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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3269-N]

Medicare Program; Proposal Evaluation Criteria and Standards for End Stage Renal Disease (ESRD) Network Organizations.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice describes the standards, criteria, and procedures we will use to evaluate an End-Stage Renal Disease (ESRD) Network Organization's capabilities to perform, and actual performance of, the duties and functions under the ESRD Network Statement of Work (SOW).

DATES: Effective Date: [Insert date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT:

Teresa Casey, 410-786-7215.

Renee Dupee, 410-786-6747.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1881(c) of the Social Security Act (the Act) authorized the establishment of, among other things, ESRD network areas and Network Organizations under the Medicare program to ensure the effective administration of the ESRD program benefits. We currently have contracts with ESRD Network Organizations to serve the 18 ESRD Network areas.

The existing 18 ESRD Network contracts have been operating under the same Statement of Work (SOW) since 2003 and have been renewed to continue to provide service to the ESRD

population. Recent major policy and legislative changes have modernized Medicare payments for ESRD care. In particular, the Medicare Improvements for Patients and Providers Act (MIPPA) required the Secretary of the Department of Health and Human Services (the Secretary) to implement an ESRD bundled payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. MIPPA also required the Secretary to establish an ESRD Quality Incentive Program (QIP).

Additionally, a heightened focus on quality improvement, public reporting and value-based purchasing in healthcare has fueled a growing need for facility-level data collection; analysis; monitoring; trending; evaluating and intervening, where necessary, to improve patient care. We have also emphasized spreading and replicating the best practices of high performing providers. Therefore, a redesigned ESRD Network SOW was drafted to incorporate these priorities in healthcare and changes in legislation. The SOW will charge the ESRD Network Organizations with establishing relationships with patients, families and facilities within their Network areas to reach the objective of optimal patient-centered care.

Section 1881(c)(1)(A)(ii)(I) of the Act provides that in order to determine whether the Secretary should enter into, continue, or terminate an agreement with an ESRD Network Organization, the Secretary shall develop and publish in the **Federal Register** standards, criteria, and procedures used to evaluate an ESRD Network Organization's capabilities to perform, and actual performance of, the network functions required by section 1881(c)(2) of the Act. These functions are to:

- Encourage participation in vocational rehabilitation programs, and develop criteria and standards relating to this participation.

- Evaluate the procedures used by facilities and providers in the network to assess patients for placement in appropriate treatment modalities.
- Implement a procedure for evaluating and resolving patient grievances.
- Conduct onsite reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary) using standards of care established by the ESRD Network Organization.
- Collect, validate, and analyze data necessary to prepare the required annual report to the Secretary and to ensure the maintenance of a national ESRD registry.
- Identify facilities and providers that are not cooperatively working toward meeting network goals, and assist those facilities and providers in developing plans for correction, as well as report to the Secretary on those facilities and providers that are not providing appropriate care.
- Submit an annual report to the Secretary on July 1 of each year.

Shortly after the publication of this **Federal Register** notice, we will post a Request for Proposals (RFP) to perform the work of the redesigned ESRD Network SOW on the Fed Biz Opps website (www.fbo.gov). The RFP will competitively award a portion of the 18 ESRD Network contracts using a best value process in accordance with Federal Acquisition Regulation (FAR) Part 15. The remaining ESRD Network contracts will be renewed and competed at a later date. The period of performance for these ESRD Network contracts will be one 12-month base year which begins on January 1, 2013 and ends on December 31, 2013, with two 12-month option periods. We may exercise an option in accordance with the FAR Part 17.2, and it may terminate a contract for convenience or for default, in accordance with FAR Part 49. This notice describes the capabilities that an applicant must demonstrate to be awarded an ESRD Network

contract and the general criteria that will be used to evaluate the ESRD Network Organizations performing under the SOW.

II. Description of the Tasks under the Revised ESRD Network Organization SOW

ESRD Network Organizations are responsible, in addition to other duties and functions that the Secretary prescribes, for performing the tasks outlined in section 1881(c)(2) of the Act.

Under the revised ESRD Network Organization SOW, ESRD Network Organizations will complete the requirements of the three Aims outlined in the SOW which support the functions required by section 1881(c)(2) of the Act. The three Aims are as follows:

- Aim 1, is the “Better Care for the Individual through Beneficiary and Family Centered Care” Aim. This Aim envisions ESRD Networks, facilities and beneficiaries working together to promote appropriateness of patient care and processes for evaluating and resolving patient grievances.
- Aim 2, is the “Better Health for the ESRD Population” Aim. This Aim considers the preparation and education of beneficiaries for transplantation and self-care settings or home dialysis.
- Aim 3, is the “Reduce Costs of ESRD Care by Improving Care” Aim. This Aim has Network Organizations assisting dialysis facilities in meeting the requirements of the ESRD Quality Incentive Program (QIP), supporting dialysis facilities in their submission of data to designated data collection systems and using data to provide necessary reports to CMS and the Secretary.

More detailed information for each Aim, Domain, and sub-domain can be found in sections C.2 through C.4. of the ESRD Network SOW posted at the www.fbo.gov website. Each Aim is also described further below.

1. Aim 1: Better Care for the Individual through Beneficiary and Family Centered Care (See section C.4.1 of the ESRD Network SOW)

The “Better Care for the Individual through Beneficiary and Family Centered Care” Aim strives to promote health care that is respectful of and responsive to individual patient preferences, needs, and values. The Network patient-centered domains will achieve Aim 1. Network patient-centered domains are Patient and Family Engagement; Patient Experience of Care; Patient-Appropriate Access to In-Center Dialysis Care; Vascular Access Management; and Patient Safety: Healthcare-Acquired Infections (HAIs).

The ESRD Network Organizations’ activities within this Aim will be enhanced by the patient’s voice. The ESRD Network Organization will take a two-tiered approach to incorporating the patient’s voice in the activities of the Network and the renal community as a whole. The two tiers are: (1) engagement at the dialysis facility level to foster patient and family involvement; and (2) development and implementation of a beneficiary and family centered care focused Learning and Action Network (LAN) to promote patient and family involvement at the Network level. Both tiers are essential and work together to promote beneficiary and family engagement to improve quality of care.

2. Aim 2: Better Health for the ESRD Population (see Section C.4.2 of the ESRD Network Statement of Work)

The “Better Health for the ESRD Population” Aim focuses on improving the quality of and access to ESRD care through a Population Health Innovation Pilot Project in one of the following areas:

- Increase HBV, Influenza, and Pneumococcal Vaccination Rates;
- Improve Dialysis Care Coordination with a Focus on Reducing Hospital

Utilization;

- Improve Transplant Coordination;
- Promote Appropriate Home Dialysis in Qualified Beneficiaries; or
- Support Improvement in Quality of Life.

Under the SOW, each ESRD Network Organization will work with low performing dialysis facilities in their Network to conduct one Population Health Innovation Pilot Project and achieve the specified outcome or outcomes for the measures related to the project area. The SOW describes the outcomes the ESRD Network Organization should achieve for each Project; however, the ESRD Network Organizations will develop and implement interventions to increase performance within the participating dialysis facilities. Additionally, ESRD Network Organizations must demonstrate a reduction in one of the disparity areas outlined in the SOW.

3. Aim 3: Reduce Costs of ESRD Care by Improving Care (See section C.4.3 of the ESRD Network Statement of Work)

The “Reducing Costs of ESRD Care by Improving Care” Aim focuses on supporting the ESRD QIP, facility performance improvement on QIP measures, and facility data submission for CROWNWeb, the National Healthcare Safety Network (NHSN), and/or other CMS-designated data collection system(s).

III. Evaluation of ESRD Network Organizations’ Capabilities to Perform, and Evaluation of the Performance of, the Responsibilities under the SOW

A. Evaluation of Capabilities to Perform the Responsibilities Under the SOW

In order to receive an ESRD Network Contract award, an applicant must demonstrate, through the submission of a technical proposal, the capability to perform the duties listed in the ESRD Network SOW. Technical proposal submissions must detail the applicant’s approach to

accomplish each of the Aims of the SOW and describe how the applicant will maximize the outcome of the specific tasks within each Aim. Additionally, successful applicants must offer sound quality improvement approaches for the intervention strategies they are proposing to meet the tasks identified in the SOW. The proposed interventions are expected to be evidence-based, efficient and effective. The proposed interventions should also be feasible in the context of the applicant's ESRD Network service area, considering geography and other relevant location-specific factors. Applicants will be expected to offer proposed solutions to anticipated challenges with a reasonable likelihood of success.

Other factors used to determine capability to receive an ESRD Network Contract award include an evaluation of the applicant's relevant past performance, the management structure that the applicant proposes to successfully perform the work of the contract as well as the qualified and experienced staff proposed to administer the tasks of the ESRD Network SOW.

We note that the solicitation posted on Fed Biz Opps is the official notice of the ESRD Network Contract Request for Proposals, and in the event that any terms within this **Federal Register** notice conflict with those of the solicitation and the SOW, the language within the solicitation and the SOW controls.

B. Evaluation of Performance of the Responsibilities under the SOW

With a focus on rapid cycle improvement, ESRD Network Organizations' performance of the responsibilities under the SOW will be monitored and measured for improvement on an ongoing basis using self-assessment and Contracting Officer Representative (COR) review. We will monitor the ESRD Network Organization's performance on the Aims and Domains against established criteria, as specified in sections C.2 through C.4., on at least a quarterly basis, and may take appropriate contract action for low or poor performing ESRD Network Organizations.

The COR will complete assessment and review of qualitative and quantitative contract evaluation objectives. Throughout the contract cycle, monitoring and measuring for improvement and general performance will be conducted. In addition, qualitative and quantitative evaluation will be conducted at the annual evaluation which generally occurs in the tenth month of the one year contract period. The annual evaluation will be based on the most recent data available. The performance results of the annual evaluation will be used, in addition to ongoing monitoring activities, to determine the performance on the overall contract

The qualitative evaluation of the ESRD Network Organizations will be based on the impact of the interventions utilized to accomplish the tasks within the SOW. We will evaluate the interventions for relationship-building, innovation, development of replicable best practices, and sustainability. The quantitative evaluation of the ESRD Network Organizations will be based on the achievement of the measurable targets for each of the Aims, as stated in the ESRD Network SOW (See Section C.4).

The following Tasks will be evaluated in accordance with the measures provided in the SOW:

AIM - Domain	Sub-Domain Tasks	ESRD SOW Reference
1 – Patient and Family Engagement	Patient Learning and Action Network Quality Improvement Activity	C.4.1A
1 – Patient and Family Engagement	Patient Learning and Action Network Campaigns	C.4.1A
1- Patient Experience of Care	Grievance Quality Improvement Activity	C.4.1.B.1
1- Patient Experience of Care	Patient Satisfaction with Network Grievance Process	C.4.1.B.1
1- Patient Experience of Care	In-center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAPHS) participation Rate	C.4.1.B.2
1- Patient Experience of Care	ICH CAPHS Quality Improvement Activity	C.4.1.B.2
1- Patient Appropriate Access to In-Center	Involuntary Discharge/Involuntary Transfer/Failure to Place rate and aversion	C.4.1.C.1- C.4.1.C.2

AIM - Domain	Sub-Domain Tasks	ESRD SOW Reference
Dialysis Care	rate	
1 – Vascular Access Management	Arteriovenous Fistula (AVF) Monthly Improvement	C.4.1.D
1 – Vascular Access Management	AVF Contract goal of 68%	C.4.1.D
1 – Vascular Access Management	Long-term Catheter (LTC) Contract goal of 2% reduction in participating facilities	C.4.1.D
1 – Vascular Access Management	Reporting of AVF/LTC data	C.4.1.D
1 - Patient Safety: Healthcare-Acquired Infections (HAIs)	National Healthcare Safety Network (NHSN) enrollment & reporting contract goal	C.4.1.E
1 - Patient Safety: Healthcare-Acquired Infections (HAIs)	NHSN Infection Quality Improvement Activity	C.4.1.E
2 – Population Health Innovation Pilot Project	Innovation Pilot Project Disparity reduction and outcomes	C.4.2.A.
3 –Reduce Costs of ESRD Care by Improving Care	ESRD Quality Incentive Program (QIP) and Performance Improvement on QIP Measures	C.4.3.A
3 –Reduce Costs of ESRD Care by Improving Care	Facility Data Submission to CROWNWeb, NHSN, and/or Other CMS-Designated Data Collection Systems(s)	C.4.3.B

The contract evaluation will determine if the ESRD Network Organization has met the performance evaluation criteria as specified in C.4 of this Statement of Work. We will evaluate whether a Network Organization has achieved each of the Aims and Domains on an individual basis. In general, evaluation of each Aim will relate only to that area, however in the event of failure in multiple Aims, we reserve the right to take appropriate contract action by, for example, providing warning of the need for adjustment, instituting a formal correction plan, terminating an activity, or recommending early termination of a contract.

An ESRD Network Organization will pass an Aim or Domain if it meets the evaluation criteria specified for that Aim or Domain. An ESRD Network Organization will fail an Aim or Domain if it does not meet the evaluation criteria specified for that Aim or Domain. Any failure

for any Aim or Domain may result in that ESRD Network Organization receiving an adverse performance evaluation. Further, failure may impact the ESRD Network Organization's ability to continue similar work in, or eligibility for, award of the next contract cycle of the ESRD Network contract.

We may revise measures, adjust the expected minimum thresholds for satisfactory performance, remove criteria from an Aim and/or Domain evaluation for any of the following reasons, including, but not limited to: data gathered on Aim and/or Domain; the level of improvement achieved during the contract cycle or in pilot projects currently in progress; information gathered through evaluation of the ESRD Network Program overall; or any unforeseen or other circumstances. Further, in accordance with standard contract procedures, we reserve the right at any time to discontinue an Aim and/or Domain or any other part of this contract regardless of the Network's performance on the Aim and/or Domain. In accordance with section 1881(c)(1)(A)(ii)(I) of the Act, when we make changes to the standards, criteria, and procedures used to evaluate an ESRD Network Organization's capabilities to perform and/or actual performance of the duties and functions under the ESRD Network SOW, we will publish an updated notice in the **Federal Register**.

If we choose, we may notify the ESRD Network Organization of our intention not to renew the ESRD Network Organization contract. We reserve our termination rights under FAR Part 49.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this regulation was not reviewed by the Office of Management and Budget.

CMS-3269-N

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare--Hospital Insurance Program; and No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: June 5, 2012.

Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

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