satisfactory performance of the contract. The Executive Director shall ensure the appropriate staff hours and staff expertise to ensure satisfactory completion of the contract. The Network shall employ a full-time Registered Nurse (RN) with nephrology experience, and a full-time Master of Social Work (MSW)-level Social Worker with experience in case review. The Network shall maintain on file all CMS-furnished ESRD Network Nondisclosure Statements signed by all Network employees and affiliates.

The Network shall disclose all actual, apparent, and potential conflicts of interest to the Contracting Officer during the term of the contract. The Network shall have programs in place to identify, evaluate, and mitigate all actual, apparent, and potential conflicts of interest that preclude, or would appear to preclude, the Network from rendering impartial assistance or advice on work performed under the Network contract.

No member of any Network board, council, committee, or subcommittee may review the ESRD services of a provider in which he or she has a direct or indirect financial interest, as described in §1126(a) and (b) of the Social Security Act; with which he or she has or had any professional involvement; from which he or she has received reimbursement; or to which he or she has supplied goods. See §1881(c) (1) (C) of the Social Security Act.

C.3.3.A. Network Council
The Network shall establish and maintain a Network Council that meets the statutory requirements of §1881(c) of the Social Security Act. The Network Council shall:

- Be composed of individuals representing renal dialysis and transplant centers located in the Network service area;
- Be representative of the geographic distribution and types of dialysis facilities and transplant centers in the Network service area;
- Include at least two dialysis and/or transplant patients receiving services in the Network service area who are representative of the geographic and cultural diversity of the communities served by the dialysis and transplant centers in the Network service area.

At minimum, the Network Council shall meet at least once a year in person, by teleconference, or by electronic communication to provide input into the activities of the Network and serve as a liaison between the Network and ESRD providers.

C.3.3.B. Corporate Governing Body
The Network shall establish a Corporate Governing Body that sets overall policy and direction for the Network and retains oversight responsibility. The CGB must comply with Section H.20 of this contract.

The CGB shall have the following:

- A stated number of members which shall consist of an odd number with a minimum of 3 members but no more than 15 members;
- Members may also be members of the Network Council, if appropriate;
- Shall have at least one patient representative as a member;
- Majority of the CGB shall not represent one facility/organization. The CGB shall represent the overall community the Network serves by having members that represent a variety of facilities/organizations, if practical.
- Majority of the CGB shall not be employees of the Network;
- Majority of the CGB shall not be physicians who primarily focus on renal disease;
- Limit individual membership to two consecutive CGB appointments. A former member may be reappointed after one three-year absence from the CGB
- Membership appointments shall be staggered such that a fraction of the total members is reappointed/elected each year (e.g., 9 total members; one set of 3 appointed for 1 year, a second set of 3 for 2 years and a third set of 3 for 3 years. Thereafter, each set of 3 serves 3-year terms.)
- Each Network shall maintain a separate and independent CGB. Separate and independent is defined as:
    - voting members cannot serve on a CGB for more than one Network; and
    - voting members cannot have a financial relationship with the Network, either directly or indirectly, with the exception of a stipend to attend CGB meetings.
- Each Network's CGB shall hold separate CGB meetings. This will allow each individual Network CGB to make decisions based solely on the requirements of the SOW and jurisdictional needs of the individual Network community.
- CGB shall not perform in such a way as to contradict federal or state laws or regulations.

The Network shall:

- Specify the number of members on its CGB,

- Establish the responsibilities of the governing body and delineate these in bylaws that are reviewed annually and updated as necessary. These responsibilities of the CGB shall include, at minimum:

    - Attendance and participation with at least two-thirds of voting members in participation at each meeting;

    - Each Network CGB shall hold separate meetings as outlined above;

    - Membership appointments shall be established as outlined above;

    - Participation in an ongoing training program that addresses ethics, compliance with CMS goals, cultural competence and healthcare disparities;

    - Other relevant topics; and participation in one or more subcommittees of the

CGB;

- Establishing committees and subcommittees to support the CGB, as deemed necessary by the CGB;

- Specifying in writing the roles and responsibilities of the CGB and its committees and any subcommittees, including the relationship of the CGB with its committees and any subcommittees;

- Documenting committee meetings, decisions, and actions;

- Publishing on its website information identifying CGB members including those serving on any committees and subcommittees. The published information should include at minimum:

    - Number of members;
    - Length of appointment for each;
    - Term limitations;
    - When appointments are made;
    - What percentage of CGB is typically appointed each year; and
    - Names, affiliations, and compensation (unless prohibited by state law) of members.

The membership of the CGB shall consist of ESRD stakeholders from the Network's service area. The patient members shall be representative of the diversity of the ESRD population in the Network service area including, but not limited to, diversity in treatment modality, race/ethnicity, education, economic status, gender, rural/urban residence, and other relevant factors to the extent possible.

The Network shall adopt policies ensuring the diversity of the non-patient CGB members. To the extent possible, the non-patient members of the CGB shall include representatives from the various healthcare settings relevant to the ESRD population (e.g., dialysis facilities, transplant centers, hospitals, and nursing homes) and from a range of professional disciplines as well as individuals from diverse racial/ethnic and socioeconomic backgrounds and individuals with non–healthcare backgrounds.

The CGB shall meet as necessary to ensure the successful operation of the Network. At minimum, the CGB shall meet at least semi-annually in-person, by teleconference, or by electronic communication. In addition, the Executive Committee (EC) of the CGB shall meet as necessary to ensure the smooth operation of the activities of the CGB.

At minimum, the CGB or its EC shall:

- Supervise and be responsible for the performance of Network staff in meeting SOW requirements and deliverables and responding to any CMS requests;
- Supervise and be responsible for the financial operation of the Network, including the IQI

Program, as detailed in Section C.3.19. of this SOW;
- Review and approve the Annual Report prior to submission to the COR;
- Approve requests for modifications to the Network's contract that involve requests for additional funding and/or staffing;
- Review and approve any recommendations from the Medical Review Board (MRB) for sanctions to be imposed on ESRD facilities prior to submission to CMS.

C.3.3.C. Medical Review Board

The Network shall establish a committee that meets the statutory requirements of §1881(c) of the Social Security Act to function as the Network's Medical Review Board. The MRB shall be composed of at least two patient representatives, as well as representatives of the professional disciplines engaged in ESRD care. The professional representatives shall include one or more individuals from each of the following: nephrologists, vascular and transplant surgeons, registered nurses with experience in the care of patients with kidney disease, dietitians, and social workers. MRB members shall be qualified to evaluate the quality and appropriateness of care delivered to patients with ESRD.

The MRB shall meet at least semi-annually. Meetings shall be held in-person, by teleconference or by electronic communication.

The functions of the MRB shall include the following:

- Serving as an advisory panel to the Network on the care and appropriate placement of ESRD patients on dialysis in the Network service area;
- Set standards regarding physician management of patient discharges that encourages all patients be maintained in consist dialysis care regardless of patient adherence;
- Serving as an advisory panel for all Network QIAs;
- Assisting Network staff in the development, implementation, and evaluation of all QIAs; and
- Working with Network staff to recommend sanctions to CMS for dialysis facilities when the criteria for a sanction recommendation are met.

C.3.3.D. Patient Advisory Council

The Network shall establish a Patient Advisory Council (PAC) consisting of at least 15 patients/caregivers/family members. At least 1 member of the PAC shall be a caregiver/family member directly associated with an ESRD patient.

To the extent possible PAC members shall be representative of the diversity of the ESRD population in the Network service area including, but not limited to, diversity in treatment modality, race/ethnicity, gender, education, economic status, rural/urban residence, and other relevant factors. PAC members shall be at least 18 years of age, and may be any patient or a caregiver or family member directly associated with an ESRD patient. The PAC may establish one or more PAC committees and/or subcommittees, with PAC members able to serve on more than one committee or subcommittee. PAC Members may also serve as Patient SMEs. The PAC shall meet at least semi-annually and with enough frequency to provide input to fulfill the

designated functions of the PAC. The meetings shall be held by teleconference or by electronic communication.

The Network may elect to include applicants outside of those selected to participate as a SME, to participate on the Network PAC. The Network shall submit a list of the minimum of 15 selected PAC Members to the COR by the 15th business day of December of each contract period.

The functions of the PAC include, but are not limited to:

- Providing input into the development of informational and educational materials for patients and families/caregivers;
- Offering a patient perspective on the selection and development of Network QIAs for which patient engagement is required;
- Offering a patient perspective to the Network in the development of interventions and in interpreting the results of all Network QIAs.

C.3.3.E. Other Committees and Subcommittees
The Network shall establish other committees or subcommittees as appropriate to meet the requirements of the SOW. To the fullest extent possible, the membership of these committees/subcommittees shall represent the diversity of the patient and practitioner communities.

C.3.3.F. Network Staff
The Network shall employ sufficient staff to perform the work requirements of the SOW. At minimum, the staff shall include:

- Key Personnel: The Executive Director, who is responsible (under the general direction of the CGB) for the overall management, supervision, and coordination of contract requirements, including meeting deliverable due dates. Specifically, the Executive Director is responsible for the program development, business and fiscal management, oversight of the IQI Program, staffing (including staff training, hiring, and firing), and liaison with Network committees, CMS, the State Survey Agency(ies) in the Network's service area, the QIO(s) in the Network's service area, and other renal-related agencies/organizations.
- Sufficient support staff (including a full-time Registered Nurse with nephrology experience, a full-time MSW-level Social Worker with case review experience, and other personnel with experience in program planning and implementation, data analysis, and evaluation) to conduct the activities and responsibilities outlined in the Network's contract and in other CMS directives.

The Network shall require all employees to sign CMS-furnished ESRD Network Nondisclosure Statements and maintain a file of all signed forms. A copy of the Network Staffing Plan shall be provided to the COR by COB the last business day of December of option year 3 and within 10 days of any changes for future option years.

C.3.4. Communication Requirements
The Network shall work with patients and providers in its service area to improve the quality of

care and quality of life of ESRD patients by providing informational material and technical assistance on ESRD-related issues. All Network correspondence to patients and to providers for distribution to patients shall be clear, concise, well-organized, and easily understood on the first reading by readers who are literate in English, regardless of functional or health literacy status and professional or academic background. Materials shall be appropriately translated for non-English speakers, as applicable. In addition, all Network correspondence to patients and facilities for distribution to patients shall contain the following language: "*To file a grievance, please contact* [insert Network name] *at* [insert Network phone number, e-mail address, mailing address, and website URL]*."*

The Network shall perform the following functions:

- **Maintain a national user-friendly, toll-free telephone number:** The Network's toll-free number shall be answered by a staff person during normal working hours. After hours, the system shall allow messages to be left. Systems shall be in place to ensure that a Network staff member can be reached by telephone in the event of an emergency or disaster by patients, dialysis or transplant center staff. During emergency or disaster the Network shall maintain and use the communication system agreed upon with KCER.
- **Maintain a Network website:** The Network website must be Section 504 and Section 508 compliant and follow all CMS standards and guidelines. The Network website shall include, at minimum: a description of the Network grievance processes; a list of the Network's goals as indicated by this contract and developed by the MRB; the Network's most recent Annual Report; a link to the Dialysis Facility Compare website (http:www.medicare.gov/dialysis); information about the availability of material in alternate formats as required by Section 504; information on all Network committees, including information on how to become a member of each committee; a link to the ESRD QIP site and other specified federal websites as directed by CMS; and, in the event of an emergency or disaster, the open and closed status of providers and other information to assist patients and providers.
- **Cover letter for the New ESRD Patient Orientation Package (NEPOP):** The Network shall provide the NCC with Network letterhead by the last business day of December of option year 3 and within 10 days of any changes for future option years for a standardized letter drafted by the NCC.

- **Investigate and resolve situations in which NEPOPs are undeliverable:** Using an IQI process, the Network shall track the error rate for distribution of the packet on initial mailing, and report on these activities monthly to the NCC. In collaboration with the NCC develop strategies to decrease the undeliverable rate.

- **Provide educational information:** The Network shall report monthly all education activities on the COR Monthly Report. The Network shall provide information on the following:

  - The educational materials provided during the month of reporting;

  - How the Network determined that education activities were effective, including

the results of that assessment;

- What educational materials are planned for the following month

The process for distributing informational material shall be based on data driven assessment of the specific needs of the ESRD patient population in the Network's service area. The Network shall use a data driven IQI process to determine the need for educational/informational materials for its community, determine the most effective method of distribution for each type of material, and evaluate the overall effectiveness of the materials and the method of distribution.

To the extent possible and practical, the Network shall utilize information that is already available through CMS, other CMS contractors (e.g., other Networks, the ESRD NCC, QIOs), other federal agencies, renal partners (e.g., renal advocacy groups, provider groups, and provider associations), and other sources. As applicable, the Network shall utilize the PAC and Network Council in fulfilling these requirements. Educational/outreach materials must include information on:

- The role of the ESRD Network;
- To facilities and patients regarding the definition of a grievance. See Attachment J-8 Grievance and Patient Appropriate Access to Care.
- To facilities on what constitutes a robust internal process for anonymous grievances to include date of incident, staff involved, description of incident, and any witnesses; and the process in which the grievance can be submitted to maintain anonymity.
- The Network's process for receiving, reporting, resolving, and tracking patient grievances;
- The Network's role in facilitating patients' access to care;
- Treatment options and new ESRD technologies available to patients, with an emphasis on those that have been shown to support patient independence (e.g., transplantation, home therapies, in-center self-care);
- Information to educate facilities/patients on the actions to take during emergency and disaster situations;
- Information to educate and encourage patients to achieve their maximum level of rehabilitation and to participate in activities that improve their quality of life (e.g., vocational rehabilitation programs, Employment Networks, volunteerism);
- Contact information for state/regional vocational rehabilitation programs and Employment Networks available in the Network's service area;
- Information on vascular access procedures;

- The Network's toll-free number, mailing address, and website address;
- Information on how to access and use the Dialysis Facility Compare website;
- Information on how to interpret a facility's ESRD QIP Performance Score Certificate;
- Information on all Network committees, including information on how to become a member of each committee;
- Information on the importance of receiving vaccinations (including hepatitis B, influenza, and pneumococcal vaccinations) and information related to the importance of disease management, the Welcome to Medicare Physical, heart-healthy living, diabetes self-management, and (if requested) smoking cessation; and
- Information on the benefits of the Medicare Prescription Drug Program (Medicare Part D), how to enroll, and any other guidance or materials related to this program of specific benefit to the individual with ESRD, as directed by CMS.
- Information regarding the Opioid Crisis, specifically information on the risks of opioid use and education regarding alternative pain management techniques.

In all written communications for internal and external audiences, the Network shall comply with the required guidance in Attachment J-2, Style Guide for the ESRD Network Program. The Network's internal audience consists of Network staff members and members of Network Boards and committees. External audiences include ESRD patients, family members and other caregivers, physicians and other practitioners, dialysis facilities and other providers, Network subcontractors, CMS, other federal and state agencies, and other members of the renal community.

C.3.5. Data Confidentiality and Disclosure

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

- Section 1160 of the Social Security Act;
- 42 Code of Federal Regulations (CFR) Part 480;
- 45 CFR Parts 160 and 164, as they pertain to "oversight" agencies;
- Section H of this contract;
- All J Attachments to this contract;
- The QNet System Security Policy Handbook; and
- Other administrative directives.

The ESRD Network shall notify the COR of any requests for data coming from entities not specified by the contract. If the request is from a researcher, the researcher shall be referred to the Research Data Assistance Center (ResDAC), CMS.gov, United States Renal Data System

(USRDS), and Dialysis Facility Reports (DFR). The ESRD Network shall not enter into or submit to a COR a request to share CMS data with anyone who is not listed in the ESRD Network contract.

The ESRD Network may provide the Corporate Governing Body (CGB) and Medical Review Board (MRB) with Protected Health Information (PHI) and Personally Identifiable Information (PII) to perform duties as described in the ESRD Network contract. If a member of the CGB or MRB requests data to perform research, the process for a researcher would be followed. The CGB or MRB member would need to request access to the data through the ResDAC process. The CGB or MRB member should be referred to CMS.gov, United States Renal Data System (USRDS), and Dialysis Facility Reports for the purposes of journal article development. Data used in journal articles must meet the cell suppression policy.

The National Healthcare Safety Network (NHSN) is a Center for Disease Control and Prevention (CDC) healthcare-associated infection tracking system. The ESRD Network shall only use the data in the NHSN system as directed by the contract, including providing aggregate data to the ESRD National Coordinating Center (NCC) for contract monitoring purposes. The ESRD Network shall not share the data contained within the NHSN system with any outside entity without approval from the Contracting Officer as described at Section I – Contract Clauses, subsection I.1 – Clauses Incorporated by Reference of the contract. The ESRD Network shall provide notification to and receive expressed consent from every ESRD facility within the group if the data disclosure is approved by the Contraction Officer. The CGB and MRB shall have access to data from the NHSN data system to perform the duties described in the ESRD Network contract.

If the Network has a request by a state agency to provide data related to certificate of need or a request by a grantee or contractor for a federal government agency, the ESRD Network shall request approval to release the data from the Contracting Officer copying the COR on the request. The ESRD Network shall not provide data without the approval of the Contracting Officer.

If the ESRD Network wishes to publish an article, using data from the CROWNWeb system the article would need to be approved by the Contracting Officer. The ESRD Network shall not use any patient-related data for any undertaking outside of those specifically identified in the ESRD Network contract without approval of the Contracting Officer.

C.3.6. Information Collection/Survey Activities

Unless otherwise specified, a Network seeking to conduct surveys or collect data as a part of any of the activities included in this SOW shall do so only with prior approval of the COR and in accordance with the Paperwork Reduction Act, Attachment J-3 of this contract, and other administrative directives. No funds from this contract shall be used for data collection activities not specified in this contract without prior approval from the COR and in accordance with other CMS administrative guidance.

C.3.7. Reporting to CMS and Others

As applicable, the Network shall maintain meeting minutes required for the tasks identified in the SOW and the Schedule of Deliverables (SOD). These minutes shall be available on request

by CMS. As specified in this contract and approved by CMS, the Network may conduct data analysis and produce data reports relevant to the local provider community and/or CMS. The Network shall maintain a repository of all data acquired and reports generated.
The Network shall use CMS-approved templates, if provided, for reporting deliverables outlined in the SOD. The Network shall adhere to all requirements in Attachment J-4, Reporting Requirements, to manage and report work performed under this SOW. The Network shall submit the following reports to the COR for approval:

- **Dashboard:** The Network shall provide any self-reported data requested to support the Dashboard to the NCC for compilation by the 10th working day of the month in the format designated by the NCC. The Network shall not provide data during the month of December because this is the first month of the new contract.
- **Monthly Progress and Status Report:** The Network shall use the CMS-approved template for its monthly reports. The reports shall be submitted three business days prior to the scheduled monthly calls. The reports shall reflect the previous month's activities and data. The Network shall not provide a monthly progress report during the month of December because this is the first month of the new contract.
- **Annual Report:** The Network shall submit to the COR by June 1st and post to the website data by July 1st of each contract year the individual Network performance in meeting contract goals provided by the NCC, indicate any facilities that been sanctioned, and recommendations with respect to the need for additional or alternative services or facilities in the Network. The Network shall only use the data graphs and figures generated by the NCC in the annual report. The Network will limit the report to 2 pages per section to report on each of the following areas the demographic make-up of the Network, grievance and access to care activities, each QIA, recommendations, and significant emergency preparedness activities.
- **Semi-Annual Cost Report:** Each Semi-Annual Cost Report shall be submitted so it is received by CMS no later than close of business on the 15th working day of the second calendar month after the close of each semi-annual cost reporting period. For the final semi-annual period of this contract, the report shall be received by the last business day of November of OY4. For purposes of this requirement, "close of business" is defined as 5pm local prevailing time at CMS Central Office in Baltimore, Maryland, on the due date (Eastern Standard or Eastern Daylight Time, as applicable). For purposes of this requirement, "working days" shall be defined as all calendar days except Saturday, Sunday, and federal holidays as observed by the federal government. The cost information supplied should reflect actual costs incurred for the period, and be supported by Network financial records/general ledger and similar documentation. See also Section F of this contract, Schedule of Deliverables. The Semi-Annual Cost Report template and instructions for use can be found Attachment J-4, Reporting Requirements.

C.3.8. Meetings
The Network shall host, participate in, and attend meetings as directed in this SOW. The Network shall receive CMS approval for all *in-person* meetings (e.g., LAN meetings) prior to January 1 of the year in which the meeting will occur. The Network shall submit title(s), objective(s), and lists of attendees for the annual QualityNet conference, LAN meetings, and/ or

other conferences 30 days prior to scheduled meetings and conferences. ESRD Network meetings shall include, but are not limited to, the following:

- Contract post-award teleconference with OAGM within 30 days of the beginning of the base year and with the Network COR each subsequent optional year unless instructed by OAGM.
- Monthly meetings with the COR. The meeting shall address each QIA of the SOW, as presented on the COR Monthly Report (see Attachment J-4), progress in complying with Section F, Schedule of Deliverables, and other contract requirements, and shall include a review of the Network IQI Plan. The IQI Plan and progress updates shall be provided to the COR electronically to allow for a WebEx-based and or video meeting in which the COR is able to see the Network's progress if requested by the COR.
- Every other month teleconference meeting with the State Survey Agency. The Network shall prepare an agenda and meeting minutes for each meeting, soliciting agenda items from all participants (surveyors, Network staff, CMS staff, and patient representative when appropriate) prior to the meeting.
- The annual QualityNet Conference or another CMS quality meeting(s) designated by CMS as requiring in-person Network participation. Network staff are expected to participate in QualityNet meetings as presenters and/or conveners of learning sessions as directed by CMS.
- National meetings related to Network task areas requiring Network attendance and participation as directed by CMS.
- Meetings related to the ESRD QIP as directed by CMS.
- ESRD Executive Office Hour calls every other month
- ESRD QIIG Leadership calls every other month
- Other national meetings as specified in this SOW or as directed by CMS.

In addition, the Network shall participate in a QIN-QIO LAN if it advances the Network's ability to advocate for better coordinated care and improved quality of care for ESRD patients in the QIN-QIO's jurisdiction. The Network shall report its involvement with its QIN-QIO counterpart(s) in the Monthly Progress and Status Report where appropriate.

C.3.8.A. SUPPORTING LEARNING AND ACTION NETWORKS

The Network shall support the NCC Learning and Action Networks (LANs). The Network shall a) actively promote the NCC LANs to all facilities within the Network service area, b) identify facilities in the Network QIA or that would benefit from the LAN topic to target for participation; c) actively engage with local and/or regional independent or corporate facility leadership to identify facilities that excel at the LAN topic area:

a. Bring different stakeholder perspectives to the LAN by building diverse communities that include perspectives from:
    1) Patients, non-professional caregivers and informal and formal support providers including dialysis technicians;
    2) Practitioners, providers, and healthcare professionals of all credentials and scopes of practice; and

3) Institutions that represent the collective perspectives of clinical, community, and business interests within the Network service area.

b. Communicate in a manner that encourages LAN members to behave in ways that align with the desired outcomes for the Network Program by using principles of change management. These principles are intended to move targeted audiences from a current to a future state in ways that are most efficient, sustainable and actionable.

C.3.8.B. RESULTS-ORIENTED LEARNING AND ACTION NETWORKS

If required under a specific QIA or area, the Network shall participate in the appropriate NCC LANs. LANs shall be designed with action-based agendas to guide quality improvement efforts to: 1) improve healthcare for ESRD patients; 2) promote a collective change motivated by goals, patient stories, shared values; and 3) establish a call to action that will build enthusiasm around the will for change. Networks shall use their role as change agents to support their designated service area quality improvement efforts by inviting participants that shall include, but may not be limited to: patients and caregivers, patient SMEs, providers, practitioners, state/local/regional stakeholders, and other constituents with shared values.

LANs are mechanisms by which large scale improvement around a goal is fostered, studied, adapted, rapidly spread and sustained regardless of the change methodology, tools, or time-bounded initiative that is used to achieve the goal. LANs engage communities around an action based agenda that gains commitment(s) towards the achievement of person-centered outcome-based goal(s).

At a minimum, the Network shall support the NCC LAN in the following ways:

a. Seek a diverse constituency, including patients, organizations, and stakeholders to consciously manage knowledge and create an open and unassuming forum for addressing specific problematic issues to be addressed by ensuring the invitation to the LAN activity by the NCC is distributed broadly in the Network service area.

b. Operate around measurable and clear goals that utilize proven effective practices, and use data to drive decision-making for tracking and gap assessment.

c. Use a change methodology to rapidly test small quality improvement changes that are specific to the community being worked in.

d. Set the pace and tone for goal-related activity that are fully transparent (including with other Networks) and seek to create a disseminated leadership model where there is a free flow exchange of ideas as well as open sharing of practice and data for the benefit of all.

The Network shall support LAN framework initiatives consistent with known implementation methodologies, such as breakthrough collaboratives, campaigns, spread initiatives, health system engineering and redesign initiatives, community organizing, coaching, and other events that focus on quality improvement.

The Network shall use LANs to launch, perform, spread and sustain momentum towards goal(s). The Network shall be able to support several NCC LANs consecutively and/or simultaneously, as needed. The Network shall perform these activities and/or a combination thereof, as directed by CMS, to support the CMS goals.

The Network shall adhere to the following minimum requirements for supporting the NCC LAN:

a. The elements to support the implementation of these learning sessions shall include, but may not be limited to:

1. Performing pre-work to ensure each session is meaningful and actionable;
2. Disseminating information to teach from and coach facilities to facilitate change in practice, identify barriers to change, and help communities transition to the spread and sustainability of best practices.
3. Support a steering committee from the community to help set the tone for events/sessions;
4. Supporting agenda and content with community and participants actively engaged throughout the LAN and/or learning session (i.e. posting questions to chat or sharing a patient story);
5. Marketing throughout the Network service area to engage a large, diverse population; and
6. Recommending subject matter expert speaker(s).

b. The Network shall actively recruit patients to participate in LANs. The Network shall use the following in targeting patients for recruitment: (1) a cultural competency approach; and (2) collection of data to identify trends and disparities and/or gaps in quality of care provided. Data collected and used for this purpose must be stratified by race, ethnicity, and language proficiency in order to better identify ethnic trends and disparities.

c. The Network shall incorporate Network performance related to the NCC LANs in internal quality improvement by:

1. Setting goals for the spread of the LAN action items
2. Setting benchmarks to assess the interest and implementation of the LAN action items
3. Evaluating progress produce from the implementation of the LAN action items
4. Using and teaching coaching tools to communities within the Network area to facilitate change in practice, identify barriers to change, and help communities transition to the spread and sustainability of successful interventions. For example, the Network may coach a community on how to use a template to highlight phases of improvements (i.e., goal development, plan-do-study-act (PDSA) cycles).

d. The Network shall support the LAN quality improvement efforts Specific, Measurable, Achievable, Relevant, and Timely (SMART) goals that connect to the CMS Goals and the National Quality Strategy.

e. The Network shall track, monitor, and disseminate tested interventions through the development of sustainment and spread plans (included in the QIA plan if applicable). Specific tasks include but may not be limited to:

1. Tracking the status of quality improvement efforts within the cohorts using standardized templates and having this information readily available to share nationally;

2. Using tracking systems to monitor the cohort's progress towards goal(s) for each improvement project; to adapt strategies based on evidence and data; to accommodate changing resources and partners; and
3. Using coaching techniques to identify tested interventions ready for sustainment and providing guidance on spread.

C.3.9. Network Collaborations

C.3.9.A. Collaboration with National Coordinating Center (NCC)

The ESRD NCC functions as a knowledge repository of Network-generated information (including best practices and lessons learned), and performs aggregate data analysis and interpretation of data from the Networks.

The Network shall:

- Assist with the ESRD NCC's knowledge repository and data analysis function by submitting data generated from its activities to the ESRD NCC as specified by CMS;
- Focus its activities based on trends or patterns detected or analyses performed by the ESRD NCC as directed by CMS;
- Participate in the collection and dissemination of best practices and other forms of knowledge transfer.
- Participate in Community of Practice calls and/or workgroup calls as necessary to complete the work of this SOW.

These best practices and information shall be made available to the ESRD NCC as directed by CMS.

C.3.9.B. Collaboration with State Survey Agency/Agencies

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

The Network shall communicate with the State Survey Agency, CMS ESRD Network Program staff, CORs, and Regional Office Survey and Certification staff on a formal basis (at minimum on an every other month basis) and share issues and/or findings related to quality, access to, and coordination of care. The Network must promptly contact the State Survey Agency and coordinate management of a response plan when the issue reported may result in harm to the patient. Whether communication is initiated by the Network or the State Survey Agency regarding facility performance or survey activities, the Network shall keep all information shared during the communication in the strictest confidence. A breach of confidentiality could result in CMS requesting a Performance Improvement Plan (PIP). Communication of information and data related to survey activities by the State Survey Agency is part of the Network contract work. As indicated in the Conditions for Coverage (CfC), 494.180 (a)(3) in the interpretative guidance

"A signed agreement between the facility and the applicable Network is required prior to the initial survey." Based on this the Network shall enter into a signed agreement with facilities prior to an initial survey as requested by facilities, the State Survey Agency, or the Regional Office Survey and Certification staff.

C.3.9.C. Collaboration with CMS Components
The Network is required to work with any identified CMS components as requested to support CMS quality and patient safety goals and priorities.

Collaboration with CMS components shall include:

- Conveying to ESRD providers information from CMS on HHS and CMS goals, strategies, policies, procedures, and initiatives, including the ESRD QIP;
- Maintaining the integrity of information and tone of messaging consistent with CMS expectations for entities acting on behalf of the agency;
- Interpreting and conveying to CMS or its designee information relevant to the ESRD healthcare system to assist with monitoring and evaluating the impact of policies and programs, including the effects of the ESRD QIP.

C.3.9.D. Collaboration with Quality Innovation Networks (QIN-QIOs) and other Quality components
The Network shall coordinate with at least one QIN-QIO in the Network's geographic territory on existing community-based efforts that directly impact dialysis facilities and the ESRD population, and at least one Network staff member shall serve on the local QIN-QIO community coalition. The Network shall support Clinical Quality Improvement Contractors (CQICs) as related to the ESRD SOW. The Network shall support and engage HIIN (Hospital Improvement Innovation Network) as related to the ESRD SOW.

C.3.9.E. Collaboration with ESRD Accrediting Organizations
Title IV, Subtitle A, Sec. 50403 of the law allows dialysis facilities to be certified by private businesses that have been accredited by CMS. There are two (2) accrediting organizations for ESRD as of the writing of this option year of the contract that have been approved by CMS, National Dialysis Accreditation Commission (NDAC) and Accreditation Commission for Health Care, Inc. (ACHC). The Network shall attempt to establish communication with the accrediting organizations on a formal basis (at minimum quarterly basis) and share issues related to quality, access to, and coordination of care. The CMS COR shall be invited to these meetings. The Network shall release the same information to these organizations as they would a state survey agency for survey purposes provided the identity of the requestor can be verified as an agent of the accrediting organization with a need to access the information. The Network shall continue to refer issues that may result in harm to the patient to the State Survey Agency even if the dialysis facility where the incident happened is accredited by one of these organizations. The Network will proceed as directed by the State Survey Agency or the Regional Office for Survey and Certification. The Network shall continue to notify the state survey agency for issues related to access to care. The Network shall refer any inquiries regarding certification or accreditation to the appropriate state survey agency or Regional Office.

C.3.10. Participate in Workgroups

The Network shall participate in workgroup activities related to the four QIAs of the SOW, and may also include, Kidney Community Emergency Response Program (KCER), the ESRD NCC Data Committee, or ad hoc committees or teams as established and agreed upon by the Network and CMS as the Network workload allows.

C.3.11. Recommendations for Sanctions

The Network shall recommend sanctions pursuant to §1881(c) (2) of the Social Security Act and procedures outlined in Attachment J-5, Recommendations for Sanctions. The Network shall conduct a thorough review of a facility reporting more than two Involuntary Discharge/Involuntary Transfers (IVD/IVTs) per month or three IVD/IVTs per quarter to ensure regulatory or statutory compliance and to consider exercising its authority to recommend sanctions.

In addition, the Network shall consider recommending sanctions for facilities that:

- Engage in inappropriate practice patterns;
- Demonstrate a pattern of not accepting the Network's offers of technical assistance;
- Demonstrate a pattern of non-adherence to Network recommendations;
- Do not meet Network-determined benchmarks as required by CMS;
- Do not meet CMS and Network goals relative to clinical performance measures and ESRD QIP measures;
- Have QIAs that do not demonstrate results of continuous quality improvement for those clinical areas with benchmarked standards.

The Network shall report any facilities being recommended for sanctions on the COR Monthly Report and provide the COR detailed documentation that supports the recommendation.

C.3.12. Reporting of Discrimination

If it is suspected that care is being compromised or denied due to discrimination on the basis of race, color, national origin, disability, age, sex, or religion, the Network shall refer the case to the Office for Civil Rights (OCR) for investigation. The Network shall also notify the CMS COR, CMS ESRD Team Lead, and Contracting Officer.

C.3.13. Emergency and Disaster Responsibilities of the Network

The 18 Networks are the foundation of the CMS ESRD emergency management structure. Under the direction of CMS, KCER is the national presence for ESRD-related emergency and disaster response. Each Network shall assign staff to participate in one or more of the KCER committees. The Network shall select two Patient SMEs and/or family members or caregivers to participate on the KCER LAN for the entirety of the contract year. The Network shall encourage and ensure at least 50% attendance of Network staff and patient representatives at required meetings and activities for each year of the contract. The two Patient SMEs shall be included on the list of selected SMEs due to the COR and NCC by the 15th business day of December of each contract period.

Within 45 days of contract award, the Network shall submit an emergency/disaster plan to its COR. The plan shall be based on input from and knowledge of the emergency preparedness

officials in the states within the Network service area, dialysis facility staff, and ESRD patients. Once the plan is approved by the COR, the Network shall submit the approved plan to KCER. The Network shall review the plan annually, revising it as necessary and providing the COR and KCER with the revised document within 10 days of any changes.

Emergency status reporting will be submitted using the KCER Emergency Situational Status Report (ESSR) and its associated Standard Operating Procedure (SOP). The Network is required to provide KCER with complete information regarding facility operational status, using the ESSR, as often as requested by KCER/CMS, but not less than daily. The Network shall invite KCER to emergency status calls held in response to an actual incident or emergency to ensure coordination at the national level with CMS EPRO and to provide KCER with comprehensive situational awareness for their own required reporting. KCER is available to coordinate, host, and facilitate emergency calls upon Network request.

The Network shall provide technical assistance to dialysis facilities when needed so that facilities develop feasible, comprehensive emergency/disaster plans. The Network may wish to utilize the Facility Emergency Plan Checklist developed by KCER.

The Network shall invite KCER to participate as part of any Network planned, facilitated, or collaborative, community based emergency preparedness exercise. The Network shall annually participate in an emergency preparedness exercise that is relevant to the types of emergency situations that would be prevalent in the Network's geographic area. Network participation shall be by teleconference, minimally, or may participate in person if the exercise is within their service area. Each Network shall coordinate with KCER and other Networks for the exercise as directed by CMS. The Network may request that local stakeholders (e.g., state disaster agencies, State Survey Agencies, CMS Regional Office Divisions of Survey & Certification) participate in the emergency exercise. At the completion of the exercise, in a template provided by KCER, the Network shall document the results of an assessment of strengths, weaknesses, opportunities for improvement, and lessons learned in an After Action Report (AAR). The Network shall submit the completed AAR to the COR no later than 30 calendar days following completion of the exercise or by November 30 for option year 4. Once the AAR is approved by the COR, the Network shall submit the approved AAR to KCER.

The Network shall have a Memorandum of Agreement (MOA) with a back-up Network and provide an annual orientation program for the back-up Network, developed by the last business day in December in option year 3 and provide the COR and KCER an updated MOA within 10 days of any changes for future option years. The Network shall choose a Network that is not a member of the same corporate structure for back-up during emergencies. The Network shall test its toll-free hotline for patients annually to ensure that the telephone line can be transferred to the back-up Network. Additionally, CMS highly recommends that the Network obtain a Government Emergency Telephone System (GETS) card to facilitate communication during an emergency situation.

C.3.14. Data Systems

The Network shall not develop software products for use by facilities or other Networks without prior written approval from CMS.

C.3.15. Infrastructure Operations Support and Data Management

Unless otherwise directed by CMS, the Network shall adhere to the most current version of the policies and procedures outlined and posted on the QualityNet and ESRD NCC websites. These include, but are not limited to, the ESRD Network Information Technology (IT) Administrator Manual, the Healthcare Quality Information Systems (HCQIS) Database Systems Administrator Guide, the QualityNet System Security Policy, and the QualityNet Incident Response Procedures. The Network shall comply with all present and future statutes as well as HHS, CMS, and other federal regulations and program instructions relating to providing a secure computer operations environment. Additional policies and procedures may be released with which the Network will be required to comply.

C.3.16. Hardware/Software

Government Furnished Equipment (GFE) and circuits will be migrated to corporate furnished equipment (CFE). All workstations (also print/file servers, circuits, and switches) will be transitioned by December 31, 2019. The required end date for all GFE is March 2020. ESRD Networks shall only access Internet facing systems with HARP credentials. For further information regarding the migration see the links below:

- Link to CFE requirements
  https://hcqis.sharepoint.com/sites/Security/SiteAssets/SitePages/Policies%20and%20Procedures/HCQIS-CFE-Gdlns-Rqrmnts.pdf

- Link to LPM GFE/CFE Transition page (Public Facing)
  https://confluence.hcqis.org/display/GTCT/

- Link to HIDS GFE/CFE Transition page (Not Public Facing) – Includes Roadmap
  https://confluence.hcqis.org/pages/viewpage.action?pageId=55740967

C.3.16.A. Hardware

Contractor-furnished equipment (CFE) is items furnished by a contractor for the purpose of performing under a contract, included, but not limited to, hardware, software, commercial items, IPv6-compliant internet connectivity, and peripherals.

To access HCQIS internal systems, the Contractor will use the current HCQIS access technology to perform its work upon CMS approval. The Contractor must provide all additional equipment needed to support the requirements of this contract. In doing so, the Contractor and any of its subcontractors must adhere to the most recent version of the HCQIS CFE Guidelines and Requirements document, which will be provided as Attachment J.32.

C.3.16.B. Software

The contractor is responsible for covering the cost for any software out of its contract funds which is not provided by the HCQIS Infrastructure Contractor. In the case(s), where software is required above what is provided, the contractor is responsible for including the expected costs for such items within its proposal. Further, if the contractor requires additional software outside of the base award, the contractor must receive approval from its COR and then submit

a request via the HCQIS Engineering Review Board (ERB) procurement process. If applicable to the Task Order, the ERB will be responsible for reviewing and recommending approval for new software. Accordingly, as applicable, the contractor shall be required to have access to the current tool used to request/track procurements. If there are items that are not listed in the Technology Roadmap and Product Portfolio (TRAPP) that the contractor would like to use in support of the contract, a request will have to be submitted through its COR to begin the TDB approval process. The TRAPP can be provided upon request.

C.3.16.C. Internet Protocol v6 (IPv6)

Per Title 48 CFR Part 7.105 paragraph (b)(4)(iii), if this project involves the acquisition of Information Technology (IT) that uses Internet Protocol (IP), the Contractor shall (1) ensure that it complies with the requirements stated in Title 48 CFR Part 11.002 paragraph (g) or be granted a waiver by the CMS Chief Information Officer (CIO). Per Office of Management and Budget (OMB) memorandum M-05-22, an IPv6 compliant product or system must be able to receive, process, and transmit or forward (as appropriate) IPv6 packets and should interoperate with other systems and protocols in both IPv4 and IPv6 modes of operation.
Specifically, any IPv6 compliant product or system developed, acquired, or produced must:

1. Conform to the appropriate technical capabilities defined in the USGv6 Profile (National Institute of Science and Technology [NIST] Special Publication [SP] 500-267) as certified in a System Declaration of Conformance (SDOC) defined in NIST SP 500-273 and verified by a NIST accredited test laboratory, per Title 48 CFR Part 11.002 paragraph (g)
2. Interoperate with both IPv6 and IPv4 systems and products, per OMB M-05-22
3. Have available contractor/vendor IPv6 technical support for development and implementation and fielded product management through the availability of IPv6 specific maintenance agreements, per OMB M05-22

C.3.17. Security

C.3.17.A. Federal Security Mandates

As mandated by the Federal Information Security Modernization Act of 2014 (Public Law 113-283) (FISMA), all federal agencies, as well as the contractors and subcontractors (hereafter referred to as "the Contractor") supporting those agencies, must develop, document, and implement an Information Security (IS) program to safeguard information and information systems. FISMA applies to any organization which has physical or electronic access to a federal agency's computer systems, networks, or information technology (IT) infrastructure; or uses information systems to generate, store, process, or exchange data with, or on behalf of, a federal agency. This includes the external third-party/outsourced and cloud hosting of agency information or information systems.

C.3.17.B. CMS Security & Privacy Requirements

General CMS Security & Privacy Policies: All CCSQ contractors, regardless of the contract size,

program objectives, funding, or other factors, are subjected to applicable Department of Health and Human Services (HHS) and CMS Security & Privacy policies.

IT Management and IT System Development: CCSQ contracts may require the management of information technology, system or application development, or data management solutions. Information Technology Management and System Development refers to systems that store, process, and/or transmit CMS data, and require additional safeguarding under FISMA, CMS Chief Information Officer (CIO) approved Authority to Operate (ATO), and continuous authorization efforts.

C.17.C. General CMS Security & Privacy Policies
This section provides an overview of general CMS Security policies and outlines requirements applicable to all CMS contractors and subcontractors. The CMS Information Security and Privacy Program website provides additional details of CMS security policies and procedures across CMS, and is referenced throughout this document.

The Contractor must adhere to all CMS and federal IT Security and Privacy standards, policies, statutes, and reporting requirements, as well as all National Institute of Standards and Technology (NIST) standards and guidelines, and other Government-wide laws and regulations for the protection and security of Government Information.

The Contractor must also adhere to the guidance and requirements provided within the CMS Information Systems Security and Privacy Policy (IS2P2). The IS2P2 consolidates existing information security and privacy policy documents into a single volume and directly integrates the enforcement of information security and privacy through the CMS CIO, Chief Information Security Officer, and Senior Official for Privacy.

The IS2P2 and other relevant documents can be obtained from the CMS Information Security and Privacy Library. The Contractor must review the CMS Information Security and Privacy Program website and Information Security and Privacy Library at minimum every 30 calendar days for updates.

The Contractor must ensure all applicable federal privacy requirements are being met, including, but not limited to, Privacy Act System of Records Notification (SORN), Privacy Impact Assessments (PIAs), Data Use Agreements (DUAs), and Computer Matching Agreements (CMAs) in accordance with CMS procedures available on the CMS Information Security and Privacy Library.

C.3.17.D. Data & Records Management
The Contractor assumes responsibility for protection of the confidentiality of government records and must ensure that all work performed by its employees and subcontractors is under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any CMS records may be made available or disclosed must be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

For security purposes, information may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor must protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, *Protection of Sensitive Agency Information* by securing it with a FIPS 140-2 validated solution.

The Contractor must perform the following activities to ensure that any information generated, collected, or provided to the Contractor is properly maintained:

1. Protect government information and information systems in order to ensure:
    - Confidentiality, which means preserving authorized restrictions on access and disclosure based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
    - Integrity, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
    - Availability, which means ensuring timely and reliable access to, and use of, information.
2. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information (available on the CMS Information Security and Privacy Library). Encrypt all sensitive federal data and information (including, but not limited to, Personally Identifiable Information (PII), Protected Health Information (PHI), proprietary information, and Federal Tax Information (FTI)) in transit (i.e., via email, network connections, etc.) and at rest (i.e., on servers, storage devices, mobile devices, backup media, etc.) with a FIPS 140-2 validated encryption solution.
3. Secure all devices (including, but not limited to, desktops, laptops, and mobile devices) that store and process government information, and ensure devices meet HHS and CMS-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
4. Contractors connecting approved Contractor Furnished Equipment (CFE) to the CMS-owned network must ensure proper security posture and controls are in place to ensure that the confidentiality, integrity, and availability of CMS-owned data is maintained at all times. Contractors connecting to the Health Care Quality Information Systems (HCQIS) Network must comply with all requirements conveyed within the *Health Care Quality Information Systems Contractor-Furnished Equipment (CFE) Guidelines and Requirements* document, J.32.

C.17.E. Training

Per to the CMS IS2P2 policy and ARS control (AT-1), All Contractors assigned to this contract that are accessing ANY CMS IT systems or networks are required to complete mandatory training such as HHS/CMS Contractor Information Security Awareness, Privacy, and Records Management training (provided upon contract award) before performing any work under this contract and annually thereafter.

- Role-based Training

Contractor employees with significant security responsibilities (as determined by the Program

Manager) must complete role-based training annually, commensurate with their role and responsibilities, and in accordance with HHS and CMS policies.

- Training Records

The Contractor must maintain training records for all its employees working under this contract in accordance with HHS and CMS policies, and supply them to CMS upon request.

C.17.F Rules of Behavior for All Types of Users

All Contractor employees must adhere to all HHS, CMS and *QNet Rules of Behavior (ROB)* before accessing data or other information, systems, and/or networks that store/process government information. Initially at the beginning of the contract, and at least annually thereafter, any contractor working on CMS systems or with CMS data must provide a signed statement attesting to the fact that it understands and will abide by the HHS ROB. This may be done as part of annual OpDiv Information Security Awareness Training. If the training is provided by the Contractor, the signed ROB must be provided as a separate deliverable to the Contracting Officer (CO) and/or Contracting Officer's Representative (COR).

C.17.G. Incident Response & Reporting

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies."

A privacy breach is a type of incident and is defined by FISMA as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses PII, or (2) an authorized user accesses or potentially accesses PII for other than an authorized purpose.

The Contractor must ensure that all suspected information security and privacy incidents are reported within 1 hour of identifying the suspected incident. Contractors utilizing HCQIS systems must report all incidents in accordance with the *QualityNet Incident Response Procedures* (which can be provided upon request). All other contractors must report all suspected incidents to the CMS IT Service Helpdesk in accordance with the *Risk Management Handbook (RMH) Chapter 08: Incident Response* (available on the CMS Information Security and Privacy Library).

C.17.H. Access to Government Owned Systems & HSPD-12

The Contractor must be aware of the appropriate level of investigation required for each staff member. Suitability investigations are required for contractors who will need access to CMS information systems and/or CMS physical space(s). All Contractor employees must comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

The Contractor must submit a roster that includes the name, position, contact information, and area of responsibility/job functions of all individual staff members (including subcontractor staff) responsible for developing or hosting and/or maintaining a federal information system(s). The roster must be submitted to the COR within 14 calendar days of the effective date of the contract.

Any revisions to the roster (for any reason) must be submitted to the COR within 15 calendar days of the change.

All contractor personnel must undergo a background investigation commensurate with the Homeland Security Presidential Directive (HSPD) 12 position-sensitivity levels in order to receive the Personal Identity Verification (PIV) card required to access, develop, or host and/or maintain a federal information system(s) and ensure suitability level/fitness. More information can be found within the *Policy for a Common Identification Standard for Federal Employees and Contractors*, OMB M-05-24, FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*, HHS HSPD-12 policy, and *Executive Order 13467, Part 1 §1.2.* PIV cards are currently not used to access CMS HCQIS due to technical limitations. However, when the technical capabilities are available, CMS/CCSQ will enforce any PIV requirements to these systems. The Contractor must adhere to all applicable requirements.

C.17.I. IT Management and IT Systems Development
Implementation of FISMA mandates that all HHS/CMS information systems require an Agency-approved Authorization to Operate (ATO) based on NIST Special Publication (SP) 800-37, *Guide for Applying the Risk Management Framework to Federal Information Systems*.

FISMA requirements apply to CMS contracts that involve utilization of IT resources that require maintenance, development, or management of CMS information systems or data. Further defined, IT Management and IT Systems Development may include, but is not limited to, operations and maintenance of CMS IT Infrastructures, General Support Systems (GSS), and networks that process, store, and/or transmit CMS data. Additionally, this includes the creation, development, or support of application/systems to meet CMS program-specific goals. These contracts are subject to CMS FISMA and System Authorization and Assessment (SA&A) requirements as defined within the *CMS Risk Management Handbook* and CMS' *Acceptable Risk Safeguards (ARS)* (which are both available on the CMS Information Security and Privacy Library).

The Contractor responsible for the system(s)/application(s) must obtain and/or maintain a valid ATO as determined by the CMS Program Business Owner and ISSO. The ATO must be authorized by the CMS CIO before a system goes into operation or begins processing CMS information. The failure to obtain and maintain a valid ATO may be grounds for termination of a contract.

C.17.J. CMS Control Implementation and Baselines: Acceptable Risk Safeguards (ARS)
The CMS Information Security and Privacy *Acceptable Risk Safeguards (ARS)* provides guidance to CMS and its contractors as to the minimum acceptable level of required security controls that must be implemented by CMS and CMS contractors to protect CMS' information and information systems, including CMS Sensitive Information. The ARS is based on:

- National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53 Revision 4 (NIST SP 800-53r4), *Security and Privacy Controls for Federal Information Systems and Organizations*, dated April 2013
- Federal Risk and Authorization Management Program (FedRAMP)

- *HHS Information Systems Security and Privacy Policy (IS2P)*
- *CMS Information Systems Security and Privacy Policy (CMS IS2P2) CMS-CIO-POL-SEC-2016-0001*
- CMS policies, procedures, and guidance
- Other federal and non-federal guidance resources
- Industry-leading information security and privacy practices adopted by CMS

C.17.K. Security Assessment and Authorization (SA&A) Process

HCQIS contracts that require the Contractor to build or support application/systems development to meet CMS/CCSQ program-specific goals are required to fully support CMS FISMA system's SA&A efforts for the application or system. Application Development Organizations (ADOs) should attempt to utilize any of CMS' Enterprise Services when applicable to help reduce cost and effort required to implement proven solutions, apply security controls, and achieve agency accreditation for a system or application. In efforts to support CMS SA&A, the Contractor must:

1. Comply with ATO requirements as mandated by federal laws and policies, including making available any documentation, physical access, and logical access needed to support this requirement. The level of effort for the ATO is based on the System's NIST FIPS 199 categorization and CMS procedures (located on the CMS Information Security and Privacy Program website).
2. Coordinate with the CMS Business Owner to create, maintain, and update all applicable ATO documentation as defined by CMS Information Security procedures.
3. Obtain an independent Security Controls Assessment (SCA) for all CMS systems and infrastructures in accordance with CMS procedures located on the CMS Information Security and Privacy Program website. The SCA is a detailed evaluation of the controls protecting an information system. It determines the extent to which controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting the security requirements for the system. Requirements for control assessments are described in the CMS *Acceptable Risk Safeguards (ARS)* and can be found within the CMS Information Security and Privacy Library.
4. Allow CMS employees (or CMS CISO-designated third-party Contractors) to conduct SCA activities, to include control reviews, in accordance with NIST SP 800-53/NIST SP 800-53A and CMS procedures and standards (located on the CMS Information Security and Privacy Program website).
5. Apply appropriate security controls to meet CMS information security requirements, as defined in the applicable appendix of the ARS manual (as amended), and in accordance with the below-listed parameters, for any/all tasks requiring the Contractor to (1) process, (2) store, (3) facilitate transport of, or (4) host/maintain federal information (including software and/or infrastructure developers/maintainers), either at the Contractor site, or at a federally-controlled facility (as defined in FAR Subpart 2.1):
    - Systems Security Level: *Low, Moderate, or High,* as defined in the applicable appendix of the ARS manual (available on the CMS Information Security and Privacy Library).
    - Information Type: is used to determine the information system security level. However, additional security controls may be required based on the specific type of data available within the system. For information identified as PII, PHI, and/or

FTI, the additional security and privacy requirements listed in the ARS manual Implementation Standards, as applicable to PII, PHI, and/or FTI, must be applied.
- E-Authentication Level: 1 through 4, as defined in the *CMS RMH, Volume III, Standard 3.1, and Authentication* must be applied to identity proof and authenticate authorized users.

6. Identify gaps between required controls and the Contractor's implementation as documented in the applicable Security Assessment Report (SAR) and track mitigation in a Plan of Action and Milestones (POA&M). The POA&M must be completed in accordance with CMS procedures (located on the CMS Information Security and Privacy Program website). Depending on the severity of the gaps, the Government may require them to be remediated before an ATO is issued.
7. Mitigate all applicable security risks found during the ATO process and continuous monitoring activities. All high-risk vulnerabilities must be mitigated within 30 days from the date the vulnerabilities are formally identified, and all moderate-risk vulnerabilities must be mitigated within 90 days from the date the vulnerabilities are formally identified. The Government will determine the risk rating of identified vulnerabilities. Systems will NOT receive an authority to operate with high-risk findings unless otherwise approved by the CMS Business Owner and ISSO.
8. Create, maintain, and update all documentation associated with the CMS Assessment and Authorization Process and maintain all records within the CMS FISMA Controls Tracking System (CFACTS), unless otherwise stated by the ISSO. These documents include, but are not limited, to:
    - Security Test Procedures and Results
    - Security Assessment Report (SAR)
    - System Security Plan (SSP)
    - IT System Contingency Plan (CP)
    - IT System Contingency Plan (CP) Test Results
    - FedRAMP Control Tailoring Workbook (Cloud Service Provider)
    - Control Implementation Summary (CIS) (Cloud Service Provider)
    - Software Code Reviews
    - Interconnection Agreements/ Memorandum of Agreements/ Interagency Agreements
    -

Applicable CMS staff will review and subsequently accept or reject information security deliverables in alignment with the CCSQ's Agile Security Framework (CASF) or CMS XLC phase in which the deliverables are completed/delivered.

The CMS Information Security and Privacy Library has several artifacts and templates available. However, the Contractor must work with its ISSO to identify the most appropriate artifacts and templates to use.

C.17.L. Cloud Services and FedRAMP ATO Compliance

The Contractor must comply with FedRAMP SA&A requirements and ensure that any information systems or services used have a valid FedRAMP-compliant (approved) ATO in accordance with the Federal Information Processing Standard (FIPS) Publication 199 defined

security categorization. If a FedRAMP-compliant ATO has not been granted, the Contractor must obtain written approval from the Business Owner and ISSO prior to utilizing any services.

CMS may leverage the Provisional Authorization granted by FedRAMP and any documentation prepared by the Contractor to obtain a CMS ATO. A CMS-issued ATO is required before any Production (vice Development or Testing) operations may commence, or CMS Sensitive Information is placed in a cloud-based environment.

C.17.M Security Roles & Responsibilities
The Contractor must maintain security staff members on the contract at all times whose experience level is commensurate with their individual levels of responsibility. Contracts working within HCQIS must assign and designate individuals to the appropriate role in alignment with the work being performed. Depending on the work being performed, an individual may obtain multiple security roles to support one contract. The Contractor must be responsible for properly protecting, safeguarding, and disposing of all information used, gathered, or developed as a result of work under this contract. The Contractor must also protect all government property or information, including, but not limited to, data and equipment, by treating the property or information as sensitive. The Contractor must consider all information about the systems gathered or created under this contract to be Controlled Unclassified Information (CUI).

For each of the applicable roles described below, the Contractor must identify the assigned personnel to the COR within one business day of contract award (as required by the onboarding process). Further, the assigned personnel must be able to perform the duties associated with the respective role within three days of the beginning of the contract's period of performance.

Role 1: Security Point of Contact (SPOC):
To ensure that the Contractor's personnel adhere to CMS policies, including, but not limited to, applicable Rules of Behavior (ROB) when using CMS and HCQIS information systems, the Contractor must assign a Security Point of Contact (and backup SPOC) to assist with helping CMS safeguard data as stated in such policies. The Contractor must use the HCQIS/QualityNet Security Point of Contact Appointment processes to identify both the SPOC and backup SPOC. The backup SPOC must be identified within 30 calendar days of the beginning of the period of performance, and must not be the same individual as the Account Administrator (AA) or Security Official (SO) in the HCQIS Access and Roles Provisioning (HARP) system).

The SPOC is required to support the *General CMS Security & Privacy Policies* and ensures the overall contractor and subcontractor personnel at each respective location(s) are compliant with security requirements set forth by the HCQIS/QualityNet System Security Policies and Procedures. The SPOC works directly with the HCQIS Infrastructure Contractor and the CMS HCQIS security team on multiple levels of security-related topics, and is the central point of contact at the Contractor organization regarding security matters. The SPOC must fulfill the following responsibilities, including, but not limited to:

1. Maintain a general understanding of CMS and HCQIS security requirements and policies.
2. Assure all users complete necessary Security and Privacy training prior to accessing any

HCQIS systems and annually thereafter.
3. Manage and maintain all users' Annual Security Awareness Training (SAT) certificates.
4. Fulfill incident management responsibilities, to include immediate response to security incidents, and report any potential security incidents involving PII or PHI in a timely manner (1 hour from the time of identification).
5. Coordinate the destruction of sensitive information.

Role 2: Account Administrator (AA) / Security Official (SO):
Within the HCQIS environment, account management is essential for security compliance. Each contractor holds the responsibility of managing HCQIS user accounts within its respective organization. The Contractor must identify an Account Administrator responsible for managing those accounts for user access related to Active Directory (AD) and/or LDAP within the HCQIS environment. In addition, the Contractor must identify one or more backup AA within 30 days of the beginning of the contract's period of performance.

The AA/SO role is required to support the *General CMS Security & Privacy Policies* and its responsibilities may include, but are not limited to, providing or requesting new user accounts, password resets, locking and unlocking accounts, and performing account reviews. Most of the application access and accounts within HCQIS are managed by Active Directory or LDAP. These applications may include, but are not limited to, the following:

- Applications using HCQIS Access and Roles Provisioning (HARP) system
- HCQIS WAN Network and VPN
- Desktop/VDI
- Office365
- CMS Quality Service Center (ServiceNow)
- Atlassian

Role 3: System Security Officer (SSO):
Contractors tasked with developing and supporting a CMS system or application must identify a System Security Officer (SO). In addition, the Contractor may identify an SO back up. The SO is only required to support *IT Management and IT System Development* and is responsible for implementing and maintaining system and application security controls and procedures to achieve and maintain technical compliance with CMS security requirements. The SO must fulfill the following responsibilities, including, but not limited to:

1. Support the CMS ISSO in the achievement and maintenance of an ATO for each application or system supported by the Contractor.
2. Have a full understanding of the CMS' SA&A Processes.
3. Implement and maintain ARS controls for the appropriate system security level.
4. Develop and maintain FISMA system documentation.
5. Ensure systems adhere to Technical Reference Architecture (TRA) foundational and supplemental documents as additional security specifications, when applicable (available upon request).
6. Use approved security tools for continuous monitoring and management of security baselines.

7. Implement audit tools or processes for auditing and reporting services that support Continuous Diagnostics and Monitoring (CDM).
8. Provide engineering services and participation in Continuity of Operations Planning (COOP) and Disaster Recovery (DR) planning and exercises.
9. Develop and implement Configuration Management and Change Management plans when necessary.
10. Develop and maintain artifacts related to the CMS eXpedited Life Cycle (XLC) and CASF (the CASF is available upon request).
11. Perform or participate in threat and vulnerability management for applicable FISMA systems.
12. Perform POA&M management.
13. Assist the CMS ISSO with other additional security support efforts within the scope of contractual responsibilities.

C.3.18. DUA Submission

The DUA shall be renewed annually as required by CMS Privacy program through the Enterprise Privacy Policy Engine (EPPE).

C.3.19. Internal Quality Improvement Program (IQI)
The objectives of the Internal Quality Improvement Program are to support and foster continuous quality improvement in Network processes in order to improve the timeliness, effectiveness, efficiency, and management control of Network activities.

The Network shall develop a written IQI Plan that encompasses the work to be performed under this contract including administrative functions, financial management, and activities in support of the QIAs.

The Network shall have an internal reporting system for all IQI activities and shall make reports available to its MRB and (on request) to CMS.

The Network IQI Program shall include built-in processes for rapid identification and correction of problems.

The Network IQI Plan shall be submitted to the COR for review no later than 30 days after the acceptance of the plan for the last quality improvement activity for the year, unless otherwise directed by CMS. Upon request by the COR, the Network shall supply IQI reports and analyses to document adherence to established processes as well as the Network's response to problems that arise in performing contract requirements.

C.3.19.A. Internal Quality Improvement Program Criteria
At minimum, the Network shall:

- Support and foster continuous quality improvement in Network activities in support of the NQS, CMS's Strategic Plan, and the Institute of Medicine report titled *Best Care*

at Lower Cost: The Path to Continuously Learning Health Care in America and other SOW activities;
- Develop and implement a plan that ensures that all aspects of the Network's activities run efficiently, comply with the contract, and are consistent with CMS' goals and objectives for the SOW;
- Develop and maintain Network IQI measures that specify a permissible range of deviation;
- Ensure the financial integrity of the contract by actively monitoring and staying within the total contract budget;
- Improve the reliability, accuracy, consistency, and timeliness of data processing and data reports; and
- Ensure the support, understanding, and participation of all patients, providers, and other constituencies that are affected by the SOW.

C.3.19.B. IQI Plan
The Network's IQI Plan (no template provided) shall identify items the Network plans to monitor and the indicators (measures) to be used for measurement. The IQI Plan shall:

- Delineate the individual process steps required for any activity that will produce a desired outcome;
- Develop measures for the critical processes involved in the attainment of the outcome;
- Set performance goals for each process measure that allow the Network to:
  - Determine if performance is acceptable; and
  - Determine if the quality and quantity of the output are adequate to support organizational and Network program objectives;
- Identify the information to be collected, the frequency of collection, and when and how the information will be shared with all Network staff;
- Include processes for determining the reason for failure to meet goals, and the actions the Network can take to correct the process failure (e.g., if the Network fails to meet established goals for several indicators, the Network may need to prioritize its improvement efforts); and
- Include steps to be taken to identify, implement, and monitor improvement actions.

The Network IQI Plan shall detail the interventions of each quality improvement activity with the expected outcomes and be revised as necessary to achieve the goal of the quality improvement activities as described in the contract. The Network shall document all of the elements of its work related to the IQI program, and provide this documentation to the COR with the COR Monthly Report, and to the Network Corporate Governing Body (CGE) on a regular basis.

C.3.19.C. IQI Program Reporting Requirements
At minimum, the Network shall (a) generate monthly progress reports as described in this SOW and (b) retain reports and make them available for CMS monitoring purposes during the COR monthly call.

C.3.20. Performance Improvement Plans (PIP)

CMS expects the Network to be successful in carrying out the activities of the SOW. If the Network fails to meet contract requirements, CMS will require a PIP to ensure that the Network will take the required steps to remedy contract performance deficiencies. There are three (3) tiers of performance improvement that the COR may require from ESRD Network:

- Tier 1: Network/COR Discussion of the Need for Performance Improvement
- Tier 2: Formal Written Notice of Performance Issue
- Tier 3: Request for a PIP

C.3.21. Patient and Family Centered Care

Literature defines patient and family engagement in varying, but similar terms; there is a consensus among sources that patient and family engagement involves including "the perspectives of patients and families directly into the planning, delivery and evaluation of healthcare, thereby improving the quality and safety of the care provided."[1] Although patient and family engagement may be implemented differently across healthcare settings, all activities should support the patient's values, preferences, and expressed needs; "provide clear, high quality information and education for the patient and family; include coordinated and integrated care and involvement of family members and friends, as appropriate"[2] and incorporate "the core concepts of dignity and respect, information sharing, active patient participation in their care, and collaboration."1 The Network shall incorporate the patient's voice in all of its activities and encourage a patient perspective within the renal community as a whole.

Patient SMEs are committed and informed patients who are representative of the demographic characteristics of the Network's service area. The Network shall recruit at least fifteen (15) Patient SMEs and/or family members or caregivers to support the Network in its quality improvement efforts. The Network shall recruit at least one caregiver or family member as a SME. The Network shall identify at least one Patient SME and/or family member or caregiver from each state in the Network's geographic region. The Network may exercise discretion in allowing existing SMEs to continue participation in new contract years; however, at least ¼ of the selected Network SMEs shall be new participants, having not been a SME of the Network in the previous contract year. For example, with the Network recruiting 15 Patient SMEs and/or family members or caregivers at the start of a given contract year, at least 4 of the selected Patient SMEs and/or family members or caregivers must be new participants. The Network shall ensure patients and caregivers wishing to participate with the Network have a place as a SME or on the Network Patient Advisory Council (PAC).

The Patient SMEs and/or family members or caregivers shall provide a patient perspective for Network activities, in the areas of promoting better health for the ESRD population; BSI, transplant, and home dialysis. Requirements for QIAs in these four areas are found in the following sections of this SOW: Section C.4.4. Pilot QIA; Section C.4.1. BSI QIA, Section 4.2 Transplant QIA, Section 4.3. Home Dialysis. The Network shall ensure that Patient SMEs and/or family members or caregivers, in collaboration with the Network's Patient Services Department, are instrumental and actively involved in developing patient-oriented interventions in the following QIAs:

- BSI QIA,
- Transplant QIA,

- Home Dialysis QIA, and
- Network-selected Pilot QIA.

The Network shall integrate the concepts of family engagement and patient-centered care in its QIAs, considering the best known available practices.

As directed by CMS and as resources allow, the Network shall participate in any additional CMS-supported and/or facilitated LANs that function to support ESRD Network activities. The Network shall actively spread knowledge gained from any such interactions to members of the renal community in its service area. Examples of members of the renal community include, but are not limited to, QIN-QIOs, large dialysis organizations (LDOs), non-large dialysis organizations (non-LDOs), the National Institutes of Health National Kidney Disease Education Program (NIH/NKDEP), and the Centers for Disease Control and Prevention (CDC).

The Network shall provide Patient SME agreement forms in the CMS-template format, in Attachment J-4, Reporting Requirements, to at least 25% of facilities located in the Network service area within 30 days of contract award in order to identify patients and/or family members or caregivers to participate in patient-and family-engagement activities or to serve on the Network Patient Advisory Council (PAC). The Network shall submit a list of the minimum of 15 selected Patient SMEs and/or family members or caregivers to the CMS SME/ COR on or before 15th business day of December of each contract period.

The Network shall provide a summary of PFE activities having occurred in the Network, including the active participation of the N-PFE LAN members and their contributions, using the PFE Synopsis Template, in Attachment J-4, Reporting Requirements, by close of business (COB) on the last business day of contract quarter 1, contract quarter 2 and contract quarter 3.

While this section of the contract is titled Patient and Family Centered Care, the acronym PFE will be used to describe the work performed by the Networks to engage patients, families, and caregivers.

C.3.21.A. Foster Patient and Family Engagement at the Facility Level
The Network shall ensure implementation of interventions at the dialysis facility level that foster patient and family involvement in the areas of promoting better health for the ESRD population; BSI, transplant, and home dialysis. Requirements for QIAs in these four areas are found in the following sections of this SOW: Section C.4.4. Pilot QIA; Section C.4.1. HAI QIA, Section 4.2 Transplant QIA, Section 4.3. Home Dialysis. Patient and Family engagement activities in these four areas should be documented in the Monthly COR Report.

The Network shall provide technical assistance to 30% project-participating dialysis facilities on establishing patient council support groups OR new patient adjustment groups OR patient councils; incorporating patient, family and caregiver participation into the Quality Assurance Performance Improvement (QAPI) Program and/or governing body of the facility; and with demonstrating patient, family and caregiver participation in the patient's care (e.g., patient, family member and caregiver involvement in the development of the individualized plan of care and/or plan of care meetings). Network efforts shall assist dialysis facilities in adjusting to the

heightened focus on patient and family centered care, aiming to help dialysis facility staff to optimize customer satisfaction and improve clinical outcomes. The Network shall submit a written plan, no longer than 4 pages, as to how technical assistance will be introduced, implemented and evaluated. Evaluation of the Network's technical assistance on fostering PFE at the facility level shall be based on achievement of the topic-specific performance benchmark (quantitative assessment). Successful performance for these three objectives shall be determined by the COR in consultation with CMS SME. The Network shall achieve:

- 10% percent relative improvement from baseline (September 2019) in the number of project-participating dialysis facilities with patient, family member and caregiver involvement in the development of the individualized plan of care and/or plan of care meetings;

- 50% percent relative improvement from baseline (September 2019) in the number of project-participating dialysis facilities with (or providing access to) established patient support groups OR new patient adjustment groups OR patient councils, by evaluation; and

- 75% percent relative improvement from baseline (September 2019) in the number of project-participating dialysis facilities that include patients and/or family/caregivers in the Quality Assurance Performance Improvement (QAPI) Program and governing body of the facility;

The Network shall report progress based on defined interim measures via the Network IQI plan and report results in the monthly COR Report and on the ESRD NCC Dashboard.

C.3.21.A.1. Involve Patients, Family Members, and Caregivers in CMS Meetings
The Network shall incorporate patients and/or family members or caregivers into CMS meetings as follows:
•In at least two monthly COR monitoring meetings held during each quarter, two Patient SMEs and/or family members or caregivers shall participate. The Network shall identify a different Patient SME and/or family member or caregiver to participate for each meeting. In each COR monthly meeting attended by patients and/or family members or caregivers, the Network shall dedicate at least one agenda item to patient-related topic(s) and provide the attending Patient SME(s), and/or family member(s) or caregivers with a 10- minute opportunity to address the agenda topic and raise additional issues. The Network shall provide the meeting agenda to the attending Patient SMEs and/or family members or caregivers in advance and inform the participants on the process of the meetings, to ensure that they are prepared for discussion with CMS. The Network shall record attendance in the meeting minutes and on the PFE Synopsis Template.

•At least two Patient SMEs and/or family members or caregivers shall be in attendance at the Network's annual evaluation site visit or equivalent conference call. The participating Patient SMEs and/or family members or caregivers shall be selected from the PAC, Patient SMEs and/or family members or caregivers that previously participated in a COR monitoring meeting during

the contract year. During the Network's annual evaluation site visit or equivalent conference call, at least 15 minutes shall be dedicated to the Patient SMEs, family member(s) and/or caregiver(s) to provide an opportunity for discussion with the COR.

The Network shall:

- Recruit members of the PAC, Patient SMEs and/or family members or caregivers to participate in other CMS meetings, including CoP Calls and LANs, as directed by CMS.

- Encourage and maintain at least 60% attendance of network representatives at required meetings and activities throughout the course of the project for each year of the contract.

C.3.21.A.2. Support the ESRD NCC Patient/Family Engagement LAN

LANs are mechanisms by which large-scale improvement around a given aim is achieved through the use of various change methodologies, tools, and/or time-bounded initiatives. LANs engage leaders around an action-based agenda. The NPFE LAN, coordinated by the ESRD NCC, creates opportunities for in-depth learning, problem-solving, and achievement of patient- driven goals. The NPFE LAN promotes patient and family engagement throughout all Networks and dialysis facilities. At the national level, the input from LAN members will assist in the development of national materials designed to improve care.

The Network shall support the ESRD NCC National Patient/Family Engagement (N-PFE) LAN in its efforts to promote patient and family engagement. To this end, the Network shall select five (5) Patient SMEs to participate as active members of the N-PFE LAN throughout the contract year. The single exception to this requirement shall be for those ESRD Networks with more than 5 states in the Network region. For example, if there are nine (9) states in a Network region, the Network shall select nine (9) Patient SMEs to participate on the N-PFE LAN. N-PFE LAN Members may be selected from the 15 identified Patient SMEs, PAC Members, and/or family members or caregivers, though not required. The Network shall recruit at least one caregiver or family member to participate on the N-PFE LAN. At least one of Patient SME must be a home dialysis patient and at least one Patient SME must be a transplant patient. There shall be at least one Patient SME and/or family member or caregiver from each state in the Network's geographic region selected to participate. The Network shall ensure that patient/family representation on the NPFE LAN is maintained at a minimum of 60% of the selected participants throughout the contract year. If a Patient SME become too ill to participate on the N-PFE LAN or passes away, the Network may select another Patient SME to participate on the N-PFE LAN. The Network shall demonstrate a plan for how continued support and education to Patient SMEs engaged at the national level will be provided, including an approach for how information and communication received by the national Patient SMEs will be disseminated from the national level to the local network level and in return. The Network shall ensure that PAC Members routinely review for consideration of dissemination N-PFE LAN developed resources to support the mandatory QIAs.

The Network shall:

•Submit a list of the selected Patient SMEs and/or caregivers/family members to the COR, CMS

SME and the ESRD NCC, by the 15th business day of December of each contract year.

•Document the active participation of the Network's NPFE LAN members and their contributions in the COR Monthly Report and on the quarterly PFE Synopsis.

C.3.22. Patient Experience of Care

C.3.22.A. Evaluate and Resolve Grievances

The Network's case review responsibilities shall include taking all necessary steps to evaluate and resolve grievances filed by, or on behalf of, one or more ESRD patients. A grievance is defined as a formal or informal written or verbal complaint that is made to any member of the dialysis or transplant center staff by a patient, or the patient's representative, regarding the patient's care or treatment. If the grievant does not feel comfortable filing a grievance with the facility a grievance may be filed directly to the Network.

The sources of grievances include, but are not limited to, ESRD patients, their representatives, other family members/caregivers, facility employees, physicians and other practitioners, federal or state agencies, QIOs, State Survey Agencies, and other agencies and organizations.

The Network shall use a number of tools intended to address the identified concerns, as directed by this SOW and Attachment J-8, Grievances and Patient Appropriate Access to Care.

Evaluation and resolution of grievances may include Immediate Advocacy; reviews of documentation, including but not limited to medical records, facility policies and procedures, and facility staffing plans; site visits; interviews with the grievant, family members, facility staff, or others; requiring facilities to submit Corrective Action Plans; and other activities consistent with guidance provided by CMS.

Network responsibilities shall focus on conducting activities to meet regulatory and statutory requirements in an efficient and effective manner, and to foster Network quality improvement efforts relative to the grievance process. To this end, the Network shall:

- Inform patients of the Network's role in receiving, investigating, referring, resolving, and tracking patient grievances in accordance with the communications requirements in C.3.4, and its role in serving as the advocate for patients while maintaining objectivity;
- Inform the provider community that patients, their representatives, or other individuals may file grievances directly with the Network without going through the facility grievance process first;
- Inform facilities and patients regarding the definition of a grievance. See Attachment J-8 Grievance and Patient Appropriate Access to Care.
- Inform facilities on what constitutes a robust internal process for anonymous grievances to include date of incident, staff involved, description of incident, and any witnesses; and the process in which the grievance can be submitted to maintain anonymity. The Network shall encourage facilities to develop an internal process for anonymous grievances.

- Follow all instructions as provided in the Grievance/Access to Care guidance document, Attachment J-8;
- Notify the COR by e-mail within one business day of all referrals to a State Survey Agency;
- As directed by CMS and/or when substantive changes are made to Network grievance processes, provide updated information on the Network's grievance processes to Medicare-certified providers in the Network service area with a directive that each provider should make the information available to its patients or inform its patients on how to contact the Network to obtain the information;
- When a grievance is filed with the Network, remind the involved provider and/or practitioner(s) of their responsibility to support the grievant during the grievance process, and that no reprisal may be imposed as a result of the grievance;
- Recommend sanctions in accordance with Section C.3.11 of this SOW;
- Include a summary of grievance review activities and findings in the COR Monthly Report;
- Maintain review timeliness, as directed by CMS; at least 80% for all Immediate Advocacy cases (IA) (7 business days for all IA cases), and at least 90% of all grievance cases (60 calendar days for all grievances cases) entered into the current version of the Patient Contact Utility (PCU);if a case requires more than 60 calendar days to complete, COR approval must be received prior to the 50th day of the 60-day limit;
- Work collaboratively with the appropriate State Survey Agency(ies) to maximize the linkage between case review information obtained during investigation of a grievance and the survey process.

In addition, the Network shall:

- The Network shall increase patient awareness of the Network as an educational resource and mediator for grievances with metrics included in the Network IQI. The Network shall improve the grievance satisfaction score provided by the NCC for the month of December by at least 10% relative improvement by the time of evaluation. Efforts to increase awareness of the Network and increase the grievance satisfaction score shall be monitored in the Network IQI. Satisfaction is defined as a weighted mean of the total Grievance Satisfaction score based on an annual calculation of all patients for the Network that have completed the Grievance Satisfaction survey. The information obtained from the grievance process, satisfaction survey data, and the collaboration with the State Survey Agency will foster quality improvement at local and state levels. The Network shall document a summary of all State Survey Agency/Network interactions on the COR Monthly Report.

The Network shall work to improve the grievance process in the Network's service area by conducting a focused audit of all grievances. The focused audit shall consist of an assessment of the number and type of grievances received by the Network during the specified quarter. The focused audit shall be conducted on the first and third quarters of grievance data. In addition, the Network shall report, at minimum, the total number of grievances received during the time period, as well as the number and type of the three most-prevalent categories of

grievances. Additionally, the Network shall report any intervention activities related to efforts to reduce the prevalence of the three highest grievance categories. Results of the audits and intervention activities shall be reported in the COR Monthly Report no later than 45 days after the end of the quarter included.

C.3.22.B. Address Involuntary Discharges (IVDs) and Transfers (IVTs)
CMS strives to assure appropriate access to dialysis care for ESRD patients who require life-sustaining dialysis treatment, regardless of modality. The Network shall work with individual facilities to identify and address issues related to difficulties in placing or maintaining patients in treatment.

To help ensure access to appropriate dialysis care, the Network shall comply with all requirements specified in Attachment J-8, Grievances and Patient Appropriate Access to Care.

The Network shall:

- Adhere to CMS-specified definitions in the J-8 Attachment and timelines for addressing IVD, IVT, and failure-to-place cases filed by providers, patients and patients' representatives;
- Document all information on IVD, IVT, and failure-to-place cases in the PCU;
- Recommend sanctions in accordance with Section C.3.11 of this SOW.

C.3.22.C. Address Patients at Risk for IVD
The Network shall work with facilities and advocate for patients to avert potential IVDs whenever possible to ensure the Network goal of supporting patient and family centered care. The Network shall:

- Adhere to CMS-specified definitions and timelines for addressing cases in which a patient is at risk for IVD;
- Develop Network standards with the MRB as noted in Section C.3.3.C related to maintaining patients in a consistent dialysis setting regardless of compliance.

The Network shall conduct a focused audit of the number and type of patients at risk for IVD cases and patient situations that progressed to IVD or IVT cases processed by the Network during the specified quarter. The focused audit shall be conducted on the first and third quarters of data. The Network shall report, at minimum, the total number of at risk for IVD, IVD, and IVT cases received during the time period, as well as the number and type of the three most-prevalent categories for the reported at risk for IVD, IVD, and IVT cases. Additionally, the Network shall report any intervention activities related to efforts to reduce the prevalence of the three highest categories. Results of the audits and intervention activities shall be reported in the COR Monthly Report no later than 45 days after the end of the quarter included.

C.3.22.D. Participate in Patient Experience of Care LAN Activities led by the NCC
The Network shall identify 2 facilities that have had issues related to grievances or access to care

issues and provide the names of contacts at these facilities to the NCC. The Network shall work with dialysis organizations to identify at least 1 facility that excel at empowering patients and has success in resolving patient issues before escalation. The Network shall provide the names of the 3 identified facilities to the NCC by December 31st of each contract year. The Network shall invite these facilities to participate in the LAN as leaders of change. The Network shall identify local leadership, such as the regional manager, to participate in the LAN. The NCC led LAN shall meet every other month. The LAN shall embrace principles of patient-centered care and the development a culture that helps to identify root causes of behavior and support behavioral change within the facility. The Network shall share the identified interventions to improve facility culture and reduce grievances and access to care issues from each LAN meeting with all facilities in the Network service area including metrics to determine uptake in the Network IQI. The Network will report on the spread and implementation of the interventions in the monthly COR report.

C.3.23. Improving Care through the Support of Innovative Approaches to Improve Quality Accessibility, and Affordability)

CMS has established the ESRD QIP to promote delivery of high-quality care by outpatient dialysis facilities to patients with ESRD. The first initiative of its kind in the Medicare program, the ESRD QIP changes the way CMS pays for the treatment of patients with ESRD by linking a portion of payment directly to facility performance on quality care measures.

The ESRD QIP is authorized by Section 153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which added Section 1881(h) to the Social Security Act. MIPPA requires CMS to select measures, set performance standards, specify a performance period for each payment year, develop a methodology for assessing the total performance of each facility, apply an appropriate payment reduction based on the facility's performance, and publicly report the results.

Details about the ESRD QIP can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html.

The ESRD Networks have a unique opportunity to support this important initiative to improve ESRD care. The Network shall provide support and technical assistance to dialysis facilities in understanding the ESRD QIP measures, improving performance scores, and providing accurate and timely data.

C.3.23.A. Support the ESRD QIP, Dialysis Facility Compare, Star Ratings, and Dialysis Facility Reports for Performance Assessment and Improvement

The Network shall assist patients and their caregivers with understanding the ESRD QIP, Dialysis Facility Compare, and Star Ratings. At minimum, the Network shall:

- Respond to questions from patients or caregivers regarding the ESRD QIP, Dialysis Facility Compare, and Star Ratings;
- Post links to CMS' Web pages on the ESRD QIP, Dialysis Facility Compare, and Star Ratings on the Network website;

- Upon request by CMS, enlist any five Patient SMEs and/or their families/caregivers to provide feedback for the ESRD QIP, Dialysis Facility Compare, Star Ratings, Dialysis Facility Reports, or any related patient-directed materials.

The Network shall assist facilities with understanding and complying with ESRD QIP, Dialysis Facility Compare, Star Ratings, and Dialysis Facility Reports processes and requirements (updated in the *Federal Register* and on the QualityNet website and on other CMS-designated websites). At minimum, the Network shall:

- Ensure that all Network staff are fully knowledgeable about measures and specifications related to the ESRD QIP and Star Ratings;
- Respond to facility questions regarding the ESRD QIP and Dialysis Facility Compare and distribute plain-language materials to aid in their understanding. (Plain language materials will be provided by CMS, or the Network shall develop these materials upon CMS request and distribute after COR approval);
- Register provider Master Account Holders (MAH) to access websites designated by CMS to enable facilities to view facility-level quality reports, such as Dialysis Facility Compare and Dialysis Facility Reports;
- Provide MAH updates if needed by COB on the tenth working day of the first month of each calendar quarter;
- Provide updated lists of credentialed users to CMS-designated contractors every quarter to support Dialysis Facility Compare and Dialysis Facility Reports;
- Notify facilities of the procedures required to access their ESRD QIP Performance Score Reports (PSRs), Quarterly Dialysis Facility Compare Preview Reports, and Dialysis Facility Reports;
- Monitor access to the PSRs and contact providers that have not accessed the report within five days of its release; encourage facilities to review their PSRs and submit necessary clarification questions or formal inquiries during the annual 30-day preview period;
- Assist facilities with accessing, printing, and posting the Performance Score Certificate (PSC) each year within 5 business days of its release date;
- Inform CMS if a facility has not posted its PSC as directed in MIPPA.

The Network also shall assist facilities with improving performance on ESRD QIP and Dialysis Facility Compare measures. At minimum, the Network shall perform the following tasks:

- Provide technical assistance for any facilities in its service area requesting assistance with quality improvement efforts related to topics addressed by ESRD QIP and/or Star Ratings measures. Technical assistance can include training facilities on quality improvement methodology, improving data quality, and implementing and monitoring their quality improvement efforts;
- Establish relationships and collaborate with stakeholders to achieve improvements on ESRD QIP and Dialysis Facility Compare measures on behalf of patients. Stakeholders can include CDC staff working with NHSN, ESRD NCC staff working on Fistula First Catheter Last, LDO staff working on dialysis adequacy and mineral metabolism, and other stakeholders;

- Join one or more existing initiative or collaborative identified by the Network, the ESRD NCC BSI LAN, CMS' Center for Clinical Standards and Quality (CCSQ), or CMS' Center for Medicare and Medicaid Innovation (CMMI) (e.g., national or state-level collaborations focusing on HAI prevention and/or vaccinations);
- Spread knowledge and innovations learned in collaboration with facilities;
- Analyze data on ESRD QIP and Dialysis Facility Compare measure performance across facilities and notify lower-performing facilities and facilities with poor quality data of opportunities for improvement,
- Educate state surveyors (e.g., on monthly calls) to ensure that surveyors are knowledgeable about the ESRD QIP, Dialysis Facility Compare, Star Ratings, and request that the surveyors reinforce with facilities the requirements of the ESRD QIP and Dialysis Facility Compare measures;
- Provide a monthly summary of ESRD QIP educational activities on the COR Monthly Report.

The Network shall assist CMS with monitoring the ESRD QIP's impact on the quality of dialysis care and access to dialysis care. At minimum, the Network shall accomplish the following tasks:

- Inform CMS or its designees of potential changes in facility practices reported to or observed by the Network that may adversely affect patients. Changes in practices may include changes in access to care or admission or transfer practices. The Network shall monitor information including grievance data, clinical data, anecdotal reports, and information from other sources available to the Network to identify these changes. The Network shall report these monitoring activities and findings to CMS on the COR Monthly Report.
- Participate in CMS-scheduled discussions on findings from ESRD QIP monitoring and evaluation (M&E) activities. The Network shall provide information to assist CMS with interpreting M&E findings and provide suggestions for further analysis. If CMS determines there is sufficient evidence to conclude that patient care or access to care is compromised, the Network shall suggest interventions upon request by CMS to improve care or access to care.
- Communicate with CMS and designated contractors regarding actionable risks or adverse effects to beneficiaries identified by or conveyed to CMS or the Network.

C.3.23.B. Provide Technical Assistance to Facilities to Promote Timely and Accurate Data Submission to CROWNWeb, NHSN, and Other CMS-Designated Data Systems

CMS relies on the data in CROWNWeb, NHSN and other data systems to establish performance on the ESRD QIP and other quality improvement initiatives. To ensure fair facility payment and appropriate stewardship of quality improvement resources, these data systems must contain the most complete and accurate data possible. The Network can help CMS achieve this goal by providing technical assistance to facilities in several areas.

The Network shall follow all instructions and guidance as provided in Attachment J-12, CROWNWeb Data Management Guidelines. All deliverables are described in Chapter 3 of this Attachment, and will be provided by the Network as instructed in this document.

The Network shall validate that all facilities have successfully completed and submitted 2744A

forms by the first Friday in May of each contract year. The Network shall report successful completion of the ESRD Facility Surveys by providing a signed confirmation to the COR electronically by the second Friday in May.

The Network shall provide monthly updates of CROWNWeb activities, as directed in Chapter 3 of the CROWNWeb Data Management Guidelines, on the COR Monthly Report, and meet compliance of CROWNWeb metrics as directed by this document.

The Network shall assist new and previously nonparticipating facilities with NHSN enrollment if requested by facilities. Additionally, the Network shall provide assistance to facilities to improve facility processes related to the submission of data to NHSN, and resolve any identified issues with COR assistance related to the individual patient / facility. The Network may use the NHSN data outside the purposes and scope of the CMS Statement of Work; however, each additional use must be preceded by informing each dialysis facility in the Network of the planned data use, and each facility must have an opportunity to explicitly consent or withhold its consent to each additional use of the facility's NHSN data. Also, in the event that dialysis facilities consent to an additional use of their data beyond the purposes and scope of the CMS Statement of Work. The Network shall have a data use agreement (DUA) in place. Whether conducted internally or via DUA, analytic work for research purposes that goes beyond the activities described within this Statement of Work should be accompanied by an informed consent process in which dialysis facilities have the opportunity to accept or reject use of their NHSN data for the additional purpose(s)."

C.4. Quality Improvement Activities (QIAs)

The Network shall incorporate a focus on disparities in conducting all of the activities outlined in this SOW. In each QIA, the Network shall analyze data and implement interventions aimed at reducing disparities. All QIAs shall use innovative approaches and rapid cycle improvement that incorporate boundariliness, unconditional teamwork, are customer-focused and sustainable to achieve the strategic goals of the ESRD Network Program.The Network shall use data provided by the ESRD NCC or NHSN for each QIA as described. The Network shall not change the data provided by the ESRD NCC in any manner or the data derived from NHSN as prescribed by CDC. The Network shall consult with the ESRD NCC or CDC if there are questions regarding the data. The Network shall evaluate the success of the interventions described in the QIA plan in the IQI process. It is expected that the QIA plan will be a living document and change throughout the QIA using Plan-Do-Study-Act cycles as established in the initial plan. The Network shall report barriers to interventions and revisions each month on the COR monthly calls in addition to successes.

C.4.1. Making Care Safer by Reducing Harm Caused in the Delivery of Care

Infections are the second leading cause of death in patients with end-stage renal disease (ESRD). The antecedent for the majority of these infections is catheter-related bloodstream infection (CRBSI)[3]. As a result, the Network will develop a QIA plan to decrease blood stream infections to achieve a 5-year national target to guide national health promotion and management

[3] Soi V, Moore CL, Kumbar L, and YeeIn J, Prevention of Catheter-related Bloodstream Infections in Patients on Hemodialysis: Challenges and Management Strategies; Int J Nephrol Renovasc Dis. 2016; 9: 95–103

to improve the health of all people in the United States living with ESRD: *by 2023, reduce the national rate of blood stream infections in dialysis patients by 50% of the blood stream infections that occurred in 2016*. The Networks shall reduce the rate of blood stream infections by supporting NHSN, participating in the ESRD NCC BSI LAN, assisting dialysis facilities in the implementation of the CDC Core Interventions, improving communication between points of care, and reducing the rate of long-term catheters for dialysis access.

C.4.1.A. Support NHSN
The Network shall comply with all requirements specified in Attachment J-9, HAI and Patient Safety, with respect to supporting NHSN to reduce rates of dialysis events.

The Network shall perform the following to support NHSN data quality:

- Assist new and returning facilities in the Network service area to successfully enroll in NHSN.
- Support facilities in reporting dialysis event data for 12 months, and support facilities in reporting data to any or all other modules in NHSN in support of ESRD QIP requirements, or as necessary for HAI prevention efforts.
- Establish the Network as group administrator for the NHSN database system for the dialysis facilities in the Network's service area.
- Assist facilities in ensuring that data are entered into the NHSN database accurately and in a timely manner.
- Support facilities in completing annual NHSN Dialysis Event Surveillance training (https://www.cdc.gov/nhsn/dialysis/event/index.html.). By the end of the third quarter each contract year, the Network shall achieve 90% or more of facilities in the Network service area completing the online annual NHSN Dialysis Event Surveillance training during that contract year. The Network shall report the percent of facilities completing training during that contract year to the NCC for inclusion in the Dashboard.
- Perform quarterly NHSN data checks using a CDC-created and CMS-approved data checklist. The Network shall follow up with facilities to correct data errors. March data checks shall review 4th quarter of the previous calendar year. June data checks shall review 1st quarter data. September data checks shall review 2nd quarter data. December data checks shall review 3rd quarter data. These quarterly data checks are designed to help facilities meet ESRD QIP requirements. The Network shall report the results of the data checks on the COR Monthly Report for the month after the data checks occur.
- Assist 10% of the Network service area to join a Health Information Exchange (HIE) or another evidence-based highly effective information transfer system as approved by the COR to receive information relevant to positive blood cultures during transition of care. The Network shall obtain documentation from the facility that use of the HIE or other evidence-based highly effective information transfer system is successful. This may include policy and procedure or less formal evidence of a system. The facility shall also demonstrate the effectiveness of the system for obtaining information regarding hospitalization in QAPI.

C.4.1.B. Participate in the ESRD NCC BSI LAN
The ESRD NCC BSI LAN has two primary purposes. The first is to improve information

communication across care settings, with emphasis on communication between hospitals and dialysis centers caring for the same ESRD patients. The second is to increase awareness of and implementation of promising practices to reduce bloodstream infections.

The Network shall perform the following to support ESRD NCC BSI LAN:

- Invite all facilities within the Network service area to participate.
- Invite QIN-QIO(s), HIINs, state/local health departments, State Survey Agencies, long-term care facilities, hospitals, dialysis facilities including regional leadership, and patient representatives to support communication and BSI QIA. The Network shall review the attendance of providers and patients in their service area and increase attendance throughout the contract year.
- Ask dialysis organizations or facilities to identify best practices within the Network service area for successfully implementing the CDC Core Interventions or other successful intervention to reduce BSIs for inclusion in the LAN as presenters.
- Attend the ESRD NCC BSI LAN every other month.
- Share identified interventions to improve the BSI rates from each LAN meeting with all facilities in the Network service area and report on the implementation of the interventions at QIA facilities in the monthly COR report and in the IQI.

C.4.1.C. Reduce Rates of BSIs
The Network shall work through facilities to reduce BSI rates in outpatient dialysis facilities by:

- Revise the BSI QIA J-7 Short Form based on information identified in the rapid cycle improvement efforts of Option Year 3 by October 31 for option year 4. The plan is not required in option year 4.
    - Include a plan to assist facilities to implement and monitor all of the CDC recommended interventions for dialysis BSI prevention (http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html)
    - Describe in detail how the Network will educate the facility on the CDC Core Interventions, how the Network will assist the facility to implement the CDC Core Interventions, how the Network will assist the facility to monitor their own progress toward implementing the CDC Core Interventions and reduction of BSIs, and how the Network will monitor the progress of QIA facilities and assist the facilities that are unable to progress to goal.
    - Describe how Patient SMEs and/or family members or caregivers will be involved at the facility level in discussion about infection control practices and ways to feel more comfortable bring issues to the attention of staff members.
    - Revise the BSI QIA J-7 Short Form to include any changes the Network identified through rapid cycle improvement to improve the project plan for the subsequent option years by October 31st.
- The Network shall select a cohort of 20% of the Network service area for participation in the BSI cohort using the NHSN excess infection report. The Network shall use CDC as a resource to access the report and select facilities.
- Provide the facilities in the BSI QIA with guidance to implement all CDC recommended interventions for dialysis BSI prevention (Surveillance and feedback using NHSN, hand

hygiene observations, catheter/vascular access care observations, staff education and competency, patient engagement/education, catheter reduction, chlorhexidine for skin asepsis, catheter hub disinfection, and antimicrobial ointment) that the facility has not adopted or is having difficulty successfully implementing. The Network shall stress to facilities the Core Interventions identified by CDC as having the greatest potential to reduce the infection rate, catheter reduction and catheter interventions (scrub the hub, chlorhexidine for skin asepsis, antimicrobial ointment at the catheter exit site, staff education regarding the interventions with competency test, and regular audits to reinforce appropriate catheter care).

- Incorporate action steps developed from each ESRD NCC BSI LAN into the plan to assist facilities in implementing the CDC recommended interventions and other promising interventions for reducing BSIs.
- Identify the number of facilities that have successfully implemented each of the CDC Core Interventions into facility practice and report this monthly. The Network may ask the facilities about the use of interventions but should ask for enough documentation to ensure the facilities have successful implementation of the Core Interventions.
- Encourage the dialysis facilities to discuss the use of the CDC Core Interventions at QAPI meetings, in addition to infection rates, with the Medical Director for the facility.
- Assist facilities to complete a root cause analysis if there was successful implementation of all the CDC Core Interventions and the BSI rate did not decrease by at least 10% during the QIA.
- Demonstrate a 20% or greater relative reduction in the semi-annual pooled mean in the cohort of 20% of facilities with the highest excess infection rates in the Network service area at re-measurement compared to the previous year.
- Report the monthly quarterly pooled-mean rates for monitoring purposes only. Base year evaluation shall be based on the semi-annual pooled mean rates, which will consist of the combined first- and second-quarter data of 2015 as the baseline, and re-measurement shall occur from the combined first- and second-quarter data of 2016, and then again from the first- and second-quarter data for each subsequent option year of the contract. Beginning in option year 2, the Network shall report the semi-annual pooled mean rate for facilities from the third- and fourth- quarter of 2017 and then third- and fourth-quarter data in the same manner for each subsequent option year as an additional data point. In 2019 and subsequently, the Network shall utilize the Excess Infection Report from NHSN to determine the 20% of facilities with the highest excess infection rate in the Network service area. The Network shall work with CDC as a resource for the use of the report and in selecting facilities.
- Report activities related to this QIA monthly in the COR Monthly Report.
- Use CDC technical assistance and tools in enrolling facilities in NHSN and encouraging accurate reporting of data
- Share best practices in the area of reducing HAIs, BSIs, and sepsis (i.e., promoting evidence-based practices for BSI prevention in dialysis facilities and best practices for implementation)
- Involve patient SMEs and direct interventions at the targeted facilities to allow patients the ability to impact the care received at the facilities.

- Notify the regional corporate representative for each facility of the facilities selection for participation in the QIA and encouraged to participate with the Network to the extent desired.
- Promote communication and discussion between dialysis facilities, hospitals, and other healthcare entities. Report results monthly on the COR report.
- Encourage facilities to participate in CDC HAI training activities by encouraging all clinical staff to complete the CDC Infection Prevention in Dialysis Settings Continuing Education course at http://www.cdc.gov/dialysis/clinican/CE/infection-prevent-outpatient-hemo.html, as well as view the CDC video "Preventing Bloodstream Infections in Outpatient Hemodialysis Patients: Best Practices for Dialysis Staff" at http://www.cdc.gov/dialysis/prevention-tools/training-video.html.

C.4.1.D. Reduce Rates of Long-Term Catheters (LTC)

The Network shall work to reduce the rate of LTCs to reduce the potential for BSIs by:

- Revise the BSI LTC QIA J-7 Short Form to include any changes the Network identified through rapid cycle improvement to improve the project plan for the subsequent option years by October 31st not necessary in option year 4.
- Using the Achievable Benchmark of Care (ABC™) model, the Network shall decrease LTC rate in the Network service area by at least 0.25% by evaluation based on data available in October by working with incident patients, prevalent patients, and dialysis facilities in the Network service area. Data available in October of the previous contract year shall be used as baseline. The data shall exclude pediatric patients under the age of 18.
- The Network shall perform a root cause analysis of the interventions from January through July if the 0.25% improvement for prevalent patients is not achieved during these specific months. The Network shall provide the root cause analysis to the COR by October 31st of each option year. Historically there has been great movement within the months of October, November, and December with little movement from January through September.

CMS recommends that the Network learn about the National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination (http://www.hhs.gov/ash/initiatives/hai/esrd.html).
Prevention of intravascular infections, blood-borne pathogen transmission (e.g., hepatitis B), and influenza and pneumococcal disease are priorities identified in the *National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination* (see http://www.hhs.gov/ash/initiatives/hai/esrd.html).

C.4.2. Improve Transplant Coordination

The benefits of transplantation extend to ESRD patients regardless of age, gender, or ethnicity, as well as those with common comorbid conditions, including diabetes and hypertension[4]. This

[4] Merion RM, Ashby VB, Wolfe RA, et al. Deceased-donor characteristics and the survival benefit of kidney transplantation. JAMA 2005;294:2726-33

is evidenced by the Executive Order on Advancing American Kidney Health (AAKH) on July 10, 2019 see here https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health . The Network shall support all the goals and initiatives detailed in the Executive Order especially the goal to improve kidney health by having 80% of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant. The intent of the Transplant Coordination QIA is to promote early referral to transplant, and assist patients and providers to improve referral patterns by addressing barriers identified as the patient moves through the steps identified by Sullivan et al[5]. The Networks shall increase the number of patients on a transplant waiting list by participating in the ESRD NCC Transplant LAN, and assisting dialysis facilities in the implementation of interventions to support patients through the process of being placed on a waiting list.

C.4.2.A. Participate in the ESRD NCC Transplant LAN

The ESRD NCC Transplant LAN has two primary purposes. The first is to improve information communication across care settings, with emphasis on communication between transplant centers and dialysis centers caring for the same ESRD patients. The second is to increase awareness of and use of promising practices to support the patient through the waiting list process.

The Network shall perform the following to support ESRD NCC Transplant LAN:

- Invite all facilities within the Network service area to participate.
- Invite QIN-QIO(s), HIINs, State Survey Agencies, hospitals, transplant centers, dialysis facilities including regional leadership, and patient representatives to support communication and Transplant QIA. The Network shall review the attendance of providers and patients in their service area and increase attendance throughout the contract year.
- Ask dialysis organizations or facilities to identify best practices within the Network service area for successfully increasing the rate of patients on the Transplant waiting list for the LAN as presenters.
- Attend the ESRD NCC Transplant LAN every other month.
- Identify best practices offered by presenters on each LAN meeting. Identify commitments from dialysis facilities within the Network service area to implement the best practices. Report on the implementation and success of the offers and commitments in facilities in the monthly COR report and in IQI.

C.4.2.B. Increase Rates of Patients on a Transplant Waiting List

The Network shall work to increase rates of Patients on a transplant waitlist in outpatient dialysis facilities by:

- Submitting the J-7 Short Form for the Transplant QIA by October 31st for option year 3

[5] Sullivan C, Leon JB, Sayre SS, Marbury M, Ivers M, Pencak JA, Bodziak KA, Hricik DE, Morrison EJ, Albert JM, Navaneethan SD, Reyes CM, Sehgal AR. Impact of navigators on completion of steps in the kidney transplant process: a randomized, controlled trial. Clin J Am Soc Nephrol. 2012 Oct;7(10):1639-45. doi: 10.2215/CJN.11731111

not necessary in option year 4.

- Describe the methodology devised to address barriers at each of 5 steps leading to receiving a transplant: 1) Patient interest in transplant, 2) Referral call to transplant center, 3) First visit to transplant center, 4) Transplant center work-up, 5) On waiting list or evaluate potential living donor.
- Describing how Patient SMEs and/or family members or caregivers will be involved at the facility level in discussion about transplant benefits, requirements, barriers, and successful interventions to overcome barriers.
- Describe how the Network will educate dialysis facility staff, patients, and family members regarding the benefits of pursuing transplant and the tradeoffs associated with timeliness of transplant, availability of organs and quality of organs.
- Describe how the Network will educate dialysis facility staff, patients, and family members about kidney allocation including the Kidney Donor Profile Index (KDPI) and the Estimated Post-Transplant Survival (EPTS) score.
- Describe how the Network will enlist patients, key patient peer mentors, key successful facilities with high rates of patients that have been added to a waiting list, and key physicians and research leaders related to transplant to participate in the transplant initiative.
- Describe how the Network will fill the gap reported by dialysis facilities and transplant centers to track patient by the use of reports to both entities.
- Describe how the Network will encourage patients to list at more than one transplant center.

- Tracking and reporting to CMS monthly the number of patients at each stage of the process as the patients are successfully moved to the next step of the process.
- Engaging successful transplant recipients, transplant centers, and other stakeholders to develop educational materials to assist in overcoming identified barriers at each step of the process.
- Notifying the regional corporate representative for each facility selected for participation in the QIA and encouraged participation with the Network to the extent desired by the corporate representative.
- Promote communication between dialysis facilities, transplant centers, hospitals, nephrologists and other healthcare providers to improve the rate of patients on the transplant waiting list. Report results monthly on the COR report.
- Encouraging facilities in the Transplant QIA to incorporate the process steps into patient education, facility practice, and the facility QAPI process.
- Engaging hospitals, transplant centers, and nephrologists along with other healthcare providers to educate patients at the earliest diagnosis of ESRD about transplant and begin the process of successfully being on a transplant waiting list.
- Using the ABC^{TM} model, the Network shall increase the rate of patients added to the Transplant waiting list in the Network service area by at least 1.25% by evaluation based on data available in October by working with incident patients, prevalent patients, and dialysis facilities. Data available in October of the previous contract year shall be used as baseline.
- Champion and advance the transplant initiatives identified in the Executive Order on AAKH for more information click here https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health.

- Participate robustly in the ESRD Treatment Choices (ETC) Model Test Learning Collaborative in support of CMMI click here https://innovation.cms.gov/initiatives/esrd-treatment-choices-model/.
- Utilize Human Centered Design (HCD) and any available changes packages to further the transplant initiatives identified in the Executive Order of AAKH.
- Support the work of the Transplant Learning Collaborative https://www.federalregister.gov/documents/2019/07/18/2019-14902/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures
- Using rapid cycle improvement to revise the methodology developed for the QIA and submit it to the COR by October 31st beginning in option year 2 for option year 3 and each subsequent option year. This is not required in option year 4 due to the ending of the contract. This shall allow for uninterrupted continuation of the QIA starting in December of subsequent option years.

C.4.3. Promote Appropriate Home Dialysis

Home dialysis modalities are underutilized in the USA with only 8% of the dialysis patients undergoing renal replacement therapy at home versus 92% being treated with center hemodialysis[6]. The Executive Order on Advancing American Kidney Health on July 10, 2019 recognizes this inequity see here https://aspe.hhs.gov/pdf-report/advancing-american-kidney-health. The Network shall support all the goals and initiatives detailed in the Executive Order especially the goal to improve kidney health by having 80% of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant. The intent of the Home Dialysis QIA is to promote referral to home dialysis modalities, identify and mitigate the barriers to timely referral, and determine the steps patients and providers can take to improve referral patterns. The Networks shall increase the number of patients on a home modality by participating in the ESRD NCC Home Dialysis LAN, increasing communication between hospitals, in-center dialysis facilities, and home dialysis facilities, and assisting dialysis facilities in the implementation of interventions to support patients through the process of training to dialyze at home.

C.4.3.A. Participate in the ESRD NCC Home Dialysis LAN

The ESRD NCC Home Dialysis LAN has two primary purposes. The first is to improve information communication across care settings, with emphasis on communication between in-center dialysis centers and home dialysis, internally between in-center and home modality staff to educate patients and between hospitals and dialysis facilities. The second is to increase awareness of and use of promising practices to support the patient through training for a home modality.

The Network shall perform the following to support ESRD NCC Home Dialysis LAN:

- Invite all facilities within the Network service area to participate.
- Invite QIN-QIO(s), HIINs, State Survey Agencies, hospitals, both in-center and home dialysis facilities including regional leadership, and patient representatives to support

[6] Thinking outside the box—identifying patients for home dialysis. Brigitte Schiller, Hayley Munroe, and Andrea Neitzer

communication and Home Dialysis QIA. The Network shall review the attendance of providers and patients in their service area and increase attendance throughout the contract year.
- Ask dialysis organizations or facilities to identify best practices within the Network service area for successfully increasing the rate of patients on a home modality for the LAN as presenters.
- Attend the ESRD NCC Home Dialysis LAN every other month.
- Share identified interventions to improve the home dialysis rates from each LAN meeting with all facilities in the Network service area and report on the implementation of the interventions at QIA facilities in the monthly COR report and IQI.

C.4.3.B. Increase Rates of Patients Dialyzing at Home
The Network shall work to increase the number of patients dialyzing at home by:

- Submitting the J-7 Short Form for the Home Dialysis QIA by October 31st for option year 3 not necessary in option year 4.
    - Describing the methodology devised to address barriers at each of 7 steps leading to home dialysis utilization: 1) Patient interest in home dialysis (after assisting the patient to determine modality options that fit the patient's lifestyle), 2) Educational session about home modality, 3) Patient suitability for home modality determined by a nephrologist with expertise in home dialysis therapy, 4) Assessment for appropriate access placement, 5) Placement of appropriate access, 6) Patient accepted for home modality training, 7) Patient begins home modality training.
    - Describing interventions to increase the awareness and education on home modality options and referral to home dialysis.
    - Describing interventions to ensure appropriate reassessment of modality choice. Changes in life events could also change receptiveness to home modality.
    - Describing how Patient SMEs and/or family members or caregivers will be involved at the facility level in discussion about home dialysis benefits, requirements, barriers, and successful interventions to overcome barriers.
- Tracking and reporting to CMS monthly the number of patients at each stage of the process and the number of patients that are successfully moved to the next step of the process for in-center dialysis facilities.
- Engaging patients successfully dialyzing at home, home dialysis centers, and other stakeholders to develop educational materials to assist in overcoming identified barriers at each step of the process.
- Notifying the regional corporate representative for each facility selected for participation in the QIA and encouraged participation with the Network to the extent desired by the corporate representative.
- Promote communication between in-center dialysis facilities, home dialysis facilities, hospitals, nephrologists and other healthcare providers to improve the rate of patients utilizing a home dialysis modality. Report results monthly on the COR report.
- Encouraging facilities in the Home Dialysis QIA to incorporate the process steps into patient education, facility practice, and the facility QAPI process.
- Engaging hospitals and nephrologist along with other healthcare provides to educate

patients at the earliest diagnosis of ESRD about home modalities and the dialysis option that best fits the patient's lifestyle.

- Using the ABC^{TM} model, the Network shall increase the rate of patients that begin training for a home modality in the Network service area by at least 2.5% by evaluation based on data available in October by working with incident patients, prevalent patients, and dialysis facilities. Data available in October of the previous contract year shall be used as baseline.
- Champion and advance the home modality initiatives identified in the Executive Order on AAKH.
- Utilize Human Centered Design (HCD) and any available changes packages to further the home modality initiatives identified in the Executive Order of AAKH.
- Using rapid cycle improvement to revise the methodology developed for the QIA and submit it to the COR by October 31st beginning in option year 2 for option year 3 and each subsequent option year. This shall allow for uninterrupted continuation of the QIA starting in December of subsequent option years.

C.4.4. Population Health Focused Pilot QIAs

The Network's activities shall include stakeholder collaborations and employ a population-based approach to improve the quality of care and access to ESRD care through a Population Health Focused Pilot QIA (PHFPQ) in **one of the following CMS pre-approved priority areas:**

- Improve Dialysis Care Coordination with a Focus on **Reducing Hospital Utilization** (QIA A)
- Positively Impact the Transition of Dialysis Care with a **Focus on Peer Mentoring (QIA B)**
- Support **Gainful Employment of ESRD Patients** (QIA C)

The objective of the PHFPQ is to facilitate achievement of national quality improvement goals and support statutory requirements set forth in Section 1881 of the Social Security Act and the Omnibus Budget Reconciliation Act of 1986. Throughout this PHFPQ, the Network shall provide leadership and guidance for the QIA's quality improvement efforts in collaboration with the CMS SME and COR.

Each Network shall conduct one QIA per contract year and shall achieve the performance requirements for the QIA selected (i.e., A, B or C) for evaluation purposes, as required by this SOW.

C.4.4.A. Population Health Focused Pilot QIAs: Technical Considerations

The Network's PHFPQ shall adhere to the confidentiality and disclosure requirements set forth in Section 1881 of the Social Security Act, the Omnibus Budget Reconciliation Act of 1986, and all applicable CMS administrative directives.

Any data given to the Network by the government for purposes of a PHFPQ shall only be used to support the PHFPQ unless the Contracting Officer specifically permits another use in writing. If the Contracting Officer allows the Network to use government-supplied data for a purpose other

than one solely in support of this PHFPQ, and if such use could result in a commercially viable project, the Contracting Officer may negotiate a financial benefit to the government. A benefit may be in the form of a reduction in the price of the PHFPQ, but the Contracting Officer may negotiate any other benefit(s) he/she determines are adequate compensation for the use of the data.

At the request of the Contracting Officer or at the completion of these PHFPQs (whichever comes first), the Network shall return or destroy all data related to the PHFPQ given to the Network by the government. The Contracting Officer may direct that the data be retained by the Network for a specified period of time agreed to by the Network. If the data are to be destroyed, then the Network shall furnish direct evidence of such destruction in a form that the Contracting Officer shall determine is adequate.

The Network shall comply with all CMS guidelines regarding the appropriate de-identification of data related to both individuals and facilities, consistent with the guidelines concerning disclosure of ESRD data.

C.4.4.B. Population Health Focused Pilot QIAs: Requirements
The Network shall, working with appropriate internal and external stakeholders for the Network-selected QIA develop and disseminate innovative interventions that support process improvement and sustainment of the improved processes. The Network shall employ proven quality improvement techniques to develop the QIA and implement interventions based on the findings of the RCA conducted. To meet established thresholds, the QIA shall incorporate the concepts of boundariliness and unconditional teamwork. The QIA plan shall include customer-focused approaches and rapid cycle improvement strategies.

CROWNWeb data will be the official data source for all QIAs. Other CMS-sanctioned data collection systems may be used, as decided by CMS. *In the proposal phase, the Network shall use CMS-identified data sources and establish measurable outcomes for consideration and CMS approval.* Data collected throughout these QIAs shall be used to impact quality improvement in the care delivered to ESRD patients and to identify trends that may be indicative of disparities in care, with the purpose of decreasing such disparities.

The Network should be knowledgeable in the topic area and the targeted populations that it is working with during the course of these QIAs. QIAs shall also be developed so that, if necessary, participating dialysis facilities may be carried into future contract periods or replaced if they have achieved pre-determined thresholds for the measures.

Using ESRD NCC-provided data, the Network shall select a topic for its PHFPQ based on the opportunity for improvement on the performance measure in the target population. *In OY 4, a disparity assessment is not required for PHFPQ.*

As the first step in choosing the target facilities for its PHFPQ, the Network shall select from one of the three CMS-approved QIA areas. The Network shall then consider patient threshold, including a minimum percentage (as defined by the ESRD NCC for each QIA) of the ESRD patient population receiving dialysis services within the Network service area. At least 3 of the

dialysis facilities included in cohort must be located in a rural area (as identified in CROWNWeb). If the network service area doesn't have at least 3 dialysis facilities in the network service area the Network shall select all facilities located in a rural area.

For this multi-year contract with a base year and four Option Years (OYs), the Network shall obtain CMS approval of the QIA facilities prior to initiating formal intervention activities related to the QIA. The Network shall initiate the QIA by selecting the topic area and target facilities to be included in the QIA. Additionally, if the Network stays with the same QIA, it may add facilities that otherwise meet the PHFPQ and topic-specific requirements, and it may petition to have facilities dropped that have other legitimate reasons for being excluded from the QIA. Legitimate reasons for exclusion include: a facility no longer provides the services related to the topic area (e.g., a dialysis facility stops providing home dialysis services), permanent closure (temporary closure is not a legitimate reason unless documentation is received from the facility that the closure will be of sufficient length that the facility would not be able to participate in the QIA for at least six months of the contract period), or a facility has participated in a QIA for longer than three contract years. All final decisions on the legitimacy of the exclusions will rest with the PHFPQ CMS SME.

For each Option Year of the contract, an initial plan for the QIA, due by December 12, shall be provided, using the PHFPQ Checklist in Attachment J-7, Quality Improvement Activities. The completed PHFPQ Checklist shall, in no more than 10 pages, explain in detail the strategies, interventions and timeframes the Network plans to implement in order to meet all of the specified goals of the QIA. The Network is responsible for developing and/or identifying interventions that improve the condition of the selected QIA demographic (i.e increase the number of patients referred to a State Vocational Rehabilitation Agency or an Employment Network). All proposed interventions for the selected QIA shall be proven to support project improvement. The proposal shall be finalized and baseline data collection and analysis for the selected QIA shall be completed, by December 20. The Network shall not opt for a different QIA after PHFPQ approval is received by December 20. Reporting of the final QIA target facilities to the NCC shall be completed by January 8.

The Network shall provide to each participating QIA facility, technical assistance with performing a root cause analysis, identifying specific inefficient processes, ineffective practices and barriers to quality service. Each facility RCA shall be completed using the PHFPQ Root Cause Analysis Template in Attachment J-7, Quality Improvement Activities. The Network shall, submit using the PHFPQ Root Cause Analysis Template, a summary of the three most frequently cited, identified root causes and proposed specific, proven interventions, to the COR and CMS SME by February 6. Intervening approaches shall begin by the first business day of February. The evaluation period for all PHFPQ QIAs shall be from January through September.

The Network shall use action-oriented Learning and Action Networks (LAN) to promote successful interventions to improve the outcomes of the selected QIA. The Network shall coordinate a LAN for the selected QIA, identifying presenters and collaborating with stakeholders as necessary. The Network shall invite all stakeholders, patient SMEs and facilities in the Network service area that participate in the specific Pilot QIA, to participate in the Pilot QIA specific LAN. The Network may choose to invite patients, family members and/or

caregivers to participate. The Network shall work with dialysis organizations to identify facilities within the Network service area that have successfully developed internal process related to the specific Pilot QIA to include in the LAN. The LAN shall meet at least twice during the project period. The Network shall share identified interventions to improve specific Pilot QIA rates from each LAN meeting with all facilities in the Network service area and report on the implementation of the interventions at QIA facilities in the monthly COR report.

C.4.4.C. Population Health Focused Pilot QIAs: Contract Monitoring and Evaluation
The PHFPQs present new opportunities for the Network to identify, implement and spread promising practices, thereby improving the quality and efficiency of services rendered to ESRD patients.

The Network shall be monitored and measured for improvement through routine COR Review, based on data reported to CMS. Data for the Network-selected QIA shall be reported to CMS monthly using the ESRD NCC Dashboard, as directed by CMS through this SOW or through supplemental CMS communication. The Network shall submit all required reports and deliverables in accordance with the SOD. Failure to meet all requirements of a chosen QIA (including, but not limited to, data reporting for all components of the QIA, achievement of topic-specific performance requirements and achievement of required attribute evaluation goals) will be referred to the Contracting Officer for determination of appropriate action.

For each year of the contract, evaluation of this QIA shall be based on two components weighted equally: 1) achievement of the topic-specific performance benchmark (quantitative assessment), and 2) successful incorporation of the six identified attributes into the QIA (qualitative assessment). Successful performance for these three objectives shall be determined by the COR in consultation with CMS SME. The evaluation period of each of these measures shall be based on data occurring between January and September for the performance measures, assessed against a baseline period of January – September of the previous contract year. CMS will re-establish baselines each contract year, regardless of whether the QIA is for a single year or spans multiple-years.

The quantitative evaluation of the PHFPQs shall be based on successful achievement of the required performance improvement for the targeted demographic of the selected QIA, as of July/August CROWNWeb data (received in September), as specified in this SOW.

Failure in the quantitative component shall result in an unsuccessful evaluation for the QIA.

The qualitative evaluation of the PHFPQs shall be based on successful incorporation of the six (6) identified attributes, as determined by monthly Network COR assessment. The Network shall achieve an average rating of at least Satisfactory by September, using the following rating scale:

Rating: Exceptional (5 points)
- Contract Requirements: Exceeds by having 3 or more interventions that meet the description of the attribute
- Problems: Few Minor

- Corrective Actions: Highly Effective

Rating: Very Good (4 points)
- Contract Requirements: Exceeds by having at least 2 but less than 3 interventions that meet the description of the attribute
- Problems: Some Minor
- Corrective Actions: Effective

Rating: Satisfactory (3 points)
- Contract Requirements: Meets the description of the attribute with at least 1 intervention
- Problems: Some Minor
- Corrective Actions: Satisfactory

Rating: Marginal (2 points)
- Contract Requirements: Does not describe an intervention that fulfills all of the description of the attribute
- Problems: Serious; Recover Still Possible
- Corrective Actions: Marginally Effective; Not Fully Implemented

Rating: Unsatisfactory (1 point)
- Contract Requirements: Does not describe an intervention that fulfills the description of the attribute
- Problems: Serious; Recovery Not Likely
- Corrective Actions: Ineffective

Evaluation Scale:
30-25 points Exceptional
24-19 points Very Good
18-13 points Satisfactory
12-7 points Marginal
6-1 points Unsatisfactory

The Network shall provide tangible evidence of demonstrations of the six attributes in each QIA on a monthly basis during the monthly COR call, including actions that support or facilitate incorporation of the attribute. The COR will monitor for inclusion of the six attributes and demonstrations of each attribute throughout the course of the QIA, reporting progress in the COR Monthly Report and providing an assessment of incorporation of the attributes on the CMS ESRD Dashboard. Demonstrations of attributes shall be displayed for each month of the QIA; therefore, the Network shall not have a month in which the attribute is shown as N/A.

The following attributes of effective QIAs will serve as the basis for assessing qualitative performance under PHFPQ:

1) Commitment to Boundarilessness and Unconditional Teamwork: To display the concept of boundarilessness, the Network shall demonstrate the ability to identify and engage various entities outside of CMS, to impact improvement for ESRD patients and/or providers. Entities

outside of CMS, include (but is not limited to) state, local and federal healthcare organizations; patient advocacy groups; professional associations; and stakeholders. These entities should be a full and active participants in the QIA. The Network shall be able to identify entities not typically included in the QIA and how the collaboration with the external entity is improving the outcomes of the QIA.

To display the concept of unconditional teamwork, the Network shall demonstrate its ability to, at minimum, partner with other Networks; divisions internal to CMS; the ESRD NCC; and QIN-QIOs; to solicit input from dialysis facilities, patients and others in the renal community to identify, develop and spread effective improvement activities. The Network shall demonstrate sharing of best practices with other Networks, as well as with QIA participants and partners. Demonstrations may include, but are not limited to: active participation on COP calls, engaging meeting presenters to identify new and different approaches, collaborations with QIN-QIOs, and participating in NCC QIA Workgroups, including dynamic discussion and exchange of ideas with other Networks.

Both attributes must be demonstrated, either separately or in a single effort.

> Attribute in Action (Boudarilessness): The Network partners with the American Association of Kidney Patients (AAKP) to develop an outreach and awareness campaign for the promotion of home dialysis.
>
> Attribute in Action (Unconditional Teamwork): The Network joins the Community Care Coordination Coalition of one of the QIN-QIOs located in their geographic region. As an active member of the Coalition, the Network participates on activities to identify barriers and improve the coordination of care within chronic care settings.
>
> Attribute in Action (Boudarilessness & Unconditional Teamwork): The Network includes in its approach to QIA A, collaborative practice with a QIN-QIO; the regional referral hospitals of QIA dialysis facilities; QIA dialysis facilities; and community nursing homes, forming a regional coalition aimed to improve the health of dialysis patients through better facilitated communication between all providers involved in the care process.

2) Customer Focus and Value of the QIAs to Patients, Participants, and CMS: The Network shall seek to meet the needs of its customers by involving patients and other stakeholders in all aspects of QIAs. Customer input should help to shape the design and ongoing operations of activities. Patients representing the diversity of the population served shall be actively engaged in activities. The Network shall be able to demonstrate that patients and other stakeholders were solicited for feedback on: the relevance of a specific QIA to the patient or stakeholder, how well a particular QIA met the needs of the patient or stakeholder, whether or not the QIA impacted a significant change for the patient or stakeholder, and/or additional suggestions for improvement. The ability of the Network to address these topics in a direct and actionable manner will be evidence of meeting the requirements for this attribute.

> Attribute in Action: The Network offers an electronic survey, monthly to all dialysis

facility QIA leads, to solicit feedback and suggestions regarding the design and ongoing execution of the PHFPQ QIA. Responses are reviewed and documented and discussed in the steering committee, for appropriate action.

3) Value Placed on Innovation: The Network shall demonstrate solicitation and/or creation of at least one a new idea or concept that maximizes improvement for the QIA participants. This includes developing a mechanism by which all entities the Network works with and/or has contact with as part of the QIA are able to contribute ideas that may be of value to the Network's improvement work. It may also include the development of one or more new tools or processes that benefit the QIA participants. The Network shall be able to demonstrate examples of these approaches as part of its QIA. To demonstrate innovation, an intervention must be a new concept or approach to the Network. Once an intervention has been established in a Network's service area, that specific intervention may no longer be viewed as innovative; however, if thru the rapid cycle improvement process, the intervention is improved, the revised approach may be considered innovative.

Attribute in Action: The Network provided web cameras to those QIA facilities in remote areas where travel to and from those facilities was difficult. With the installation of the cameras, the Network conducted virtual site visits and QIA update meetings with facility staff.

4) Patient and Family Engagement: The Network shall provide technical assistance to dialysis facilities on developing strategies to promote and encourage Patient SMEs and/or family members or caregiver participation with the PHFPQ QIA. The Network shall demonstrate assessment at the dialysis facility level for Patient SMEs and/or family members or caregiver involvement on task forces and teams working on patient safety and quality improvement endeavors related to the selected QIA. At the Network level, Patient SMEs and/or family members or caregivers shall be instrumental in the planning, development and selection of interventions and tools that support advancement of the PHFPQ QIA. As part of QIA update meetings with dialysis facilities or any onsite visits to dialysis facilities participating with the PHFPQ QIA, the Network shall incorporate discussion, education and evaluation of how the dialysis facility has implemented patient and family centered care into the selected PHFPQ QIA. During these meetings, the Network shall assess for the presence of quality improvement focused meetings including: Patient SMEs and/or family members or caregivers (e.g., patient council, LANS, QAPI meetings); patient and family involvement in the governing body of the facility; and policies and procedures related to family participation in the patient's care (e.g., involvement in the development of the individualized plan of care and decisions about mental health treatment or employment). A summary of the related findings and actions taken, resulting from these discussions/visits and documentation of patient and family engagement at the facility level shall be documented in the COR Monthly Report.

Attribute in Action: In response to numerous accounts of feelings of isolation, the Network established a patient-led support group for those patient residing in rural areas.

5) Rapid Cycle Improvement in QIAs and Outputs: The Network shall routinely reassess the value of the interventions and technical assistance used for the QIA. The Network shall make

interim adjustments based on the feedback it receives from its participants and CMS, as well as from its own performance monitoring toward achieving contractual goals. The Network shall report what changes have been made in regard to the performance and/or disparity components of the QIA, why they were made, and how they are expected to impact the QIA metrics. Examples of evidence include that the Network demonstrates that results and the impact of interventions are reviewed on at least a monthly basis, adjustments are made to the interventions and that interventions that do not yield positive results are discontinued.

> Attribute in Action: The Network identifies a risk calculator, developed by a university's School of Medicine. The MRB researches and reviews the tool, which shows estimates for a patient's risk of survival and death with different treatment options, based on age, gender, length of time on dialysis, and patient history. The Network introduces the tool to the PAC aiming to increase dialogue regarding patient treatment options and to help patients make better educated treatment decisions. The Network disseminates a pre-test to ¼ of the PAC members. For two weeks, the small group of PAC members uses the calculator. The Network administers the pre-test again (now a post-test) to measure if patients' knowledge of treatment options had increased. Patient SMEs recommend a change in the way the tool is disseminated and explained. The Network administers the pre-test to another ¼ of the PAC members and tests the new approach for two weeks, administering the post-test afterwards. Noticing improved results compared to the first round of testing, the Network disseminates the calculator to the remaining ½ of the PAC members using the revised approach. After two weeks, receiving a few more suggestions, but recognizing consistent outcomes, additional tweaks are made and the calculator is disseminated to all QIA facilities.

6) **Ability to Prepare the Field to Sustain the Improvement**: Early in the QIA, the Network shall begin establishing a plan to increase the probability that the quality improvement activity(s) are maintained and that improvement continues when the Network completes its formal work with the participants. The Network shall provide a framework and education for the QIA participants that will allow them to sustain or continue improvement in the absence of the Network. The Network shall demonstrate how the facilities involved in the PHFPQ are able to incorporate the interventions into their own activities and processes in order to sustain the QIA once the Network's involvement is completed. The Network may develop a new QIA while the interventions developed in a former QIA remain in use. Examples of demonstrated sustainment include process changes facilities have implemented or new approaches that the facilities have undertaken that directly impact future results.

> Attribute in Action: As an intervention for QIA A, the Network supports facilities in implementing post-hospitalization evaluations for patients during the first treatment, post hospitalization. Through frequent dialogue with LDO leadership throughout the QIA and by demonstrating successful outcomes of the intervention, the LDO now requires a new dialysis order from the nephrologist prior to the first treatment, post hospitalization. The order includes key sections from the post-hospitalization evaluation.

C.4.4.D. QIA A: Improve Dialysis Care Coordination with a Focus on Reducing Hospital Utilization

The intent of QIA A is to identify the drivers of ineffective care transitions such as a lack of timely and complete communication, poor patient activation, and other system level process deficiencies that can lead to poor health outcomes resulting in increased utilization of acute care services. QIA A also serves to aid the Network in identifying and implementing appropriate facility-level interventions that improve the care coordination for ESRD patients and their family members between care settings.

In support of QIA A, the Network shall perform specific root cause analyses of unplanned hospital admissions in QIA dialysis facilities, identifying/developing and implementing evidenced based interventions that improve the overall rate of unplanned hospitalizations in the Network for those dialysis facilities having a high rate of home dialysis patients and/or a high of LTC patients. The NW shall select as participants, facilities with high rates of home dialysis and/or LTC patients; however, the NW is expected to work with all patients in the selected facilities to improve the rate of hospitalizations as a result of ESRD-related diagnoses.

The Network shall coordinate the QIA by forming a coalition or participating as an active member and advocate for ESRD-related issues on a current coalition. The coalition should be comprised of the appropriate stakeholders, including, at minimum, the QIN-QIO(s) within the Network's geographic territory; area hospitals; home dialysis agencies; LDOs; skilled nursing facilities; emergency response agencies; transportation companies; and advocate groups and service organizations. The Network shall submit a list of confirmed coalition members by agency and title, by the last business day of February.

In conjunction with the intervention strategies selected by the Network, the Network shall conduct, by the last business day in February, a "QIA kickoff" meeting with the selected referral hospitals and those dialysis facilities that primarily refer to those medical centers, to explain the QIA in detail and allow opportunity for QIA participants to communicate specific needs and barriers experienced. QIA kick-off meetings may be conducted virtually, if necessary and most convenient for participants. The Network shall document meeting discussion in official meeting minutes. The Network shall also disseminate to QIA participants (hospitals and dialysis facilities) the Transitions of Care Toolkit developed by the Forum of ESRD Networks' Medical Advisory Council, reviewing chapters 1, 5, and 8-10 with dialysis facilities. QIA results shall be reported to the ESRD NCC Dashboard, on a monthly basis, as directed by this SOW or through supplemental CMS communication.

The Network shall include in the QIA 10% of patient population, not to exceed 30 facilities (without prior approval from CMS SME and COR notification). The Network may choose to include dialysis facilities and hospitals that participated in the QIA in the previous option year. The Network may choose to include dialysis facilities and hospitals that participate in a Health Information Exchange (HIE) or another evidence-based highly effective information transfer system as approved by the COR to receive information relevant to hospitalizations during transition of care. The facility shall demonstrate the effectiveness of the system for obtaining information regarding hospitalization in QAPI.

Measurement will be obtained from CMS-specified hospital measures, with data reported to CMS for the targeted facilities on a monthly basis. Numerator and denominator figures for QIA A will be provided by the ESRD NCC. To assist the ESRD Network in identifying ESRD-related hospitalizations, the ESRD NCC will receive the related ICD-10 Codes from those dialysis organizations with the capability to process the information through a batch job. The ESRD Network shall select as participants of the QIA, only those dialysis centers from dialysis organizations that are presently capable of batching the related ICD-10 codes.

Evaluation of QIA A shall be based on two components weighted equally: 1) achievement of the topic-specific performance benchmark (quantitative assessment) and 2) successful incorporation of the six identified attributes into the QIA (qualitative assessment). Successful performance for these two objectives shall be determined by the COR in consultation with CMS SME. The participating Network shall achieve a 1 percentage point decrease in the rate of ESRD related hospitalizations from the baseline period. Baseline period is January 2019 (data from November 2018) through September 2019 (data from July 2019). The Network shall demonstrate and document on the COR Monthly Report, that at least two root causes for hospitalizations have been identified with appropriate, evidenced based interventions implemented.

C.4.4.E. QIA B: Positively Impact the Transition of Dialysis Care with a Focus on Peer Mentoring

Peer-to-peer (P2P) mentoring programs have the potential to assist patients with kidney failure in managing their complex chronic illness to improve outcomes.[7] Peer programs may improve goal setting, decision-making and increase self-management. The Network shall develop a systematic process to ensure the initial training, continued training and pairing of ESRD patient mentors with CKD patient mentees. The Network shall use as a reference, the methods outlined in Attachment J.7-7, the *Continuing Nursing Education* Journal article "A Peer-to-Peer Mentoring Program for In-Center Hemodialysis: A Patient-Centered Quality Improvement Program" by Jennifer St. Claire Russell, et. al. The Network shall provide technical assistance to dialysis facilities with selecting appropriate mentors and mentees following the described criteria:

<u>Mentors</u>

- Mentors must be receiving or have received treatment at the hemodialysis facility for one or more years, with at least six months of their treatment performed in-center, as confirmed by the patient's electronic health record;
- Patients on home dialysis and former patients of the hemodialysis facility (those transplanted) are eligible to serve as mentors;
- Complete all training activities associated with the program;

[7] St. Claire Russell, J.J (2016). *Development and Evaluation of a Peer-to-Peer Intervention to Increase Self-Management among Adult In-Center Hemodialysis Patients* (Doctoral dissertation). Retrieved from https://scholarscompass.vcu.edu/etd/4360?utm_source=scholarscompass.vcu.edu%2Fetd%2F4360&utm_medium=PDF&utm_campaign=PDFCoverPages

- May not be assigned more than two mentees at a time; and
- Willing to dedicate the time necessary to provide ongoing one-on-one support to another patient in the facility.

Mentors must also meet all mentee requirements.

Mentees

- Diagnosed by a physician with chronic kidney disease and receiving in-center hemodialysis treatment at the same hemodialysis facility as the assigned mentor;
- Adults (over 18 years of age);
- Able to provide consent;
- Able to comprehend English without the aid of a support person; or is a fluent or native speaker of the mentor's native language;
- Willing to commit for the duration of the program, through September 30, 2020 (e.g., willingness to complete surveys and other program-related forms such as a confidentiality agreement and meeting logs); and
- No evidence, as documented in the electronic health record and/or a physician diagnosis, of mental illness (e.g., major depression, dementia, Alzheimer's disease, schizophrenia, bipolar disorder, alcoholism, or drug abuse), or intellectual disability.

The Network shall closely collaborate with the QIN-QIO(s) in their region, to ensure that appropriate mentees are identified for participation. In OY4, peer mentoring efforts shall be focused on use for those patients when: first diagnosed with CKD or ESRD, making decisions about treatment therapy (i.e. modality, access type) and/or considering a transplant.

The Network shall provide to mentors, at minimum, a five-hour, skills based training allowing mentors to learn content through demonstration and role-playing, before the mentor may be matched with mentees. Mentor training topics shall include:

- Basic kidney disease information.
- Leadership.
- Communication skills and relationship building.
- Active listening.
- Difference between medical information and medical advice.
- Privacy and confidentiality.

The Network shall ensure that peer mentoring efforts begin by March 2. The Network shall maintain at least 1 mentor per project-participating dialysis facility, through September of the contract period. The Network shall document implementation of the Peer Mentoring Task on the ESRD NCC Dashboard for the following:

- Number of assigned patient mentors
- Number of mentees
- Number of patients that have completed the mentor training
- Number of mentor-mentee interactions

Regional Education

The Network shall coordinate in collaboration with the QIN-QIO(s) in the shared region, an ESRD webinar for the QIN-QIO provider community. The webinar shall provide specific training on evidence based toolkits and strategies to facilitate a smooth transition to ESRD care ("how not to crash in") and slowing the progression of CKD to ESRD. The webinar shall be facilitated by the Network in coordination with the QIN-QIO and led by a nephrologist on the Network's MRB. The Network shall conduct the webinar by June 30 of contract year.

The Network shall include in the QIA a minimum of 10% of the dialysis facilities in the Network service area. At least 3 of the dialysis facilities included in the cohort must be located in a rural area (as identified in CROWNWeb). If there are fewer than 3 rural facilities in the Network service area, all rural facilities shall be selected.

Evaluation of QIA B shall be based on two components weighted equally: 1) achievement of the topic-specific performance benchmark (quantitative assessment), and 2) successful incorporation of the six identified attributes into the QIA (qualitative assessment). Successful performance for these two objectives shall be determined by the COR in consultation with CMS SME. Successful completion of the quantitative assessment of QIA B shall be evaluated based on the completion of the ESRD webinar and the number of trained mentors maintained, as reported on the ESRD NCC Dashboard, through September.

C.4.4.F. QIA C: Support Gainful Employment of ESRD Patients

The intent of QIA C is to assist ESRD patients with seeking gainful employment/ job training/ higher education and/or returning to work.

The Social Security Administration (SSA) administers the Ticket to Work Program. Under this free and voluntary program, eligible beneficiaries between the ages of 18 and 64, who are blind or have a disability and receive Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) benefits, are entitled to sign up with an Employment Network (EN) or a State Vocational Rehabilitation (VR) agency of their choice. These approved service providers coordinate and provide appropriate services to help eligible beneficiaries find and maintain employment. Appropriate services may include training, career counseling, vocational rehabilitation, job placement, and ongoing support services necessary to achieve a work goal.[8]

In support of QIA C, the Network shall identify a minimum of five (5) approved Employment Networks that serves the recruited patient population and educate patients regarding the researched and identified EN resources. The Network shall include in the QIA at least 10% of the patient population not exceeding 50 facilities. The Network shall provide to dialysis facilities technical assistance with developing a process to ensure that at least 95% of patients are screened for interest in vocational rehabilitation services. The Network shall demonstrate at least 50% increase from the baseline, in the rate of eligible patients referred during the re-measurement period for EN services in closed CROWNWeb data by September 30. The Network shall demonstrate at least 1% of the denominator population receiving services in closed CROWNWeb data by September 30.

[8] Social Security Administration. Ticket to Work Program overview [cited 2017 Jul 6]. Available from: https://www.ssa.gov/work/overview.html.

Eligible patients include those that are:

- Age 18-54 years
- Blind or have a disability AND receive Social Security Disability Insurance (SSDI) or Supplemental Security Income (SSI) benefits
- Not currently employed, in school or receiving specialized training
- Interested in receiving vocational rehabilitation services

The Network shall demonstrate referral of at least 10 eligible patients, between the ages of 55-64, by September 30.

The ESRD NCC will provide to the Network, based on CROWNWeb data, the numerator and denominator. The number of eligible patients reported as receiving EN services that have been positively impacted by direct intervention of the Network efforts will be used as the numerator. The denominator will be the number prevalent, eligible patients age 18-54 years. The results shall be reported to the ESRD NCC Dashboard, monthly as directed by this SoW or through supplemental CMS communication.

Evaluation of QIA C shall be based on two components weighted equally: 1) achievement of the topic-specific performance benchmark (quantitative assessment) and 2) successful incorporation of the six identified attributes into the QIA (qualitative assessment). Successful performance for these two objectives shall be determined by the COR in consultation with CMS SME. Successful completion of the quantitative assessment of QIA C shall be evaluated based on the number of eligible patients referred for EN services and the number of eligible patients receiving EN services, as reported on the ESRD NCC Dashboard, through September. The baseline for the number of patients identified in CROWNWeb as receiving EN/VR services in the patient demographics, is January-September of the previous option year.