Medicare ESRD Network Organizations Manual

Chapter 2 - Administration

Table of Contents

10 - Organizational Structure

(Rev. 1, 07-11-03)

ENO 200

As an ESRD Network, you must have an organizational structure, basic administrative staff, infrastructure to operate your statutory requirements, and other work activities as set forth in the ESRD Statement of Work (SOW) at http://www.cms.hhs.gov/esrd/2.asp. You are required to:

- Establish various boards or committees;
- Specify appropriate roles and functions for these entities; and
- Maintain minutes or documentation of committee meetings and actions.

20 - Network Council (NC)

(Rev. 1, 07-11-2003)

ENO 205

20.1 - Establishing the NC

(Rev. 1, 07-11-03)

ENO 205.A

Establish and maintain an NC that meets the statutory requirements of §1881(c) of the Act. The NC must:

- Be composed of members from renal dialysis and transplant providers located in the network area;
- Be representative of the geography and the types of providers in the network area; and
- Have at least one patient representative. (A patient representative can be a dialysis patient and/or a transplant patient within the network area.)

20.2 - Functions of the NC

(Rev. 1, 07-11-03)

ENO 205.B

At a minimum, the NC will provide input into the activities of the Network and serve as a liaison between the Network and the provider membership. The Network supports and coordinates the activities of the NC.

30 - Board of Directors (BOD)

(Rev. 1, 07-11-03)

ENO 210

The ESRD Network Organization must be governed by a BOD composed of representatives from the network area including at least one patient representative. The BOD, or Executive Committee (EC) of the Board, will meet as necessary (suggest quarterly by teleconference or face-to-face meeting) to ensure the successful operation of the Network.

At a minimum, the BOD or EC will:

- Supervise and be responsible for the performance of the Network's administrative staff in meeting contract deliverables and requirements;
- Supervise and be responsible for the financial operation of the Network including the Internal Quality Control (IQC) program (see §80);
- Review and approve the Annual Report prior to submission to the project officer (PO);
- Approve requests for modifications to the Network's contract that involve requests for additional funding; and
- Review and approve any recommendations from the medical review board to sanction ESRD facilities (prior to submission to CMS).

40 - Medical Review Board (MRB)

(Rev. 1, 07-11-03)

ENO 215

The Network establishes a committee that meets the statutory requirements of §1881(c) of the Act to function as the Network's MRB. The MRB must be composed of at least one patient representative and representatives of each of the professional disciplines (e.g., physician, registered nurse, dietitian, and social worker), engaged in treatment related to ESRD. MRB members must be qualified to evaluate the quality and appropriateness of care delivered to patients with ESRD. This committee must meet at least quarterly (by teleconference or face-to-face meeting).

The functions of the MRB include the following:

- The MRB will serve as an advisory panel to the Network on the care and appropriate placement of ESRD patients on dialysis in the network area. The MRB will also serve as the primary advisory panel for all Networks quality improvement activities, including the analyses of local data on the Clinical Performance Measures (CPMs) and ESRD grievances.

- The MRB will assist the Networks staff in the development, implementation and evaluation of quality improvement projects.

NOTE: A MRB member must not review the ESRD services of a provider in which he or she has a direct or indirect financial interest (as described in §1126(a)(1) of the Act), has or had, any professional involvement, received reimbursement, or supplied goods.

50 - Other Committees

(Rev. 1, 07-11-03)

ENO 220

The Network establishes other committees (or subcommittees) as appropriate, to meet the requirements in the SOW. To the fullest extent possible, your committees must be composed so as to represent the diversity of the patient and practitioner community. The Network’s BOD or bylaws determine the appropriate committee member compositions.

60 - Network Staff

(Rev. 1, 07-11-03)

ENO 225

The Network must have an administrative staff that performs the work requirements of the ESRD SOW. At a minimum, the staff must include:

- The Executive Director/Project Director who, under the general direction of the BOD, is responsible for the overall management, supervision, and coordination of the contract requirements between the Network and CMS, including meeting deliverable due dates. The Executive Director/Project Director is responsible for program development, business and fiscal management, the IQC program, personnel staffing (including staff training, hiring, and firing), and liaison with Network committees, external agencies, QIOs, and renal related agencies/organizations.

- A Quality Improvement Manager/Coordinator who is responsible for the development, implementation, evaluation, and management of your quality improvement projects and other related quality improvement activities such as the collection of data on the CPMs.

- A Data Manager who is responsible for overseeing and/or assisting the Executive Director/Project Director in managing the daily operations, maintenance, and integrity of the Network's database and data systems.

- Sufficient support staff (including a registered nurse with nephrology experience) to conduct the activities and responsibilities in the Network's contract and in other CMS directives.

- A quality improvement project development consultant with an advanced degree (MS, Ph.D., or DrPH) in epidemiology or an equivalent advanced health care research/evaluation degree. Alternatively, the Network may use a consultant with sufficient work experience in developing and conducting health care quality improvement efforts that demonstrates an equivalent level of expertise. The Network must plan on utilizing the consultant during all stages of its QIP, including project development, data analyses, and final report preparation; and
- An individual with a Masters in Social Work (a minimum .5 FTE) or an equally qualified individual (i.e., experienced nephrology nurse or counselor) who is responsible for resolving patient and/or facility complaints or grievances, and conducting educational training on managing difficult patients, mediation, and conflict resolution.

70 - Required Administrative Reports

(Rev. 1, 07-11-03)

ENO 230

The Network submits the following administrative reports to its PO:

70.1 - Quarterly Progress and Status Reports

(Rev. 1, 07-11-03)

ENO 230.A

The Quarterly Progress and Status Reports are used to:

- Provide a summary of Network activities conducted during the previous quarter;
- Alert the PO of potential quality of care or other problems in the network area;
- Alert the PO of problems encountered in fulfilling contract requirements; and
- Monitor the Network's performance in meeting contract requirements.

The Network submits one copy of the report to its PO and a copy to CMS Central Office by the 15th working day after the beginning of each calendar quarter. The Network may provide an electronic or hardcopy submission of its report at its own or the PO's discretion. Include the following information:

- A summary of quality improvement project activities;
- A summary report of ESRD grievances which includes:
    - New grievances received during the quarter (number and issues);
    - Status of grievances under investigation;
    - Grievances that have been resolved; and
    - Grievances that were not resolved by the Network.
- Potential quality of care problems identified or suspected that may affect the care provided by the facility/provider or the facility's Medicare certification;
- Policy and/or other concerns to be addressed by the PO;

- Number and type/name of United States Renal Data System (USRDS) special study data collection forms completed or received, and the date the forms were mailed to the USRDS, when applicable;

- Number of inquires from Medicare+Choice (M+C) Organizations regarding:

    - Form CMS-2728;

    - The transplant status of beneficiaries; and

    - All other inquiries received during the quarter;

- Notice of meetings to be held in the following quarter (e.g., MRB, ESRD-related workshop or seminar, etc.);

- Brief summary of meetings attended in the previous quarter;

- Community Information and Resource activities conducted during the quarter, when applicable;

- A cost and expenditures report (i.e., the total amount spent for the reporting quarter and the amount that remains of the annual contract award);

- Any problems encountered that affected the meeting of contract requirements including deliverables; how the problem(s) are to be/or were resolved, and if extensions for meeting due dates are required (e.g., unexpected computer failure, unexpected illness of key staff, etc.);

- Additional information/meeting minutes requested by the PO; and

- Other information that the Network believes is important.

70.2 - Annual Report

(Rev. 1, 07-11-03)

ENO 230.B

Include in the report a statement of the Network goals and the activities conducted to meet the CMS goals for the ESRD Network program during the previous calendar year, an assessment as to whether those activities were effective in meeting the goals, and a summary of the impact these goals had on the ESRD population, which includes the comparative performance regarding the placement of patients in appropriate settings for self-care, transplants, and vocational rehabilitation programs, as required by 42 CFR 405.2112(f). Identify those facilities that failed to cooperate with the Network goals, and identify those facilities and providers that are not providing appropriate

medical care. Provide any recommendations for additional or alternative ESRD services and/or facilities in the network area.

The Annual Report covers the reporting period for the preceding calendar year of January 1 through December 31. A member(s) of the Network's BOD must review and approve the report before it is submitted to the Network's PO. The Network submits a draft of its Annual Report for review to its PO by May 15 of each calendar year and forwards the final Annual Report (original) to its PO on or before June 30 of each calendar year following the instructions and format in Exhibit 2-1. Reference and cite the CMS contract number and identify CMS as the sponsoring agency.

After the PO approves the Network's report, the Network distributes the Annual Report to the facilities/providers in the network area and to the renal community or other individuals upon request. The Network submit one copy of the Annual Report to CMS central office and one copy to the ESRD Network Clearinghouse for compilation of the Network's annual reports within 2 weeks of approval of the final report to CMS PO. Within 90 days after PO approval, the Network makes the report available on its Web site.

NOTE: The Network may discuss with the PO the option of not submitting a draft Annual Report if the Network does not anticipate major changes to its report.
Follow the general instructions below for formatting the Annual Report. (See Exhibit 2-1 for content.)

- Include a Network identifier on each page of the report;
- Include page numbers in the table of contents;
- Paginate (throughout the entire report) with consecutive numbers (do not re-number the pages in each section);
- Use only one side of a page to allow for reproducing the report;
- Address each section (1 through 6), shown in the report, starting a new page with each section (do not skip any sections; report that the Network has not conducted an activity, or whatever is appropriate rather than skipping over the section); and
- Format with a 1-inch left margin, use a standard 3-hole punch in the left margin, and submit in a 3 ring binder to allow for reproducing the report.

80 -Internal Quality Control (IQC) Program

(Rev. 1, 07-11-03)

ENO 235

80.1 - Objectives of the IQC Program

(Rev. 1, 07-11-03)

ENO 235.A

The objectives of the IQC program, at a minimum, are to:

- Support and foster continuous quality improvement within the Network in support of the Health Care Quality Improvement Program (HCQIP) and other SOW activities;

- Develop and implement a plan that ensures all aspects of the Network activities run efficiently, comply with the contract, and are consistent with CMS's goals and objectives for the HCQIP and the SOW;
- Maintain the Network activities within a permissible range of deviation with minimum effort;

- Ensure the financial integrity of the contract by actively monitoring and staying within the total fixed price of the contract;

- Improve the reliability, accuracy, consistency, and timeliness of data processing and data reports; and

- Ensure the support, understanding, and participation of all beneficiaries, facilities, providers, and other constituencies that are affected by the HCQIP.

80.2 - IQC Program Requirements

(Rev. 1, 07-11-03)

ENO 235.B

Each Network must have an IQC program that encompasses the major SOW activities of the HCQIP. The major activities are:

- Quality improvement projects;

- ESRD complaints;

- Community information and resource activities;
- Information management; and
- Administration (including financial management).

Not all sub-activities within the major activities must be monitored continuously or simultaneously. The Network must have a plan to evaluate each major area at least once during the contract and more often, as performance indicates.

80.3 - IQC Control Process

(Rev. 1, 07-11-03)

ENO 235.C

The IQC program should use a control process. The following instructions under each step are intended to provide guidance in formulating your plan:

- Identify what you are controlling and the elements measured:
    - Monitor the organization's and individual's performance;
    - Monitor specific inputs, processes, and/or outcomes; and
    - Identify the most vital elements that account for most of the major variations in performance;
- Set the control standards (including tolerance limits):
    - Use measures that allow the Network to determine if performance is acceptable, and if the quality and quantity of the output is adequate to support organizational and Network program objectives;
- Identify the information to be collected and how performance is to be measured, i.e., what is being done and what should be done;
- Determine the reason for deviations:
    - Determine the causes of any deviations from the standards and provide feedback on performance; and
- Identify and monitor improvement actions:

- Decide on the best course of action for eliminating deviations or for exceeding current performance.

80.4 - Analysis and Reporting Requirements

(Rev. 1, 07-11-03)

ENO 235.D

At a minimum, the Network:

- Analyzes the areas of deviation in performance (identified through internal as well as external monitoring), and develop plans to continuously improve operations. In particular, continually evaluates HCQIP activities and identifies how analysis, feedback and education techniques/processes can be made more effective;

- Monitors your plans to improve performance;

- Generates periodic progress reports (based on activity being monitored and the IQC plan) on all IQC activities listed in §80.2; and

- Retains and makes available reports for CMS monitoring purposes.

90 - CMS Meetings

(Rev. 1, 07-11-03)

ENO 240

Networks are expected to attend all CMS-sponsored/sanctioned meetings when requested. At a minimum, Networks are required to attend annually a CMS-sponsored/sanctioned meeting, and two meetings at their respective regional offices. CMS or the Network Executive Director/ Project Director, as appropriate, will recommend which Network staff members are to participate at the CMS-sponsored/sanctioned meetings. Networks are also expected to attend at least one national renal meeting.

100 - Cooperative Activities With State Survey Agencies and Quality Improvement Organizations (QIOs)

(Rev. 1, 07-11-03)

ENO 245

In addition to quality improvement activities outlined in Part 5 of this manual, the Network works with the appropriate CMS RO(s), State survey agency(ies) and QIOs in other areas that will assist each organization to improve the quality of care for ESRD patients. These activities should include, but are not limited to, the following:

- Sharing information to assist the State survey agencies and/or QIOs in carrying out their legislative responsibilities (i.e., sharing facility/patient specific information so that surveys and quality improvement activities can be targeted to those needing additional interventions); and

- Referring quality of care issues, as appropriate, and assisting the State survey agency or QIO in the investigation of the quality of care issues upon request, which may include:

    - Conducting reviews cooperatively (e.g., off-site visits, parallel reviews, or sequential reviews, as needed);

    - Providing technical assistance;

    - Providing information regarding expected outcomes; and/or

    - Reporting patterns of complaints or grievances.

Coordinating and collaborating with the State survey agency in regards to QI interventions when a provider is uncooperative or unable to implement and maintain improvements, whether in compliance with the conditions for coverage or in the provision of care, that is consistent with current professional knowledge. Some other suggestions for other activities should include the following:

- Sharing data/information such as the Clinical Performance Measures Reports, standardized mortality ratios, standardized hospitalization ratios, ESRD complaints/grievances, and other educational type materials;

- Collaborating in quality improvement projects;

- Providing technical assistance or training on dialysis-related patient care issues;

- Assisting State survey agencies in focusing survey resources; and

- Assisting State surveyors in understanding how to interpret and utilize the Network, CMS, and/or USRDS data.

110 - Exhibits

Exhibit 2-1 - Annual Report Format

(Rev. 1, 07-11-03)

(This exhibit is under review and subject to revision at a later date.) The content of the annual report will include the following:

1. Preface

    a. An introductory statement signed by the Board or Council Chairperson

    b. Table of Contents

2. Introduction

    a. Network Description - A brief narrative describing the States in the network area and the general population characteristics.

    b. Structure

        1) Staffing

        2) Names and titles of staff, and

        3) Brief description of key responsibilities, and

        4) Committees

        5) Describe the function of each committee and any special accomplishments or activities conducted by the committees.

3. CMS National Goals and Network Activities

    Describe the Network's performance (activities conducted) in meeting the goals listed in section C.1.C of the SOW of the contract (also see below) and provide an evaluation/analysis of your accomplishment of the goals, and what impact, if any, these goals had on the ESRD population, which includes the comparative performance regarding the placement of patients in appropriate settings for self-care, transplants, and vocational rehabilitation programs, as required by 42 CFR 405.2112(f). Include under this section those facilities that failed to

cooperate with Network goals and those facilities and providers that are not providing appropriate medical care.

- **Improving the quality of care of health care services and quality of life for ESRD beneficiaries -** Include under this goal a summary of quality improvement projects in progress or completed, a summary of educational and other materials provided to facilities and/or patients, a summary of technical or other assistance provided to facilities and/or patients, and other activities related to improving the quality of care. Also include a summary of how these projects affected the ESRD population.

- **Improving data reporting, reliability and validity among ESRD facilities/providers, Networks, and CMS (or other appropriate agency) -** Include under this goal a summary of information management related activities.

- **Establishing and improving partnerships and cooperative activities among and between the ESRD Networks, QIOs, State survey agencies and ESRD facilities/providers, ESRD facility owners, professional groups, and patient organizations** - Include under this goal a summary of activities conducted with State survey agencies, QIOs, other Networks, professional groups, and patient organizations.

- **Evaluating and resolving patient grievances as categorized in the Standard Information Management System (SIMS) -** Include under this activity the total number of grievances received during the year, total number resolved, total number unresolved, total number referred and to what agency/or to whom, and the status of grievances under investigation.

4. Sanction Recommendations

5. Summarize any sanctions that have been imposed, identifying the facility(s), the reason(s) for the sanction(s), and any remedial action or post sanction action undertaken by the facility, if known.

6. Recommendations For Additional Facilities

7. Provide any recommendations for additional or alternative ESRD services and/or facilities in the network area.

8. Data Tables

9. Supply the following tables, using the SIMS template for your data table formats as guidelines:

    a. Table 1: ESRD Incidence - One year statistics;

b. Table 2: ESRD Dialysis Prevalence - One year statistics;

c. Dialysis Patients Modality and Setting - Status on 12/31:

    1) Table 3: Home;

    2) Table 4: In-Center;

d. Renal Transplants:

    1) Table 5: Number by transplant State;

    2) Table 6: Number by transplant type, age, race, sex, and primary diagnosis;

e. Table 7: Dialysis Deaths; and

f. Table 8: Vocational Rehabilitation.

ESRD Network Table 8

VOCATIONAL REHABILITATION BY DIALYSIS FACILITY PATIENTS AGED 18 - 55 AS OF DECEMBER 31, ____				
Provider	Number of Patients Aged 18 - 55	Referrals To Voc Rehab [1]	Patients Employed or Attending School Full or Part Time[2]	Offers Dialysis Shift Beginning At 5 p.m. or Later
LIST ALL FACILITIES				
TOTAL				

SOURCE OF INFORMATION:

DATE OF PREPARATION:

[1] Number of patients (aged 18 - 55) who were referred to VR programs sponsored by the State or private agencies (or other programs if applicable), and

[2] Number of patients (aged 18 - 55) who were employed or attending school full-time or part-time during the reporting year regardless of the patient's State of residence (as reported by each dialysis facility in the network area).

The patient selection for this table shall be all dialysis patients between ages 18 - 55 receiving dialysis as of December 31 of the reporting year, as reported by each dialysis facility. Source of information should be based on data collected by the Network.

Exhibit 2-2 - Quarterly Progress and Status Report Format

I. Quality Improvement

A. Narrative status of CMS approved quality improvement project. Include the following information:

1. Name of project;
2. Primary contact at the Network and phone number;
3. Report on progress made during quarter, comparing to the approved timeline;
4. Report on any problems in meeting approved timeline; and
5. Report on changes made to the originally approved QIP.

Attach a copy of any changes to timelines, data abstraction tools and new interventions, etc.

B. Narrative status of other quality management activities. Include the following information:

1. Description of activity;
2. Primary contact at the Network and phone number;
3. If quality management activity was initiated in reporting quarter, provide the following information:
    a. Purpose;
    b. Objectives;
    c. Methods (these could include proposed baseline measurement, sampling, data sources, data analysis, potential Network interventions and evaluation strategies); and
    d. Timeline.
4. If activity was initiated in a prior quarter, provide the following information:
    a. Progress of activity;
    b. Changes in activity design from prior report period; and

c. Problems meeting original timeline.

C. Narrative on collaborations and other activities (e.g., working with QIOs and State agencies, other outside organizations, or Network MRBs).

II. Challenging Situations and Grievances

A. Narrative description of proactive activities (see Chapter 6, §30).

B. Report on any complaints/concerns and grievances initiated in the reporting period, and provide update/status on current open caseload and any resolution/closure of caseload during reporting period. Provide the following information:

1. Case number;

2. Open date;

3. Current status;

4. Area of concern (report using the following SIMS Contact Categories, i.e., formal grievance, beneficiary complaint, and facility concerns);

5. Type of contact/caller (e.g., beneficiary, facility staff, other);

6. Description: Be specific enough so that the PO understands the issue and concern. Do not provide patient or facility name;

7. Resolution: Provide information on the Network's action towards resolution or closure of this case; and

8. Date closed.

C. Aggregate contact information for complaints/concerns and grievances (Contact Category and Classification of Complaints) by (1) total contacts for the reporting contract quarter (e.g., July, August, September, or October, November, December); and (2) total contacts for the current contract year to date (see Table 1 - Quarterly Reporting Format - Complaints/Concerns and Grievances).

III. Community Information and Resources

A. Provide narrative highlights of educational information provided, such as requests for:

1. QI information;

2. Data research information;

3. Grievance information;

4. Treatment options;

5. Transient patient/care;

6. Vocational rehabilitation information;

7. Reimbursement/financial issues; and

8. Miscellaneous requests.

B. Provide narrative highlights of technical assistance provided.

C. Provide the following information on the new ESRD Patient Packages:

1. The number of returns due to death of the beneficiary; and

2. The number of returns due to incorrect/change in address for the beneficiary.

IV. Data

A. Number of 2728 forms processed in the reporting quarter

B. Number of 2746 forms processed in the reporting quarter

C. Number of inquiries from Medicare+Choice organizations regarding:

1. CMS-2728 forms; and

2. Transplant status of beneficiaries.

D. CMS Special Studies:

1. Provide narrative description of CPM activity.

2. Provide a narrative description of USRDS requests for information and the Network's participation in the study.

3. Provide narrative on any other CMS approved special studies.

E. SIMS issues

F. Other

V. General Administrative Information

A. Administrative Issues/Information

B. Other Information

1. Meeting schedule
    a. Summary of meetings attended/held in the reporting quarter; and
    b. Notice of meetings in the next quarter.
2. Potential quality of care problems that the Network has identified
3. Policy and/or concerns to be addressed by PO
4. Cost expenditure report, in following format:
    a. Contract Award;
    b. Contract Modification during the reporting quarter;
    c. Quarterly Expenditures;
    d. Percent Expended to Date; and
    e. Amount of Award Remaining.
5. Additional information requested by PO.

Table 1 - Quarterly Reporting Format - Complaints/Concerns and Grievances

Table 1 - Quarterly Reporting Format - Complaints/Concerns and Grievances								
Contract Cycle: (1, 2, or 3)	Reporting Quarter (Insert months covered during this period)							
Contact Type (Categories of Complaint)	Contact Categories (Areas of Concern)						Totals Current Contract Quarter	Totals Contract Year to Date
	Formal Grievances	**Beneficiary Complaints**	**Beneficiary Inquiries**	**Facility Concerns**	**Facility Inquiries**	**Other Concerns**		
Physical Environment								
Staff Related								
Treatment Related/ Quality of Care								
Information								
Disruptive/Abusive Patient								
Patient Transfer/Discharge								
Professional Ethics								
Other								
Totals								