

## 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 (Reform, Strengthen, and Modernize the Nation’s Health Care System, Protect the Health of Americans Where They Live, Learn, Work, and Play, Strengthen the Economic and Social Well-Being of Americans Across the Lifespan, Foster Sound, Sustained Advances in the Sciences, and Promote Effective and Efficient Management and Stewardship) 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: Reform, Strengthen, and Modernize the Nation’s Health Care System**
- **Priority 2: Protect the Health of Americans Where They Live, Learn, Work, and Play**
- **Priority 3: Strengthen the Economic and Social Well-Being of Americans Across the Lifespan**
- **Priority 4: Foster Sound, Sustained Advances in the Sciences**
- **Priority 5: Promote Effective and Efficient Management and Stewardship**

The CMS Goals are interpreted for purposes of the SOW as:

- **Goal 1: Empower patients and doctors to make decisions about their health care**
- **Goal 2: Usher in a new era of state flexibility and local leadership**
- **Goal 3: Support innovative approaches to improve quality, accessibility, and affordability**
- **Goal 4: Improve the CMS 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 by performing any or all the following:

- Interaction with the contractor on behalf of the COR, while avoiding providing technical direction;
- Monitoring and evaluating the contractor's performance and providing feedback to the COR;
- Including the COR in substantive communications with the contractor;
- Assisting the COR with the inspection and evaluation of products and services delivered by the contractor;
- Notifying the COR promptly of any actual or potential contractor performance issues.

### **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 (NQS Principle 1) (Priority 2) (Goal 1)
- Protecting ESRD patients' access to and quality of dialysis care, especially among vulnerable populations (NQS Principle 3) (Priority 1) (Goal 2)
- Network relationship with ESRD facilities (NQS Principle 4) (Priority 1) (Goal 1)
  - Identifying opportunities for quality improvement at the individual facility level and providing technical assistance (NQS Principle 5) (Priority 1) (Goal 3)
  - Promoting all modalities of care, including home modalities and transplantation, as appropriate, to promote patient independence and improve clinical outcomes (NQS Principle 5) (Priority 2) (Goal 1 and 3)
  - Facilitating processes to promote coordination between care settings (NQS Principle 8) (Priority 1 and 2) (Goal 1 and 3)
  - 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. (NQS Principle 6) (Priority 1) (Goal 3)
- Coordination and sharing across 18 Networks
  - Using standardized procedures to collect data and address grievances to promote consistency across Networks (NQS Principle 6) (Priority 1 and 2) (Goal 3)
  - Collaborating to share information, such as data on patient migration, across Networks to promote care coordination (NQS Principle 8) (Priority 1) (Goal 1 and 3)
  - Coordinating with regional Quality Innovation Network-Quality Improvement Organizations (QIN-QIO) and Hospital Improvement Innovation Networks (HIIN), as well as other recognized subject matter experts in the quality improvement field. (Priority 2) (Goal 3)
  - Sharing information to promote care coordination for ESRD patients (NQS Principle 8) (Priority 1 and 2) (Goal 1 and 3)
  - Sharing best practices to improve quality of care for ESRD patients, including Network involvement in Learning and Action Networks (LANs) (NQS Principle 5) (Priority 2) (Goal 3)
- 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 (Priority 1 and 2) (Goal 3 and 4)

- Maintaining integrity of information and tone of messaging consistent with CMS expectations for entities acting on behalf of the agency (Priority 1 and 2) (Goal 4)
- 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. (Priority 1 and 2) (Goal 3 and 4)

### **C.2.2.B. Network Activities:**

The Network staff shall continue several specific functions through the base and four (4) OYs of the contract. The Network shall conduct patient engagement activities through the Patient and Family Engagement (C.3.21.) and Patient Experience of Care 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 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 31<sup>st</sup> of each contract year and once approved submit updates to the COR by the 2<sup>nd</sup> 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 Input Form (DIF). For each QIA, unless otherwise specified, all QIA Short Forms (Attachment J-7) and/or Pilot QIA Checklists are due to the CMS SME and the COR by the last business day of December for option year 2. Beginning in option year 2 for option year 3, 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 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. The Network shall provide updated QIA target facility/populations lists of facilities continuing in the QIA to the NCC by November 30<sup>th</sup> for the subsequent contract period.

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, 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 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 (CGB)**

The Network shall establish a Corporate Governing Body (CGB) 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.A 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 (MRB). 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 compliance;
- 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. 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. 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 shall annually contact at least 25% of the dialysis facilities in its service area for recommendations of potential PAC members or for patient volunteers to serve on the PAC. The Network shall provide an annual updated listing of PAC members to the COR by the last 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 each contract period.

#### **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 case 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 for a standardized letter drafted by the NCC stating:
  - The role of Network;

- The Network's toll free number, mailing address, and website address;
  - The address(es) and phone number(s) for the State Survey Agency(ies) in the Network's service area;
  - Information on the functions of State Survey Agencies, including the role of the State Survey Agency in receiving and investigating grievances;
  - Information on how to contact the Network in order to file a grievance (phone number, e-mail address, and mailing address).
- **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 a thorough knowledge of the specific needs of the ESRD patient population in the Network's service area. The Network shall use an 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, volunteerism);
- Contact information for state/regional vocational rehabilitation programs 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.

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.

### **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 Input Form (DIF):** The Network shall utilize the CMS- approved template and criteria for the DIF. The Network shall update the DIF with the latest available data by the 15th day of each month. The Network shall not be more than one month behind in reporting information on Network-controlled projects on the DIF.
- **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.
- **Annual Report:** The Network shall submit to the COR by June 1<sup>st</sup> and post to the website data by July 1<sup>st</sup> 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.

- **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 15<sup>th</sup> 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 CMS within 30 days of the beginning of the base year and each subsequent optional year with at least the Network COR.
- Monthly meetings with the COR. The Network shall prepare an agenda and meeting minutes for each meeting. 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 videomeeting 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.
- 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 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 support quality improvement efforts performed by LANs by:
  1. Setting goals



2. Setting benchmarks
3. Evaluating progress
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, 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. Whenever 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).

### **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 Practice Transformation Network (PTN) and Support and Alignment Network (SAN) as related to the ESRD SOW. The Network shall support and engage HIIN (Hospital Improvement Innovation Network) as related to the ESRD SOW.

### **C.3.10. 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 on or before January 8 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.

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. 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 of each Option Year. 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**

CMS, either directly or through a CMS contractor, shall provide each Network with a file/print server, a domain controller, a database server, and a workstation and/or laptop for each 0.5 or greater full-time-equivalent (FTE) employee. The servers, workstations, and laptops shall be equipped with a standard operating system and a software suite following approved CMS Federal Desktop Core Configuration (FDCC) standards. If the Network requires additional hardware and/or software, the Network must receive approval from the Engineering Review Board (ERB). The Network must pay for the additional equipment and software out of Network contract funds. No additional hardware peripherals or non-approved software may be connected or installed to any Government Furnished Equipment (GFE) without prior written approval by CMS.

### **C.3.17. Security**

#### **Certification by Security Point of Contact (SPOC) For Compliance with CMS Security Requirements**

The ESRD Network shall appoint a Security Point of Contact (SPOC) or equivalent within 90 days. The SPOC shall assist the CMS ISSO in ensuring the ESRD Network adheres to the CMS Information Security (IS) program requirements located at <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html>.

#### **a. Administer and Adhere to the CMS Information Security (IS) Program**

- 1) The ESRD Network shall comply with the CMS Policy for the Information Security and Privacy (PISP) and all CMS methodologies, policies, standards, and procedures contained in the CMS PISP, unless otherwise directed by CMS in writing. The ESRD Network shall also adhere and comply with any specific policies as they relate to security within the Health Care Quality Improvement System (HCQIS).
- 2) The ESRD Network shall comply with all CMS security program requirements as specified in the CMS Information Security (IS) “Virtual Handbook” (a collection of CMS policies, procedures, standards and guidelines that implements the CMS Information Security Program) and the QualityNet Security Policy. The Virtual Handbook can be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html> and the QualityNet System Security Policy is located at <http://qualitynet.org/>.
- 3) The ESRD Network shall provide a list of assigned ESRD Network Information Technology (IT) staff upon request to the CMS COR with required information.
- 4) The ESRD Network shall conduct Security Awareness Training (SAT) for all employees utilizing or accessing CMS data within the HCQIS environment on an annual basis, by March 30 of each contract year. Security Awareness Training for employees will be

tracked and logged locally by the Network SPOC as identified by the CMS ISSO. A QNET SAT Certification Letter shall be provided to the CMS COR and QNET ISSO annually in accordance with the Schedule of Deliverables (SOD).

- 5) The ESRD Network shall visit the CMS security website <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html> and the internal secure intranet site <http://esrdnec.org> at least every 30 calendar days for updates. [Note: The QualityNet security documents are located on an Intranet website; thus, access is restricted to only active users within the QualityNet Enterprise.]

**b. Federal Information Security Management Act (FISMA) Compliance**

- 1) The ESRD Network shall comply with CMS, FISMA, OIG, and other relevant audits, reviews, evaluations, tests, and assessments of ESRD Network systems, processes, and facilities related to program security and compliance. The ESRD Network shall provide all related artifacts upon request. The ESRD Network shall deliver the artifacts in the format and method prescribed by CMS.
- 2) The ESRD Network shall provide CMS with a Network System Security Plan (SSP) and Information Security (IS) Risk Assessment (RA) annually on April 28 and also within 30 days after any major changes.
- 3) The ESRD Network shall document its compliance with CMS security requirements and maintain such documentation in the Network System Security Plan (SSP) and the IS RA as directed by CMS.
- 4) The ESRD Network shall develop, in conjunction with CMS, Corrective Action Plans (CAPs) for all identified weaknesses, findings, gaps, or other deficiencies in the IS Program (e.g., those items identified during a FISMA audit or similar activity) in accordance with IOM Pub. 100-17 (BPSSM) or as otherwise directed by CMS. CAPs shall be submitted to the CMS QNET ISSO within 30 days after the audit or finding in accordance with Schedule F Schedule of Deliverables.

Moreover, the ESRD Network shall comply with the guidance and requirements of the CMS Information Security Plan of Action & Milestones (POA&M) Procedure, which is located at [www.cms.hhs.gov/InformationSecurity](http://www.cms.hhs.gov/InformationSecurity) in the Information Security Library. The POA&M shall be submitted to the CMS QNET ISSO within 15 days of approval of a CAP and monthly thereafter until the CAP is closed.

The ESRD Network shall comply with the guidance for reporting requirements for all CAPs and the CMS POA&M Procedure.

**c. Inventory of Government Furnished Equipment (GFE)**

The ESRD Network shall comply with CMS guidance for requirements associated with GFE. The ESRD Network shall update Remedy inventory for all procured, transferred and received government property (including hardware and software). The ESRD Network shall be responsible for providing a list of all purchased and leased equipment in an HHS 565 submission Final Report by October 31<sup>st</sup> of each contract period, upon request, upon contract termination, or at normal contract conclusion.

**d. Maintenance of Systems and Software**

The ESRD Network shall comply with all CMS system and software maintenance procedures. All digital media must be encrypted before physically leaving the ESRD Network building. The ESRD Network shall perform maintenance of systems and software in compliance with applicable configuration requirements. Network IT staff are responsible for completion of IT tasks as assigned in Remedy tickets for ESRD Network local systems.

**e. Security Incident Response**

The ESRD Network shall comply with CMS Incident Handling Standards and Procedures (RMH Vol III Standard 7-1 Incident Handling, RMH Vol II Procedure 7-2 Incident Handling Procedure) located at <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html> and report suspected security breaches within the designated time periods. The ESRD Network shall assist the CMS ISSO on active investigations and provide requested documentation as needed.

**General Contract Management (Security)**

In accordance with Certification by Security Point of Contact (SPOC) for Compliance with CMS Systems Security Requirements of the Base Contract, the ESRD Network shall:

- 1) Identify a SPOC and backup for each year of the contract.
- 2) Conduct SAT for all employees utilizing or accessing CMS data within the HCQIS environment on an annual basis. The training shall be tracked and a log maintained of employees trained. A QNET SAT Certification Letter shall be provided to CMS.
- 3) Visit the CMS security website <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/index.html> and the QualityNet NCC internal secure intranet site <http://esrdncc.org> at least every 30 calendar days for updates. Note: The QualityNet security website is an Intranet website; thus, access is restricted to only active users within the QualityNet Enterprise.
- 4) Submit, by April 28 of each contract period and/or within 30 days of any change, a Business Continuity and Contingency Plan (BCCP) and updates after completion of any major IT or serious structural changes. Serious structural changes consist of building relocations or major structural changes to the current infrastructure.
- 5) Provide upon request, all related artifacts, in the format and method prescribed by CMS, resulting from compliance with CMS, FISMA, OIG, and other relevant audits, reviews, evaluations, tests, and assessments of ESRD systems, processes, and facilities related to program security and compliance.
- 6) Provide an ESRD Network System Security Plan (SSP) and Information Security (IS) Risk Assessment (RA).

- 7) Develop within 30 days following an audit or finding, in conjunction with CMS, Corrective Action Plans (CAPs) for all identified weaknesses, findings, gaps, or other deficiencies in the IS Program (e.g., those items identified during a FISMA audit or similar activity) in accordance with IOM Pub. 100-17 (BPSSM) or as otherwise directed by CMS.
- 8) Submit the Plan of Action & Milestones (POA&M) for the approval of a CAP until the CAP is closed.
- 9) Provide a list of all purchased and leased equipment in an HHS 565 submission Final Report, by September 30 of each contract period or upon request, upon contract termination or normal contract conclusion.
- 10) Comply with all CMS system and software maintenance procedures. All digital media must be encrypted before physically leaving the ESRD Network building. The ESRD Network shall perform maintenance of systems and software in compliance with applicable configuration requirements. ESRD Network IT staff are responsible for completion of IT tasks as assigned in Remedy tickets for ESRD Network local systems.
- 11) Comply with CMS Incident Handling Standards and Procedures (RMH Vol III Standard 7-1 Incident Handling, RMH Vol II Procedure 7-2 Incident Handling Procedure) located at <http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html> and report suspected security breaches within the designated time periods. The Network shall assist the CMS ISSO on active investigations and provide requested documentation as needed for all security incidents.
  - a. The ESRD Network shall also:
    - 1) Adhere to the privacy, confidentiality, and disclosure requirements set forth in Section 1160 of the Social Security Act, and in Title 42 of the Code of Federal Regulations (CFR) Part 480, which are incorporated by reference in Attachment J.2 and be prepared to document adherence to these privacy, confidentiality and disclosure requirements.  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_02/42cfr480\\_02.html](http://www.access.gpo.gov/nara/cfr/waisidx_02/42cfr480_02.html).
    - 2) Be prepared, if required, to provide a copy of training materials developed or used to meet the confidentiality training requirement specified in 42 CFR §480.115. CMS may request documentation that users of the Network review system have been trained in the proper handling of confidential information prior to being given access to that information and review system.
    - 3) Obtain all Data Use Agreements (DUAs) necessary to comply with contract requirements and to execute required services by September 30 and as required. A CMS DUA is required when individually identifiable data is disclosed to the ESRD Network under its contract with CMS.



### C.3.18. DUA Submission

The DUA shall be renewed annually as required by CMS Privacy program  
[https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA\\_-\\_Forms.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/Data-Disclosures-Data-Agreements/DUA_-_Forms.html)

1. Any incorrect contact information must be corrected, with confirmation from the DUA team, prior to requesting an extension. Refer to the DUA - Contact Changes instructions.
2. The Requestor or any Custodian must email the request for extension
3. Only send one (1) request for one (1) DUA in each e-mail; create an e-mail which must originate from the Requestor or a Custodian for the DUA:
4. Make the e-mail Subject line: **DUA ##### - Extension** (where ##### is the DUA #)
5. Copy/paste the following extension justification statements into the body of your e-mail
  1. We are currently still using this data as originally requested for our Project/Study.
  2. In accordance with the terms and conditions of the DUA, we understand that the data for this DUA may not be used in any form for any additional work outside the scope of this DUA without the expressed written consent of CMS' DUA Team.
  3. All contacts on the DUA are correct and their contact information is accurate.
  4. We request a one (1) year [or less if applicable] extension for the DUA number listed in the Subject of this e-mail.
6. Send to your CMS COR, who will forward with their approval to [DataUseAgreement@cms.hhs.gov](mailto:DataUseAgreement@cms.hhs.gov)
7. The DUA Team will Reply All with confirmation of the extension.

### 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 45 days after the

beginning of the contract 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 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 NW BOD on a regular basis.

### **C.3.19.C. IQI Program Reporting Requirements**

At minimum, the Network shall (a) generate quarterly 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.

#### **C.3.20.A. COR Monitoring Responsibilities**

The role of the COR is to monitor the ESRD Network's progress, promote innovation and share successes, and make known to the Contracting Officer potential problems that threaten performance so that corrective measures may be taken.

The COR, in consultation with the Contracting Officer, is responsible for determining whether the Network meets contractual expectations. If the Network fails to meet contract requirements or other performance expectations, the COR will initiate a three-tier process to ensure that the Network will take appropriate steps to remedy contract performance deficiencies.

The movement from tier to tier will be at the discretion of the COR in consultation with the Associate Regional Administrator (ARA), the appropriate CMS SME, the CMS SME's manager and/or other CMS SMEs. After each monthly call, the COR will advance the action to a higher tier if he/she believes that the Network is not progressing satisfactorily to correct the shortcoming(s). Because CMS data may not be refreshed on a monthly basis, the COR may use data provided by the Network and other information sources to make his/her determination. The COR is not required to advance sequentially through the three tiers; when warranted, the COR may move to Tier 3 early in the process.

#### **Tier 1: Network/COR Discussion of the Need for Performance Improvement**

When a possible performance issue is identified during a monthly call, the COR will have a discussion with the Network following the general pattern of a Plan-Do-Study-Act (PDSA) cycle to explore the reasons behind the insufficient progress toward meeting performance expectations and the Network's actions to improve its performance. The COR, ARA, CMS SME, CMS SME's manager, and other SMEs may consider data lags, small numbers, or other factors (e.g., state law) that may have impacted the Network's performance. With the assistance of the COR as appropriate, the Network will be encouraged to determine whether other Networks are having similar issues, have developed best practices, or have knowledge that can be shared. The COR will require the Network to conduct a root cause analysis (RCA) for the identified problem(s). The COR will maintain notes of this discussion to use as a reference should further action be required.

#### **Tier 2: Formal Written Notice of Performance Issue**

In the next monthly call (or earlier, if the COR believes it is warranted), the COR will follow up on the Network's progress with respect to the performance issue. If the COR (in consultation with the ARA, CMS SME, CMS SME's manager, and other SME[s]) believes that the Network

is not progressing satisfactorily, the COR will send a formal written notification of the performance issue to the Network. The notice will identify the need for a detailed review of the activities that the Network has undertaken to address the identified problem(s), along with the IQI measures that the Network is using to monitor its own performance, findings from any PDSA cycle(s) that the Network has conducted, and discussions of the experience of other Networks facing similar challenges. This letter will state the contract expectation that has not been met or is in danger of being missed in the future, as well as the COR's monitoring expectation for the next time period. The time horizon may vary depending upon the frequency of occurrence of the performance issue, timing of data releases, and similar considerations.

### **Tier 3: Request for a PIP**

The COR will continue to discuss the performance issue with the Network in subsequent monthly calls. At any point that the COR (in consultation with the ARA, CMS SME, CMS SME's manager, and other SME[s]) believes the Network is not continuing to progress, the COR will request a formal PIP.

The COR also has discretion (with input from the ARA and appropriate CMS SME, CMS SME's manager, or other SME[s]) to determine if failure to meet non-performance contract expectations warrants a PIP.

In certain instances, when a PIP is requested for concerns not related to SOW requirements (e.g., issues related to Federal Acquisition Regulations requirements, Section G and H requirements), the PIP request letter may be sent by the Contracting Officer.

The request for the PIP will clearly identify the specific deficiency in contract performance. It will:

- Specify how and when the deficiency was identified;
- Specify how the deficiency adversely affects, or is expected to adversely affect, the Network's contract performance; and
- Specify the authority under which the correction is required (e.g., Social Security Act, CFR, or SOW).

The COR request for a PIP will not instruct the Network on how to correct the deficiency, but will only provide information on the issues that resulted in the PIP. It is the Networks responsibility to develop the appropriate corrective actions.

If a fully acceptable PIP is not submitted by the Network within five working days (or a negotiated alternate date), the COR may initiate a recommendation to the Contracting Officer to take further action. If the Network is unsuccessful at fulfilling the activities within 30 days of the effective start date of the PIP, the COR will make a recommendation to the Contracting Officer for further action.

### **C.3.20.B. Submission and Acceptance of a PIP**

When the COR requests submission of a PIP, the Network shall submit a CAP within five working days of receipt of the request, unless an extension of this deadline is authorized by the COR.

The PIP shall identify the steps the Network will take to remedy the identified performance issue and prevent its recurrence. As one of these steps, the Network shall perform an RCA to identify the reasons for failure to meet performance expectations.

For a PIP to be considered fully acceptable, it must:

- Meet the submission deadline;
- Address each issue identified by CMS;
- Define the problem(s);
- Specify how and when each problem was identified;
- Describe the RCA methodology used and findings;
- Specify the relationship between the improvement actions and the findings of the RCA;
- Describe how improvement will be monitored by the Network, specifying measures and reporting frequency;
- Provide estimates of the degree of improvement expected during the PIP period;
- Identify the staff member(s) who will be involved in implementing the PIP and the individual responsible for oversight of the PIP and progress monitoring;
- Include a timeline with milestones for expected Network progress and an estimated completion date;
- Address sustainability, including staff training needs and process changes; and
- Demonstrate Network ownership of the problem(s) and a commitment to meeting contract requirements.

On receipt of the PIP, the COR has five working days to review and notify the Network if the PIP is accepted. Acceptance will be based on whether the PIP was completed in accordance with any instructions provided by the COR in requesting submission of the PIP, and meets the criteria detailed above.

If the COR finds that the PIP is fully acceptable, the COR will notify the Network in writing that the PIP has been accepted. That acceptance will specify:

- Criteria CMS will use to monitor implementation of the PIP;
- Monitoring plan (see C.3.19.C);
- Criteria that will be used to evaluate the successful completion of the PIP;
- The circumstances under which CMS will require revisions to the PIP; and
- Guidelines for submitting a request in writing to revise the PIP based on barriers encountered in implementing the PIP.

If the PIP does not meet the criteria for acceptability and/or sustainability, the COR will notify the Network in writing that the plan is not accepted. The notification will identify the problems or shortcomings of the submitted PIP. The COR will request the Network to respond within five business days of the notice with corrections addressing each shortcoming identified. The COR has up to three business days to review a revised PIP for acceptability. If the corrections are accepted, implementation and assessment of the corrected plan will follow the procedures for an

initially acceptable PIP. If the corrected plan is unacceptable, the COR will notify the Network and explain why the PIP is not accepted, and will refer the Network's performance to the Contracting Officer for additional action.

### **C.3.20.C. Monitoring the PIP**

Once the PIP is approved, the COR will monitor the Network's progress on the actions outlined in the plan. The plan will remain open until it meets the criteria for closing a performance issue, as described below.

The COR monitoring plan will be tailored to the proposed PIP in order to ensure steady progress, achievement of proposed milestones, and sustainability. The Network may be asked to:

- Submit periodic reports of progress achieved, milestones met or unmet, and expected improvement on the PIP monitoring measures and the contract evaluation measures;
- Submit data reports/graphs to demonstrate improvement achieved and to identify any obstacles or barriers; and/or
- Attend periodic meetings by teleconference to discuss progress and barriers (these meetings may be scheduled in conjunction with regular monthly calls by inviting the Network's PIP team, if different from the regular attendees, to attend the discussions).

If the Network's performance continues to be unsatisfactory following the implementation of a PIP, the government will act to correct unsatisfactory performance or to protect the government's interest in the event of actual contract default. The COR may recommend to the Contracting Officer one or more of the following actions:

- Bringing the particular deficiency to the Network's attention by letter and obtaining a commitment for appropriate corrective action;
- Withholding contract payments in cases in which the Network fails to comply with delivery or reporting provisions of the contract; or
- Terminating some or all work on the contract for default.

### **C.3.20.D. Closing the PIP**

A PIP is closed when the COR determines that the contractor has satisfactorily completed the actions spelled out in the PIP and addressed the issue that led to the PIP and then notifies the Network, Contracting Officer, and ARA in writing that the PIP has been closed. If the Network is unsuccessful in completing the PIP, the COR will notify the Network, Contracting Officer, and ARA of the continued deficiency.

### **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.”<sup>[1]</sup> 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”<sup>[2]</sup> and incorporate “the core concepts of dignity and respect, information sharing, active patient participation in their care, and collaboration.”<sup>1</sup> 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. The Network shall ensure patients and caregivers wishing to participate with the Network have a place as a SME or on the PAC. 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 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. HAI 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.

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<sup>[1]</sup> Institute for Patient-and Family-Centered Care. (no date) *Advancing the Practice of Patient-and Family-Centered Care in Hospitals-How to Get Started*. Retrieved December 30, 2014, from Institute for Patient-and Family-Centered Care: [http://www.ipfcc.org/pdf/getting\\_started.pdf](http://www.ipfcc.org/pdf/getting_started.pdf)

<sup>[2]</sup> Committee on Quality of Health Care in America. Institute of Medicine. (2001). *Crossing the quality chasm: a new health system for the 21st century* (1st edition). Washington, DC: National Academies Press.

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 at least six (6) Patient SMEs and/or PAC Members to participate as active members of the N-PFE LAN. NPFE LAN Members may be selected from the 15 identified Patient SMEs and/or family members or caregivers, though not required. 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 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.

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. The Network may elect to include applicants outside of those selected to participate as a SME, on the Network PAC. The Network shall submit a list of the minimum of 15 selected Patient SMEs and/or family members or caregivers to the COR on or before January 8 of each contract year. 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 each contract quarter.

#### **C.3.21.A. Foster Patient and Family Engagement at the Facility Level**

The Network shall provide technical assistance to project-participating dialysis facilities on establishing patient council support groups/new patient adjustment groups; incorporating patient, family and caregiver participation into the Quality Assurance Performance Improvement (QAPI) Program and governing body of the facility; and with developing policy and procedures related to patient, family and caregiver participation in the patient's care (e.g., policy establishing the dialysis facility's position on patient, family member and caregiver involvement in the development of the individualized plan of care and 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 as to how technical assistance will be introduced, implemented and evaluated. The Network shall establish measures and goals for the implementation of these activities at the facility level. Additionally the Network shall report progress based on defined interim measures via the Network IQI plan and report results in the monthly COR Report.



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.

#### **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 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 Patient SMEs and/or family members or caregivers to participate in other CMS meetings, including CoP Calls and LANs, as directed by CMS.

#### **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, managed 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.

By January 8<sup>th</sup>, the Network shall support the NPFE LAN by enlisting the participation of 6 of 15, at a minimum, selected patient SMEs and/or family members or caregivers to serve as representatives on the NPFE LAN throughout the contract year one of which must be a family

member or caregiver. At least one of Patient SME must be a home dialysis patient and at least one Patient SME must be a transplant patient.. The Network shall ensure that at least one Patient SME and/or family member or caregiver from each state in the Network's geographic region is selected to participate and that patient/family representation on the NPFE LAN is maintained at a minimum of three participants throughout the contract year.

The Network shall:

- Submit a list of the five Patient SMEs and/or family members or caregivers selected to participate on the NPFE LAN to the COR and NCC on or before January 8<sup>th</sup> of each contract period.
- Document the active participation of the Network's NPFE LAN members and their contributions in the COR Monthly Report.

### **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:

- Provide de-identified PCU data to the ESRD NCC every six months as directed by CMS for analysis of grievance trends and patterns;
- By the 5<sup>th</sup> of each month submit to the NCC a query of all closed non-anonymous grievances for the previous month.
- Maintain an 80% satisfaction level for grievance satisfaction. 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. Any Network receiving at least 6 out of 10 of the monthly Grievance Satisfaction Data Reports will be evaluated during the annual evaluation in October based on the

thresholds provided in J-11. Any Network not included in the Grievance Satisfaction measure shall work with the Patient Experience of Care LAN to increase the knowledge of the Network as a case review resource, and provide grievance outreach to the patient population. These activities shall be beyond other SOW requirements.

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 provide a monthly analysis through the COR Monthly Report of all cases involving IVDs, IVTs, failures to place, and patients at risk for IVD, including cases referred by patients, patients' representatives, and providers. These monthly analyses shall be based on cumulative data from the beginning of the contract year.

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;
- Document characteristics of patients that may be indicative of disparities in care in the PCU or other CMS-designated data system and in the COR Monthly Report, including race, ethnicity, and tenure of dialysis treatment (less than or equal to three months; four months to one year; one year to three years; and more than three years)
- Recommend sanctions in accordance with Section C.3.11 of this SOW;

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### **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;
- Document characteristics of patients that may be indicative of disparities in care in the PCU or other CMS-directed data system and in the COR Monthly Report, including race, ethnicity, tenure of dialysis treatment (less than or equal to three months; four months to one year; one year to three years; and more than three years);
- 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;
- Report data on averted IVDs in the COR Monthly Report, as directed by CMS.

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 invite all facilities in the Network service area to participate in the NCC led LAN. The Network shall identify 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 45 days after the quarter 1 focused audits. The Network shall provide the NCC additional names of contacts at facilities every other month as grievances and access to care issues occur. The Network shall work with dialysis organizations to identify facilities that excel at empowering patients and have success in resolving patient issues before escalation. 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 and report on the implementation of the interventions at required facilities 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 HAI 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 monitor vascular access reporting and if less than 95% of facilities in any given month are not reporting at least 95% of vascular access data for all eligible patients, the Network shall identify barriers to achieving this goal, and potential interventions to improve the reporting rate, on the COR Monthly Report. The Network shall provide individualized assistance to identify and resolve the root causes in facilities that are reporting vascular access data for less than 90% of their eligible patients. The Network shall report vascular access data on a monthly basis using the COR Monthly Report.

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.

#### **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. 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.

##### **C.4.1. Patient Safety: Healthcare-Associated Infections**

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)<sup>3</sup>. As a result, the following AIM with a 5-year target has been set to guide national health promotion and management 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 HAI LAN, and assisting dialysis facilities in the implementation of the CDC Core Interventions.

##### **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.

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<sup>3</sup> 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

- 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 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 on the monthly COR report.
- 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 4<sup>th</sup> quarter of the previous calendar year. June data checks shall review 1<sup>st</sup> quarter data. September data checks shall review 2<sup>nd</sup> quarter data. December data checks shall review 3<sup>rd</sup> 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 at least 20% of the BSI QIA cohort to join a Health Information Exchange (HIE) or another evidence-based highly effective information transfer system as approved by the COR and SME to receive information relevant to positive blood cultures during transition of care.

#### **C.4.1.B. Participate in the ESRD NCC HAI LAN**

The ESRD NCC HAI 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 CDC Core interventions.

The Network shall perform the following to support ESRD NCC HAI 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. At a minimum the Network shall ensure there is a participating cohort formed by all facilities participating in the BSI QIA, a minimum of two (2) hospitals from each state in the Network service area, and two (2) patients, family members and/or caregivers from each state in the Network service area.
- Ask dialysis organizations to identify facilities within the Network service area that have successfully implemented all of the CDC Core Interventions and have had no infections reported in NHSN for a minimum of six (6) months for inclusion in the LAN.
- Provide a list of participants for the NCC HAI LAN by December 31<sup>st</sup> of option year 2.
- Provide an updated list of participants for the NCC HAI LAN by October 31<sup>st</sup> of option year 2 for option year 3.
- Provide an updated list of participants for the NCC HAI LAN by October 31<sup>st</sup> for each subsequent option year.
- Attend the ESRD NCC HAI 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.

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#### **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 1 by December 31<sup>st</sup> of option year 2
  - 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 31<sup>st</sup>.
- Select at least 50% of facilities in the Network's service area including those facilities reporting the highest BSI rates.
- 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 HAI LAN to assist facilities in implementing the COR interventions.
- Identify the number of facilities that have successfully implemented each of the CDC Core Interventions into facility practice and report this monthly in the DIF. 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.

- Use NCC provided data to identify facilities with a long-term catheter (LTC) (catheter in use  $\geq$  90 days) in use rate above 15% (from the 50% of facilities in the Network's service area reporting the highest BSI rates). The Network shall report the LTC rate on the DIF monthly, as part of the Core Interventions, with the expectation that this rate will decrease by at least 2 percentage points by evaluation based on data available in October. June of the previous contract year shall be used as baseline.
- Demonstrate a 20% or greater relative reduction in the semi-annual pooled mean in the cohort with the highest 20% of BSIs 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. The Network shall create a custom report in NHSN for the QIA facilities as described by CDC to monitor and report the BSI rate on facilities in the QIA cohorts that have the highest 20% of BSIs in the Network service area.
- Report activities related to this QIA monthly in the COR Monthly Report.
- Provide the ESRD NCC with the names of BSI QIA facilities that continue or new facilities for the next option year by December 31<sup>st</sup> for option year 2 and by October 31<sup>st</sup> for subsequent option years. A facility may be removed and replaced for the next option year in the QIA if it is no longer in the cohort of facilities with the highest 20% of BSIs in the Network service area or maintains a BSI rate of zero for at least six (6) months of the QIA.
- 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.
- 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-prevention-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>.

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<sup>4</sup>. As a result, the following AIM with a 5-year target has been set to guide national health promotion and management to improve the health of all people in the United States living with ESRD: *by 2023 increase the percentage of ESRD patients on the transplant waitlist to 30% from the 2016 national average of 18.5%*. 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<sup>5</sup>. The Networks shall increase the number of patients on a transplant waitlist 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 waitlist.

##### **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 ways to support the patient through the waitlist 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. At a minimum the Network shall ensure there is a participating cohort formed by all facilities participating in the Transplant QIA, a minimum of two (2) transplant centers from each state in the Network service area or all transplant centers in the state if less than two (2), and two (2) patients, family members and/or caregivers from each state in the Network service area.
- Ask dialysis organizations to identify facilities within the Network service area that have successfully implemented process to support patients through the transplant waitlist

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

<sup>5</sup> 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

process.

- Provide a list of participants for the NCC Transplant LAN by December 31<sup>st</sup> of option year 2.
- Provide an updated list of participants for the NCC Transplant LAN by October 31<sup>st</sup> of option year 2 for option year 3.
- Provide an updated list of participants for the NCC Transplant LAN by October 31<sup>st</sup> for each subsequent option year.
- Attend the ESRD NCC Transplant LAN every other month.
- Share identified interventions to improve the Transplant waitlist 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.4.2.B. Increase Rates of Patients on a Transplant Waitlist**

The Network shall work through facilities 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 December 31<sup>st</sup> of option year 2
  - Describe the methodology devised to address barriers at each of 7 steps leading to receiving a transplant: 1) Patient suitability for transplant (defined as absence of absolute contraindication identified in the medical record), 2) Patient interest in transplant, 3) Referral call to transplant center, 4) First visit to transplant center, 5) Transplant center work-up, 6) Successful transplant candidate, 7) 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.
- Identifying at least 30% of the dialysis facilities within the Network's service area regardless of modality to participate in the Transplant QIA.
- Tracking and reporting to CMS monthly on the DIF the number of patients at each stage of the process as the patients are successfully moved to the next step of the process.
- Reporting the number of patients added to a transplant waitlist monthly in the DIF as directed by this SOW or through supplemental CMS communication.
- Providing a list of the facilities identified to participate in the Transplant QIA to the NCC by December 31<sup>st</sup> for option year 2.
- 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.
- Encouraging facilities in the Transplant QIA to incorporate the process steps into patient education, facility practice, and the facility QAPI process.
- Using October – June of the previous year as provided by the NCC for baseline.
- Demonstrating at least a 10 percentage point increase in the rate of patients placed on a waitlist for transplant of eligible patients by evaluation of each option year based on data

available in October.

- Using data provided by the NCC to identify new facilities to replace facilities that have 40% of the patients on the transplant waitlist and have improved internal process to ensure continued assistance of patients through the transplant process. The Network shall provide the list of facilities to be included in the QIA for option year 3 to the NCC by October 31<sup>st</sup> beginning in option year 2 and each subsequent option year.
- Using rapid cycle improvement to revise the methodology developed for the QIA and submit it to the COR by October 31<sup>st</sup> 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.

Patients on the waitlist shall not be counted during the baseline of the project, as these patients will have already been counted or the process occurred outside of the timeframe of the project. The Network shall collect waitlist counts to be used as numerator data from target facilities. The ESRD NCC will provide to the Network, the number of prevalent patients to be used as the denominator.

### **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<sup>6</sup>. As a result, the following AIM with a 5-year target has been set to guide national health promotion and management to improve the health of all people in the United States living with ESRD: by 2023, increase the number of ESRD patients dialyzing at home to 16% from the 2016 national average of 12%. 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, 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 three primary purposes. The first is to improve information communication across care settings, with emphasis on communication between in-center dialysis centers and home dialysis centers to promote and support transition of care for ESRD patients. The second is to promote and support communication internally between in-center and home modality staff to educate patients. The third is to increase awareness of and ways 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

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<sup>6</sup> Thinking outside the box—identifying patients for home dialysis. [Brigitte Schiller](#), [Hayley Munroe](#), and [Andrea Neitzer](#)

communication and Home Dialysis QIA. At a minimum the Network shall ensure there is a participating cohort formed by all facilities participating in the Home Dialysis QIA, a minimum of two (2) home dialysis centers from each state in the Network service area, and two (2) patients, family members and/or caregivers from each state in the Network service area.

- Ask dialysis organizations to identify facilities within the Network service area that have successfully implemented process to support patients through transition to a home modality.
- Provide a list of participants for the NCC Home Dialysis LAN by December 31<sup>st</sup> of option year 2.
- Provide an updated list of participants for the NCC Home Dialysis LAN by October 31<sup>st</sup> of option year 2 for option year 3.
- Provide an updated list of participants for the NCC Home Dialysis LAN by October 31<sup>st</sup> for each subsequent option year.
- 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.

#### **C.4.3.B. Increase Rates of Patients Dialyzing at Home**

The Network shall work through facilities to increase the number of patients dialyzing at home by:

- Submitting the J-7 Short Form for the Home Dialysis QIA by December 31<sup>st</sup> of option year 2
  - Describing the methodology devised to address barriers at each of 7 steps leading to home dialysis utilization: 1) Patient interest in home dialysis, 2) Educational session to determine the patient's preference of home modality, 3) Patient suitability for home modality determined by a nephrologist with expertise in home dialysis therapy, 4) Assessment for appropriate access placement, 4) Placement of appropriate access, 5) 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, for those patients recently initiating dialysis within the previous 6 months. Research shows that, "The study was a bit underpowered so some of our outcomes were not statistically significant. However, we know from four years of work in addition to the RCT [Randomized Controlled Trials] that our results are consistent: with over 800 patients treated, preemptive transplant is sharply increased, home dialysis rates and placement of arteriovenous fistulas for in-center hemodialysis are greatly increased, and that initiation of hemodialysis without a hospitalization is consistently achieved."<sup>7</sup>

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<sup>7</sup> Neumann, ME. Can Augmented Care in CKD Stages 4-5 Change the Path to ESRD?  
<https://www.nephrologynews.com/can-augmented-care-ckd-stages-4-5-change-path-esrd/>



- 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.
- Identifying at least 30% of dialysis facilities providing in-center dialysis care within the Network's service area to participate in the Home Dialysis QIA.
- Tracking and reporting to CMS monthly on the DIF 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.
- Reporting the number of patients training for a home dialysis modality monthly in the DIF as directed by this SOW or through supplemental CMS communication.
- Providing a list of the facilities identified to participate in the Home Dialysis QIA to the NCC by December 31<sup>st</sup> for option year 2.
- 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.
- Encouraging facilities in the Home Dialysis QIA to incorporate the process steps into patient education, facility practice, and the facility QAPI process.
- Using October – June of the previous year as provided by the NCC for baseline.
- Demonstrating at least a 10 percentage point increase in the rate of patients that start home dialysis training by evaluation of each option year based on data available in October.
- Using data provided by the NCC to identify new facilities to replace facilities that have 40% of the patients trained or in training for home dialysis and have improved internal process to ensure continued assistance of patients through transition to home. The Network shall provide the list of facilities to be included in the QIA for option year 3 to the NCC by October 31<sup>st</sup> beginning in option year 2 and each subsequent option year.
- Using rapid cycle improvement to revise the methodology developed for the QIA and submit it to the COR by October 31<sup>st</sup> 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 focus on improving 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 A1, A2, or A3)
- Positively Impact the Quality of Life of the ESRD Patient with a Focus on Mental Health (QIA B)
- Support Gainful Employment of ESRD Patients (QIA C)

- Positively Impact the Quality of Life of the ESRD Patient with a Focus on Pain Management (QIA D)

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.

In OY 1 and OY 2, each Network shall conduct one QIA per contract year and shall achieve the performance requirements for the QIA selected (i.e., A1, A2, B, C, or D) for evaluation purposes, as well as demonstrate reduction in an identified disparity (for applicable QIAs), as required by this SOW. In OY 3 and OY 4, all Networks shall conduct the National Hospital Care Coordination QIA (QIA A3), using methodology developed by CMS. CMS will further determine if the Network will be required to select and complete a second PHFPQ for another focus area.

#### **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 and implementing proven quality improvement techniques, develop the QIA and interventions based on the findings of the RCA conducted. To meet established thresholds, the QIA shall incorporate the concepts of boundariliness and unconditional teamwork into

innovative approaches that are customer-focused and sustainable. The QIA plan shall include 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 (a) the opportunity for improvement on the performance measure in the target population and (b) the ability to reduce an identified disparity (for applicable QIAs).

As the first step in choosing the target facilities for its PHFPQ, the Network shall select from one of the four CMS-approved QIA areas. The Network shall then determine from the baseline data whether >25% of the target population demonstrated the desired outcome(s) for the selected topic area. If  $\geq 25\%$  of the target population demonstrated the desired outcome(s), then the Network shall select one of the other QIA areas that would meet the <25% criterion.

The Network shall then conduct a disparity assessment using baseline data provided by the ESRD NCC, if selecting QIA B, QIA C, or QIA D. In OY 2, a disparity assessment is not required for QIA A. The disparate categories that follow shall be assessed based on the category having the greatest point difference between the designated categories, as determined by ESRD NCC calculation.

- Age (65 and older vs. 18-64),
- Ethnicity (Hispanic vs. Non-Hispanic),
- Facility Location (Rural vs. Urban),
- Gender (Female vs. Male), or
- Race (Populations Other than White, including African American or Asian or Native American or Pacific Islander, etc. vs. White).

The disparate category with a  $\geq 5$  point difference between the designated categories, as demonstrated by ESRD NCC provided data, will be used for the QIA. Once the final QIA is approved, the disparity cannot be further modified for the remainder of the contract year.

For this multi-year contract with a base year and four Option Years (OYs), the Network shall obtain CMS approval of the QIA facilities and disparity prior to initiating formal intervention activities related to the QIA. The Network shall initiate the QIA by selecting the topic area, target facilities and disparity to be included in the QIA. If the Network decides to continue the

QIA from the previous contract year, it shall replace any facilities that have achieved the threshold where at least 75% of the facility patient population achieved the desired outcome. For example, if a facility started the base contract period with 10% of its patients with an employment referral, and at the end of base contract period has achieved 80% of its patients with a referral to a State Vocational Rehabilitation Agency or an Employment Network, this facility would be replaced by another facility that is below the 25% threshold for inclusion. 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 otherwise either do not meet the requirements of the QIA or 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 15, shall be provided, using the PHFPQ Checklist in Attachment J-7, Quality Improvement Activities. The completed PHFPQ Checklist shall 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) **and** reduce the disparity for the highest-ranking disparate group (for applicable QIAs). All proposed interventions for the selected QIA shall be reviewed and approved by the Network MRB, prior to implementation, with acceptance and/or rejection recorded in meeting minutes. The proposal shall be finalized and baseline data collection and analysis for the selected QIA shall be completed, by the last business day in December. The Network shall not opt for a different QIA after PHFPQ approval is received by the last business day in December. Reporting of the final QIA target facilities to the NCC shall be completed by January 8 for the Option Years of the contract.

A root cause analysis for each participating QIA facility, identifying specific inefficient processes, ineffective practices and barriers to quality service and proposing specific interventions, shall be submitted to the COR and CMS SME and finalized by January 25 of OY2. The RCA shall be completed using the PHFPQ Root Cause Analysis Template in Attachment J-7, Quality Improvement Activities. 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 invite all facilities in the Network service area to participate in the Pilot QIA specific NCC led LAN. The Network shall invite all facilities participating in the specific Pilot QIA, and two (2) patients, family members and/or caregivers from each state in the Network service area. 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 every other month. 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. The Network will provide a list of participants for the NCC by December 31 of each option year.

#### **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 CMS DIF, 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, specific requirements related to disparity reduction, 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 three components weighted equally: 1) achievement of the topic-specific performance benchmark (quantitative assessment), 2) reduction in the disparity (for applicable QIAs), (quantitative assessment) and 3) successful incorporation of the six identified attributes into the QIA (qualitative assessment). Successful performance for these three objectives shall be determined by mutual agreement between the COR and CMS SME. The evaluation period of each of these measures shall be based on data occurring between January and July for the performance and disparity measures, assessed against a baseline period of October – June 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:

- a) Achievement of the required performance improvement for the targeted demographic of the selected QIA, as of July CROWNWeb data (received in October), as specified in this SOW; and
- b) Relative improvement of the project patient pool percentage for the disparity, for applicable QIAs.

To achieve the disparity reduction requirement, the Network should improve the disparaging condition of the disparate population by the CMS-designated improvement goal from the baseline (October – June of the previous year). The non-disparate group must at a minimum not be negatively impacted by the implemented interventions, while the disparate group improves. A decline for the initially higher-performing group will not be considered as successful completion of the QIA, even if such a decrease lowers the overall rate of disparity.

The ESRD NCC will provide to the Network, a calculation of the disparity rate for both the disparate and non-disparate groups. The Network shall, for baseline determination and re-measurement each month, use the calculation of the disparity rate provided by the ESRD NCC to monitor improvement for the selected disparate population.

Failure in either 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 Network COR assessment. 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 (Boundarilessness): 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 A1: Improve Dialysis Care Coordination with a Focus on Reducing Hospital Utilization**

“Transition of care between settings is a critical part of care coordination and is particularly complex for kidney patients. Approximately 35% of hospitalized dialysis patients are re-hospitalized within one month, often for the same problem that caused the first hospitalization. Good discharge processes can decrease the risk of re-hospitalization, but many other processes are also important for safe transitions”.<sup>8</sup> 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. An unplanned hospitalization is one that is designated in CROWNWeb as “ER Visit Resulted in Hospitalization”. The Network shall coordinate the QIA by involving appropriate stakeholders, including at minimum, at least one QIN-QIO within the Network's geographic territory. The Network shall include in the QIA at least 10% of the dialysis facilities within the

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<sup>8</sup> Medical Advisory Council, Forum of ESRD Networks. Transitions of care toolkit. Birchwood (WI): Forum of ESRD Networks; 2017 [cited 2017 Jul 6]. Available from: <http://esrdnetworks.org/resources/toolkits/mac-toolkits-1/new-toolkit-transitions-of-care-toolkit>.

Network's geographic territory. The target facilities shall be selected from those facilities in the top 25<sup>th</sup> percentile for patients with unplanned hospitalizations. Measurement will be obtained from CMS-specified hospital measures in CROWNWeb, 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. In conjunction with the intervention strategies selected by the Network, the Network shall conduct, by the last business day in January, 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 CMS on a monthly basis, as directed by this SOW or through supplemental CMS communication.

Evaluation of QIA A1 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 mutual agreement between the COR and CMS SME. The participating Network shall achieve a 2-point decrease in the average rate of overall hospitalizations from the baseline period (October – June of the previous contract year), each year the QIA is conducted and a 10% decrease in ESRD related hospitalizations. The Network shall demonstrate that at least two root causes for hospitalizations have been identified with appropriate, evidenced based interventions implemented.

#### **C.4.4.D. QIA A2: Network Workgroup Focus on Reducing Hospital Utilization**

As an alternative to PHFPQ-QIA A1 (Improve Dialysis Care Coordination with a Focus on Reducing Hospital Utilization), CMS will work with up to six Networks to further explore the issues surrounding unplanned hospitalizations in the ESRD population. This effort will specifically be under the direction of CMS for the activities, including interventions to be implemented. If the Network decides to apply for consideration to participate and is selected by CMS, the Network agrees to be an active member of a workgroup of up to six (6) Networks working collaboratively to assess the issues surrounding unplanned hospitalizations and to test intervention strategies for consideration of future use in this task area. If selected, the Network agrees to participate in the QIA for the entire QIA year.

The Networks within this workgroup shall:

- a) Actively participate in scheduled workgroup meetings throughout the QIA year, including but not limited to, discussions of measurement, interventions and proposed next steps for advancing CMS's ability to impact unplanned ESRD hospitalizations;
- b) Identify as a QIA participant, at least one QIN-QIO or state hospital association within their ESRD Network territory to actively collaborate on QIA outcomes;
- c) Identify as QIA participants, three (3) to five (5) medium-sized hospitals that:

- a. Are capable of providing chronic dialysis services to inpatients either through their own capability or arrangements with another provider, and
- b. Transfer less than 10% of their ESRD patient population to other healthcare facilities due to inability to meet medical needs (e.g., need to transfer to a burn unit, trauma facility);
- d) Identify as QIA participants, 10 to 15 dialysis facilities whose patients are admitted or use the Emergency Department services at the hospitals specified in (c), maintaining at least 10 QIA facilities throughout the QIA;
- e) Complete facility specific root cause analyses with each QIA dialysis facility;
- f) Initiate a process for QIA dialysis facilities to receive ESRD patient medical record information from participant medical centers;
- g) Conduct, a “QIA kickoff” meeting with the selected referral hospitals and those dialysis facilities that primarily refer to those centers, to explain the QIA in detail and allow an opportunity for QIA participants to communicate specific needs and barriers experienced;
- h) Ensure that a post-hospitalization assessment is completed for each patient having an unplanned admission between January 1 and August 30 of the QIA year; and
- i) 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

The interventions specified above are not intended to be an exhaustive list of implemented interventions, as the Network is also expected to identify interventions that specifically address the root cause of unplanned hospital admissions at each dialysis facility.

Evaluation of QIA A2 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 mutual agreement between the COR and CMS SME. The participating Network shall achieve a 1-point decrease in the average rate of overall hospitalizations from the baseline period (October – June of the previous contract year), each year the QIA is conducted and a 7% decrease in ESRD related hospitalizations.

The participating Network shall collect, assess, and report results all five of the disparity categories, where possible, based on the hospitals and dialysis facilities included in the QIA. No disparity reduction shall be required, but a report of results for the performance measures and the applicable disparity categories shall be provided through the CMS DIF on a monthly basis.

The participating Network shall provide presentations as requested by CMS at the Quality Conference or other appropriate venues to inform on the findings and progress of workgroup activities.

The Networks shall submit the PHFPQ QIA Checklist by December 15, selecting QIA A2, in order to be considered for participation in the workgroup. Consideration by CMS will be based on geographic representation by the workgroup members, the ability of the Network to identify appropriate hospitals and dialysis facilities for inclusion in the QIA and the Network’s ability to impact and sustain quality improvement in the QIA. Networks will be selected for this QIA by

the PHFPQ CMS SME, with notification to the Network occurring no later than last business day of December of each option year of the contract.

#### **C.4.4.D. QIA A3: National Care Coordination QIA**

For OYs 3 and 4, all Networks shall participate in a National Care Coordination QIA as directed by CMS. All QIA details, including measures and methodology, will be developed by CMS, with consideration of feedback and findings from QIA A2 workgroup members, and distributed to all Networks prior to the initiation of the third OY. The Network shall provide the COR with the target population by the last business day of December for OY3 and OY4. The Network shall follow all CMS direction related to this QIA without deviation.

#### **C.4.4.E. QIA B: Positively Impact the Quality of Life of the ESRD Patient with a Focus on Mental Health**

The intent of QIA B is to improve the screening and treatment of depression for ESRD patients. “Depression is the most common psychological disorder in end-stage renal disease (ESRD) patients with a prevalence rate as high as 20% to 25% by some contemporary estimates. There are several studies linking depression with mortality in ESRD, making early diagnosis and treatment essential”.<sup>9</sup>

The Network shall provide to dialysis facilities technical assistance with developing a process to ensure the completion, documentation and appropriate follow-up of an annual depression screening for 100% of qualifying patients, as determined by the CY 2017 ESRD PPS Final Rule (2016). If a diagnosis of clinical depression is made, treatment options shall be tailored to the specific needs of the patient and the resources available to the dialysis facility. Each diagnosed patient shall have an individual assessment completed with appropriate action taken or shall have a treatment plan developed.

“Patients with moderate to advanced CKD and ESRD have generally been excluded from large antidepressant trials because of concerns for adverse events and the paucity of data on safety of antidepressants in this population”.<sup>10</sup> In partnering with dialysis facilities, the Network shall increase awareness of and encourage consideration of nonpharmacologic interventions, including but not limited to, art therapy, cognitive behavioral therapy, exercise training programs, and music therapy.

The Network shall include in the QIA, at least 10% of the dialysis facilities within the Network’s service area with the highest response rate to either “Clinical depression screening not documented, and no reason is given” or “Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given”. The ESRD NCC will provide to the Network, based on CROWNWeb, the number of patients reported as screened to be used as the numerator and to be used for the denominator, the number

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<sup>9</sup> Kimmel PL, Cukor D, Cohen SD, Peterson RA. Depression in end-stage renal disease patients: a critical review. *Adv Chronic Kidney Dis.* 2007;14(4):328-34.

<sup>10</sup> Hedayati SS, Yalamanchili V, Finkelstein FO. A practical approach to the treatment of depression in patients with chronic kidney disease and end-stage renal disease. *Kidney Int.* 2012;81(3):247-55. doi: 10.1038/ki.2011.358. Epub 2011 Oct 19.

prevalent patients. Successful completion of QIA B will be evaluated based on the percentage of patients screened, the percentage of documented screenings and the percentage of documented follow-up plans, as reported in closed CROWNWeb data, by September of each option year. The Network shall decrease the response to “Clinical depression screening not documented, and no reason is given” to zero (0). The Network shall decrease the response to “Screening for clinical depression documented as positive, the facility possesses no documentation of a follow-up plan, and no reason is given” by 10%. QIA results for the targeted population shall be reported to CMS on a monthly basis as directed by this SOW or through supplemental CMS communication. The baseline for this QIA shall be October – June of the previous option year.

#### **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 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 55, 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.<sup>11</sup>

In support of QIA C, the Network shall identify a minimum of five (5) Employment Networks and/or the State Vocational Rehabilitation (VR) agency that serves the recruited patient population and educate patients regarding the researched and identified EN and/or VR resources. The Network shall demonstrate at least a five (5) percentage point increase in referrals to the identified EN and/or VR in by September 30<sup>th</sup> of the contract year. The Network shall demonstrate at least a two (2) percentage point improvement in the number of patients receiving EN and/or VR services in closed CROWNWeb data by September 30<sup>th</sup> of the contract year. The Network shall monitor the number of referrals that are received by the EN and/or VR. The ESRD NCC will provide to the Network, based on CROWNWeb, the number of patients reported as receiving EN and/or VR services to be used as the numerator and to be used for the denominator, the number prevalent patients between the ages of 18 and 55. The results shall be reported to CMS on a monthly basis, as directed by this SOW or through supplemental CMS communication. The Network shall include in the QIA, at least 10% of the dialysis facilities within the Network’s service area. The baseline for this QIA shall be the number of patients identified in CROWNWeb as working in the patient demographics, in October – June of the previous option year.

#### **C.4.4.E. QIA D: Positively Impact the Quality of Life of the ESRD Patient with a Focus on Pain Management**

The Network shall provide to dialysis facilities technical assistance with developing a process to

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<sup>11</sup> Social Security Administration. Ticket to Work Program overview [cited 2017 Jul 6]. Available from: <https://www.ssa.gov/work/overview.html>.

ensure the completion, documentation and appropriate follow-up of the twice annual pain assessment of qualifying patients, as determined by the CY 2017 ESRD PPS Final Rule (2016). If the pain assessment is documented as positive, treatment options shall be tailored to the specific needs of the patient and the resources available to the dialysis facility. Each patient shall have an individual assessment completed with appropriate action taken or shall have a treatment plan developed.

The Network shall include in the QIA, at least 10% of the dialysis facilities within the Network's service area with the highest response rate to either "No documentation of pain assessment, and no reason is given" or "Pain assessment documented as positive using a standardized tool, a follow-up plan is not documented, and no reason is given". The ESRD NCC will provide to the Network, based on CROWNWeb, the number of patients reported as screened to be used as the numerator and to be used for the denominator, the number prevalent patients. Successful completion of QIA D will be evaluated based on the percentage of patients screened, the percentage of documented screenings and the percentage of documented follow-up plans, as reported in closed CROWNWeb, by September of each option year. The Network shall decrease the response to "No documentation of pain assessment, and no reason is given" to zero (0). The Network shall decrease the response to "Pain assessment documented as positive using a standardized tool, a follow-up plan is not documented, and no reason is given" by 10%. QIA results for the targeted population shall be reported to CMS on a monthly basis as directed by this SOW or through supplemental CMS communication. The baseline for this QIA shall be October – June of the previous option year.