

Medicare ESRD Network Organizations Manual

Chapter 1 - Background and Responsibilities

Table of Contents *(Rev. 8, 12-14-07)*

Transmittals for Chapter 1

- 10 – *Background/Authority*
- 20 – *Program* Responsibilities of ESRD Network Organizations
- 30 – *Statutory Responsibilities of* ESRD Network Organizations
- 40 – Health Care Quality Improvement Program (HCQIP) *and the Network Organizations' Role*
- 50 – *ESRD Network Organization Program Strategic Goals*
- 60 – Purpose of *the Medicare* ESRD Network Organizations *Manual*
- 70 – Revisions to the *Medicare* ESRD Network Organizations Manual
- 80 – Acronyms and Glossary

10 - Background/Authority

(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

In October 1972, passage of Section 299I of Public Law 92-603 created the National End Stage Renal Disease (ESRD) Program that extended Medicare benefits to cover the high cost of medical care for most individuals suffering from ESRD.

The Social Security Amendments of 1972 (PL 92-603) extended Medicare coverage to individuals with ESRD who require either dialysis or transplantation to maintain life. At that time, the broad array of professionals and providers involved in the treatment of persons with ESRD indicated the need for a system to promote effective coordination of Medicare's ESRD Program. The federal government believed that integration of hospitals and other health facilities into organized Networks was the most effective way to assure delivery of needed ESRD care. Therefore, proposed regulations were published on July 1, 1975. Final regulations, which included provisions for implementing ESRD Network Organizations, were published on June 3, 1976. These regulations established 32 ESRD Network Organizations throughout the nation.

Congress enacted modifications of the Medicare ESRD Program on June 13, 1978 (PL 95-292) to improve cost-effectiveness, ensure quality of care, encourage kidney transplantation and home dialysis, and increase program accountability. This legislation amended Title XVIII of the Social Security Act by adding Section 1881, which designated ESRD Network areas and established a statutory requirement for the Network Organization Program, consistent with criteria determined by the Secretary of the Department of Health and Human Services. To help achieve coordinated delivery of ESRD services, representatives of hospitals and health facilities serving dialysis and transplant patients in each area of the country were linked with patients, physicians, nurses, social workers, dietitians, and technicians into Network Coordinating Councils.

In 1987, Networks were condensed from 32 service areas into 18. Each Network includes representatives of the federally approved ESRD treatment facilities in its region, as well as patients and professionals involved in the delivery of ESRD services.

On July 1, 1988, CMS awarded contracts to 18 geographically designated ESRD Network Organizations to administer the ESRD Program. In 1989, CMS developed a Statement of Work (SOW) for one- year extensions of existing contracts to provide for operation of the Network Organizations as specified by §1881(c) of the Act. Also, in 1989, §1881(c) of the Act was amended by PL 101-239 to provide the Network Organizations both confidentiality in the medical review process and a limitation on liability. In 1990, CMS awarded two-year Network Organization contracts, with a one-year renewal period. Starting in July 1997, CMS entered into one-year contracts with two option years with the ESRD Network Organizations.

20 - Program Responsibilities of ESRD Network Organizations

(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

CMS contracts nationwide with the 18 ESRD Network Organizations geographically located in designated areas. The Networks were established for the purposes of assuring effective and efficient administration of the benefits provided under the Social Security Act (the Act) for individuals with ESRD.

The Network Organization is responsible for conducting activities in the areas of quality improvement, community information and resources, administration, and information management. The function of the Network Organization is to:

- *Provide an efficient organizational framework for improving quality of care;*
- *Identify opportunities to improve care, develop quality improvement interventions, and measure their effectiveness;*
- *Identify and address instances of substandard care including patient safety concerns;*
- *Investigate and resolve patient complaints and grievances; and*
- *Coordinate the collection, analysis, and reporting of data, which is used to: 1) monitor and evaluate the quality of care; and 2) determine beneficiary entitlement to Medicare coverage.*

30 - Statutory Responsibilities of ESRD Network Organizations **(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)**

Final regulations issued on June 3, 1976, in *the Federal Register* (41 FR 22511) included provisions for creating ESRD Network *Organizations and the ESRD Network Organization Program*. These regulations, with updates, are now found in *the Code of Federal Regulations (CFR)*, 42 CFR Part 405, Subpart U. These regulations require ESRD treatment facilities to be organized into groups called Networks in order to promote a system of effective coordination. It was believed that an organized Network would *ensure* coordinated patient referral *and* access to resources. An organized *Network* of facilities would permit the concentration of equipment and specially trained personnel in centers where they would be used efficiently to treat large numbers of patients.

Section 1881 (c) of the Act lists the specific responsibilities for Network Organizations. Section 1881(c)(1)(A)(i) states: “For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)—

- (1) establish at least 17 end stage renal disease network areas, and*

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish:

(aa) a network council of renal dialysis and transplant facilities located in the area and

(bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and social workers engaged in treatment relating to end stage renal disease.”

Section 1881(c)(2) of the Act states the legislatively mandated responsibilities of the Network Organizations, which include:

”(A) Encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) Developing criteria and standards relating to the quality and appropriateness of patient care . . . ;

(C) Evaluating the procedure by which facilities and providers in the Network assess the appropriateness of patients for proposed treatment modalities;

(D) Implementing a procedure for evaluating and resolving patient grievances;

(E) Conducting on-site reviews of facilities and providers as necessary (as determined by a Medical Review Board or the Secretary), utilizing standards of care established by the Network Organization to assure proper medical care;

(F) Collecting, validating, and analyzing such data as are necessary to prepare . . . [certain] reports . . . and to assure the maintenance of the [national ESRD registry] . . . ;

(G) Identifying facilities and providers that are not cooperating toward meeting the Network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary any facilities or providers that are not providing appropriate medical care; and

(H) Submitting an annual report to the Secretary on July 1 of each year. . . .”

Network Organizations are also responsible for performing tasks that assure the Secretary’s maintenance of a national ESRD registry, as required under Section 1881(c)(7) of the Social Security Act.

Activities, projects, and deliverables to be performed by the Network Organizations as required by CMS are delineated in Section C of the Network Organization contract, the Statement of Work (SOW), available online at <http://www.cms.hhs.gov/ESRDNetworkOrganizations>. The SOW is amended, as necessary, to reflect statutory and programmatic changes. When there is a difference between the requirements of the SOW and the guidance found in this Manual, the SOW requirements take precedence.

40 - Health Care Quality Improvement Program (HCQIP) and the Network Organizations' Role

(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

CMS believes that health care should be patient-centered, effective, safe, efficient, equitable, and timely. These goals encompass the mission of CMS' Health Care Quality Improvement Program, which is based on the Institute of Medicine's work in the quality improvement arena, specifically the Institute's 2001 report, Crossing the Quality Chasm. CMS designed the HCQIP to improve health outcomes of all Medicare beneficiaries regardless of personal characteristics (e.g., socioeconomic status, health status, ethnic group), physical location (urban or rural), or setting (e.g., physicians' offices, Medicare Advantage Organizations, hospitals, nursing homes).

The ESRD Network Organization Program supports achievement of the mission of the Health Care Quality Improvement Program (HCQIP) by promoting the requirements of Section 1881(c)(1)(A)(i) of the Social Security Act, which tasks the Secretary with developing the Program "for the purpose of assuring effective and efficient administration" of the ESRD benefit. The Network Organization, in conducting the activities listed in the SOW, assists CMS in achieving the strategic goals of the ESRD Network Organization Program and the mission of the HCQIP.

Specifically, the mission of the HCQIP as it relates to the ESRD Network Organization Program is to ensure the delivery of care to individuals with ESRD that is:

- 1. Patient-centered: Care delivery and processes of care are focused on patient needs, concerns, values, and expressed priorities to empower the patient. Caregivers are empathic and care is provided in a compassionate, responsive manner.*
- 2. Safe: Patients receive safe care in ESRD facilities and, when appropriate, in-home settings. Systems of care are designed to allow staff to anticipate and prevent or minimize adverse events, learn from system failures, and seek system improvements. Caregivers are trained to recognize and anticipate errors and recover from them.*
- 3. Effective: Caregivers use scientific knowledge, evidence-based guidelines, and best demonstrated practices to offer individuals with ESRD the best available*

- care. Caregivers use this medical advice, and consider the individual preferences of patients, to derive effective care plans.*
- 4. Efficient: National and local resources are used to deliver high quality care. Care delivery systems incur only those administrative and production costs that result in high quality care.*
 - 5. Equitable: Care provided to an individual with ESRD does not vary in quality because of personal characteristics or socioeconomic status.*
 - 6. Timely: ESRD providers/facilities have processes in place to measure and minimize unnecessary delay in provision of services; health care interventions occur neither too soon nor too late.*

The Network Organization's role in the HCQIP is to encourage ESRD providers and facilities to assess and improve the care provided to Medicare ESRD beneficiaries. This is accomplished by conducting quality improvement projects (QIPs) and other activities that support the HCQIP. The Network Organization's quality improvement responsibilities include the following:

- Develop and conduct QIPs based on one or more of the established set of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, or vascular access, or other CPMs developed or adopted by CMS;*
- Monitor, track, and disseminate Network area- and facility-specific (if available) clinical performance data (e.g., CPM data) to identify opportunities to improve care within the Network area or within a specific facility; and*
- Upon request and/or upon identifying poor performance or a specific need (either at the Network level or facility level based on the results of the annual CPM data collection, other more frequent data collection, or a site survey or other investigation), assist ESRD providers and facilities (either individually or in groups) in developing and implementing facility-specific quality improvement activities to improve their patient care processes and outcomes.*

All projects and/or activities not specified or directed by CMS shall be evaluated by the Network Organization's Medical Review Board (MRB) and reviewed by the Network Organization's Project Officer using CMS-supplied guidance for compliance with Office for Human Research Protections regulations. If it is determined by the MRB and/or the Network Organization's Project Officer that a project and/or activity requires Institutional Review Board (IRB) approval, the project and/or activity shall be submitted to the CMS entity that has jurisdiction for the IRB review. If a specific MRB member is required to additionally submit the project and/or activity to his/her local IRB, it shall be the responsibility of that MRB member to seek such approval. The cost of submitting the project and/or activity for review will be borne by the Network Organization. Since it is not the purpose of ESRD Network Organizations to conduct research, CMS does not

expect many projects and/or activities to require IRB approval. IRB processes shall be conducted in accordance with CFR Title 45, Part 46.

50 - ESRD Network Organization Program Strategic Goals
(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

In accordance with the legislative mandate for the ESRD Network Program; to assist CMS in meeting Agency goals (e.g., ensuring the right care for every person every time); and in keeping with sound medical practice, the strategic goals of the ESRD Network Program are to:

- 1. Improve the quality and safety of dialysis-related services provided to individuals with ESRD.*
- 2. Improve the independence, quality of life, and rehabilitation (to the extent possible) of individuals with ESRD through support for transplantation, use of self-care modalities (e.g., peritoneal dialysis, home hemodialysis), and in-center self care, as medically appropriate, through the end of life.*
- 3. Improve patient perception of care and experience of care, and resolve patients' complaints and grievances.*
- 4. Improve collaboration with providers and facilities to ensure achievement of goals 1 through 3 through the most efficient and effective means possible, with recognition of the differences among providers (e.g., independent, hospital-based, member of a group, affiliate of an organization.) and the associated capabilities.*
- 5. Improve the collection, reliability, timeliness, and use of data to measure processes of care and outcomes, to maintain a patient registry, and to support the goals of the ESRD Network Program.*

For the purpose of the contract, CMS uses the IOM definition of quality: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Further, CMS defines rehabilitation for the purpose of the contract as restoring an individual to the maximum level of independence and quality of life that he/she can achieve. The Network Organization shall work to achieve these goals through implementation of the work requirements outlined in the SOW.

60 - Purpose of the Medicare ESRD Network Organizations Manual
(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

This manual provides detailed procedures and guidelines for Network Organizations to use when performing activities outlined in the SOW.

70 - Revisions to the *Medicare* ESRD Network Organizations Manual
(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

CMS updates the *Medicare* ESRD Network Organizations Manual when the Act is amended, regulations are implemented, or policies are changed or clarified. When the Office of Clinical Standards and Quality (OCSQ) changes Manual instructions, it issues a transmittal *by e-mail*. Each transmittal includes a cover page(s) that *gives* a summary of the changes made and the effective date of the changes. In addition, the *online version of the Manual is updated, with the* changed text shown on the screen in red, italicized *type*.

80 - Acronyms and Glossary

(Rev. 8, Issued: 12-14-07; Effective: 12-03-07; Implementation: 01-07-08)

- A list of commonly used acronyms can be found *in the* Acronyms *section*.
Definitions of commonly used words can be found in the Glossary.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R8ESRD	12/14/2007	ESRD Network Organization: Background and Responsibilities	01/07/2008	5844
R02ESRD	09/12/2003	Miscellaneous Revisions	10/27/2003	N/A
R01ESRD	07/11/2003	Initial issuance of Manual in IOM	N/A	N/A