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 who 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 Centers for Medicare & Medicaid Services (CMS)Three-Part Aim (Better Care, Better Health, Lower Cost), 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 should be applied to the ESRD SOW.

C.2.1.Domains

The Network shall promote positive change relative to Three-Part Aim outlined in the NQS and CMS priorities. These Aims are interpreted for purposes of this SOW as:

- **AIM 1:** Better Care for the Individual through Patient and Family Centered Care
- **AIM 2:** Better Health for the ESRD Population
- **AIM 3:** Reduce Costs of ESRD Care by Improving Care.

The three Aims are subdivided into multiple domains, as defined in this SOW. (See Table 1.) Many factors influence these domains, including patient characteristics, patients' social support/environment, and aspects of the healthcare delivery system. To substantively impact these domains, the Network may need to deploy interventions that target patients, dialysis/transplant providers, other providers, and/or stakeholders.

The Network shall incorporate a focus on disparities in conducting all of the activities outlined in this SOW. In each domain, the Network shall analyze data and implement interventions aimed at reducing disparities. All projects shall use innovative approaches and rapid cycle improvement that incorporates boundariliness, unconditional teamwork, and are customer-focused and sustainable to achieve the strategic goals of the ESRD Network Program.

Contracting Officer's Representative (COR): is 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): is an individual who may assist the COR by performing 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;

- Keeping the COR informed of substantive communications with the contractor;
- Assisting the COR with the inspection and evaluation of products and services delivered by the Contractor;
- Notifying promptly the COR of any actual or potential contractor performance issues.

Table 1: AIMs, Domains, and Sub-Domains

AIM	Domain	Sub-Domain
AIM 1: Better Care for the Individual through Patient and Family Centered Care	Patient and Family Engagement	Foster Patient and Family Engagement at the Facility Level and involve Patient Subject Matter Experts in Patient Experience of Care and Healthcare Associated Infection QIAs
		Involve Patients/Families/Caregivers in CMS Meetings
		Support the ESRD National Coordinating Center (NCC) Patient and Family Engagement Learning and Action Network (LAN)
	Patient Experience of Care	Evaluate and Resolve Grievances
		Conduct QIA to improve Facility Grievance process
		Promote Use of In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) and/or Any Similar Survey Identified by CMS
		Address Issues Identified through Data Analysis
		Recommend Sanctions
	Patient-Appropriate Access to In-Center Dialysis Care	Decrease Involuntary Discharges (IVDs) and Involuntary Transfers (IVTs)
		Address Patients at Risk for IVD/IVT and Failure to Place
		Report data on Access to Dialysis Care Monthly
	Vascular Access Management	
		Reduce Catheter Rates for Prevalent Patients
		Support Facility Vascular Access Reporting
		Spread Best Practices
		Provide Technical Support in the Area of Vascular Access
	Patient Safety: Healthcare-Associated Infections (HAIs)	Support National Healthcare Safety Network (NHSN)
		Establish HAILAN
		1) Reduce Rates of Dialysis Events(HAI/bloodstream infection (BSI)/Sepsis) 2) Increase Hepatitis B (HBV)and Pneumococcal Vaccination Rates

AIM	Domain	Sub-Domain
AIM 2: Better Health for the ESRD Population	Population Health Innovation Pilot Project	Reduce Identified Disparity through: Project A: Reducing Hospital Utilization or Project B: Improve Transplant Referrals or Project C: Promote Appropriate Home Dialysis or Project D: Support Improvement in Quality of Life For Option Year (OY)3 – OY4 all Network will conduct Project A; additional Network selected project may occur
AIM 3: Reduce Costs of ESRD Care by Improving Care	Support for ESRD Quality Incentive Program (ESRD QIP) and Performance Improvement on ESRD QIP Measures	Assist Facilities in Understanding and Complying with ESRD QIP Processes and Requirements
		Conduct Quality Improvement Activities (QIA) to assist Facilities in Improving their Performance on ESRD QIP Measures
		Assist CMS in Monitoring the Quality of and Access to Dialysis Care
		Assist Patients and Caregivers in Understanding the ESRD QIP
	Support for Facility Data Submission to CROWNWeb, NHSN, and/or Other CMS-Designated Data Collection System(s)	1) Provide support for CROWNWeb (CW) NHSN, other CMS data systems as directed; 2) Conduct Data Quality QIA for NHSN with hospitals and dialysis facilities 3) Provide necessary CW functions as directed by SOW

C.2.2.A Role of Network

The Networks are critical to achieving bold CMS goals for healthcare transformation and the aims of the NQS.

The successful Networks will 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.

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

- Network relationship with Medicare patients
    - Ensuring representation of Medicare patients in shared decision making related to ESRD care in order to promote person-centeredness and family engagement (NQS Principle 1)
    - Protecting Medicare patients' access to and quality of dialysis care, especially among vulnerable populations (NQS Principle 3)
- Network relationship with ESRD facilities (NQS Principle 4)
    - Identifying opportunities for quality improvement at the individual facility level and providing technical assistance (NQS Principle 5)
    - Promoting all modalities of care, including home modalities and transplantation, as appropriate, to promote patient independence and improve clinical outcomes(NQS Principle 5)
    - Facilitating processes to promote care coordination between different care settings(NQS Principle 8)
    - Ensuring accurate, complete, consistent, and timely data collection, analysis, and reporting by facilities in accordance with national standards and the ESRD QIP (NQS Principle 6). This also includes the submission of Master Account Holder information for all new facilities to the ESRD Network
- Coordination and sharing across 18 Networks
    - Using standardized procedures to collect data and address grievances to promote consistency across Networks (NQS Principle 6)
    - Collaborating to share information such as patient migration across Networks to promote care coordination (NQS Principle 8)
    - Coordinating with regional Quality Improvement Organizations (QIO) and Hospital Engagement Networks (HEN), as well as other recognized subject matter experts in the quality improvement field
    - Sharing information to promote care coordination for ESRD patients (NQS Principle 8)
    - Sharing best practices to improve quality of care for ESRD patients, including Network involvement in LANs (NQS Principle 5)

- Network acting on behalf of CMS
    - Conveying information from CMS to facilities on HHS and CMS goals, strategies, policies, and procedures including the ESRD QIP
    - Maintaining integrity of information and tone of messaging consistent with CMS expectations for entities acting on behalf of the agency
    - Interpreting and conveying to CMS or its designee information relevant to the ESRD healthcare system to assist with monitoring and evaluation of policy and program impacts, including the effects of the ESRD QIP.

C.2.2.B Network activities:
Networks will continue several specific functions through the base and four (4) OYs for the contract. Networks will provide Patient-oriented engagement activities through the Patient and Family Engagement (C.4.1.) and Patient Experience of Care section of the contract. These activities shall include, but not be limited to:

1) Selection of a diverse group of 15 Patient subject matter experts (SME), and integration of these individuals in to the Grievance, ICH CAHPS, and HAI QIAs, at a minimum;
2) Conduct Patient Engagement at the Facility Level;
3) Process of Grievances and Access-to-Care issues;
4) Facilitate grievances and access-to-care cases;
5) Supply the ESRD NCC with patient contact information for those that have agreed to participate in the CMS Grievance Satisfaction Survey;
6) Conduct a QIA directed at one area of the ICH CAHPS survey results;

A major function of the Networks will be to conduct a number of QIAs. These QIAs are listed below: For each of year of the contract, Networks will have eight (8) QIAs. During OYs 3 and 4, all Networks will work on a National Hospital Care Coordination QIA developed during the first three (3) years of the contract. CMS will decide which of seven (7) of the other QIAs will not be completed during OY3 and OY4.

Table 2.QIAs for Base and Option Years

AIM	QIAs	Base	OY1	OY2	OY3	OY4	Template to use
1	Grievance	Yes	Yes	Yes	Yes	Yes	Grievance
1	ICH CAHPS	Yes	Yes	Yes	TBD	TBD	QIA SF
1	Vascular Access: Long-Term Catheter	Yes	Yes	Yes	TBD	TBD	QIA SF
1	HAI BSI/Sepsis	Yes	Yes	Yes	TBD	TBD	QIA SF
1	HAI Vaccinations	Yes	Yes	Yes	TBD	TBD	QIA SF
2	Network-selected	Yes	Yes	Yes	TBD	TBD	AIM2

							Checklist
2	National	No	No	No	Yes	Yes	AIM2 Checklist
3	ESRD QIP	Yes	Yes	Yes	TBD	TBD	QIP QIA
3	Data Quality	Yes	Yes	Yes	Yes	Yes	QIA SF

Note: Grievance= Grievance template in J-7; QIA SF=QIA Short Form in J-7; AIM2 Checklist= AIM2 Checklist in J-7; QIP QIA= QIP QIA form in J-7

For each of the three AIMs, unless otherwise specified, evaluation for each of these QIAs shall be based on achievement of results by the end of September of each contract period, as based on the October DIF, or for those dependent on CROWNWeb Data, the December DIF (or earlier if available). For each AIM QIA for the base contract period, unless otherwise specified, all QIA Short Forms (Attachment J-7) and or the AIM2 Checklist shall be reviewed by the CMS SME and approved by the COR by the last business day of March. During the 4th Quarter (Oct-Dec) of each contact period, Networks will re-assess the membership of 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). Networks will also re-assess their interventions methods and activities and revise them as necessary. Networks shall provide updated QIA target facility/populations lists to the NCC by the last working day in November for the subsequent contract period. During the Option years all QIA Short Forms and/or the AIM2 checklist, as appropriate, shall be reviewed by the CMS SME and approved by the COR by the last business day in January.

Additionally, Networks will conduct the process of supporting CMS-designated data systems (e.g. CROWNWeb, NHSN, and Patient Contact Utility) and utilizing 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, Board of Directors (BOD), Medical Review Board, and Patient Advisory Committee. The Patient Advisory Committee may be comprised in part or whole by the 15 SMEs denoted in section C.4.1.A.1. 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 as a component of the Network staff. 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 member 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. Board of Directors
The Network shall establish a governing body (BOD) that sets overall policy and direction for the Network and retains oversight responsibility. The BOD must comply with Section H.20 of this contract.

The Network shall:

- Specify the number of members on its governing body (BOD), which shall not exceed 20 members except when appropriate justification is provided to CMS

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

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

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

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

    - Establish committees and subcommittees to support the governing body, as deemed necessary by the governing body

    - Specify in writing the roles and responsibilities of the governing body and its committees and any subcommittees, including the relationship of the Board with its committees and any subcommittees

    - Document committee meetings, decisions, and actions

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

        - Number of members
        - Length of appointment
        - Term limitations
        - When appointments are made
        - What percentage of governing body, committee, or subcommittee members is typically appointed each year
        - Names, affiliations, and compensation (as compensation is permitted) of members.

The membership of the BOD shall consist of ESRD stakeholders from the Network's service area, including at least two patient representatives. Section 1881(c) (1) (A) (i) of the Social Security Act requires a minimum of at least two consumer representatives on the governing body. 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 BOD members. To the extent possible, the non-patient members of the BOD 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 BOD shall meet as necessary to ensure the successful operation of the Network. At a minimum, the BOD shall meet at least semi-annually in-person, by teleconference or by electronic communication. In addition, the Executive Committee (EC) of the BOD shall meet as necessary to ensure the smooth operation of the activities of the BOD.

At minimum, the BOD 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.3.1 of this SOW;
- Review and approve the Annual Report prior to submission to the Contracting Officer's Representative (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 of 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;
- Serving as an advisory panel for all Network QIAs;
- Assisting Network staff in the development, implementation, and evaluation of all QIAs;
- 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. PAC members that 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 to the extent possible. PAC members shall be of at least 18 years of age, and may be any patient, and/or 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 will 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 within its Network for recommendations or patient volunteers to serve on the PAC. The Network shall provide an annual updated listing of PAC members to the COR by February 1 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 interpreting the results of all Network QIAs and the development of interventions.

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 community.

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 BOD) for the overall management, supervision, and coordination of contract requirements, including meeting deliverable due dates. The Executive Director is responsible for the overall operation of the Network, including 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, implementation, data analysis, and evaluation) to conduct the activities and responsibilities 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, February 1st 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.
- **Maintain a Network website:** The Network website must be Section 508 compliant and follow all CMS standards and guidelines. The Network website shall include, at a minimum: a description of the Network grievance processes; a list of the Network's goals; the Network's most recent Annual Report; a link to the Dialysis Facility Compare website (http:www.medicare.gov/dialysis); 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.
- **Prepare a cover letter for the New ESRD Patient Orientation Package (NEPOP):** Using Network stationary, the Network shall make a letter available for duplication and distribution to new ESRD patients in the Network's service area. The letter shall be in English and be provided to the ESRD NCC to distribute in the NEPOP, with a copy to the Network's COR when the content is revised or as otherwise directed by CMS. The letter shall:
    - Explain the role of Network;
    - Give the Network's toll free number, mailing address, and website address;
    - Provide the address(es) and phone number(s) for the State Survey Agency(ies) in the Network's service area;
    - Provide information on the functions of State Survey Agencies, including the role

of the State Survey Agency in receiving and investigating grievances;

- Include 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 set an acceptable target for the error rate. The Network shall report on these activities monthly on the COR Monthly Report, and include any activities taken to decrease the undeliverable rate.
- **Provide educational information:** The Network shall report monthly all education activities and assessments of materials provided 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;

  - The Network's process for receiving, reporting, resolving, and tracking patient grievances;

  - The Network's role in facilitating patient's 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 shall 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 HBV, 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;

- 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 and a copy simultaneously to the CMS SME .

- **Dashboard:** The Network shall utilize the CMS approved template and criteria for the Dashboard. The Network shall update the Dashboard 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 CMS Dashboard Input Form (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 an Annual Report of Network Activities during the second quarter of the year for the previous year's work using the template provided in Attachment J-4, Reporting Requirements. A draft of the Annual Report is due on the 30th calendar day of April and a final version shall be submitted to the COR for approval by the 15th calendar day of June. The Annual Report shall be sent to the ESRD NCC within two weeks of COR approval by the Network. The Network shall post a copy of its report on its website and notify the COR when this is completed.
- **Semi-Annual Cost Report:** Each semi-annual cost report shall be submitted so they are received by CMS no later than close of business on the 15th working day of the second calendar month after the close of each semi-annual cost reporting period. For the final semi-annual period of this contract, the report shall be received by the last business day of November of OY4. For purposes of this requirement, "close of business" is defined as 5pm local prevailing time at CMS Central Office in Baltimore, Maryland, on the due date (Eastern Standard or Eastern Daylight Time, as applicable). For purposes of this requirement, "working days" shall be defined as all calendar days except Saturday, Sunday, and federal holidays as observed by the Federal Government. The cost information supplied should reflect actual costs incurred for the

period, and be supported by Network financial records/general ledger and similar documentation. See also Section F of this SOW, 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. Networks 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 list 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 beginning of the base year.
- Monthly meetings with the COR. Each Network shall prepare an agenda and meeting minutes for each meeting. The meeting shall address each AIM 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 meeting in which the COR is able to see the Network's progress if requested by the COR.
- Every other month Teleconference meeting with the State Survey Agency. The Network shall prepare an agenda and meeting minutes for each meeting, soliciting agenda items from all participants (surveyors, Network staff, CMS staff, and patient representative when appropriate) prior to the meeting.
- The annual QualityNet Conference or another CMS quality meeting(s) designated by CMS as requiring in-person Network participation. Network staff is 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.
- Other national meetings as specified in this SOW or as directed by CMS.

In addition, the Network shall participate in a 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 QIO's jurisdiction. The Network shall report its involvement with its QIO counterparts in the Monthly Progress and Status Report where appropriate.

C.3.9. Network Collaborations

C.3.9.A. Collaboration with National Coordinating Center

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 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.

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 teleconference meetings, a defined manner of communication, and establishment of mutually agreeable goals to help carry out each organization's legislative or regulatory responsibilities (as permitted by statute, regulations, or other CMS policy guidance).

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 a 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 CMS components to support CMS quality and patient safety goals and priorities.

Collaboration with CMS components will include:

- Conveying to facilities 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 QIO-QIN's
The Network is required to work with QIO-QIN's as stakeholders, as directed throughout this SOW; making reasonable efforts to include at least one QIO-QIN where directed by this SOW.

C.3.10. Participate in Workgroups
The Network shall participate in workgroup activities related to the Three AIMs of the SOW, which may include, at a minimum, Kidney Community Emergency Response Program (KCER) workgroups, 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 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 (gender), 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 SME, 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 is encouraged to assign staff to participate in one or more of the KCER committees.

Within 45 days of contract award, the Network will submit an emergency/disaster plan to its COR. The plan will 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.

The Network shall cooperate with KCER in coordinating emergency preparedness, response, and recovery activities for the renal community inclusive of reporting open/closed facilities, alterations in dialysis facility schedules, and missing patients.

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 annually participate in an emergency preparedness exercise that is relevant to the types of emergency situations that would be prevalent within the Network's geography. 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. 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. The SPOC shall assist the CMS ISSO in ensuring the ESRD NETWORK adheres and complies with 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 within 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.

2) The ESRD NETWORK shall comply with all CMS security program requirements as specified within 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. 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 this Scope of Work Schedule of Deliverables.

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://esrdncc.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. 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 as it relates 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 May 28th 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 Information Security (IS) Risk Assessment (RA) as directed by CMS.

4) The ESRD NETWORK shall develop, in conjunction with CMS, Corrective Action Plans (CAP) 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 Task Order 001, 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 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 Information Security Plan of Action & Milestones (POA&M) Procedure.

c. Inventory of Government Furnished Equipment

The ESRD NETWORK shall comply with CMS guidance for requirements associated with Government Furnished Equipment. The ESRD NETWORK shall update Remedy inventory for all procured, transferred and received Government Property (including hardware and software). The ESRD NETWORK will be responsible for keeping a list of all purchased and leased equipment in a HHS 565 submission Final Report.

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. The ESRD NETWORK shall perform maintenance of systems and software in compliance with applicable configuration requirements. NETWORK IT staffs 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)

a. In accordance with Section C.x.x.x 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 Security Point SPOC and backup for each year of the contract.

2) Provide a list of assigned ESRD Network IT staff with the required information.

3) Conduct Security Awareness Training (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.

4) Visit the CMS security website (www.cms.hhs.gov/informationsecurity) 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.]

5) Submit 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.

6) 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 as it relates to program security and compliance.

7) Provide an ESRD Network System Security Plan (SSP) and Information Security (IS) Risk Assessment (RA).

8) Develop, in conjunction with CMS, Corrective Action Plans (CAP) 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.

9) Submit the Plan of Action & Milestones (POA&M) for the approval of a CAP until the CAP is closed.
10) Maintain a list of all purchased and leased equipment in a HHS 565 submission Final Report.

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

12) 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:
        1) Adhere to the privacy, confidentiality, and disclosure requirements set forth in Section 1160 of the 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, confidential and disclosure requirements. 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.

C.3.18. Internal Quality Improvement Program

The objectives of the Internal Quality Improvement (IQI) 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 three AIMs.

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 its response to problems that arise in performing contract requirements.

The Network is required to have an IQI Program in place to facilitate compliance with contract requirements including the ability to demonstrate improvement in areas in which performance does not meet Network and/or CMS goals.

C.3.18.A. Internal Quality Improvement (IQI) Program Criteria
The ESRD Network criteria of the IQI Program, at minimum, are to:

- Support and foster continuous quality improvement in Network activities in support of the NQS, CMS's Strategic Plan, 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 which demonstrate 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.3.18.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 processes 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 is 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 other Network staff;
- Determine 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 taken to identify, implement, and monitor improvement actions;
- Document all of the elements of their work related to the IQI, and provide to the COR with the COR Monthly Report, and with the NW BoD on a regular basis.

C.3.18.C. IQI Program Reporting Requirements
At minimum, the Network shall (a) generate periodic 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.3.19. 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, then CMS will require a PIP to ensure that the Network will take the required steps to remedy contract performance deficiencies.

C.3.19.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, then 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 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, GCMS SME's manager, and 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 SME(s)) believes that the Network is not progressing satisfactorily, then 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 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 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 which resulted in the PIP. It is the Networks responsibility to derive the appropriate corrective actions.

If a fully acceptable PIP is not submitted by the Network within five (5) working days (or a negotiated alternate date), then 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, then the COR will make a recommendation to the Contracting Officer for any further action.

C.3.19.B. Submission and Acceptance of a PIP
When the COR requests submission of a PIP, the Network shall submit a PIP within five (5) 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 (5) working days to review and notify the Network if the PIP is approved and 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:

- The criteria CMS will use to monitor implementation of the PIP;
- The monitoring plan (see C.3.19.C);

- The 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, then 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, then implementation and assessment of the corrected plan will follow the procedures for an initially acceptable PIP. If the corrected plan is unacceptable, then 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.3.19.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, following implementation of a PIP, continues to be unsatisfactory, then 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.3.19.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 communicates closure of the PIP to the contractor. To close a PIP, the COR will notify the Network,

Contracting Officer, and ARA in writing that the PIP has been closed. If the Network is unsuccessful in completing the PIP, then the COR will notify the Network, Contracting Officer, and ARA of the continued deficiency.

C.4. AIMS AND DOMAINS

C.4.1. AIM 1: Better Care for the Individual through Patient and Family Centered Care

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

The Network shall incorporate the patient's voice in all of its activities, and encourage a patient perspective within the renal community as a whole. The Network shall implement interventions at the dialysis-facility level to foster patient and family involvement in the areas of grievances and non-grievance access to care concerns; support for ICH CAHPS; and HAIs. Requirements for QIAs in these three areas are found in the following sections of this SOW: Section C.4.1.B.1, Evaluate and Resolve Grievances; Section C.4.1.B.4, Promote Use of ICH CAHPS; and Section C.4.1.E., Patient Safety: Healthcare-Associated Infections.

The Network shall recruit Patient SMEs and/or family members or caregivers to provide a patient perspective on Network activities. Patient SMEs are committed and informed patients who are representative of the demographic characteristics of the Network's service area. The Network may exercise discretion in selecting new SMEs for each contract year, or allowing existing SMEs' continued participation in new contract years. Patient SMEs and/or family members or caregivers shall provide a patient perspective for Network improvement activities in the above-mentioned areas. In addition, 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 identify a subset of its identified Patient SMEs and/or family members or caregivers and support their active participation in the N-PFE LAN.

Additionally, the Network shall coordinate with at least one Quality Innovation Network (QIN-QIO) within the Network's geographic territory on existing community-based efforts that

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[1] 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

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

directly impact dialysis facilities and the ESRD population; and at least one Network staff member shall serve on the local QIN-QIO community coalition.

C.4.1.A. Foster Patient and Family Engagement at the Facility Level
The Network shall assist providers in adjusting to the heightened focus on patient and family centered care, aiming to help providers optimize customer satisfaction and improve clinical outcomes. The Network shall perform the following tasks.

- Provide Patient SME agreement forms to at least 25% of facilities located in the Network service area in order to identify patients and/or family members or caregivers to participate in patient-and family-engagement activities within 30 days of contract award.

- Enlist 15 patient SMEs and/or family members or caregivers to provide patient perspective on Network activities.

- Enlist two or more selected Patient SMEs and/or family members or caregivers (per project) to provide input and to actively participate in the development of the following QIAs, in collaboration with the Network's Patient Services Department:

    - Patient Experience of Care (Patient SMEs involved in both)
        - Grievance QIA
        - ICH CAHPS QIA
    - Patient Safety: Hospital Associated-Infections (select either or both)
        - HAI BSI QIA
        - HAI Vaccination QIA

  The Network shall integrate the concepts of family engagement and patient-centered care in its QIAs, considering the best known available practice in the domains of Patient Experience of Care (C.4.1.B) and Patient Safety: Healthcare Associated Infections (C.4.1.D). The Network shall ensure that Patient SMEs and/or family members or caregivers are instrumental and actively involved in development of patient-oriented interventions in each area.

- Submit a list of the 15 selected Patient SMEs and/or family members or caregivers to the COR on or before February 15th of each contract year.

- As part of any onsite visits to dialysis facilities, incorporate discussion, education, and evaluation of how the dialysis facility has implemented patient and family centered care. Examples include:

    - Review and discuss with the facility whether the Quality Assurance Performance Improvement Program incorporates patient and family participation

    - Review for the presence of patient and family meetings (e.g., patient council, support groups, vocational rehabilitation groups, and new-patient adjustment groups)

- Review and discuss patient and family involvement in the governing body of the facility
- Review and discuss policy 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 cannulation)
- Determine the percentage of patients and/or family members or caregivers who participate in plan of care meetings
- Review, and assess for patient and family involvement on, task forces and teams working on patient safety and other quality improvement endeavors
- Provide technical assistance to facilities in developing strategies to promote and encourage patient and family engagement
- Document all observations of patient and family engagement during facility visits in the COR Monthly Report.

- Submit by November 30 a report summarizing the level of patient engagement and the patient-engagement activities noted/reviewed at any facilities receiving a site visit. The report shall note any facilities that have processes in place to encourage patient involvement, and detail these processes.

C.4.1.A.2. 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 and record attendance in the meeting minutes.

- In at least two of the monthly COR monitoring meetings held during each quarter, two or more Patient SMEs and/or family members or caregivers shall participate. In each COR monthly meeting attended by patients and/or family members or caregivers, the Network shall dedicate one or more agenda item(s) to patient-related topic(s), and provide the attending patient SME(s) with a 10- minute opportunity to address the agenda topic, raise additional issues, and/or provide an agenda item for the next attended meeting.
- At least two Patient SMEs and/or family members or caregivers shall be in attendance at the Network's annual evaluation site visit. During the Network's annual evaluation site visit, at least an hour shall be dedicated to the Patient SMEs to provide an opportunity to discuss answer questions from the COR.
- Patient SMEs and/or family members or caregivers shall participate in other CMS meetings as directed by CMS. See Attachment J-6, Learning and Action Networks, for additional guidance.

C.4.1.A.3. 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. They engage leaders around an action-based agenda. The National Patient/Family Engagement LAN

(N-PFE), managed by the ESRD NCC, creates opportunities for in-depth learning, problem-solving, and achievement of patient- driven goals. The N-PFE LAN promotes patient and family engagement throughout all Networks and dialysis facilities.

The Network shall support the N-PFE LAN by enlisting the participation of 5 of the 15 selected patient SMEs and/or family members or caregivers to serve as representatives on the N-PFE LAN by the end of the first quarter of each contract year. The Network shall ensure that patient/family representation is maintained at a minimum of 3 participants throughout the contract, and at least one serves as a Network representative. At the national level, the input from participating patient SMEs and/or family members or caregivers will assist in the development of national materials designed to improve care.

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 such LANs include, but are not limited to, the ESRD NCC, QIOs, dialysis facilities and other ESRD providers, large dialysis organizations (LDOs), the National Institutes of Health National Kidney Disease Education Program (NIH/NKDEP), the Centers for Disease Control and Prevention (CDC), the United States Renal Data System (USRDS), and the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC).

The Network shall accomplish the following tasks:

- On or before February 15 of each contract period recruit five (5)Patient SMEs and/or family members or caregivers (from the group of 15 Patient SMEs) to participate on the N-PFE LAN throughout the contract year, 3 of whom must be eligible patients on the transplant waitlist.

- Submit a list of the five (5)Patient SMEs and/or family members or caregivers selected to participate on the N-PFE LAN to the COR On or before February 15 of each contract period.

- Document the active participation of the five (5) Patient SMEs and/or family members or caregivers and their contributions in the COR Monthly Report.

- Provide an update, by close of business on the last business day of each quarter, on the number of participants who remain active in patient-and family-engagement activities, including the N-PFE LAN and QIAs, throughout each contract year. Active involvement can be demonstrated by multiple means, including lists of attendance at meetings/webcasts/conference calls; documented requests for technical assistance; documented requests for resources; or an attestation of participation signed by the participant.

- Encourage and maintain 100% membership, with 60% attending required meetings and activities throughout the course of the project for each year of the contract.

C.4.1.B. Patient Experience of Care

C.4.1.B.1. 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.

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 under C.4.1.B.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 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;
- Follow all instructions as provided within the Grievance/Access to Care guidance document found in Attachment J-8;
- Notify by e-mail the COR within one business day of all referrals to a State Survey Agency (SA);
- 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.3.11of 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) [timeliness is 7 business days for all IA cases], and at least 90% of all grievance cases [timeliness is 60 calendar days for all grievances cases] entered into the Patient Contact Utility (PCU);if a case requires more than 60 days to complete, then the approval of the COR must be received prior to the 60-day limit;
- Work collaboratively with the appropriate State Survey Agency or Agencies to maximize the linkage between case review information obtained during investigation of a grievance and the survey process.

In addition, the Network shall:

- Ensure that 100% of all contact data for patients that have agreed to participate in the CMS Grievance Satisfaction survey are provided to the ESRD NCC monthly
- At CMS direction, provide de-identified PCU data to the ESRD NCC as requested for analysis of grievance trends and patterns;
- Work with the ESRD NCC to conduct a patient satisfaction survey relative to satisfaction with the grievance process (The goal by the end of the third quarter of the contract year is to achieve 80% of respondents having a satisfied or very satisfied response).

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

Networks shall work to improve the grievance process within the Network environment by conducting two activities. The first shall be 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. 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. In addition, the Network shall report, at a 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, for April through September, the Network will report any intervention activities related to efforts to improve the prevalence of the three highest grievance categories.

The second Network Grievance activity shall be a QIA on the Grievance process in a subset of selected dialysis facilities. With the assistance of patient SMEs and other appropriate stakeholders, the Network shall conduct a project to improve the utilization of the grievance process at the targeted facilities, as well as improve communication between the patients at the targeted facilities, the facility staff, and the Network. Underlying this project must be a clear message that patients always have the right to contact the Network at any time, without first addressing the issue at the facility, and without retaliation. The QIA shall include a minimum of 10 dialysis facilities, based on the Network's assessment of those facilities that have reported the most grievances and/or access to care issues to the network. The QIA shall use a single weighted measure for the project. For the facilities included in the project, the Network will obtain a copy

of the facility grievance log, and score the facilities using a five-point scale. The scale will weight items as follows in the following order of importance (i.e., the first item is weighed more than the second, which is weighted more than the third, and so forth):

1. Major QoC or Access to Care issues (e.g., major bleeds, wrong dialyzer, prescription changes without physician order, IVDs either at risk or actual)
2. Minor QoC issues(e.g., simple bleeding after dialysis, minor infection control issues)
3. Operational issues(e.g., inadequate staffing, other issues related to the operation of the facility)
4. Interpersonal Issues(e.g., conflicts between patients, conflicts between staff and patients)
5. Environmental issues(e.g., facility too cold, basic maintenance issues such as chair, lobby)

Grievances with more than one category will be scored at the lowest ranking possible. That is, if a grievance contains both an Interpersonal (4) and a Minor QoC (2) issue, the item would be rated as a 2, which carries a higher weighting than 4, as described above.

The Network will decrease the target facility's average score by a relative 20% by focusing on the facility grievance processes and their ability to address the more heavily weighted items. At no time will patients be informed that they will lose their ability to contact the Network for a grievance or access to care issue without first working through the facility. The objective of the QIA is to get the facility to have an effective and efficient grievance process so that patients feel capable of handling their environmental, interpersonal, and operational issues with the facility, thereby leaving the more QoC and Access to Care-involved issues for the Network to address with the facility.

Networks shall use the template in Attachment J-7 for this QIA. Networks shall provide a copy of the grievance template and accompanying instructions to the selected facilities for data collection prior to February 1 of the base contract year. Networks shall provide the QIA to the COR by March 31 for Base year and January 31 for Option years. Networks will collect and assess the grievance templates from the target facilities for February and March as a trial period. The Network shall work with the target facilities to improve the submission of data in a timely and complete manner prior to initiation of the QIA activities in April. Data collected for April shall be used as the baseline for the QIA. Improvement for this QIA will be measured for May through October. Data for this QIA shall be provided monthly on the DIF as directed by CMS. The Network shall report a summary of activities related to this QIA on the COR Monthly Report.

C.4.1.B.2. 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 reported 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 and timelines for addressing IVD, IVT, and failure-to-place grievances filed by patients, patients' representatives, and providers, in accordance with Section C.4.1.B.1 of this SOW;
- Adhere to CMS-specified definitions and timelines for addressing non-grievance IVD, IVT, and failure-to-place cases;
- Document all information on IVD, IVT, and failure-to-place cases in the PCU or another CMS-designated system;
- 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).

C.4.1.B.3. 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 providing 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);
- Report data on averted IVDs in the COR Monthly Report, as directed by CMS.

C.4.1.B.4 Promote Use of ICH CAHPS and/or Any Similar Survey Identified by CMS
The Network shall encourage in-center hemodialysis qualified facilities to use the ICH CAHPS tool using the current ESRD QIP rules and Agency for Healthcare Research and Quality (AHRQ) guidelines posted at http://cahps.ahrq.gov to report ICH CAHPS information as directed by CMS**.** The Network shall inform providers of ESRD QIP Patient Experience of Care Survey measure requirements, and encourage provider activities to fulfill the measurement requirements. Any requirements in this section also apply to any other similar survey identified by CMS (including quality of life) for any modality.

Upon notification that the ICH CAHPS data is available, the Network shall assist qualified facilities with interpretation of results and development of an action plan to improve the patient's experience of care. Networks shall assist qualified facilities with conducting trend analyses.

Networks shall review and evaluate for disparities in care. These measures will assist facilities in capturing missed opportunities for improvement over time.

For information regarding measure specifications for the ESRD QIP see http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/index.html.

The Network shall develop a QIA based on the results from the latest ICH CAHPS results administered during the previous year (e.g., Spring 2015 for the 2016 base contract period). The Network shall use the QIA Short Form in Attachment J-7 to document their proposed efforts, and provide to the COR and CMS SME for review. COR approval shall be achieved by March 31st for the base year of the contract, and by January 31st of each of the Option years.

The QIA ICH CAHPS data received will be used to access potential quality improvement opportunities on a Network-wide basis by examining the various components of the survey. The Network will select the worst of the issues (as defined by the number of patients reporting the problem and the lowest scores from the ICH CAHPS survey). Patient SMEs shall be integral to the development of appropriate intervention(s) for the problem area identified. Patient SME involvement and approval shall be demonstrated in the QIA provided to the COR for approval. Networks will obtain monthly results from the target dialysis facilities by administering a single measure, that is not an administrative or demographic measure of the ICH CAHPS survey that is appropriate for the QIA. The CMS SME and COR must review and approve the measure selected, prior to the Network submitting its QIA plan. The measure selected shall have reasonable potential for positive change, and be directly related to the problem or issue of the baseline data used for determination of the QIA.
The COR-approved QIA shall include methodology as provided by Attachment J-7, Quality Improvement Activities, and shall identify a single primary process or outcome measure for evaluation purposes. The QIA methodology shall impact at least 5% of the Network population, with a minimum of 20 dialysis facilities, and demonstrate at least a 5% relative improvement on the Network-selected component. The population of the target facilities shall be divided by 6, with 1/6th of the target population assessed the single question each month for April through September. No more than identifiers and the single question shall be administered. For example, in a Network with 20K patients, if the target population of 22 facilities includes 2400 patients at baseline, then 400 patients would be assessed each month. Networks shall assess the target population in a random manner that no patient is included more than once, but that all patients are given one opportunity to provide a response. Networks shall also assess patients that the monthly results provide a snapshot of the targeted facilities as a whole. Networks shall not restrict assessment to individual facilities, but assessments shall be distributed among all facilities included in the target facility population that will provide adequate results for the Network to make appropriate interventions. Monthly results from the QIA shall be provided to CMS electronically on the DIF or otherwise as directed by CMS. The Network shall provide a summary description of activities related to this QIA on the COR Monthly Report.

C.4.1.C. Vascular Access Management
The Network is responsible for meeting its CMS-defined vascular access goals, and for tracking its progress in meeting those goals monthly using the CMS Dashboard and any other CMS-

designated reporting tools.

C.4.1.C.1. Reduce Catheter Rates for Prevalent Patients
The Network shall track long-term catheter use rates (catheter in use ≥90 days) using the CW Vascular Access Dashboard provided by the ESRD NCC, and shall target a Network reduction in the rate of long-term catheter use among prevalent patients by at least 2 percent in dialysis facilities that have a >10% rate of long-term (≥90 days) catheter use in prevalent patients at baseline. The baseline period shall be September of the prior calendar year, and the re-measurement period shall be the last day of the last month of the third quarter of the contract year. The Network shall report a summary of activities related to this QIA monthly on the COR Monthly Report.

C.4.1.C.2. Support Facility Vascular Access Reporting
The Network shall provide support to dialysis facilities for the submission of vascular access data. The Network shall be responsible for knowing the vascular access rates of all facilities in its service area, and for reporting to the Network's COR if there is a concern with facility reporting. If less than 95% of facilities in any given month are not reporting at least 95% of vascular access data for all eligible patients, then the Network shall identify barriers to achieving this goal, and potential interventions to improve the reporting rate, on the COR Monthly Report.

Additionally, the Network will 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.

C.4.1.C.3. Spread Best Practices
Successful interventions and system changes shall be spread to the other facilities in the Network's service area, and shall be shared with the ESRD NCC, any appropriate LAN, and other Networks.

C.4.1.C.4. Provide Technical Support in the Area of Vascular Access
The Network shall provide, at minimum, the following technical support activities for dialysis facilities in the area of vascular access:

- Deliver targeted technical assistance for lower-performing providers;
- Perform root cause analyses;
- Provide assistance with utilizing strategies that incorporate simultaneous patient and staff vascular-access management education(e.g., educating patients and staff together during staff orientation, or vascular access competency training or testing);
- Promote staff initial cannulation training, annual competency training, and annual competency testing;
- Promote early vascular-access teaching to patients with catheters during their orientation to the unit, and following up with further information regarding complications associated with catheters;
- Promote patient self-cannulation;

- Implementation of evidenced-based interventions: The Network shall propose the intervention(s) that it plans to use in achieving the AV fistula-in-use goal based on the assessment of the population served and regional considerations that may be indicative of disparities in care. The CW Vascular Access Dashboard provided by the ESRD NCC and the Fistula First website (http://www.esrdncc.org/index/fistula-first) provide information that can be used by the Network as it considers the most appropriate intervention(s) for its service area. The Network shall include interventions aimed at decreasing the use of catheters in an effort to promote catheters last and fistulas first. The Network shall evaluate the effectiveness of all implemented interventions.

The Network shall report activities related to the provision of technical support on the COR Monthly Report.

C.4.1.D. Patient Safety: Healthcare-Associated Infections

The Network shall provide support for a Healthcare-Associated Infections LAN (called HAI LAN). By implementing the HAI LAN, the Network shall seek to (a) improve relationships between dialysis centers and hospitals that care for the same ESRD patients; (b) improve the quality of data reported to NHSN so that it may more reliably be used to target and evaluate prevention activities, (c) reduce HAI rates among ESRD patients receiving dialysis care in both in-center and home settings, with a priority focus on prevention of and reduction in the incidence of BSIs; (d) improve ESRD patient vaccination rates.

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. In addition to patient involvement with the HAILAN, Networks shall include Patient SMEs and/or family members or caregivers in the development and implementation of interventions of at least one, if not both, of the QIAs in the section (BSI/Sepsis QIA and Vaccination QIA). Patient SMEs shall be integral to the development of appropriate intervention(s) for the problem area(s) identified. QIAs must integrate the concepts of family engagement and patient-centered care, considering evidenced-based practice, as well as innovative approaches that may be recommended by Patient SMEs and/or family members or caregivers. Patient SMEs' and/or family members' or caregivers' involvement and approval shall be demonstrated in the QIA provided to the COR for approval.

C.4.1.D.1. Support NHSN

In support of the ESRD QIP final rule requirements, the Network shall help new and returning facilities in the Network service area to successfully enroll in the NHSN. In addition, the Network shall support facilities in reporting dialysis event data for twelve months, and support facilities in reporting data to any or all other modules in NHSN in support of ESRD QIP requirements, or as desired by the Network or facility user for their HAI prevention efforts. The Network shall establish itself as the group administrator for the NHSN database system for the dialysis facilities in the Network's service area. The Network shall obtain group administrator rights from every facility in the Network's service area. Finally, the Network shall assist facilities in ensuring that data are entered into the NHSN database accurately and in a timely manner.

CMS anticipates that many facilities will work to achieve the goal of meeting all NHSN

reporting requirements reflected in the ESRD QIP final rule. As a result, many facilities are likely to develop best practices in reporting, be willing to share information, and seek the advice of others on how to achieve success.

C.4.1.D.2. Establish HAI/Sepsis LAN

The primary focus of the HAI/SEPSIS LAN is to improve information communication across care transitions, specifically between hospitals and dialysis centers caring for the same ESRD patients. The expected benefits of this activity include increased awareness among ESRD and hospital providers of important clinical diagnoses and treatments that would impact care of the ESRD patient and/or infection control precautions needed in both clinical setting (e.g., provision of better post-discharge outpatient clinical care as a result of full knowledge of patient's hospital course and expected ongoing treatment plan), as well as improved reporting of dialysis events to NHSN (e.g., reportable positive blood cultures identified during a hospitalization).

CMS has charged the QIN-QIOs with establishing HAI LANs that are primarily focused on the reduction of HAIs in the hospital setting. The Network shall coordinate with its local QIN-QIO(s) and state/local health departments, State Survey Agencies, and hospitals to support the communication and HAI QIAs.

The HAI/Sepsis LAN shall provide guidance and support to facilities in order to reduce BSIs and improve vaccination quality improvement activities. 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).

Additional priorities identified in the Action Plan include implementation bundles, as well as education and training for providers, patients, and caretakers.

CMS recommends that the Network learn about the National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Eliminationhttp://www.hhs.gov/ash/initiatives/hai/esrd.html.

The LAN membership shall include Network staff, at least one QIN-QIO representative, and other stakeholders (e.g., dialysis facility staff, hospital infection preventionists or other hospital staff, representatives of state/local health departments, CDC, HENs, State Survey Agencies, and/or patient representatives).

The Network HAI/Sepsis LAN shall promote quality improvement. The Network shall use various approaches, such as:

- Improving partnerships among healthcare facilities in a geographic region or area;
- Promoting a collaborative, multi-facility, quality improvement environment to support effective change;
- Involving facility management to further institutional climate change;
- Providing access to the HAI/Sepsis LAN infection control policy and procedures in facilities in the Network's service area;
- Training and education for staff and patients;

- Observation and feedback from infection control audits by facility patients/staff;
- Development and implementation of interventions that permit patients to be more engaged in their own care with regard to infection control and prevention of infections.

Interventions shall use CDC-developed tools and toolkits and education resources located on the CDC website, or interventions at least at the level of CDC recommendations. BSI prevention materials and other helpful guidelines and educational materials are found at http://www.cdc.gov/dialysis/. Networks are encouraged to incorporate stronger interventions, such as those used by State Survey Agency surveyors. Such additional tools may be used, but must be reviewed by the CMS SME, and approved by the COR prior to their utilization.

The list of CDC's Recommended Interventions for Dialysis Bloodstream Infection Prevention is available at http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html. Corresponding intervention implementation tools (e.g., protocols, checklists, and audit tools) are available at http://www.cdc.gov/dialysis/prevention-tools/index.html.

The LAN shall provide outreach to encourage facilities to participate in CDC HAI training activities by encouraging all clinical staff to complete the CDC Infection Prevention in Dialysis Settings Continuing Education course at http://www.cdc.gov/dialysis/clinican/CE/infection-prevent-outpatient-hemo.html, as well as view the CDC video "Preventing Bloodstream Infections in Outpatient Hemodialysis Patients: Best Practices for Dialysis Staff" at http://www.cdc.gov/dialysis/prevention-tools/training-video.html.

The LAN shall encourage all staff, and other providers and practitioners, to undergo training on the CDC-recommended toolkit on sepsis at http://www.cdc.gov/sepsis/clinicaltools/index.html.

The LAN shall also encourage all facility clinical managers to undergo training on CDC-recommended BSI prevention measures, and encourage all facilities to have appropriate staff complete the annual CDC protocol training on NHSN reporting (available resources include CDC's 30-minute online training course). The Network shall report monthly activities related to the HAI LAN in the COR Monthly Report.

C.4.1.D.3. Reduce Rates of Dialysis Events

The Network shall conduct at least one QIA to reduce dialysis event rates, specifically BSI rates. In conducting the QIA, the Network shall use CDC intervention materials, or more stringent practices such as State Surveyor HAI requirements for dialysis facilities, to reduce BSI rates. Any additional materials used by the Network must be reviewed by the CMS SME, and approved by the COR. The Network is encouraged to use Patient/Family SMEs, as identified in Section C.4.1.A of this SOW, to develop and implement interventions from a patient perspective, so that patients at the target facilities can be engaged in their own care and improve the HAI-related circumstances at the facilities involved in the project.

The Network shall work through facilities to reduce BSI rates in outpatient dialysis facilities by:

- Promoting implementation of the CDC Recommended Interventions for Dialysis BSI Prevention (http://www.cdc.gov/dialysis/prevention-tools/core-interventions.html)

- Using CDC technical assistance and tools in enrolling facilities and encouraging accurate reporting of data
- Sharing best practices in the area of reducing HAIs, BSIs and Sepsis(i.e., promoting evidence-based practices for BSI prevention in dialysis patients and best implementation practices)
- Involving patient SMEs and directing interventions at the targeted facilities to allow patients the ability to impact their own care at the facilities.

Beginning in the base contract period, the Network shall develop and implement a COR-approved QIA using the QIA Short Form in Attachment J-7, aimed at reducing BSI/sepsis, by March 31st, based on infection data obtained from the NHSN database and other sources of information. For the Option Years, the updated QIA Short Form shall be approved by January 31st. At least 20% of facilities within each Network shall be included in the QIA, and these facilities shall be provided with guidance to improve implementation of the CDC Recommended Interventions for Dialysis BSI Prevention. Although completion of CDC audit tools is not required as part of the QIA, facilities should be encouraged to use these tools as part of their routine infection-prevention efforts. In the fourth quarter of each contract period, the Network shall determine which QIA facilities to continue or replace during the Network contract period.

Networks shall monitor the BSI rate for QIA facilities and report monthly results (quarterly pooled numerators and denominators which will be used to calculate quarterly pooled mean rates) from the QIA facilities to CMS electronically using the CMS DIF, or as otherwise directed by CMS. The monthly quarterly pooled-mean rates will be for Network 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. For each contract year, the Network shall demonstrate a 5% or greater relative reduction in the pooled mean at re-measurement compared to the previous year. Although first- and second-quarter data are used for the performance evaluation, all available data for QIA facilities from 2015 onward should be reported on a monthly basis by the Network. Semi-annual Pooled mean rates will only be reported twice a year on the DIF. Networks shall monthly report activities related to this QIA in the COR Monthly Report.

C.4.1.D.4: Vaccinations: Increase Hepatitis B and Pneumococcal Pneumonia Vaccination Rates

Beginning in the base contract period, the Network shall develop and implement a COR-approved QIA based on infection data obtained from the CROWNWeb database and other sources of information using the QIA Short Form in Attachment J-7, by March 31st. For the Option Years, the updated QIA Short Form shall be approved by January 31st. The Network shall identify at least 10% of low-performing (i.e., within the lowest quintile) facilities, with a maximum of 25 facilities, to participate in the Vaccination QIA. All measures must be implemented in all facilities in the target group. The Network is to conduct an RCA prior to implementing any interventions, and target its efforts based on the results of the RCA. All intervention efforts shall include rapid cycle improvement, and demonstrate appropriate stakeholder involvement to produce sustainable improvement within the target facilities. Patient

SMEs are encouraged to be involved in the development and implementation of all interventions, including those that permit patient involvement in improvement at the facilities and encourage patient involvement in their own care.

The Network shall use the CROWNWeb data provided by CMS to establish the baseline for the base contract year, as well as for measurement throughout the project. Facilities may be kept within the project until they achieve at least 60% vaccination rates for each measure, at which time they are to be replaced by different facilities in the lowest quintile for the subsequent year. For example, Facility X starts the baseline with Hepatitis-B and pneumococcal pneumonia vaccination (PPV) rates of 17% and 20%, respectively. In Option Year 1, Facility X obtains rates of 52% and 63%, respectively. In Option Year 2, the facility obtains respective rates of 62% and 75%. In this example, the facility would be replaced with Facility Y for Option Year 3; the facility would not be replaced in OY1, because it had not achieved the greater than 60% vaccination threshold for both measures.

For the base year, of the contract, the Network shall achieve a 2 percentage point increase over baseline within the target facilities by the end of the third contract quarter for the Network evaluation for each of the two vaccine types. For Option Years 1 through 4, the Network will have progressively increasing goals to achieve, with the Network making appropriate substitutions as described. The goals for the Option Years are as follows:

Option Year 1: 3 Point Improvement

Option Year 2: 5 Point Improvement

Option Year 3: 7 Point Improvement

Option year 4: 10 Point Improvement

Improvement levels are for all facilities within the project regardless of when they were brought into the project. CMS expects that the Network shall be able to achieve the progressive improvement goals without additional expenses due to the learning and efficiencies gained from the previous efforts. Evaluation for each contract year, unless otherwise noted, shall be assessed as to whether the specific improvement level for both measures has been achieved by the September CW data (received in December or earlier).

Hepatitis B Vaccination is considered as receipt of all vaccinations of the series. Medical reasons and levels of Hepatitis B surface antibodies that indicate immunity are appropriate reasons to be removed from the denominator as determined by CROWNWeb data. The baseline for this project will be calendar year 2015 for the Base Year, with each previous calendar year serving as the baseline following for the subsequent Option Years. For Example, 2016 will serve as the baseline for OY1 (2017); 2017 will serve as the baseline for OY2, and so forth. Project results shall be reported to CMS on a monthly basis on the DIF as directed by this SOW once the project has been reviewed by the CMS SME and approved by the COR, or through supplemental CMS communication. The Network shall report on activities related to the QIA in the COR Monthly Report.

C.4.2. AIM 2: Better Health for the ESRD Population

The Network's activities to promote AIM 2 shall focus on improving access to and the quality of ESRD Care through a Population Health Focused Pilot Project (PHFPP) in one of the following areas that are pre-approved CMS priorities:

- Improve Dialysis Care Coordination with a Focus on Reducing Hospital Utilization
- Improve the Frequency of Transplant Referrals
- Improve the Frequency of Home Dialysis Referrals
- Improve the Quality of Life of ESRD Patients

The objective of the PHFPP is to support achievement of national quality improvement goals and statutory requirements set forth in Section 1881 of the Social Security Act and the Omnibus Budget Reconciliation Act of 1986.

For the Base Year and OY 1 and 2, each Network shall conduct one project per contract year, and shall achieve the performance requirements for the Project selected (i.e., A1, A2, B, C or D) for evaluation purposes, as well as demonstrate reduction in an identified disparity, as required by this SOW. For OY 3 and 4, all Networks shall conduct the Hospital Care Coordination QIA, using the criteria and measures developed by CMS. CMS will further determine whether Networks will conduct a Network-selected PHFPP based on one of the three remaining focus areas.

C.4.2.A. Population Health Focused Pilot Projects: Technical Considerations

The Network's PHFPP 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 shall be used only for the performance of the PHFPPs unless the Contracting Officer specifically permits another use in writing. If the Contracting Officer permits the Network the use of government-supplied data for a purpose other than solely for the performance of this PHFPP, and if such use could result in a commercially viable project, then the Contracting Officer may negotiate a financial benefit to the government. Although this benefit often should take the form of a reduction in the price of the PHFPP, the Contracting Officer may negotiate any other benefits he/she determines are adequate compensation for the use of the data.

Upon the request of the Contracting Officer or the expiration of these PHFPPs (whichever comes first), the Network shall return or destroy all data given to the Network by the government. The Contracting Officer nevertheless 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.4.2.B. Population Health Focused Pilot Projects: Requirements

The Network shall, using appropriate internal and external stakeholders for the Network-selected project, conduct appropriate development of the project, and develop interventions based on the RCA conducted for the project. The project shall use innovative approaches and rapid cycle improvement that incorporates boundariliness and unconditional teamwork, and that are customer-focused and sustainable to achieve the strategic goals of the ESRD Network Program. The Network shall use CMS-identified data sources and measurable outcomes as part of the proposal phase. Data gleaned from these projects 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.

Networks should be knowledgeable of the topic area and the targeted populations that they are working with during the course of these projects. Projects shall also be developed so that, if necessary, facilities may be carried into future contract periods, or exchanged if they have achieved pre-determined thresholds for the measures.

The Network shall select a topic for its PHFPP based on (a) the opportunity for improvement of the performance measure within the target population and (b) the ability to reduce an identified disparity.

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

The Network shall then conduct a disparity assessment for its chosen project area using baseline data, as directed by CMS. Disparities shall be assessed in the following order:*

1. Race (African American vs. White, or Groups Other than White vs. White).
2. Ethnicity (Hispanic vs. Non-Hispanic).
3. Facility Location (Rural vs. Urban).
4. Gender (Female vs. Male).
5. Age (65 and older vs. Younger than Age 65).

*Populations listed first in each order are the disparate group.

The highest-ordered disparity with a $\geq$ 5 point difference between the designated categories will be used for the project. For example, for improving transplant coordination, if a 3 point disparity for Race and a 10 point disparity for Ethnicity are found, then the project would focus on Ethnicity. The Network is permitted to adjust membership in the target population of facilities in order to impact a particular disparity that the Network will include for its project. Once the final project is approved, however, the disparity cannot be further modified for the remainder of the contract year.

As a multi-year contract with a base year and four Option Years (OYs), the Network shall obtain approval of the project target facilities and disparity prior to initiating formal intervention activities related to the project. For the base year of the contract, the Network will initiate the project by selecting the topic area, target facilities, and disparity to be included in the project. For each subsequent OY, the Network will decide if it wishes to continue the project or change to a different topic area. If it changes to a different topic area, then the Network would go through the same process as was conducted for the base year (i.e., selecting the topic, identifying the target population, and identifying the disparity).

If the Network decides to continue the same project, then it will 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 their patients with a transplant referral, and at the end of base contract period has achieved 80% of their patients with a referral for transplant, this facility would be replaced by another facility that is below the 25% threshold for inclusion. Additionally, if the Network stays with the same project, it may add facilities that otherwise meet the PHFPP and topic-specific requirements, and it may petition to have facilities dropped who otherwise either do not meet the requirements of the project or have other legitimate reasons for being excluded from the project. Legitimate reasons for exclusion include a facility no longer providing the services related to the topic area (e.g., a dialysis facility stops providing home dialysis services)closing permanently (note that 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 project for at least six months of the contract period); or remaining in a project for longer than three contract years. All final decisions for the legitimacy of the exclusion will rest with the CMS SME.

For the base year of the contract, the Network shall inform the COR and CMS SME of the topic area chosen (with the exception of A2), the facilities to be included, and the resulting disparity groups by the last business day of February of the contract year. An initial plan for the project shall be provided, using the AIM-2 Checklist found in Attachment J-4, Reporting Requirements. The AIM-2 Checklist shall contain sufficient detail to determine the strategies and timeframes in which the Network plans to enact to reach the specified goals of the project (including meeting the disparity reduction). As the Network makes annual adjustments to the target facilities included in the project, it should consider that the disparity groups may change. The Network is responsible for providing interventions to reduce the disparity for the highest-ranking disparity grouping within the project, and should make appropriate adjustments annually to do so. The proposal shall be finalized, and baseline data collection and analysis for the selected project shall be completed, by the last business day of March. Reporting of the final project target facilities to the NCC shall be completed by the second business day in April for the base year of the contract. The Network shall not opt for a different project after PHFPP approval is received by the last business day in March.

For the Option years of the contract, if the Network decides that they will change project topics, they will follow the time period of the base year. If the Network opts to continue with the same topic area, the Network shall provide an updated plan, using the AIM-2 Checklist, and achieve approval from the COR in consultation with the CMS SME by the last business day in January.

All revisions to the project target facilities shall be reported to the NCC by the last business day in January.

C.4.2.C. Population Health Focused Pilot Projects: Contract Monitoring and Evaluation
The PHFPPs present new opportunities for the Networks to improve the quality and efficiency of services rendered to Medicare Patients through review and analysis of data (i.e., CROWNWeb, the Kidney Disease Quality of Life (KDQOL) survey, and other CMS-sanctioned data collection systems); identification and spread of best practices; implementation of proven quality improvement techniques; and input from providers, patients and other field experts. CROWNWeb data will be the official data source for all projects (except for the KDQOL survey, which will use the RAND tool). For Transplant Referral (Project B) and Home Dialysis Referral (Project C), Networks will obtain numerator data (i.e., those referred) from the appropriate facilities. The COR shall approve, in consultation with the CMS SME, the proposed numerator data collection process for these projects prior to project initiation.

The bold and innovative approach to change involved in PHFPPs does not lend itself well to the traditional forms of contract evaluation, which are more suited for assessing performance by the Network alone, rather than engagement in collaborative partnerships to strive for maximal, sustainable improvement. Evaluation remains nonetheless important, as such high expectations require quantitative and qualitative measures of accountability to ensure forward progress and prudent use of limited resources.

Evaluation of the PHFPPs shall consist of two components: A quantitative evaluation of the project performance and disparity reduction, and a quality assessment of the utilization of the six attributes for the PHFPP project. The quantitative evaluation of the PHFPPs shall be based on successful:

a) Achievement of the required performance improvement for the project topic target population chosen as of the September CW (received in December) or KDQoL results (received in October), as specified by the topic-specific descriptions; and

b) Reduction in the disparity for the outcome measure by at least 1 percent. To meet the disparity reduction requirement, an increase in the selected disparate group must be evident to be judged successful. Decrement from the baseline for the non-disparate group will not be considered as successful completion of this task.

Failure in either quantitative component shall result in an unsuccessful evaluation for the project. In summary, there are two primary quantitative objectives of the PHFPP projects. The performance objective is to get patient populations at the target facilities to significantly increase the proportion of their population achieving the desired outcome (i.e., going from under 25 percent, to over 75% achieving the desired outcome) over a multi-year period, and annually updating the target facility population as current facilities achieve their goals, and removing facilities that no longer have the capacity for improvement. The disparity objective is to reduce the disparity in achievement for the target facilities for those with the largest level of disparity of those included in the project.

The qualitative assessment will consist of assessment of six (6) attributes that are to be applied monthly to the project and will be assessed by the Networks COR. The following attributes will serve as the basis for assessing qualitative performance under this task:

1) **Rapid Cycle Improvement in QIAs and Outputs:** The Network shall regularly reassess the value of the interventions and technical assistance used for the project. 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 project, why they were made, and how they are expected to impact the project metrics. Examples of evidence include that the Network demonstrates that it is reviewing results and impact of its interventions on at least a monthly basis, that it demonstrates adjustments to the interventions, and that it is able to stop interventions that are not working.
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. Solicitation of customer feedback may focus on topics such as: how relevant the topics were to the work of the participants; how well the project met the needs of patients, other participants, and CMS; the perceived quality of the activities as reported by the patients, participants, and CMS; and suggested areas of improvement. The ability of Networks to answer these topics in a direct and actionable manner will be evidence of meeting this attribute.
3) **Ability to Prepare the Field to Sustain the Improvement**: Early in the project, the Network shall begin establishing a plan to increase the probability that the quality improvement(s) are maintained, or that improvement continues when the Network completes its formal work with the participants. The Network shall be expected to provide a framework and education for the project participants that will allow them to sustain or continue improvement in the absence of the Network. The Network shall be able to demonstrate how the facilities involved in the PHFPP are able to incorporate the interventions into their own activities and processes in order to sustain the project once the Network's involvement is completed. Examples would include process changes that the Network can demonstrate that the facilities have completed, or new approaches that the facilities have undertaken that directly impact the project results.
4) **Value Placed on Innovation:** The Network shall demonstrate solicitation and/or creation of new ideas that maximize improvement for the project participants. This includes designing a mechanism by which all entities the Network works with and/or has contact with as part of the project 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 products, services, or features for the benefit of the project participants. The Network shall be able to demonstrate examples of these approaches as part of its project.
5) **Commitment to Boundarilessness:** The Network shall demonstrate the ability to identify and engage multiple entities to impact improvement for patients and/or providers. This includes (but is not limited to) entities outside of CMS (e.g., state, local, and national healthcare organizations; patient advocacy groups; professional associations). The Network

shall be able to identify entities not normally included in the project, and how they are improving the outcomes of the project positively.

6) **Unconditional Teamwork:** The Network shall demonstrate its ability to work with other Networks and stakeholders to spread effective improvement activities. The Network is expected to demonstrate sharing of best practices with other Networks, as well as with project participants and partners.

Networks shall provide tangible evidence of meeting these attributes on a monthly basis during the COR monthly report.

The Network shall be monitored and measured for improvement on an ongoing basis through data reported to CMS and through COR review. Data for the Network-selected project shall be reported to CMS monthly using the CMS DIF, as directed by CMS through this SOW or through supplemental CMS communication. Additionally, the COR shall monitor for inclusion of the six attributes (above) and examples of meeting each of the attributes throughout the course of the project as reported in the COR Monthly report, and provide an assessment of achievement of the attributes to the CMS ESRD Dashboard. Networks shall indicate that an attribute is not applicable (N/A) for a particular month, but shall not have two consecutive months for which the attribute is N/A. Failure to meet all requirements of a chosen project (including but not limited to data reporting for all components of the project, 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 project shall be based on three components weighted equally: 1) the achievement of the topic-specific performance measure; 2) the reduction of the disparity; and 3) the successful incorporation of the six attributes into the project. 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 September for the performance and disparity measures, assessed against the topic-specific baseline period. CMS will re-establish baselines each contract year, regardless of whether the project is for a single year or spans multiple -years.

Throughout this PHFPP, the Network shall provide leadership and guidance for the project's quality improvement efforts in collaboration with the CMS SME and COR. The Network shall submit all required reports and deliverables in accordance with the SOD.

C.4.2.D. Project A1: Focus on Reducing Hospital Utilization

The Network shall coordinate the project by including appropriate stakeholders to include, at minimum, a state hospital association, at least one QIN-QIO within the Network geographic territory, and appropriate ESRD professionals. The Network shall work with a sufficient number of facilities to sustain at least 500 ESRD patients throughout the project (i.e., at baseline and for each month up to and through the evaluation). The patient population at the target facilities shall be selected from those facilities in the top 25th percentile of those having patients with hospitalizations. Measurement will be obtained from CMS-specified hospital measures in CROWNWeb, with data reported to CMS for the targeted facility population on a monthly basis.

The baseline for this project will be the second and third quarters of the previous year. The project will achieve a 5-point improvement from the baseline period each year the project is conducted to receive full evaluation points available. The project shall be able to demonstrate that it has identified one or more causal reasons for hospitalizations, and taken appropriate actions to intervene. Project results for the targeted population shall be reported to CMS on a monthly basis, as directed by this SOW or through supplemental CMS communication.

C.4.2.D. Project A2: Network Workgroup Focus on Reducing Hospital Utilization

As an alternative for this Network-specific topic only, CMS will work with up to five Networks on a special effort on hospitalizations. This effort will have decreased performance requirements, but be specifically under the direction of CMS for the activities, including interventions to be involved. If a Network chooses to participate, and is selected by CMS, then the Network will be part of a group-activity of up to five (5) Networks working collaboratively to assess the issue of hospitalizations and help create new measures for use in this task area. The Networks within this workgroup will:

a) Agree to participate in the project for the baseline and first two OYs;
b) Attend an introductory meeting in late January to further discuss the project(all final decisions for inclusion in the project must be completed by February 15of the base year of the contract);
c) Participate in a workgroup meeting at least bi-weekly from late February of the base year through April; subsequent meeting times will be determined by the needs of the workgroup;
d) Identify at least one QIN-QIO and other appropriate stakeholders within their ESRD Network territory (e.g. state hospital associations, other ESRD professionals);
e) Identify 5 to 7 medium-sized hospitals which are
    a. capable of providing chronic dialysis services to inpatient patients 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);
f) Identify approximately 20 to 25 dialysis facilities whose patients are admitted or use the Emergency Department services at the hospitals in (d);
g) Obtain permission from the hospitals in (d) to receive copies of ESRD patient medical record information;
h) Use CROWNWeb data and hospital-provided information to assess the accuracy of CROWNWeb reported hospitalizations, and to identify root causes for hospitalizations for the ESRD population;
i) Use reporting templates developed by the workgroup and share de-identified and aggregate results of the RCA (see k, below) and primary causes of hospitalization among the Workgroup members;
j) Initiate a process for working with appropriate stakeholder organizations (e.g., Renal Physicians Association (RPA) and other clinically relevant organizations) to develop an intervention package to be employed during the first OY of the contract;
k) Complete the RCA development of the intervention by the end of the base year of the contract, and implement the intervention during the first two option years. The

workgroup members are expected to achieve at least a 2 point reduction in the hospitalization rate based on a measure of hospitalizations per 100 persons during a base year baseline of second and third quarters by end of each OY;

l) The Network is expected to collect, assess, and report results for a maximum of five disparity categories, where possible, based on the hospitals and dialysis facilities included in the project. No disparity reduction will be required, but report of results for the performance measures and the applicable disparity categories will be achieved through the CMS DIF on a monthly basis;
m) Network workgroup members will also continue to participate in monthly discussion of the project, including but not limited to measurement, interventions, and appropriate next steps for advancing CMS's ability to impact ESRD hospitalizations.
n) Network workgroup members will provide presentations as requested by CMS at the QualityNet Conference or other appropriate venue to inform non-workgroup Networks prior to the initiation of the National Hospital Care Coordination QIA (Project A3).

Networks will notify their COR and CMS SME that they wish to be considered for Project A2 by January 15 of the base year of the contract. Consideration by CMS will be based on geographic representation by the workgroup members, the ability of the Networks to identify appropriate hospitals and dialysis facilities for inclusion in the project, and the reasons put forth by the Network on why it wishes to be a participant in the project. A submission template will be provided to all Networks that wish to be considered for this project by the January 1 of the base year. All decisions will be made by the AIM2 workgroup members, with notification to the Network occurring no later than January 31of the base year of the contract.

C.4.2.D. Project A3: National Hospital Care Coordination Project

For OYs 3 and 4, all Networks will participate in a National Hospital Care Coordination Project as directed by CMS. All project details, including measures, will be created by Project A2 and distributed to all Networks prior to the initiation of the third OY. Networks will provide COR with the target population and disparity by the second business day in April for OY3 & OY4. Networks will follow all CMS direction related to this project without deviation.

C.4.2.E. Project B: Improve Transplant Coordination

A "Transplant Referral" is defined as any first-time referral for a patient (i.e., the patient has not already been referred or been placed on a transplant waitlist), and for which either a dialysis facility or transplant center provides an indication that the patient has been referred. Patients who have had transplant failures are considered as restarting the referral process anew, and would be eligible for "first-time" referrals. Referrals are counted for the baseline and duration of the project. No patient on the waitlist is counted in during the baseline and duration of the project, as this patient's referral will have been counted or the referral occurred outside of the timeframe of the project.

The project shall include at least 5% of the ESRD patient population in the Network's service area, regardless of modality. The project shall demonstrate at least a 5 percentage point increase in the rate of transplant referrals for eligible patients by the end of the third contract quarter. Measurement shall be obtained from CMS-sanctioned data reflecting the Transplant Referral denominator measure, and supported by CROWNWeb demographic data. Networks shall collect

referral information (numerator data) from target facilities. Project results for the targeted population shall be reported to CMS on a monthly basis as directed by this SOW or through supplemental CMS communication. Baseline for this project shall be the second and third quarters of the previous year.

C.4.2.F. Project C: Promote Appropriate Home Dialysis in Qualified Patients

The Network shall work with a sufficient number of facilities to include at least 5% of the Network service area in-center hemodialysis patient population at baseline and throughout the project. The Network shall demonstrate at least a 5 percentage point improvement in home dialysis referrals by qualified patients (i.e., any patient currently receiving in-center dialysis) by the end of the third quarter of the contract. Denominator measurement shall be obtained from a CMS-specified modality measure in CROWNWeb. Networks shall collect referral information (numerator data) from appropriate facilities. Data for the targeted population shall be reported to CMS on a monthly basis, as directed by this SOW or through supplemental CMS communication. Baseline for this project shall be the second and third quarter of the previous year.

C.4.2.G. Project D: Support Improvement in Quality of Life

The Network shall use the CMS-mandated KDQOL measures for this project (http://www.rand.org/health/surveys_tools/kdqol.html). The Network shall select a patient population that includes at least 250 patients (but covering no more than 10 dialysis facilities). For each month, the Network shall obtain at least an 80% response rate from the patient population (i.e., 200 valid instruments received each month). A valid instrument is one that meets the RAND criteria for this instrument, as identified at their website for this tool. The Network shall achieve at least a 10-point improvement on the overall KDQOL score (items 1 – 36) by the end of the third contract quarter. The Network shall provide monthly data updates on the DIF for this project to CMS. Baseline for this project shall be February of each calendar year, and shall include only this month for the baseline.

C.4.3. AIM 3: Reduce Costs of ESRD Care by Improving Care

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 addresses the Three-Part Aim and six NQS priorities.

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.4.3.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 Quality Net website and on other CMS-designated websites). At a 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 quarterly updates if needed;
- 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 of the PSR 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 their PSC as directed in MIPPA.

The Network also shall assist facilities with improving performance on ESRD QIP and Dialysis Facility Compare measures. At a 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 ESRD staff working on ICH CAHPS,
- Join one or more existing initiatives or collaboratives identified by the Network, the ESRD NCC, CMS, or the 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 Network monthly calls), to ensure that surveyors are knowledgeable about the ESRD QIP, Dialysis Facility Compare, Star Ratings, and Dialysis Facility Compare measures 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 a 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 the admission or transfer practices. The Network shall monitor incoming 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, then 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.

The Network shall perform QIAs with facilities at risk for payment penalties based on their

recent ESRD QIP performance. The Network shall submit QIP QIA Short Form in Attachment J-7, by March 31st. CMS will provide data on the QIA-eligible measures to inform the planning and evaluate success of the QIAs. At minimum, the Network shall:

1. **Select ESRD QIP QIA Outcome Measures** – By the start of each contract year CMS will communicate the set of QIA-eligible measures and improvement targets to the Network. If more than one measure is eligible for the ESRD QIP QIA, then the Network shall review available data and select the measure, (or combination of measures), that presents the greatest opportunity for improvement among facilities in its service area. During the base year of the contract the Network shall work on the topic of Hypercalcemia performance. The improvement target for each facility is at least 25% relative improvement from baseline or to exceed the ESRD QIP penalty threshold.

2. **Select Facilities for Participation** – The Network shall select 10 or more facilities in its service area that achieved the poorest performance on the QIA-eligible measure(s). The Network shall submit a brief report to the COR and CMS SME by the last business day of January. The report shall include the following:

    a. A list of the facilities the Network selected for the QIA, and if applicable, the Network shall include the rationale for the measure(s) selected;
    b. The rationale for the selection of the facilities;
    c. The baseline results at each facility for the measure(s) to be worked on;
    d. The extent to which the selected facilities represent all facilities within the Network service area that are at risk for a payment penalty based on their performance on the QIA-eligible measure(s).

3. **Implement QIA** – The Network shall complete individual facility RCA and planned PDSA cycle, and report on these tasks by the last business day in March.

    a. **Perform Root Cause Analyses with Each Facility** – The Network shall contact each facility selected for the ESRD QIP QIA and engage staff in RCA to determine which factors might be driving poor performance at that facility. CMS expects the root causes of poor performance to differ by facility.
    b. **Plan PDSA Cycle with Each Facility** – Upon completion of the RCA, the Network shall develop plans to lead each facility through the PDSA cycle to address the root causes of poor ESRD QIP performance that were identified at that facility.
    c. **Support facilities' implementation of the PDSA plan –** The Network shall work with the selected facilities until the facility completes the PDSA cycle. A facility has completed the PDSA cycle when performance on the QIA measures are at or above the improvement target for three consecutive months.

4. **Drop and add new facilities** – When a facility successfully completes the PDSA cycle the Network shall replace the successful facility with a new facility that would benefit from the ESRD QIP QIA and repeat steps 1 through 3 above. Because facilities will exit and enter the QIA at different times, the completion dates for these

steps for the new facilities cannot be defined in advance. CMS expects the Network to be working with a minimum of 10 ESRD QIA facilities at any given time once the initial selection in Q1 of the base year is completed.

5. **Report to CMS** – The Network shall maintain sufficient documentation to describe the QIAs and report in detail the degree of success achieved at each facility. The Network shall report on the QIAs in the following reports,
    a. **The ESRD Network Dashboard**. Each month, the Network shall indicate on the DIF the number of facilities that completed the PDSA cycle that month,
    b. **The COR Monthly Report**. Beginning with the April submission, the Network shall describe progress on the ESRD QIP QIA, identify reasons for success or failure, and describe mitigation plans for any facilities that are struggling with the QIA,
    c. **ESRD QIP QIA Results Report**. On or before the DIF submission is due, the Network shall submit a report (using the QIP QIA Template in Attachment J-7) to the COR and CMS SME for each facility that completed the PDSA cycle that month. The ESRD QIP QIA Results Report shall contain the facility's performance results to verify the facility achieved performance targets for three consecutive months. At minimum, the report should contain the baseline result, and the results for the three months that qualified the facility for completion of the PDSA cycle,
    d. **The Annual Report (C.3.7).** CMS will provide the Network with a template for this report. The template will direct the Network to report only highlights or successes from the ESRD QIP QIAs and will not require full details on every project.

6. **Present learning's at a "Virtual Conference"** – CMS will schedule a series of no more than three webinars per contract year to bring together ESRD Networks to share learning's from the ESRD QIP QIA process.

The Network's performance goal for the ESRD QIP QIA will be met by examining the results in two-year cycles. For the base year of the cycle, if all 10 selected facilities have initiated their PDSA cycles by evaluation (Sept or Oct) then the performance goal has been met, and at least eight facilities complete the PDSA cycle (i.e., achieved target three months in a row) by the end of OY1. For each subsequent OY of the contract, the same requirements (all facilities initiate PDSA in first year (e.g. OY1), and at least eight out of 10 facilities complete the PDSA cycle (e.g. OY2). This process shall continue for four (4) cycles from the base year of the contract through OY4.

The Network shall support development of new quality measures; distributing CMS-provided materials relevant to facility/staff recruitment, training, education, and participation in CMS' efforts to test the feasibility, validity, and reliability of dialysis facility quality measures.
The Network shall support cross-program alignment within CMS; specifically by:

- Coordinating with designated CMS components and contractors to support alignment between network quality efforts and other CMS ESRD programs.

- Sharing data and analyses with designated CMS components and contractors to support shared program goals and alignment.
- Coordinating with designated CMS components and contractors to ensure consistent messaging and communications about ESRD quality efforts.

C.4.3.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 ESRD QIP and other QIAs. To ensure fair facility payment and appropriate stewardship of quality improvement resources, these data systems must contain the most complete and accurate data possible. The Network can help CMS achieve this goal by providing technical assistance to facilities in several areas.

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

Networks shall validate that all facilities have successfully completed and submitted 2744A forms by the first Friday in May. The Network shall report successful completion of the ESRD Facility Survey by providing a signed confirmation to the COR electronically by the second Friday in May.

Networks shall provide monthly updates of CROWNWeb activities as directed by the *CROWNWeb Data Management Guidelines*, Chapter 3 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 submission of data to NHSN, and resolve any identified issues with COR assistance related to the individual patient/facility.

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

- Support facilities in completing annual NHSN Dialysis Event Surveillance training (http://nhsn.cdc.gov/nhsntraining/courses/C18/). By the end of the third quarter each year, the Network shall achieve 90% or more of facilities completing the online annual NHSN Dialysis Event Surveillance training during that contract year.
- Perform quarterly NHSN data checks using a CDC-created and CMS-approved data checklist and report results to CMS on March 31, June 30, September 30, and December 31. The Network shall follow-up with facilities to correct data errors. March data checks shall review 4th quarter of the previous calendar year. June data checks shall review first-quarter data. September data checks shall review second-quarter data. December data checks shall review third- quarter data. These quarterly data checks are designed to help facilities meet ESRD QIP requirements. The Network shall report the data checks on the COR Monthly Report for the month after the data checks occur.

NHSN Data Quality QIA

Previous data quality evaluation activities performed by CDC, ESRD Networks and others, have identified a substantial gap in BSI reporting among dialysis facilities. Dialysis facilities are frequently unaware of patient BSI, because the infections are diagnosed after the patient is admitted to the hospital. Insufficient information transfer from hospitals to outpatient dialysis facilities is a concern for both the purposes of surveillance of BSIs and quality of care for patients.

The Network shall plan and perform QIAs to increase facility reporting of BSIs among dialysis patients that are identified within one calendar day following a hospital admission. The Network shall work with three cohorts of facilities. For each cohort, the QIA will consist of one year of planning followed by one year of implementation, and up to three years of monitoring results. The Network shall initiate QIAs with each cohort according to the schedule depicted in Figure 1.

During the planning year for each cohort, the Network shall:

- Select at least 20 dialysis facilities for QIAs that lack access to hospital electronic medical records (EMR) or are known to have challenges retrieving hospital medical record information for their patients;
- Identify at least five hospitals that receive patients from these QIA facilities;
- Collaborate with their QIO(s) and state/local health departments to identify, implement, and evaluate successful communication strategies among dialysis facilities and hospitals;
- Team with an existing HAI LAN to incorporate an already established community of appropriate stakeholders or establishing (or establish a community if none exists in the Network service area) to identify resources, barriers and potential QIAs,
- Submit a report to the COR/CMS SME on the last business day of April and October of each planning year. The report shall describe:
    - Method and rationale for which facilities and corresponding hospitals were identified for recruitment;
    - Resources, barriers, and ideas for intervention identified from communication with state stakeholders;
    - A plan for conducting the QIA during the option years that incorporates sound methodology as described in Attachment J-7 Quality Improvement Activities.

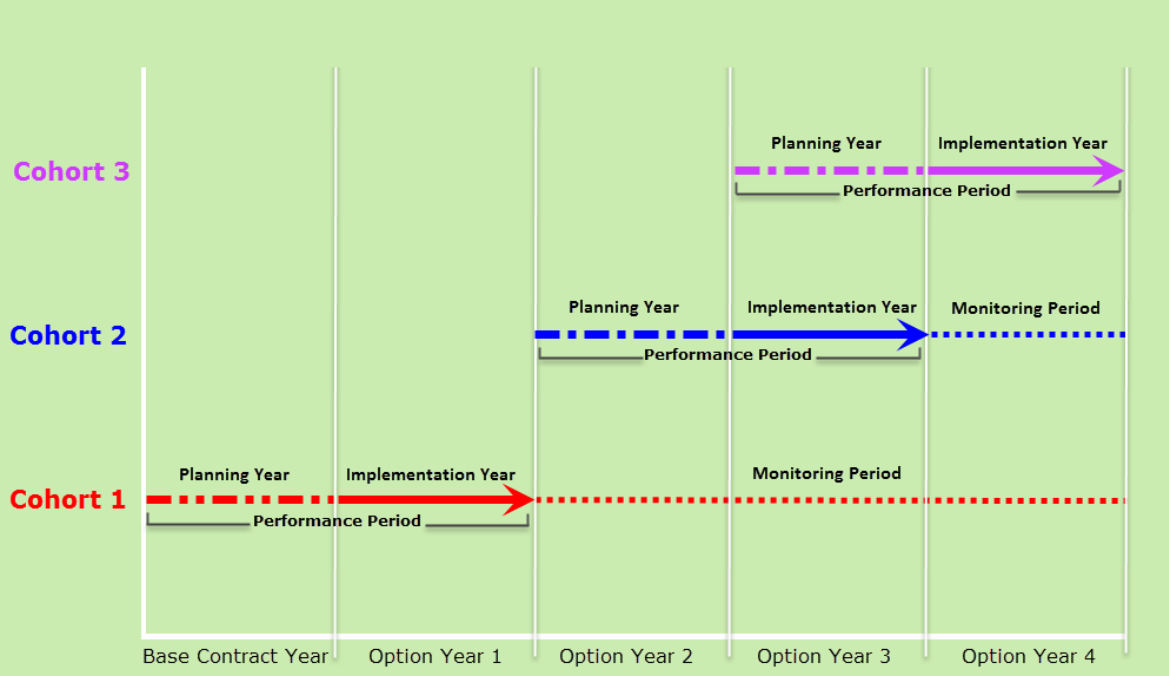
During the implementation year for each cohort, the Network shall:

- Implement appropriate QIAs to improve communication of key information between hospitals and facilities using RCA and the PDSA cycle as described elsewhere in this contract;
- Demonstrate that each QIA facility adopted a strategy to improve communication with hospitals and capture positive blood cultures identified in hospitals;
- By June 30 of the Re-measurement Period (see Table 3), demonstrate an increase over baseline in the percentage of BSI's reported in NHSN that were identified by hospitals. The percentage of BSIs will be calculated as shown:

$$\text{Percentage} = \frac{\text{Count of BSIs in denominator that were identified in the hospital*}}{} \times 100\%$$

All BSIs reported in NHSN during measurement period
*The numerator data will be collected from the dialysis event form variable 'PBCcollHospEDCt'

Figure 1: Performance and Monitoring Period for Each Cohort.



During OY3, the Network shall repeat the implementation process described for OY1 with cohort 2, monitor cohort 1, and identify facilities for cohort 3. During OY4, the Network shall monitor results for Cohort 2 to assess sustained improvement. Network performance will be assessed on each cohort separately; cohort results will not be pooled – (see Table 4).

Throughout the five-year contract period the Network shall:

- Disseminate successful strategies to facilities throughout the Network service area Support 100% of facilities in the Network to report to NHSN the variable that identifies location of the patient at the time of positive blood culture draw, and assess the completeness of this reporting.
- Electronically submit results from the QIA on the monthly CMS Dashboard Input Form (DIF) as directed by CMS.
- Provide CMS two times during the year feedback on changes in facilities participating in the communication and data quality improvement QIA using a tool provided by CDC
- Provide feedback to the COR/CMS SME on facilities' gaps in understanding or implementation of the surveillance protocol and suggest areas for improvement through the COR Monthly Report (at CMS's discretion, this information may be shared with CDC).

Table 3: NHSN Data QIA Measurement Periods

Cohort	Baseline	Re-measurement*	Monitoring
1	Jan 2016 – Jun 2016	Jan 2017 – Jun 2017	Every 6 months thru Jun

			2020
2	Jan 2018 – Jun 2018	Jan 2019 – Jun 2019	Every 6 months thru Jun 2020
3	Jan 2019 – Jun 2019	Jan 2020 – Jun 2020	Not applicable

*Results achieved during January through June of the Re-measurement period will be considered in annual Network performance evaluations.

Table 4: NHSN Data QIA Measurement Due Dates in DIF

Contract Year	Measure	Due Date (last business day of)
2016	Jan-Jun 2016 Cohort 1 Baseline	October
2017	Jul-Dec 2016 Cohort 1 interim	April
	Jan-Jun 2017 Cohort 1 Re-measurement	October
2018	Jul-Dec 2017 Cohort 1 Monitoring	April
	Jan-Jun 2018 Cohort 1 Monitoring	October
	Jan-Jun 2018 Cohort 2 Baseline	October
2019	Jul-Dec 2018 Cohort 1 Monitoring	April
	Jul-Dec 2018 Cohort 2 Interim	April
	Jan-Jun 2019 Cohort Monitoring	October
	Jan-Jun 2019 Cohort 2 Re-measurement	October
	Jan-Jun 2019 Cohort 3 Baseline	October
2020	Jul-Dec 2019 Cohort 1 Monitoring	April
	Jul-Dec 2019 Cohort 2 Monitoring	April
	Jul-Dec 2019 Cohort 3 Interim	April
	Jan-Jun 2020 Cohort 1 Monitoring	October
	Jan-Jun 2020 Cohort 2 Monitoring	October
	Jan-Jun 2020 Cohort 3 Re-measurement	October