CMS Manual System

Pub. 100-14 Medicare End Stage Renal Disease Network Organizations

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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I. SUMMARY OF CHANGES:

In Chapter 1, Background and Responsibilities, revisions were made to change the title to one of the subsections in the Table of Contents, correct and to clarify reference to statutory citations in sections 10, 20 and 30. In sections 40 and 60 we clarified the responsibilities and goals of ESRD Network Organizations and added new material to section 70 requiring all projects to be reviewed by the Network's Medical Review Board and the Project Officer.

NEW/REVISED MATERIAL - EFFECTIVE DATE: October 27, 2003
IMPEMENTATION DATE: October 27, 2003

Disclaimer: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. SCHEDULE OF CHANGES (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1 / Table of Contents
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R	1 /10 /10.1 Purpose of the Network Manual
R	1 /10 /10.2 Statutes and Regulations
R	1 /10 /10.3 Revisions to the ESRD Organizations Manual
R	1 /20 /Purpose of ESRD Network Organizations
R	1 /30 /Requirements for ESRD Network Organizations
R	1 /40 /Responsibilities of ESRD Network Organizations
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Medicare ESRD Network Organizations Manual

Chapter 1 - Background and Responsibilities

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10 - Foreword

(Rev. 2, 09-12-03)

Foreword

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

Title II of the Act grants individuals who are medically determined to have ESRD entitlement to Part A benefits and eligibility to enroll under Part B of title XVIII, subject to the deductible, premium, and coinsurance provisions of that title. Section 1881 of the Act provides the statutory authority for the broad objectives and operations of the ESRD program and the establishment of ESRD Network Organizations. Networks promote improvement in the quality of care provided to Medicare ESRD patients in dialysis and transplant facilities as provided under the Act.

Some of the legislative responsibilities of the Networks include:

- Identifying opportunities to improve health care related to the quality and appropriateness of patient care;
- Assessing the appropriateness of patients for proposed treatment modalities;
- Collecting, validating, and analyzing data for the preparation of reports; and
- Assuring the maintenance of a national ESRD registry.

Activities, projects, and deliverables to be performed by the Networks as required by CMS are contained in the Statement of Work (SOW) at http://www.cms.hhs.gov/esrd/2.asp, which is located in Section C of the Networks' contract. The SOW is amended, as necessary, to reflect statutory and programmatic changes. Occasionally, policy changes occur faster than we can update this manual. Therefore, if inconsistencies occur between the requirements of the SOW and this manual, the SOW requirements take precedence.

10.1 - Purpose of the Network Manual

(Rev. 2, 09-12-03)

Foreword

This manual provides detailed procedures and guidelines for Networks to use when performing activities outlined in the SOW. It consists of chapters and sections. The table of contents contains a list of each. This manual is primarily self-contained. However, there *are a* few cross-references to other CMS publications.

10.2 - Statutes and Regulations

(Rev. 2, 09-12-03)

Foreword

Title XVIII of the Act is the statutory basis for the establishment of the ESRD Networks and is the foundation for all regulations that refer to Networks. Regulations contain interpretations and policies that *implement* the statute and are formally approved and published by the Secretary of the Department of Health and Human Services. Regulations have the force and effect of law and are binding on all parties (whether or not they have been incorporated into manual instructions).

10.3 – *Revisions to the* ESRD Network Organizations Manual

(Rev. 2, 09-12-03)

Foreword

The CMS updates the 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. Each transmittal includes a cover page(s) that includes a summary of the changes made and the effective date of the changes. This is issued by e-mail. In addition the Internet pages for the manual are changed. Changed Internet text is shown on the screen in red, italicized font.

10.4 - Acronyms and Glossary

(Rev. 2, 09-12-03)

Foreword

When a term is first used on the transmittal page, the table of contents, and/or the text of each part, it is followed by an acronym enclosed in parentheses (e.g., End Stage Renal Disease (ESRD)). A list of commonly used acronyms can be found at Acronyms. Definitions of commonly used words can be found at Glossary.

20 - Purpose of ESRD Network Organizations

(Rev. 2, 09-12-03)

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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 the 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 Networks, were published on June 3, 1976.

Subsequently, the ESRD Amendments of 1978 (PL 95-292) amended title XVIII of the Act by adding §1881. Section 1881(c) of the Act statutorily authorized the establishment of ESRD network areas and Network Organizations. This amendment provided an approach for Network operation and performance as well as other quality assurance issues that relate to treatment of ESRD.

On July 1, 1988, CMS awarded contracts to 18 geographically designated Network Organizations to administer the ESRD program. In 1989, CMS developed a Statement of Work (SOW) for 1-year extensions of existing contracts to provide for operation of the Networks as specified by §1881(c) of the Act. Also, in 1989 §1881(c) of the Act was amended by PL 10*1*-239 to provide the Networks both confidentiality in the medical review process and a limitation on liability. In 1990, CMS completed 2-year Network contracts, with a 1-year renewal period. In July 1997 and 2000, CMS entered into 1-year contracts with 2-option years with the ESRD Networks.

30 - Requirements for ESRD Network Organizations

(Rev. 2, 09-12-03)

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Final regulations issued on June 3, 1976, in 41 FR 22511 included provisions for creating ESRD Networks. (These regulations, with updates, are now found in 42 CFR 405, Subpart U.) These regulations required 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 assure coordinated patient referral, as well as 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.

In 1978, PL 95-292 amended title XVIII of the Act by adding §1881(c), which statutorily authorizes the establishment of ESRD network areas and Network Organizations to assure the effective and efficient administration of ESRD program benefits. This statute and regulations specify certain requirements. A Network Organization must:

- Establish a Network Council (NC) of renal dialysis and transplant facilities located in each area that includes at least one patient representative; and

- Establish a medical review board (MRB) that includes physicians, nurses, and social workers, engaged in treatment relating to ESRD *and qualified to evaluate the quality and appropriateness of care [see §405.2113(a)]*, and at least one patient representative.

40 - Responsibilities of ESRD Network Organizations

(Rev. 2, 09-12-03)

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The statute and regulations specify certain responsibilities. The Network is responsible for:

- Encouraging the use of those treatment settings most compatible with the successful rehabilitation of the patient;
- Encouraging the participation of patients, providers of services, and ESRD facilities in vocational rehabilitation programs;
- Developing criteria and standards relating to the quality and appropriateness of patient care and Network goals with respect to the placement of patients in self-care settings and transplantation;
- Evaluating procedures used by facilities and providers to assess the appropriateness of patient treatment type;
- Implementing procedures for evaluating and resolving patient grievances;
- Conducting on-site reviews of facilities and providers, as necessary, utilizing standards of care established by the Network;
- Collecting, validating, and analyzing data for the preparation of reports and assuring the maintenance of a national ESRD registry;
- Identifying facilities *consistently* not meeting Network goals, assisting facilities in developing appropriate plans for correction, and reporting to the Secretary on facilities and providers that are not providing appropriate medical care;
- Submitting an annual report to include:

    1. Network's goals, and activities conducted to meet goals;
    2. Data on the comparative performance of facilities with respect to patients in self-care settings, transplantation and vocational rehabilitation programs;
    3. Identification of facilities that have *consistently* failed to cooperate with Network goals; and

4. Recommendations for additional or alternative ESRD services or facilities in the network area.

- Establishing a Network Council to include dialysis and transplant facilities in the network area and a MRB to include at least one patient, physicians, nurses, and social workers.

The Network is also responsible for performing all other activities specified in the SOW, including any modifications, CMS regulations and instructions, and relevant statutory provisions.

50 - Health Care Quality Improvement Program (HCQIP)

(Rev. 2, 09-12-03)

ENO 125

The mission of the HCQIP is to promote the quality, effectiveness, and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to monitoring and improving quality of care, communicating with beneficiaries and heath care providers in order to promote informed health choices, protecting beneficiaries from poor care, and strengthening the health care delivery system.

The Institute of Medicine defines quality as: "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Using this definition, quality care under the HCQIP includes access to care, appropriateness of care, desired outcomes of care, and consumer satisfaction. By conducting the activities listed in the Network's SOW and as outlined in this manual, the Network assists CMS in achieving the mission of the HCQIP. The HCQIP supports the strategic goals of CMS to assure health care security for Medicare beneficiaries. Health care security means:

- Access to quality health care;

- Protection of the rights and dignity of beneficiaries; and

- Dissemination of clear and useful information to beneficiaries and/or their representatives, facilities/providers, and practitioners to assist them in making health care decisions.

60 - Goals

(Rev. 2, 09-12-03)

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The national goals of the ESRD Network program include the following:

- Improving the quality of health care services and quality of life for ESRD beneficiaries.

- Improving data reliability, validity, and reporting between ESRD providers/facilities, Networks, and CMS (or other appropriate agency).

- Establishing and improving partnerships and cooperative activities. These activities may include *other* ESRD Networks, Quality Improvement Organizations (QIOs), State survey agencies, Medicare+Choice Organizations, ESRD providers/facilities, ESRD facility owners, professional groups, and patient organizations.

- *Supporting the marketing, deployment, and maintenance of CMS approved software (i.e., CROWN - Consolidated Renal Operations in a Web- enabled Network).*

The Network achieves the above goals of the ESRD program by developing and conducting the activities and the work requirements as outlined in its SOW and this manual. In addition, the Network establishes measures to evaluate the effectiveness of the activities conducted to meet these goals.

70 - Network Organization's Role in HCQIP

(Rev. 2, 09-12-03)

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The Network's role in HCQIP is to assist 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 activities, which support the HCQIP. The Network'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, vascular access, or other CPMs developed or adopted by CMS;

- Monitor, track, and disseminate regional (Network) and facility-specific (if available) clinical performance data (such as the CPM data) to identify opportunities to improve care within the network area or within a specific facility;

- 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 results of a site survey or other investigation), assist ESRD providers and facilities (either individually or in groups) in developing and implementing facility-specific quality improvement actions to improve their patient care processes and outcomes*; and*

- *In the development of any quality improvement project or activity, the question of meeting Office of Human Research Protection (OHRP) regulations may arise. All projects will be evaluated by the Network's MRB and reviewed by the MRB and/or the project officer using CMS supplied guidance for compliance with OHRP regulations. If it is determined by the MRB and/or project officer that a project requires Institutional Review Board (IRB) approval, the project will be submitted to the CMS entity that has jurisdiction for CMS IRB review. If a MRB member is required to additionally submit their project to their local IRB, it will be the responsibility of that MRB member to seek such approvals. Since it is not the purpose of the ESRD Network to conduct research, CMS does not expect many projects to require IRB approval.*