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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NEW/REVISED MATERIAL--EFFECTIVE DATE: Not Applicable
IMPLEMENTATION DATE: Not Applicable

This is the initial issuance of Pub. 100-14, ESRD Network Organizations Manual, which replaces instructions in Pub. 81, ESRD Network Organization Manual. Pub. 100-14 is an Internet document and may be accessed from the CMS Web site: http://www.cms.hhs.gov/manuals/.

Related instructions in Pub.81, ESRD Network Organizations Manual, are being retired in a separate revision. A crosswalk from this publication to the respective sections of this manual is included.

NOTE*:* Normally red italicized font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Medicare ESRD Network Organizations Manual

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(Rev. 1, 07-11-03)

Medicare ESRD Network Organizations Manual

Chapter 1 - Background and Responsibilities

Table of Contents

10 - Foreword

(Rev. 1, 07-11-03)

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.

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. 1, 07-11-03)

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 area few cross-references to other CMS publications.

10.2 - Statutes and Regulations

Rev. 1, 07-11-2003)

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 expand on 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 - ESRD Network Organizations Manual Revisions

(Rev. 1, 07-11-03)

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. 1, 07-11-03)

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. 1, 07-11-03)

ENO 110

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 100-239 to provide the Networks both confidentiality in the medical review process and a limitation on liability. In 1990, CMS competed 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. 1, 07-11-03)

ENO 115

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 at least one patient representative.

40 - Responsibilities of ESRD Network Organizations

(Rev. 1, 07-11-03)

ENO 120

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 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 failed to cooperate with Network goals; and

    4. Recommendations for additional or alternative ESRD services for 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. 1, 07-11-03)

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. 1, 07-11-03)

ENO 130

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); and

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

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. 1, 07-11-03)

ENO 135

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; 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 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.

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								

Medicare ESRD Network Organizations Manual

Chapter 3 - Confidentiality and Disclosure

Table of Contents

10 - Statutory and Regulatory Requirements

(Rev. 1, 07-11-03)

ENO 300

10.1 - Extension of Confidentiality Provisions

(Rev. 1, 07-11-03)

ENO 300.A

Section 6219 of the Omnibus Budget Reconciliation Act of 1989 (PL 101-239) amended §1881(c)(8) of the Social Security Act (the Act) to extend the confidentiality provision of §1160 of the Act to ESRD Network Organizations (including medical review boards [MRBs]). Section 1160 of the Act provides the statutory basis for the disclosure of information. It also:

- Establishes the scope of the Network's authority to disclose information for program purposes, including any required disclosures;

- Addresses the Network's responsibility to protect information and/or data collected from unauthorized disclosure and provides penalties for unauthorized disclosure; and

- Exempts the Network from the disclosure provisions contained in the Freedom of Information Act.

10.2 - Regulations in 42 CFR Part 480

(Rev. 1, 07-11-03)

ENO 300.B

These regulations, which apply for the most part to ESRD Networks as well as to QIOs, contain rules concerning the Network's authority to disclose information and the Network's responsibility to protect information from unauthorized disclosure. The statute and regulations apply only to information that the Network generates and acquires as a result of its Medicare review and required CMS data collection activities.

20 - General Requirements

(Rev. 1, 07-11-03)

ENO 305

All data provided to the Network by CMS and all materials prepared for CMS are considered confidential and cannot be disclosed to anyone other than the Network staff except as provided by 42 CFR 480.130 - 143. The Network must comply with all applicable rules CMS establishes relating to confidentiality and disclosure.

20.1 - Network Access to Information

(Rev. 1, 07-11-03)

ENO 305A

As specified in 42 CFR 405.2139(b), the ESRD facility must make medical records available for the Network's inspection as required to carry out its statutory responsibilities.

20.2 - Responsibility to Protect Information

(Rev. 1, 07-11-03)

ENO 305.B

As specified in 42 CFR 480.115, the Network must implement reasonable security measures to ensure the integrity of its information and to prevent unauthorized access. Instruct officers, employees, and committee members of their responsibility to maintain the confidentiality of information. Network information means any data or information

collected, acquired, or generated by a Network in the exercise of its duties and functions under title XVIII of the Act.

20.3 - Network's Notification Requirement

(Rev. 1, 07-11-03)

ENO 305.C

Prior to disclosing Network information, comply with any applicable notification requirements in 42 CFR 480.104(a) and 480.105. Also, comply with the general notice requirements specified in 42 CFR 480.116. Exceptions to the notice requirements are found in 42 CFR 480.106.

20.4 - Verification and Amendment of ESRD Information

(Rev. 1, 07-11-03)

ENO 305.D

If for any reason the facility or physician has concerns about Network information pertaining to the patient, practitioner, and/or facility and requests an amendment of pertinent Information in the Network's possession, 42 CFR 480.134 requires the Network to:

- Verify the accuracy of any information the Network has submitted concerning patients, practitioners, reviewers, and facilities;
- Make any necessary corrections if the individual or facility requests an amendment of pertinent information that is in its possession;
- Forward the amended information to the requestor if the information being amended has already been disclosed, and when the amended information may affect decisions about a particular facility, practitioner, or case under review; and
- Annotate the request, if the Network disagrees with the request for amendment, with the reasons for the request and the reasons for refusal, and include or attach annotations to any disclosure of the information.

20.5 - Individual's Access to Information About Himself or Herself

(Rev. 1, 07-11-03)

ENO 305.E

As specified in 42 CFR 480.132(a)(2), disclose information about an individual to himself/herself within 30 calendar days of receipt of the request.

20.5.1 - Disclosure to Beneficiary

(Rev. 1, 07-11-03)

ENO 305.E.1

Disclose information to the beneficiary or his/her representative as specified in 42 CFR 480.132. A beneficiary is entitled to have access to information pertaining to him or her, including psychiatric records and records concerning alcohol/drug abuse. However, if knowledge of the information would be harmful to the beneficiary, disclose the information to his/her representative rather than to the beneficiary. Determine whether direct disclosure could harm the beneficiary in accordance with 42 CFR 480.132(a)(2).

When a beneficiary's request for his/her medical record is not related to an appeal of the Network's denial determination, as specified in 42 CFR 478.24(a), the Network provides him/her with any applicable records in its possession, as required by 42 CFR §480.132(a). Before disclosing information under this authority, remove any material that explicitly or implicitly identifies practitioners, other patients, or Network reviewers, if no consent is given for disclosure. Disclose the Network deliberations and quality review study information only as specified in 42 CFR 480.139(a) and 480.140.

NOTE: The Network may encourage the beneficiary to seek the medical record from the appropriate health care facility directly. If the beneficiary declines this advice, the Network is still bound to provide the records as specified above.

20.5.2 - Disclosure to Beneficiary's Representative

(Rev. 1, 07-11-03)

ENO 305.E.2

Disclose information to the beneficiary's representative instead of directly to the beneficiary when required by 42 CFR 480.132, or when the beneficiary designates a representative. If the beneficiary chooses to designate a representative or a beneficiary's condition necessitates the designation of a representative, a properly designated beneficiary representative may exercise the same rights and privileges as the beneficiary

in seeking beneficiary information. If the beneficiary is deceased, disclose the information to the first appropriate individual according to the following order:

- To the executor of the estate or personal representative, as established by law or the deceased's will;
- To the administrator of the estate; or
- To an individual verified in writing to be the beneficiary's designated representative.
-

20.6 - Disclosure of Information About Practitioners, Reviewers, and Facilities

(Rev. 1, 07-11-03)

ENO 305.F

20.6.1 - Practitioners and Reviewers

(Rev. 1, 07-11-03)

ENO 305.F.1

Disclose information to practitioners and the Network reviewers as specified in 42 CFR 480.133(a)(1). The Network may also disclose information on a particular practitioner or reviewer to a third party if the individual identified in the information consents to the disclosure. The disclosed information, however, cannot identify other individuals without their consent.

20.6.2 - Health Care Facilities

(Rev. 1, 07-11-03)

ENO 305.F.2

Disclose information to health care facilities as specified in 42 CFR 480.133(a)(1). Facility-specific information is nonconfidential unless the material is part of the Network's deliberations or contains confidential information (such as quality review studies which identify patients, practitioners, or facilities), as defined in 42 CFR 480.101(b). Disclose quality review study information only as specified in 42 CFR 480.140.

30 - Nonconfidential Information

(Rev. 1, 07-11-03)

ENO 310

30.1 - Types of Nonconfidential Information

(Rev. 1, 07-11-03)

ENO 310.A

Nonconfidential information generally includes any information that does not meet the definition of confidential information found in 42 CFR 480.101(b). It includes, but is not limited to, those items specified in 42 CFR 480.120(a).

Facility-specific information that does not contain the Network's deliberations or confidential information (as defined by 42 CFR 480.101(b)) is nonconfidential.

30.2 - Disclosure of Nonconfidential Information

(Rev. 1, 07-11-03)

ENO 310.B

Disclose nonconfidential information, upon request, as specified in 42 CFR 480.120. As provided by 42 CFR 480.121, the Network may also disclose nonconfidential information on its own initiative.

Upon request, the Network may disclose material such as lists of its meetings and dates of their occurrence, as long as there is no confidential information included in the material. Disclose summaries of proceedings of meetings, if the material contains no confidential information. The Network may release any of the ESRD Network-approved deliverable, which do not explicitly or implicitly identify a patient, practitioner, or reviewer (e.g., the approved Network Annual Report), without prior approval.

The Network may release utilization data (e.g., treatment information not specifically related to quality of care) without prior approval when the cell size is 11 or greater if:

- The utilization data are single dimension counts (i.e., referring to one characteristic such as transplants, peritoneal patients) by:

    1. State;

    2. Facility; or

3. Zip code.

- The utilization data are two dimension counts by geographic area and:

    1. Age interval;

    2. Modality; or

    3. Sex.

- The utilization data are multi-dimensional counts by any characteristics that do not include geographic data lower than State level.

40 - Confidential Information

(Rev. 1, 07-11-03)

ENO 315

40.1 - Definition of Confidential Information

(Rev. 1, 07-11-03)

ENO 315.A

Confidential information, as defined in 42 CFR 480.101, is information that explicitly or implicitly identifies an individual patient, practitioner, or reviewer, sanction reports and recommendations, quality review studies which identify patients, practitioners, or facilities, and Network deliberations. Information that implicitly identifies individuals is information so unique that identification of an individual patient, practitioner, or reviewer may be deduced from an examination of the information.

40.2 - Disclosure of Confidential Information

(Rev. 1, 07-11-03)

ENO 315.B

Disclose confidential information only as authorized under 42 CFR 480.130 through 480.143.

40.3 - Disclosure and Redisclosure of ESRD Facility Information Among ESRD Networks, State Survey Agencies (SA), and Department of Health and Human Services (DHHS) Regional Offices

(Rev. 1, 07-11-03)

ENO 315.C

A Network must disclose confidential facility-specific and patient-specific information (data and observation), upon request, to a SA, and/or a CMS RO that is responsible for the Medicare certification of that institution. (See 42 CFR 480.130 and 480.138(a)(1).) The Secretary has the legislative authority to request and receive whatever information is required to make certification determinations for Medicare providers and suppliers. (See 42 CFR 480.107(b).) Disclose the Network information that displays patterns of care to the extent that it is required by a licensure, accreditation, or certification agency to carry out a function of that agency. (See 42 CFR 480.138(a)(1) and 480.140(a)(1).) One such function could be to focus survey resources on specific facilities or specific areas within a facility.

NOTE: Upon request, SAs must disclose facility-specific information (data and observations) to the public, including the ESRD Networks. (See 42 CFR 431.115.) Facility-specific information that is released by the Network to the SA is releasable to the public by the SA in whole or in part if it is used as the basis for citing deficiencies, whether or not the deficiencies result in an enforcement action. SAs may use data received from a Network to direct the survey of a provider's performance, but must have its own documentation to support deficiencies cited.

As specified in 42 CFR 480.135(a), the Network discloses confidential information as necessary to fulfill its duties and functions under title XVIII of the Act. This includes any disclosures needed to properly complete an appeal. As specified in 42 CFR 480.135(c), disclose confidential information to another Network when the material is related to practitioners who are subject to review by the other Network. This includes sanction information, as well as the usual quality review information.

Disclose practitioner-specific information about potential and confirmed quality problems to the involved practitioner and to the facility where the services were furnished. Send all notices regarding quality problems to both the practitioner and facility. An institution

should designate specific officials to receive Network notices and other confidential disclosures.

40.4 - Disclosure of Confidential Information to Elected Officials
(Rev. 1, 07-11-03)

ENO 315.D

If a beneficiary or practitioner writes to an elected official requesting assistance, the elected official has the implied consent of the individual to receive Network information about his/her situation. Accordingly, when an elected official requests information from the Network on behalf of a beneficiary or practitioner, the Network discloses the same information that it would disclose to the beneficiary/practitioner if he/she had made the request directly.

40.5 - Disclosure of Information - Contract Deliverables

(Rev. 1, 07-11-03)

ENO 315.E

Deliverables prepared under a Network contract (e.g., Annual Report, Quarterly Progress, and Status Reports) may be released to the public after approval by the Network's PO. Forward all requests for disclosure of material, other than aggregate data, to the PO who will make a disposition of the request in accordance with applicable CMS policies and Government requirements.

40.6 - Disclosure and Redisclosure of Patient-Specific and Facility-Specific Information by SA

(Rev. 1, 07-11-03)

ENO 315.F

Patient-specific and practitioner-specific information are not releasable by the SA to the public. (See 42 CFR 431.115(h)(3).) Confidential information released by the Network to the SA is not subject to subpoena or discovery in a civil action, including an administrative, judicial, or arbitration proceeding, and is not releasable to the public by the SA. Therefore, a SA may not use the Network's data and/or information as the basis for citing a deficiency and must keep information received from the Network separate from the routine survey records. Both the Network and the SAs must be very clear about the exact uses that data will be put to in the certification process because of issues regarding the confidentiality and releasability of data.

50 - Disclosure of Network Deliberations

(Rev. 1, 07-11-03)

ENO 320

Regardless of any other provision, the Network discloses its deliberations only as specified in 42 CFR 480.139(a).

60 - Disclosure of Confidential Network Information to Officials and Agencies

(Rev. 1, 07-11-03)

ENO 325

60.1 - Disclosure to DHHS

(Rev. 1, 07-11-03)

ENO 325.A

Upon request, disclose confidential information to the Department in the manner and form required as specified in 42 CFR 480.130.

60.2 - Disclosure for Purposes of Monitoring and Evaluation

(Rev. 1, 07-11-03)

ENO 325.B

Upon request, the Network discloses confidential information to CMS or any person, organization, or agency authorized by the Department or Federal statute to monitor its performance, as specified in 42 CFR 480.131. The information required to be disclosed includes copies of medical records of Medicare beneficiaries that are maintained by health care facilities or health care practitioners.

60.3 - Disclosure to Consultants and Subcontractors

(Rev. 1, 07-11-03)

ENO 325.C

As specified in 42 CFR 480.135(b), the Network discloses information to consultants and subcontractors when the individual/organization needs the information to provide the Network with specified services.

60.4 - Disclosure to Intermediaries and Carriers

(Rev. 1, 07-11-03)

ENO 325.D

Disclose confidential information to intermediaries and carriers as specified in 42 CFR 480.136, which authorizes disclosure of information relevant to the intermediary's or carrier's responsibility for making proper payment determinations. This includes disclosures needed to coordinate medical review activities between the Network and the intermediary or carrier.

60.5 - Disclosures to Federal and State Enforcement Agencies

(Rev. 1, 07-11-03)

ENO 325.E

Disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs to Federal and State enforcement agencies under the terms stated in the regulation. (See 42 CFR 480.106(b), 480.130, 480.137, 480.138(b), 480.139(a), and 480.140(a)(1), (b), and (e).)

NOTE: The facility and/or practitioner is not to be notified of any information released to Federal and/or State enforcement agencies in potential fraud or abuse cases.

60.6 - Disclosure to State and Local Public Health Officials

(Rev. 1, 07-11-03)

ENO 325.F

The Network discloses information to State and local public health officials whenever it determines that the disclosure of the information is necessary to protect against a substantial risk to the public health. If the requested information is necessary to protect against an imminent danger to individuals or the public health, the Network may release facility and patient-specific data to State and local authorities that need the information to respond to the situation. (See 42 CFR 480.106(a) and 480.138(a)(2).) The Network notifies CMS when it makes such a disclosure, and it sends a notice simultaneously to the facility that must still be given the opportunity to comment on the information about itself.

60.7 - Disclosure for Purposes of Conducting Review

(Rev. 1, 07-11-03)

ENO 325.G

The Network discloses or arranges for disclosure of information to individuals within its Network reviews area as necessary to fulfill its particular duties and functions under the statute. (See 42 CFR 480.135(a).)

60.8 - Disclosures to Quality Improvement Organizations (QIOs)

(Rev. 1, 07-11-03)

ENO 325.H

Disclose to QIOs information, as necessary to fulfill their particular duties and functions under Title XI, Part B, on patients and practitioners who are subject to review by the QIO.

60.9 - Disclosures to Medical Review Boards

(Rev. 1, 07-11-03)

ENO 325.I

Disclose to MRBs established under §1881 of the Act information on patients, practitioners, and institutions receiving or furnishing ESRD services who are subject to review by the ESRD Network Organizations.

70 - Disclosure of Network Information Involving Beneficiary Complaints

(Rev. 1, 07-11-03)

ENO 330

The Network is required to conduct an appropriate review of all written complaints from Medicare beneficiaries (or their designated representatives) about the quality of Medicare services. (See §1881(c)(2)(D) of the Act.) Ensure that any disclosure of information is consistent with applicable provisions of 42 CFR Part 480. (See Chapter 7, §§100 of this manual.)

80 - Disclosure of Network Information for Research Purposes

(Rev. 1, 07-11-03)

ENO 335

80.1 - Independent Research Activities

(Rev. 1, 07-11-03)

ENO 335.A

The Network does not disclose information that explicitly identifies patients, practitioners, or reviewers without their consent. Upon approval from CMS, the Network may disclose information after deleting all confidential identifiers and any other information from which identification of the individual can be deduced. The Network may replace the confidential identifiers with numerical or alphabetical codes that researchers can use to track specific patients or practitioners without knowing the actual identities of the individuals. After the Network deletes all identifying information, the remaining material is nonconfidential and may be disclosed upon approval.

80.2 - Department Research Activities

(Rev. 1, 07-11-03)

ENO 335.B

Research entities that conduct research activities for CMS as contractors or subcontractors of the Department, and who are bound by a CMS confidentiality agreement, have access to the Network's confidential information when it is needed to accomplish the Department's objectives. Provide this information in the manner and form required to the Department component to whom the request was issued in accordance with 42 CFR 480.130. The Department component will then re-release this information to the requestor under 480.107(b).

90 - Disclosure of Network Sanction Information

(Rev. 1, 07-11-03)

ENO 340

As specified in 42 CFR 480.142, disclose sanction recommendation reports to the Office of the Inspector General (OIG), CMS, and agencies that investigate and prosecute fraud and abuse. Disclose relevant sanction information.

Concurrent with the Network's final notice, the Network provides the affected practitioner or other person with a copy of the complete sanction report and recommendations that it is submitting to OIG.

100 - Redisclosure of Network Information

(Rev. 1, 07-11-03)

ENO 345

100.1 - Redisclosure of Nonconfidential Information

(Rev. 1, 07-11-03)

ENO 345.A

There are no statutory or regulatory restrictions that limit a recipient's redisclosure of nonconfidential information.

100.2 - Redisclosure of Confidential Information

(Rev. 1, 07-11-03)

ENO 345.B

All recipients of confidential information, including SAs, cannot redisclose the information except under the limited circumstances authorized by 42 CFR 480.107.

For example, recipients of the Network's confidential information (beneficiaries and practitioners) may redisclose information about themselves provided the redisclosure does not explicitly or implicitly identify another individual.

100.3 - Notifying Recipients About Redisclosing Confidential Information

(Rev. 1, 07-11-03)

ENO 345.C

According to 42 CFR 480.104(a)(2), the Network is required to inform recipients, in writing, that they cannot redisclose confidential information previously disclosed to them, except as permitted under 42 CFR 480.107. The Network's written notice should also advise the recipient of the penalties for unauthorized disclosures.

The Network explains in its notice to the recipient that, except as authorized in 42 CFR 480.107, confidential information cannot be redisclosed unless the individuals

who would be identified consent to the redisclosure, or all confidential personal identifiers are removed. The notice can be a separate attachment to the information provided, or can be included within the notice to the recipient.

As part of the Network's responsibility to educate individuals and facilities about its review process, the Network conducts activities that inform individuals and facilities in its area of the rules and restrictions applicable to confidential information. (See 42 CFR 480.116.) Improper redisclosures of confidential information are generally inadvertent rather than intentional. Accordingly, the Network provides educational programs to avoid problems.

Medicare ESRD Network Organizations Manual

Chapter 5 - Quality Improvement

Table of Contents

10 - Authority

(Rev. 1, 07-11-03)

ENO 500

Section §1881(c)(2)(E) of the Social Security Act (the Act) requires ESRD Network Organizations to perform on-site review of facilities utilizing standards of care established by the Network Organization to assure proper medical care.

20 - ESRD Health Care Quality Improvement Program (HCQIP)

(Rev. 1, 07-11-03)

ENO 505

As stated in CMS's Strategic Plan, HCQIP is a program that supports CMS's mission to assure health care security for beneficiaries. The mission of 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 the quality of care; communicate with beneficiaries, health care providers, and practitioners in order to promote informed health choices; protect beneficiaries from poor care; and strengthening the health care delivery system.

As part of the Network's role in conducting quality improvement activities, the Network should work to improve processes and outcomes of patient care by developing, implementing, and evaluating quality improvement projects in collaboration with ESRD facilities, providers, and other partners. These activities support the ESRD HCQIP.

30 - Responsibilities

(Rev. 1, 07-11-03)

ENO 510

The Network's quality improvement responsibilities include:

- Developing and conducting quality improvement projects based on one or more of the established sets of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, and vascular access, or other CPMs developed or adopted by CMS;

- Monitoring, tracking, and disseminating regional (Network) and facility-specific (if available) clinical outcomes data (such as the CPM data) to identify opportunities to improve care within the network area or within a specific facility; and

- Upon request of a facility and/or upon identifying poor performance or a specific need, assisting 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.

40 - Quality Improvement Projects (QIPS)

(Rev. 1, 07-11-03)

ENO 515

40.1 - Background and Project Topics

(Rev. 1, 07-11-03)

ENO 515.1

One of CMS's National Performance Review (NPR) goals is that 80 percent of adult in-center hemodialysis patients achieve a delivered dose of dialysis greater than or equal to 65 percent measured by the Urea Reduction Ratio (Hemodialysis (HD) Adequacy CPM III). Therefore, for the Network's first QIP under this contract, the Network must use HD Adequacy CPM III as the primary CPM to measure/improve adequacy. The Network is required to continue conducting QIPs based on this CPM for at least the first contract year. The Network may include in the project design of the Network's first QIP, one or more of the vascular access CPMs I-IV to try to measure and improve; however, these CPMs must be treated as care processes that will lead to improvement in the overall adequacy of dialysis (HD Adequacy CPM III) in its network area.

NOTE: If, after the first contract year, the Network does not meet the 80 percent target for HD Adequacy CPM III, it must continue to conduct QIPs utilizing the HD Adequacy CPM III.

After the first contract year, if the Network reaches or exceeds the 80 percent target for HD Adequacy CPM III, CMS, with input from the Networks, will determine what topics or CPMs the Network's subsequent QIPs will be based on. Potential topics or CPMs for QIPs include the following:

- Adequacy of dialysis (in-center hemodialysis patients) CPMs I-V;
- Adequacy of dialysis (peritoneal dialysis patients) CPMs I-III;
- Anemia management CPMs I-III;
- Vascular access CPMs I-IV; and

- Other standard measures/indicators identified by CMS.

The Network may also propose a QIP not based on one of the CPMs listed in §40.1; however, this must be adequately justified and approved in advance by CMS. The CMS reserves the right to direct its quality improvement project activities, including directing participation in specific projects/special studies, and discontinuing or deferring projects at any time. The choice of other CPMs (topic) on which to conduct a QIP may be based on the analysis of local and/or other data, such as the Core Indicators (predecessor to the CPM) or CPM data, Network resources, patient care improvement needs, and the priorities of the renal community and/or CMS. The Network must, at a minimum, use one or more of the standard CPMs in its QIP. The current standard set of CPMs on which to base QIPs may be found in Exhibit 5-1. Other measures related to the QIP topic that are not part of the current standard set of CPMs may also be included in the QIP as approved by CMS through the Narrative Project Plan (NPP). (See Exhibit 5-4.)

The Network does not research new or suspected relationships between processes and outcome, undertake projects that do not have a strong scientific base, or rest on solid professional consensus, unless directed by CMS.

The evaluation of projects, where possible and feasible, requires similar, comparable data on similar groups of providers/patients that do not experience the intervention. This can be accomplished through appropriate sampling even if the intervention group data is population based (i.e., 100 percent of providers/patients records, etc., are utilized for measurement). These evaluations provide support for observations that interventions directly led to, or contributed to, the improvements observed. The interventions utilized should be based on previous implementation or a good rationale for probability for success, and as such, evaluations are not technically "researching" the effectiveness of the intervention, but evaluating the degree to which a high quality intervention was successfully implemented. Good interventions, if not appropriately and thoroughly implemented, may lead to poor improvements in actual clinical care and outcomes.

The primary purpose of the evaluation is, therefore, to determine the extent to which a good intervention was successfully implemented - not the potential effectiveness of the intervention itself. A high quality QIP with a well documented and implemented intervention may indeed support the observation that a planned and conducted high quality intervention in one setting may not be particularly effective in another, despite the assumptions at the time of project approval. Such outcomes do not constitute project failure; rather they are successful projects that provided important scientifically supported lessons in the developing practice of intervening to improve care for ESRD beneficiaries. The instructions in §40.4.C.4 of the manual and the NPP attempt to maximize the probability that high quality interventions are adequately designed, implemented, and documented so as to minimize situations where intervention data and documentation are not sufficient to assess their contribution to apparently negative outcomes.

40.2 - QIP Frequency, Project Consultant, and Required Reporting

(Rev. 1, 07-11-03)

ENO 515.2

Develop and implement at least one QIP annually, unless directed otherwise by CMS. The Network electronically submits a project idea(s) to its project officer (PO) for approval using the Project Idea Document (PID) (see Exhibit 5-3 prior to developing and implementing the QIP Narrative Project Plan (NPP) (see Exhibit 5-4PP format). Exhibit 5-5 contains the format for the Final Project Report (FPR).

The Network QIP consultant (SOW §C.4.C) must be involved in all phases of the project: planning, analyzing, evaluating, and in preparing the Final Project Report. The project consultant must be identified in the appropriate fields in the PID, NPP, and the FPR.

The Network's first PID is due to its PO as soon as possible, but no later than 60 days after award of the contract. PIDs will be due annually thereafter, unless directed differently by the Network's PO.

Sixty days after CMS approval of the PID, the Network electronically submits a NPP to its PO. The Network's PO and regional office scientific staff may be involved during this stage of the NPP development to provide guidance and assistance. The Network's PO will evaluate proposed QIPs based on the following criteria:

- Feasibility;
- Potential impact on the patient population;
- Project design;
- Cost-effectiveness; and
- Timeliness.

After initiation of the approved NPP, the Network documents all of the project phases and activities through the narrative portion of the Standard Information Management System (SIMS) and reports the status of its QIP in the Quarterly Progress and Status Report (see §40.8). The Network electronically submits any changes to the approved NPP to its PO for review and approval.

NOTE: The Network must also submit its PID, NPP, FPR, and any other modifications of its QIPs via E-mail using Word software to prepare its document until the reporting component of the SIMS software is available and functioning reliably. The CMS will advise the Network when to submit its reports via SIMS. The Network may also submit hard copies of its reports, if necessary.

Within 90 days after completion of the QIP, the Network electronically submits a FPR to its PO that describes and evaluates the project. See instructions in Exhibit 5-5.)

40.3 - Project Idea

(Rev. 1, 07-11-03)

ENO 515.3

In the Network's first contract year, it is required to conduct QIPs based on hemodialysis adequacy CPM III (minimum delivered dose of HD is a URR greater than or equal to 65) until it reaches or exceeds the target of 80 percent of the adult in-center HD patients in its network area meeting this URR level. The Network may include in the project design of its first QIP, one or more of the vascular access CPMs I-IV to try to measure and improve; however, these CPMs must be treated as care processes that will lead to improvement in the overall adequacy of dialysis (HD Adequacy CPM III) in its network area. If, after the first contract year, the Network reaches the 80 percent target for HD adequacy CPM III, CMS, with input from the Networks, will determine what topics or CPMs the Network's subsequent QIPs will be based on. The Network develops its projects in collaboration with its ESRD providers and/or beneficiaries. In addition, the Network may also partner with other Networks, QIOs, State Survey Agencies, national and/or local renal related organizations and ROs when appropriate. The Network QIP consultant must be involved in the development of the Network's project idea.

Surveys to obtain information for project development or implementation must relate to the project being considered. Prior to dissemination, the Network forwards survey questions to its PO for review and approval, and to determine the type of clearance needed, if necessary. The PO or other RO staff will inform the Network of any clearance the survey requires.

The Network assesses the appropriateness of its QIPs using the following general criteria:

- For the first contract year, projects shall be based on HD Adequacy CPM III, until it has met the 80 percent target (as described above).

- In the Network's QIP, it may measure other processes that it believes are associated with achieving adequate dialysis (HD Adequacy CPM III), as approved by CMS. These measures are often useful in determining if the interventions and strategies in the QIP were effective and/or to assess whether the presupposed cause and effect relationships between process and outcome were valid or as strong as suspected.

- Projects should strive to be high-impact/high-feasibility (i.e., the project should result in improved processes of care and outcomes for a large number of the targeted population with a high probability of success). The Network is

encouraged to adopt completed projects of other Networks that have proven to be successful (i.e., where measurable improvement has been demonstrated).

The Network submits its project idea, not exceeding three pages, using the format for the PID in Exhibit 5-3. The first project idea is due to the PO no later than 60 days after award of the contract (approximately September 1, 2000). Subsequent project ideas will be due annually thereafter, unless directed otherwise by the PO.

40.4 - QIP Narrative Project Plan (NPP)

(Rev. 1, 07-11-03)

ENO 515.4

After the approval of the Network's project idea, the Network completes the NPP and submits it to the PO within 60 days. The Network involves its QIP consultant in the development of the NPP. Some of the components of the NPP will have been identified in the PID. It is appropriate to request preliminary review or assistance at any point during the preparation of the NPP. In any event, before the PO officially approves the NPP, the Network's PO or RO scientific staff may ask the Network to include additional information and/or ask for revisions to its NPP. The format for the NPP is found in Exhibit 5-4. Components and instructions for certain sections of the NPP include the following:

A. Network Identification Information - Include the Network number, Network name and contract number.

B. Project Identification Information - Include the following:

1. Project title;

2. Topic (must be a CMS priority CPM (topic area) or preapproved as instructed in §C.2.C of the Network SOW and §40.1 of this manual;

3. Network project contact person;

4. Network Epidemiologic Consultant (must be involved in the PID and NPP as required in the Statement of Work (see §C.4.C) and Chapter 2, §60, of this manual);

5. Regional project officer;

6. Regional scientific advisor;

7. Current date;

8. Initial NPP submission date; and

9. NPP revision number.

C. Objectives of the Project - The project should:

1. State the National ESRD CMS Priority CPM (topic area) - Clearly state the national ESRD CMS priority CPM (topic area) that will be addressed in the project. The CMS has determined that the first project must be based on HD Adequacy CPM III, until the Network has met the 80 percent target as described in §40.1. If the Network's regional office has preapproved a non-priority CPM (topic area) please indicate the measure(s) here.

2. State the Immediate Process and/or Outcome Objectives and Goals - Describe the specific processes and related clinical outcomes to be measured and improved in this project. Describe the long-term goals and impact of the project.

3. List the Quality Indicators - List the CPM(s) to be used in measuring the listed processes and outcomes. List all other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project. These quality indicators must relate directly to the processes and outcomes of this project as found in the previous section.

4. Quantitatively Define "Improvement" in Project-Specific Process and Outcome Indicators - A predetermined target "amount" of improvement helps identify the level of effort and importance of each particular indicator in the overall project, and the importance of targeting interventions for each area of the project where improvement is directly related to expected outcomes.

   Improvement "target" amounts may be expressed in terms of absolute improvement or reduction in failure rates (see examples below). Reaching the target amount of improvement for each quality indicator is not the basis for determining whether a project is "successful". Success is the development and implementation of a sound, high quality plan to measure and improve performance. Measuring the actual amount of improvement for each quality indicator assists in the effort to identify the relationship between the interventions applied to improve specific dimensions of clinical (or patient, where applicable) behavior and the actual improvement in that performance. It is also the key to exploring the relationship between improving clinical performance (process indicators) and the improvements in project-specific outcomes.

EXAMPLES

Absolute Improvement/Process Indicator Example - Time on Dialysis - The target is 20 percent improvement over baseline rates of adherence (as specified in the appropriate quality indicator section, e.g., within 10 minutes of prescribed time). If the baseline rate is 55 percent, and the rate at remeasurement is 73 percent, the absolute improvement is 18 percent and the intervention was apparently effective. There is no penalty for not reaching 20 percent. If the improvement was only 3 percent however, there is an opportunity to explore the relevance and actual conduct (i.e., was the intervention carried out as planned) of the intervention.

Reduction in Failure Rate/Outcome Indicator Example - URR greater than or equal to 65 percent - The Network rate of adherence at baseline is 70 percent. The Network proposes and targets a reduction in failure rate (RFR) of 25 percent. The project was carried out and the rate at remeasurement was 77.4 percent.

RFR = (% absolute improvement from baseline/100-baseline rate)*100

EXAMPLE

(7.4%/30%)*100 = 24.6% (rounded up to 25%) - the failure rate (30%) was reduced by 25%.

D. Background - List:

1. Opportunity for Improvement - Describe the size, severity, and consequences of the problem in the network area. The CMS has identified "improving the percentage of adult in-center hemodialysis patients achieving an adequate delivered dose of dialysis (HD Adequacy CPM III)" as the priority topic for Networks' QIPs. One of CMS's National Performance Review goals is that 80 percent of adult in-center HD patients shall achieve a delivered dose of dialysis greater than or equal to 65 percent. Improvement opportunities may be identified in sub-regions of the entire Network.

2. Potential for Change - What is the current state of practice in the population targeted for improvement? What factors come together to allow and enable the Network to work effectively with the dialysis population and the providers. Which groups are targeted for improvement? Who would need to accept change to improve performance (processes and outcomes)? What factors or prior improvement efforts warrant the expected magnitude of improvement as discussed in the previous section?

3. Prior Projects or Studies - Are there any previous projects (Networks, Quality Improvement Organizations, providers, etc.) that attempted to

improve performance in these areas? What was the magnitude of improvement?

E. Methods

1. Quality Indicators (refer to the CPM definitions in Exhibit 5-1) - Each QIP must include the review of one or more quality indicators or CPMs. A quality indicator is a quantifiable measure of a health care process or outcome that is related to practice guidelines or standards. The focus of the indicators should generally be on processes of care where there is broad consensus on the treatment approach, or there is scientific evidence that the indicators have previously been linked to improved outcomes. Do not research new or suspected relationships between processes and outcome, undertake projects that do not have a strong scientific base, or do not rest on solid professional consensus unless directed by CMS.

    a. Process Measure Indicators - For each process indicator or CPM addressed in the project, provide a clear and succinct statement describing how the indicator or CPM is actually measured in numerator/denominator format that will clearly explain the origins of the numeric data that will be provided in the measurement section of the QIP.

    b. Outcome Measure Indicators - For each outcome indicator or CPM addressed in the project, provide a clear and succinct statement describing how the indicator or CPM is actually measured in numerator/denominator format that will clearly explain the origins of the numeric data that will be provided in the measurement section of the QIP.

2. Project Setting - Describe and enumerate the clinical settings to be included (dialysis centers, physician offices, hospitals, etc.) and the size of population of beneficiaries involved in the project (i.e., experiences the intervention).

3. Study design - Describe the type of study design and the analyses to be used to determine changes or improvements from baseline. Describe control or comparison groups considered or included to help gauge actual impact of interventions versus secular trends.

4. Data - Include the following:

    a. Sources - Describe the specific source of the data, the specific data elements to be utilized in the analyses as described above, details behind the collection of the data, and the accuracy/validity of the data.

b. Collection Methods - Describe in detail the method, tools (existing or developed), and time lines required to collect the data for this project. Indicate proposed pre- and field-testing of data collection instruments. All questionnaires or surveys must be pre-reviewed and approved by CMS.

c. Case selection - Include the definition of cases eligible/ideal for project, and the sample size, sampling frame, sampling strategy, biostatistical power calculations (if sampled). It is important to understand the efficiency introduced by appropriate sampling. Projects that propose to identify and collect data on 100 percent of patients will be scrutinized to assess the costs/benefit of such activities.

5. Intervention

a. Description - Provide a summary of the project's proposed intervention plan, including; description of intervention(s)/intervention arms, indicators used for tracking the actual implementation and progress of the intervention (if different from the project's quality indicators), settings, target population, intervention type, timetable, and intervention evaluation (i.e., was the intervention implemented properly and thoroughly).

b. Objectives for Behavior Changes - Discuss the objectives for behavior changes in various target audiences for this project. Differentiate between the various types of interventions used for the project.

- Target audience interventions are aimed at one or more target audiences whose behavior ultimately should be changed, e.g., physicians, beneficiaries, etc. and which the Network itself implements ("direct" intervention).

- Agent audience interventions are aimed at one or more entities such as, State or local health departments, professional associations, and advocacy groups, which are also working to change the behavior of the target audience. For agent interventions, describe:

    - Expectations (if any) for intervention partners and/or collaborators (e.g., advocacy groups, professional associations, providers, practitioners, plans, State and local health departments);

- Limitations, if any, of targeting one or more agents; and

- The outcomes related to agent behavior desired.

c. Description of Network's and Collaborator's Roles - Describe the Network's and collaborator's roles in the development of interventions and the expected degree of acceptance and implementation. Include in the description:

- The implementation plan (i.e., who is responsible for doing what, when, where, and how);

- How to track and monitor adherence to this plan; and

- Any process assessments that are incorporated and used to track and improve the intervention as it is being implemented where warranted.

6. Feasibility and Risk

- Estimate overall length of time that intervention activities are estimated to require.

- Discuss labor intensity, political sensitivity, resource requirements, and complexity.

- Discuss the potential impact of these issues on the success of the project.

- Estimate the total cost of the project.

- Discuss the potential generalizability of this project to similar target populations.

- Assess the likelihood that the intervention effect is likely to be sustained beyond the implementation period.

F. Results - Upon implementation of the project, include the following:

1. Baseline Measurement Results - Present baseline measurement results for all indicators using appropriate and clear methods (tables, graphs, etc.).

2. Interim Results for All Indicators - Present interim results for all process or outcome indicators that were proposed in the methods section.

3. Follow-Up Measurement Results - Present follow-up measurement results in a manner consistent with the baseline results.

4. Outcome or Impact Evaluation of Project Success - Present an outcome or impact evaluation of project success based on the analyses proposed and the quantitative targets for improvement as found in the proposal. Typically these include two dimensions: (1) absolute or relative improvements (RFRs) from baseline in performance as intended by the planned remeasurement of quality indicators, and (2) comparing these results to the change in quality indicator results from the comparison group(s). These biostatistical analyses must be proposed and explained in the NPP prior to approval.

G. Conclusions and Discussion

1. Conclusions Based on Results - Was the project successful? If not, why not?

2. Limitations of Project Findings - What were the project findings limitations?

3. Overall Evaluation of Project - What was the overall evaluation of the project?

H. Appendices - Include the following:

1. Bibliography.

2. Data collection forms (provide separately, if necessary).

3. Publications or reports.

4. Data collection, abstraction, analysis and evaluation instruments.

5. Other, miscellaneous.

40.5 - Final Project Report (FPR)

(Rev. 1, 07-11-03)

ENO 515.5

Within 90 days after completing the QIP, the Network submits a FPR to its PO using the format in Exhibit 5-5. The Network involves the QIP consultant in the preparation of this report.

40.6 - Disseminating Results

(Rev. 1, 07-11-03)

ENO 515.6

The Network disseminates the results of the project to all providers in its network area, CMS, project partners, and other Networks. The information shared must conform to all Network regulations and or requirements. Protect the identities of individual providers practitioners, plans, and beneficiaries.

40.7 - Identifying Additional Opportunities for Improvement

(Rev. 1, 07-11-03)

ENO 515.7

In this phase of the project, building on experience gained by completing one iteration of the project process, the Network may identify additional intervention strategies or improvement potential within the current project. This final phase of the project process is a checkpoint for the Network to determine how successful the project was in achieving the objectives; whether additional interventions are warranted; and whether the Network should consider the project for exporting and/or expansion within its area (if it was not a Network-wide project).

40.8 - Quarterly Progress and Status Report

(Rev. 1, 07-11-03)

ENO 515.8

The Network documents its project phases/activities on an ongoing basis into the Standard Information Management System (SIMS) and completes its RO reporting requirements. At least quarterly, the Network includes in its Quarterly Progress and Status Report the status of its QIPs, using a format prescribed by its RO. The Network completes a Final Project Report for each completed quality improvement project (see Exhibit 5-5), and it submits the completed project report to the project officer within 90 days after completion of the QIP.

50 - Improvement Plan

(Rev. 1, 07-11-03)

ENO 520

If the Network identifies problems or concerns that could impact the quality of care dialysis patients are receiving, request the facility to complete and initiate an improvement plan to correct the problem. The Network's medical review board will provide guidance as to when the Network should request a facility to initiate an improvement plan.

A request for an improvement plan must be data based and state clearly the issue(s) that warrants improvement. The improvement plan must include the goals/objectives to be achieved, the process/measurements/tools to be used to assess the issue(s) and to measure improvement, and the time frame for accomplishing the improvement plan, including monitoring/documenting improvement. The action to improve the quality of care described in this plan must be sustainable.

60 - Clinical Performance Measures (CPMs)

(Rev. 1, 07-11-03)

ENO 525

Clinical performance measures are methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality. A clinical measure or indicator can be used to identify or direct attention to specific performance issues within a health care organization that should be the subject of more intense review.

Annually, collect data on specific ESRD CPMs by requesting selected dialysis facilities to provide patient-specific data for a sample of ESRD patients in the facilities. The collection of data on CPMs is designed to:

- To describe/analyze the processes (when able) and outcomes of care for the targeted patient population, both at a point in time and over time;

- To describe/analyze conformance to clinical practice guidelines both at a point in time and over time; and

- To provide the facilities/providers with information to stimulate improvement in patient care processes and outcomes for the targeted patient population.

The CMS, working with the Network and the ESRD CPM Quality Improvement (QI) Committee (composed of both Network renal and community representatives), will determine what CPMs to collect and what ESRD patient population(s) to target.

60.1 - CPMs - Network/National Sample

(Rev. 1, 07-11-03)

ENO 525.1

The CPM process is designed to assess the quality of care regarding the CPMs listed in Exhibit 5-5 in a consistent way, on a representative sample of a targeted ESRD patient population in each network area and/or in the United States. Data to calculate the CPMs are collected annually for purposes of:

- Describing and analyzing the care practices for the targeted patient population both at a point in time and over time; and

- Providing the facilities and providers with information to stimulate improvement in patient care processes and outcomes for the targeted patient population.

Report the data collected on the CPMs to CMS or CMS's designee. The CMS will aggregate these results and report Network and/or national profiles of care back to each Network.

60.2 - CPMs - Sampling Method

(Rev. 1, 07-11-03)

ENO 525.2

The CMS or its designee annually selects a targeted patient population of dialysis and/or renal transplant patients. Obtain CPM-related information for these patients, which describes the population and care practices. The level of work effort for this activity remains the same in each contract year.

The CMS or its designee annually selects the patient samples using information from the Network's database. From the Network's databases, CMS or its designee selects a random sample of in-center hemodialysis (HD) patients stratified by the Network, and a national random sample of peritoneal dialysis (PD) patients. The HD patient sample is designed to allow a Network-specific estimate of the prevalence of occurrence of the CPMs within +/- 5 percent accuracy and a 95 percent level of confidence. The aggregate data allows national prevalence estimates with an even tighter accuracy range. The specific sample size for both HD and PD is in the range of 600 to 700 records annually per Network.

Patients are selected from the targeted patient population using a random sampling technique. The CMS over-samples the targeted patient population to compensate for possible non-responses. A non-response could result if the patient's medical record is missing. Do not substitute for patients in the sample.

Each contract year, CMS or its designee provides the Network with the patient listing, data collection forms, and the instructions for completing the form prior to implementing the data collection effort.

NOTE: The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year. The reporting period for PD patients is October, November, and December of each year, and January, February, and March of the following year.

60.3 - CPMs - Data Collection

(Rev. 1, 07-11-03)

ENO 525.3

Staff from each selected dialysis facility will abstract clinical data annually for the CPMs project. Provide the selected facilities with:

- A cover letter explaining the facility staff's abstraction of the CPM data;
- Copies of the CPM data collection form(s); and
- Instructions for completing the data collection forms on the patients selected.

Assume that each dialysis facility in the network area completes a range of 2 to 10 data collection forms per year. The data collection form is preprinted with patient-specific demographic information from the Network's database. The Network must:

- Request that the facility verify the preprinted patient-specific information and enter on the form any corrections to the patient-specific information and the appropriate clinical information for the CPMs from the patient's medical record; and
- Specify the length of time the facility is allotted to complete and return the collection forms. Transmit all data from the completed collection forms to CMS or its designee within 90 calendar days after receipt of the CMS-selected patient sample.

Upon receipt of the CPMs data, CMS or its designee will:

- Merge the data from each Network, conduct edit checks, and aggregate the results; and

- Prepare an annual report that describes the CPMs nationally and at the Network level (when possible), and Network and national profiles of care practices and outcomes of care based on the CPMs data.

60.4 - CPMs - Data Validation

(Rev. 1, 07-11-03)

ENO 525.4

The Network re-abstracts and validates a random 5 percent of the HD and 10 percent of the PD forms completed by facility personnel in its network area. The CMS or its designee will provide the Network with the names of the HD and PD patient records to abstract. This validation activity may be done by the Network's staff conducting onsite record review (if the facility is within 100 miles of the office) or by requesting copies of the pertinent medical records. The Network completes the validation activity, including submitting validation results to CMS or its designee, within 120 calendar days after receiving validation patient samples.

The Network must pay the facility for the costs associated with photocopying medical records for review. Facilities may claim payment for photocopying at the rate of seven cents per page. In addition, the Network must pay the facility for the cost of first-class postage incurred, if records are mailed to it.

60.5 - CPMs - Data Validation Reporting

(Rev. 1, 07-11-03)

ENO 525.5

For each patient in the Network validation sample, enter the CPMs data and any corrections to the patient-specific demographic information into the CMS designated data-entry software program or into SIMS, if available, and transmit to CMS or its designee electronically or on diskette. The CMS or its designee will provide the data-entry software program and instructions for installation. Verify that the correct information has been entered before transmitting the data to CMS or its designee. Annually, the Network transmits data for all patients in its Network sample to CMS or its designee within 120 calendar days after receipt of the Network patient validation samples.

70 - CMS - Compiled Data Reports

(Rev. 1, 07-11-03)

ENO 530

The CMS may develop/compile reports or data files using the CPMs and CMS administrative data to describe the quality of care for ESRD patients. The information on these reports can be used in developing Network QIPs to stimulate facility-specific improvement activities. The CMS will provide these reports or data to the Network (electronically and/or on hard copy).

On occasion, CMS may produce two to three supplemental reports on the CPM data. The CMS or its designee will provide these reports to the Networks as camera-ready copies. The Networks will make these reports available to its facilities and/or providers.

Annually, the Network provides one copy of the CMS ESRD CPM Report, based on the CPMs data, to the medical director, head nurse, and unit administrator of each facility in the network area.

80 - Quality Improvement Projects Versus Research Studies

(Rev. 1, 07-11-03)

ENO 535

Although the Network may use many of the tools and terminology of epidemiological, clinical, or health services research when carrying out QIPs, they should not involve:

- Research efforts to prove that a process of care is effective or ineffective;
- Development of practice guidelines. In general, cooperative projects should rely on a consensus that has already been developed and, where possible, guidelines that have already been written; or
- Development of survey instruments. (A survey is any collection of information or data for any reason from more than ten beneficiaries or from more than ten providers or practitioners except where the collection of data is from medical records for a QIP.)

Surveys to obtain information for project development or implementation must relate to the project being considered. Prior to dissemination, the Network forwards the survey questions to its PO for review and approval, and to determine the type of clearance needed, if necessary. The PO or other RO staff will inform the Network of the type of clearance, if any, the survey requires.

Surveys to obtain information not related to a QIP must be submitted to the Network's PO for review and approval prior to implementation. The PO or other RO staff will inform the Network of the type of clearance necessary for a non-project related survey.

90 - Network Resources to Support the United States Renal Data System (USRDS)

(Rev. 1, 07-11-03)

ENO 540

In addition to the resources and activities the Network conducts to support the ESRD Program Management and Medical Information System (PMMIS) database, which CMS provides to the USRDS, make available Network resources annually to support national and/or regional special studies developed by the USRDS. It is anticipated that the USRDS special study centers will conduct four to five special studies over the 3-year contract period. Assume the following additional Network resources to support USRDS special study activities:

- Staff to conduct activities listed in the assumptions below (staff may be a combination of administrative, data, and quality improvement personnel);
- Postage cost to a 20 percent random sample of facilities in the network area, assume two mailings per year at $10 per mailing; and
- Postage cost to mail completed data collection forms monthly to the national renal registry.

The above annual resource estimate is based on the following:

- A national sample of 5,000 to 7,000 patients per study;
- A patient sample selection per Network that is proportional to the number of patients in each Network (see Exhibit 5-2);
- Staff labor or work effort of one hour per patient; and
- A selection of no more than 20 percent of the facilities in any Network annually.

The Network reports to the CMS PO, using the Quarterly Progress and Status Report, the work conducted to support the USRDS special studies, as appropriate, such as the number of data collection forms completed and the date these forms were mailed to the USRDS.

The CMS, the National Institutes of Health/National Institute of Diabetes, and Digestive and Kidney Diseases (NIH/NIDDK), the Networks, and the USRDS will work together to

design special studies that can be conducted with the resources listed above. Separate technical instructions will be provided to describe the specific activities the Network is to conduct. If additional Network resources or work effort is required by the USRDS to conduct special study activities, additional resources/funding will be provided.

100 - Exhibits

Exhibit 5-1 - ESRD Clinical Performance Measures (CPMs)

(Rev. 1, 07-11-03)

1. Hemodialysis (HD) Adequacy CPM I:

Monthly Measurement of Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 1 - Regular Measurement of the Delivered Dose of Hemodialysis (Evidence). The dialysis care team should routinely measure and monitor the delivered dose of hemodialysis.

HD Adequacy Guideline 6 - Frequency of Measurement of Hemodialysis Adequacy (Opinion). The delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients. The frequency of measurement of the delivered dose of hemodialysis should be increased when:

a. Patients are noncompliant with their hemodialysis prescriptions (missed treatments, late for treatments, early sign-off from hemodialysis treatments, etc.).

b. Frequent problems are noted in delivery of the prescribed dose of hemodialysis (such as variably poor blood flows, or treatment interruptions because of hypotension or angina pectoris).

c. Wide variability in urea kinetic modeling results is observed in the absence of prescription changes.

d. The hemodialysis prescription is modified.

Numerator:

Number of patients in denominator with documented monthly adequacy measurements during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample.

2. HD Adequacy CPM II:

Method of Measurement of Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 2 - Method of Measurement of Delivered Dose of Hemodialysis (Evidence). The delivered dose of hemodialysis in adult and pediatric patients should be measured using formal urea kinetic modeling (UKM), employing the single-pool, variable volume model.

Numerator:

Number of patients in denominator for whom delivered HD dose was calculated using formal urea kinetic modeling, or Daugirdas II, or urea reduction ratio (URR) during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample.

3. HD Adequacy CPM III:

Minimum Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

HD Adequacy Guideline 4 - Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a Kt/V of at least 1.2 (single-pool, variable volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio (URR), the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average URR of 65%; however, URR can vary substantially as a function of fluid removal.

Numerator:

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was either Kt/V greater than or equal to 1.2 or URR greater than or equal to 65% during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample who have been on HD for six months or more.

4. HD Adequacy CPM IV:

Method of Post-Dialysis Blood Urea Nitrogen (BUN) Sampling.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 8 - Acceptable Methods for Blood Urea Nitrogen (BUN) Sampling (Evidence). Blood samples for BUN measurement must be drawn in a particular manner. Pre-dialysis BUN samples should be drawn immediately prior to dialysis, using a technique that avoids dilution of the blood sample with saline or heparin. Post-dialysis BUN samples should be drawn using the Slow Flow/Stop Pump Technique that prevents sample dilution with recirculated blood and minimizes the confounding effects of urea rebound.

Numerator:

Number of facilities in denominator with written policies requiring post-dialysis blood urea nitrogen (BUN) sampling to be done using the slow-flow/stop pump technique (15-60 seconds after slowing or stopping blood flow) during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All dialysis facilities included in sample.

5. HD Adequacy CPM V:

Baseline Total Cell Volume Measurement of Dialyzers Intended for Reuse.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 11 - Baseline Measurement of Total Cell Volume (Evidence). If a hollow-fiber dialyzer is to be reused, the total cell volume (TCV) of that hemodialyzer should be measured prior to its first use. Batch testing and/or use of an average TCV for a group of hemodialyzers is not an acceptable practice.

Numerator:

Facilities in the denominator that during the reporting/study period, pre-volumed 100% of dialyzers intended for reuse. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All facilities in the sample that reuse dialyzers.

6. Peritoneal Dialysis (PD)Adequacy CPM I:

Measurement of Total Solute Clearance at Regular Intervals.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 4 - Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion). Both total weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 11 - Dialysate and Urine Collections (Opinion). Two to three total solute removal measurements are required during the first six months of peritoneal dialysis. (See Guideline 3.) After six months, if the dialysis prescription is unchanged:

a. Perform both complete dialysate and urine collections every four months; and

b. Perform urine collections every two months until the renal weekly K_rt/V_{urea} is <0.1. Thereafter, urine collections are no longer necessary, as the residual renal function contribution to total Kt/V_{urea} becomes negligible. (See Guideline 5.)

Numerator:

Number of patients in denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year, and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

7. PD Adequacy CPM II:

Calculate Weekly Kt/V_{urea} and Creatinine Clearance in a Standard Way.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 4 - Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion). Both total weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 6 - Assessing Residual Renal Function (Evidence). Residual renal function (RRF), which can provide a significant component of total solute and water removal, should be assessed by measuring the renal component of Kt/V_{urea} (K_rt/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance.

PD Adequacy Guideline 9 - Estimating Total Body Water and Body Surface Area (Opinion).

V (total body water) should be estimated by either the Watson or Hume method in adults using actual body weight.

Watson method:

For Men: V (liters) = 2.447 + 0.3362*Wt(kg) + 0.1074*Ht(cm) - 0.09516*Age(years)

For Women: V = -2.097 + 0.2466*Wt + 0.1069*Ht

Hume method:

For Men: V = -14.012934 + 0.296785*Wt + 0.192786*Ht

For Women: V = -35.270121 + 0.183809*Wt + 0.344547*Ht

BSA should be estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method using actual body weight.

For all formulae, Wt is in kg and Ht is in cm:

DuBois and DuBois method: $BSA\ (m^2) = 71.84*Wt^{0.425}*Ht^{0.725}$

Gehan and George method: $BSA\ (m^2) = 0.0235*Wt^{0.51456}*Ht^{0.42246}$

Haycock method: $BSA\ (m^2) = 0.024265*Wt^{0.5378}*Ht^{0.3964}$

Numerator:

The number of patients in denominator with all of the following:

a. Weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} used to measure delivered PD dose; and

b. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} (K_ft/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance: and

c. Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

   *negligible = < 200 cc urine in 24 hours.

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

8. PD Adequacy CPM III:

Delivered Dose of Peritoneal Dialysis.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 15 - Weekly Dose of CAPD (Evidence). For CAPD, the delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.0 per week and a total creatinine clearance (C_{Cr}) of at least 60 L/week/1.73 m^2.

PD Adequacy Guideline 16 - Weekly Dose of NIPD and CCPD (Opinion). For NIPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.2 and a weekly total creatinine clearance of at least 66 L/1.73 m^2. For CCPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.1 and a weekly total creatinine clearance of at least 63 L/1.73 m^2.

Numerator:

a. For CAPD patients in the denominator, the delivered PD dose was a weekly Kt/V_{urea} of at least 2.0 and a weekly C_{Cr} of at least 60 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

b. For cycler patients in the denominator without a daytime dwell, the delivered PD doses was a weekly Kt/V_{urea} of at least 2.2 and a weekly C_{Cr} of at least 66 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

c. For cycler patients in the denominator with a daytime dwell, the delivered PD doses was a weekly Kt/V_{urea} of at least 2.1 and a weekly C_{Cr} of at least 63 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

9. Vascular Access CPM I:

Maximizing Placement of Arterial Venous Fistulae (AVF).

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 29A - Goals of Access Placement-Maximizing Primary Arterial Venous Fistulae (Opinion). Primary arterial venous fistulae (AVF) should be constructed in at least 50% of all new patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have a native AV fistula. (See Guideline 3, Selection of Permanent Vascular Access and Order of Preference of AV Fistulae.)

Numerator:

a. The number of incident patients in the denominator who were dialyzed using an AVF during their last HD treatment during reporting/study. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of prevalent patients in denominator who were dialyzed using an AVF during their last HD treatment during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

a. Incident adult (greater than or equal to 18 years old) HD patients in sample who were on HD continuously during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. Prevalent adult (greater than or equal to 18 years old) HD patients in sample who were on HD continuously during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

10. Vascular Access CPM II:

Minimizing Use of Catheters as Chronic Dialysis Access.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 30A - Goals of Access Placement-Use of Catheters for Chronic Dialysis (Opinion). Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

Numerator:

The number of patients in the denominator who were dialyzed with a chronic catheter continuously for 90 days or longer prior to the last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) patients in the sample who were on HD continuously during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

11. Vascular Access CPM III:

Preferred/Non-Preferred Location of Hemodialysis Catheters Located above the Waist.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 5B - Type and Location of Tunneled Cuffed Catheter Placement (Evidence). The preferred insertion site for tunneled cuffed venous dialysis catheters is the right internal jugular vein. Other options include: the right external

jugular vein, the left internal and external jugular veins, subclavian veins, femoral veins, or translumbar access to the inferior vena cava. Subclavian access should be used only when jugular options are not available. Tunneled cuffed catheters should not be placed on the same side as a maturing arterial venous access, if possible.

Vascular Access Guideline 6D - Acute Hemodialysis Vascular Access-Noncuffed Catheters (Evidence). The subclavian insertion site should not be used in a patient who may need permanent vascular access.

Numerator:

a. The number of patients in denominator who used a jugular vein catheter as dialysis access at their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of patients in the denominator who used a subclavian vein catheter as dialysis access at their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) patients who were on HD continuously during reporting/study period and who were dialyzed through a catheter during their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

12. Vascular Access CPM IV:

Monitoring Arterial Venous Grafts for Stenosis:

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 10 - Monitoring Dialysis AV Grafts for Stenosis (Evidence/Opinion).

Physical examination of an access graft should be performed weekly and should include, but not be limited to, inspection and palpation for pulse and thrill at the arterial, mid, and venous sections of the graft (Opinion). Dialysis arterial venous graft accesses should be monitored for hemodynamically significant stenosis. The DOQI Work Group recommends an organized monitoring approach with regular assessment of clinical parameters of the arterial venous access and dialysis adequacy. Data from the monitoring tests, clinical assessment, and dialysis adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each dialysis center as part of a Quality Assurance/

Continuous Quality Improvement (QA/CQI) program (Opinion). Prospective monitoring of arterial venous grafts for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis (Evidence). Techniques, not mutually exclusive, that can be used to monitor for stenosis in arterial venous grafts include:

a. Intra-access flow (Evidence)

b. Static venous pressures (Evidence)

c. Dynamic venous pressures (Evidence)

Other studies or information that can be useful in detecting arterial venous graft stenosis include:

d. Measurement of access recirculation using urea concentrations (See Guideline 12.) (Evidence)

e. Measurement of recirculation using dilution techniques (nonurea-based) (Evidence)

f. Unexplained decreases in the measured amount of hemodialysis delivered (URR, Kt/V) (Evidence)

g. Physical findings of persistent swelling of the arm, clotting of the graft, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft (Evidence/Opinion)

h. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow (Evidence/Opinion)

i. Doppler ultrasound (Evidence/Opinion)

Persistent abnormalities in any of these parameters should prompt referral for venography(Evidence).

Numerator:

The number of patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis during reporting/study period by one of the following methods and with the stated frequency:

a. Color-flow Doppler at least once every 3 months;

b. Static venous pressure at lease once every 2 weeks;

c. Dynamic venous pressure every HD session;

d. Dilution technique at least once every 3 months.

Denominator:

All adult (greater than or equal to 18 years old) patients who were on HD continuously during reporting/study period and who were dialyzed through an arterial venous graft during their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

13. Anemia Management CPM I:

Target Hemoglobin for Epoetin Therapy

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 4 - Target Hemoglobin (hgb) for Epoetin Therapy (Evidence/Opinion). The target range for hemoglobin should be 11 g/dL - 12 g/dL (Evidence). This target is for Epoetin therapy and is not an indication for blood transfusion therapy (Opinion).

Numerator:

Number of patients in denominator with documented mean hgb of 11-12gm/dL during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year; and for PD patients, October, November, and December of each year and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) HD or PD patients in sample, exclude patients with mean hgb greater than or equal to 12 who are not prescribed Epoetin at any time during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year; and for PD patients, October, November, and December of each year and January, February, March of the following year.)

14. Anemia Management CPM IIa:

Assessment of Iron Stores among Anemic Patients or Patients Prescribed Epoetin.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 5 - Assessment of Iron Status (Evidence). Iron status should be monitored by the percent transferrin saturation (TSAT) and the serum ferritin.

Anemia Management Guideline 6A - Target Iron Level (Evidence). Chronic renal failure patients should have sufficient iron to achieve and maintain a hgb of 11 to 12 g/dL.

Anemia Management Guideline 7A - Monitoring Iron Status (Opinion). During the initiation of Epoetin therapy and while increasing the Epoetin dose in order to achieve an increase in hematocrit/hemoglobin, the TSAT and the serum ferritin should be checked every month in patients not receiving intravenous iron, and at least once every 3 months in patients receiving intravenous iron, until target hematocrit/hemoglobin is reached.

Anemia Management Guideline 7B - Monitoring Iron Status (Opinion). Following attainment of the target hematocrit/hemoglobin, TSAT and serum ferritin should be determined at least once every 3 months.

Numerator:

a. The number of HD patients in the denominator with at least one documented TSAT and ferritin result every 3 months.

b. The number of PD patients in the denominator with at least two documented TSAT and ferritin result every 6 months.

Denominator:

a. All adult (greater than or equal to 18 years) HD patients included in sample, excluding patients with hgb > 12 for all 3 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. All adult (greater than or equal to 18 years) PD patients included in sample, excluding patients with hgb > 12 for all 6 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.) [Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

15. Anemia Management CPM IIb:

Maintenance of Iron Stores-Target.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 6B - Target Iron Level (Evidence). To achieve and maintain target hgb of 11-12 g/dL, sufficient iron should be administered to maintain a transferrin saturation (TSAT) of 20%, and a serum ferritin level of 100 ng/mL.

Numerator:

a. The number of HD patients in the denominator with at least one documented TSAT result 20% and at least one documented ferritin result 100 ng/mL during a 3 month period.

b. The number of PD patients in the denominator with at least one documented TSAT result 20% and at least one documented ferritin result 100 ng/mL during a 6 month period.

Denominator:

a. All adult (greater than or equal to 18 years old) HD patients included in sample, excluding patients with hgb > 12 for all 3 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. All adult (greater than or equal to 18 years old) PD patients included in sample, excluding patients with hgb > 12 for all 6 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.) [Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

16. Anemia Management CPM III:

Administration of Supplemental Iron

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 8A - Administration of Supplemental Iron (Evidence). Supplemental iron should be administered to prevent iron deficiency and to maintain adequate iron stores so that chronic renal failure patients can achieve and maintain a hgb of 11 to 12 g/dL in conjunction with Epoetin therapy.

Anemia Management Guideline 8C - Administration of Supplemental Iron (Evidence/Opinion).

The adult pre-dialysis, home hemodialysis, and peritoneal dialysis patient may not be able to maintain adequate iron status with oral iron. Therefore, 500 to 1000 mg of iron dextran may be administered intravenously in a single infusion, and repeated as needed, after an initial one-time test dose of 25 mg.

Anemia Management Guideline 8D - Administration of Supplemental Iron (Opinion/Evidence). A trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain the transferrin saturation (TSAT) $\geq$ 20%, serum ferritin $\geq$ 100 ng/mL, and hgb at 11-12 g/dL.

Anemia Management Guideline 8G - Administration of Supplemental Iron (Opinion/Evidence). Most patients will achieve a hgb 11 to 12 g/dL with TSAT and serum ferritin levels < 50% and < 800 ng/mL, respectively. In patients in whom TSAT is 50% and/or serum ferritin is 800 ng/mL, intravenous iron should be withheld for up to three months, at which time the iron parameters should be re-measured before intravenous iron is resumed. When the TSAT and serum ferritin have fallen to 50% and 800 ng/mL, intravenous iron can be resumed at a dose reduced by one-third to one-half.

Anemia Management Guideline 8H - Administration of Supplemental Iron (Opinion). It is anticipated that once optimal hematocrit/hemoglobin and iron stores are achieved, the required maintenance dose of intravenous iron may vary from 25 to 100 mg/week for hemodialysis patients. The goal is to provide a weekly dose of intravenous iron in hemodialysis patients that will allow the patient to maintain the target hematocrit/hemoglobin at a safe and stable iron level. The maintenance iron status should be monitored by measuring the TSAT and serum ferritin every three months.

Numerator:

a. The number of HD patients in denominator prescribed intravenous iron in at least one study/reporting month. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of PD patients in denominator prescribed intravenous iron in at least two study/reporting months. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

a. All adult (greater than or equal to 18 years old) HD patients included in sample if first monthly hgb < 11 g/dL for at least 1 month out of 3 month period or prescribed Epoetin at any time during reporting/study period regardless of hgb level, with at least one TSAT < 20% or at least one ferritin < 100 ng/mL. **EXCLUDE** patients with TSAT $\geq$ 50% or ferritin $\geq$ 800 ng/mL and **EXCLUDE** patients in first 3 months of dialysis and prescribed oral iron.

b. All adult (greater than or equal to 18 years old) PD patients included in sample if first monthly hgb < 11 g/dL for at least 1 month out of 3 month period or prescribed Epoetin at any time during reporting/study period regardless of hgb level, with at least one TSAT < 20% or at least one ferritin < 100 ng/mL. **EXCLUDE** patients with TSAT $\geq$ 50% or ferritin greater than or equal to 800 ng/mL and **EXCLUDE** patients in first three months of dialysis and prescribed oral iron.

Exhibit 5-2 - Annual Estimate of Patient Sample Per Network for USRDS Special Studies

(Rev. 1, 07-11-03)

Network	Number of Patients
1	326
2	658
3	390
4	440
5	521
6	742
7	515
8	498
9	532
10	389
11	500
12	289
13	359
14	664
15	328
16	202
17	412
18	637

Exhibit 5-3 - ESRD Network - Project Idea Document (PID) Format

(Rev. 1, 07-11-03)

ESRD Network Number:

ESRD Network Name:

Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a CMS priority area or preapproved as instructed in the Network SOW §C.2.C and §40.1 in this manual).

C. Network Project Contact Person

D. Network Epidemiologic Consultant (must be involved in project idea document and narrative project plan according to Network SOW §C.4.C) and §40.2 in this manual).

E. Regional Project Officer

F. Regional Scientific Advisor

G. Current Date

H. Initial Project Idea Document (PID) Submission date

I. PID Revision Number _____

II. Objectives (see §40.3 for additional information and instructions for completing the Project Idea Document - please limit the PID to 3 pages maximum).

A. Clearly state the national ESRD CMS priority topic that will be addressed in the project.

B. Outline:

1. The immediate process and/or outcome objectives and goals;

2. The clinical processes and the related clinical outcomes to be measured and improved in this project; and

3. The long term goals and impact of the project.

C. List:

1. The quality indicators;

2. The CPM (s) to be used in measuring the listed processes and outcomes; and

3. All other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project.

III. Background

Opportunity for improvement - outline the size, severity and consequences of the problem in the Network. Identify sub-regions affected. Outline the potential for change. Which groups are targeted for improvement? Who would need to accept change in behavior to improve performance for both processes and outcomes? In general, what magnitude of improvement is expected? Indicate if prior projects or studies exist. Indicate the magnitude of improvement realized.

IV. Methods (refer to §40.1 for topics to highlight)

Summarize:

- The methods to be utilized;
- The data to be used;
- The interventions to be used;
- The comparison or control group to be used, and
- The feasibility and risks.

V. Results

Summarize the expected results.

VI. Appendices

A. Bibliography

B. Description of potential data collection, abstraction, analysis, and evaluation instruments

C. Other, miscellaneous information

Exhibit 5-4 - ESRD Network - Narrative Project Plan (NPP) Format

(Rev. 1, 07-11-03)

ESRD Network Number:

ESRD Network Name:

Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a CMS priority area or preapproved as instructed in the Network Statement of Work (SOW) §C.2.C and §40.1 in this manual).

C. Network Project Contact Person

D. Network Epidemiologic Consultant (must be involved in project idea document and narrative project plan according to Network SOW §C.4.C. and §40.2).

E. Regional Project Officer

F. Regional Scientific Advisor

G. Current Date

H. Initial Narrative Project Plan (NPP) Submission Date

I. NPP Revision Number ____

II. Objectives (see §40.4 for additional information and instructions for completing the Narrative Project Plan (NPP)).

A. Clearly state the national ESRD CMS priority topic that will be addressed in the project. If the regional office has preapproved a non-priority project area please indicate here.

B. Immediate Process and/or Outcome Objectives and Goals - describe the specific clinical processes and the specific related clinical outcomes to be measured and improved in this project. Describe the long term goals and impact of the project.

C. Quality indicators - list the CPM (s) to be used in measuring the listed processes and outcomes. List all other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project. These quality indicators must relate directly to the processes and outcomes of this project as found in §II.B.

D. Define "improvement" in quantitative terms as they relate to each project-specific process and outcome indicator.

III. Background

A. Opportunity for improvement - describe the size, severity and consequences of the problem in the network area.

B. Potential for change - what factors come together to allow and enable the Network to work effectively with the dialysis population and the providers for this project. Which specific groups are targeted for improvement? Who would need to accept change in behavior to improve performance for both processes and outcomes? In general, what magnitude of improvement is expected?

C. Prior projects or studies - are there any previous projects (Networks, Peer Review Organizations, providers, etc.) that attempted to improve performance in these areas? What was the magnitude of improvement?

IV. Methods

A. Quality Indicators (please refer to the CPM definitions in Exhibit 5-1.)

1. Process measure indicators (formulas)

a. Numerator

b. Denominator

2. Outcome measure indicators (formulas)

a. Numerator

b. Denominator

B. Project Setting

1. Describe and enumerate the clinical settings to be included (dialysis centers, physician offices, hospitals, etc.).

2. Describe the size of population of beneficiaries involved in the project (i.e., experiences the intervention).

C. Study design

1. Describe the type of study design and the analyses to be used to determine changes or improvements from baseline.

2. Describe control or comparison groups considered or included to help gauge actual impact of interventions versus secular trends.

D. Data

1. Sources - describe the specific source of the data, the specific data elements to be utilized in the analyses as described above, details behind the collection of the data, and the accuracy/validity of the data.

2. Collection methods - describe in detail the method, tools (existing or developed), and timelines required to collect the data for this project. Indicate proposed pre- and field-testing of data collection instruments. All questionnaires or surveys must be pre-reviewed and approved by CMS.

3. Case selection

a. Definition of cases eligible/ideal for project;

b. Sample size, sampling frame, sampling strategy, biostatistical power calculations (if sampled).

E. Intervention

1. Description - provide a summary of the projects proposed intervention plan, including;

a. General description of intervention(s)/intervention arms;

b. Indicators used for tracking the progress of the intervention (if different from the project's quality indicators);

c. Settings;

d. Target population;

e. Intervention type;

f. Timetable; and

g. Evaluation (i.e., was the intervention implemented properly).

2. Discuss the objectives for behavior changes in various target audiences for this project.

F. Feasibility and Risk

1. Estimate overall length of time that intervention activities are estimated to require.

a. Discuss labor-intensity, political sensitivity, resource requirements, and complexity;

b. Discuss the potential impact of these issues on the success of the project.

2. Estimate the total cost of the project.

3. Discuss the potential generalizability of this project to similar target populations. Assess the likelihood that the intervention effect is likely to be sustained beyond the implementation period.

V. Results (to be entered as project is implemented)

A. Present baseline measurement results for all indicators using appropriate and clear methods (tables, graphs, etc.).

B. Present interim results for all process or outcome indicators that were proposed in the methods section.

C. Present follow-up measurement results in a manner consistent with the baseline results.

D. Present an outcome or impact evaluation of project success based on the analyses proposed and the quantitative targets for improvement as found in the proposal. Typically these include two dimensions.

1. Absolute or relative improvements (RFRs) from baseline in performance as intended by the planned remeasurement of quality indicators; and

2. Comparison of these results to the change in quality indicator results from the comparison group(s). These biostatistical analyses shall be proposed and explained in the NPP prior to approval.

VI. Conclusions and Discussion

A. Conclusions based on results (see §V of the NPP). Was the project successful - if not, why not.

B. Limitations of project findings. What were these limitations?

C. Overall evaluation of project.

VII. Appendices

A. Bibliography.

B. Data collection forms (provide separately, if necessary).

C. Publications or reports.

D. Data collection, abstraction, analysis, and evaluation instruments.

E. Other, Miscellaneous.

Exhibit 5-5 - ESRD Network - Final Project Report Format

(Rev. 1, 07-11-03)

This report should be prepared much like an article for publication. Please limit to 6 pages, single spaced lines (unless otherwise directed).

Sections:

- Organization and authors of report/project staff
- Abstract or Executive Summary of entire project (maximum one page)
- Introduction and objectives (specify quality indicators and targeted improvements)
- Methods (describe analyses and other evaluations)
- Results (see §V of the NPP, describe changes in QIs and contrast results from comparison or control group)
- Conclusions (see §VI of the NPP, describe the extent of success, and likely causes of deviations from target goals and objectives)

Medicare ESRD Network Organizations Manual

Chapter 4 - Information Management

Table of Contents

10 - Background/Authority

(Rev. 1, 07-11-03)

ENO 400

Data collected and maintained by End Stage Renal Disease (ESRD) Network Organizations and reports generated by the Networks are governed by §§1157, 1160 and 1881(c)(8) of the Social Security Act (the Act) as amended, and by regulations at 42 CFR 405.2112(j) and 42 CFR Part 480.

The Network is required to perform the data management and reporting activities listed in its Statement of Work using the Standard Information Management System (SIMS) developed to fulfill its data processing, information management, and reporting contractual requirements to CMS. The CMS will be replacing the current Renal Beneficiary and Utilization System (REBUS), used to update the Program Management and Medical Information System (PMMIS) Database for the ESRD program. The new system will be named the Renal Management Information System (REMIS). The Network will be required to use REBUS/REMIS as directed by CMS.

20 - Responsibilities

(Rev. 1, 07-11-03)

ENO 405

The Network's responsibilities for data processing, information management, and reporting include the following:

- To have sufficient system capacity and the appropriate computer hardware and software to carry out its contractual responsibilities;
- To effectively manage the collection, validation, storage, and use of data, including data provided by CMS, for review, profiling, pattern analysis, and

sharing with CMS and the State survey agency for use in their ESRD Medicare survey and certification activities;

- To ensure timely and accurate reporting by the facilities/providers;
- To maintain and ensure the integrity and accuracy of ESRD patient and facility databases;
- To ensure the quality and accuracy of the data submitted to CMS for inclusion in the ESRD PMMIS and the United States Renal Data System (USRDS); and
- To ensure current patient status is reported to CMS in a timely manner for appropriate enrollment and disenrollment into the Medicare program for ESRD benefits.

30 - System Capacity

(Rev. 1, 07-11-03)

ENO 410

The Network must maintain a system that provides the capacity to meet its contractual responsibilities for data collection, validation, entry, retrieval, profiling, analysis, reporting, and electronic data interchange. The system, at a minimum, shall utilize and consist of the following:

- SIMS software, and program documentation, for the entry and transmission of the CMS ESRD forms (described later in this section);
- CMS-approved software for the entry and transmission of the clinical performance measures (see Chapter 5 of this manual);
- Office automation software compatible with the CMS standard;
- Internet-capable electronic mail capability compatible with CMS, including the ability to send and receive attachments;
- Host on Demand 3270 Terminal Emulation Application via CMS Intranet;
- CMS-compatible Web browser access for connection to REMIS;
- CMS-supplied or other statistical software for data analysis and profile analysis, including profiling patients and facilities by county, to facilitate disaster planning and other studies;
- Provisions for disaster recovery of the databases and data system; and
- Sufficient hardware to run the above software applications.

40 - Hardware/Software (HW/SW) Requirements

(Rev. 1, 07-11-03)

ENO 420

All HW/SW necessary for the ESRD Standard Information Management System (SIMS), as determined by CMS, must be purchased through the Quality Improvement Organization (QIO) Standard Data Processing System (SDPS) Contractor, the Iowa Foundation for Medical Care, Inc. (IFMC). In the event the Network requires additional HW/SW, the Network's request must be made and approved through the SDPS Engineering Review Board (ERB) process:

- Complete an ERB Request Template. See Exhibit 4-1- Engineering Review Board (ERB) Request Template (Hardware Information) and Exhibit 4-2 - Software Information, for the appropriate ERB Request Template.)
- Submit the completed template and documentation to the ERB (IFMC).
- The ERB will review the request and make its recommendation to the CMS Project Officer (PO).
- The CMS PO will assess the request. The Network will be notified of the decision through receipt of a copy of the ERB Request Template and, if approved, the Network will receive instructions for purchasing the requested HW/SW.

50 - CMS Computer Systems Access

(Rev. 1, 07-11-03)

ENO 425

After the award of the contract, if the Network requires access to CMS data systems, the Network must contact the CMS PO to obtain user identification (ID) and a password. If the individual assigned the user ID and password for the CMS data systems changes, submit the name of the replacement individual to the CMS PO using the form shown in Exhibit 4-3.

60 - Data Security

(Rev. 1, 07-11-03)

ENO 430

Comply with the requirements found at 42 CFR 480.115; in OMB Circular A-130, "Management of Federal Information Resources;" CMS AIS Guide, "Systems Security Program Standards and Guidelines Handbook;" and the Privacy Act of 1974, 5 USC 552a. If the Network needs a copy of these documents, it must contact the PO.

70 - Confidentiality of Data

(Rev. 1, 07-11-03)

ENO 435

All data provided to the Network by CMS and all reports containing confidential data prepared by the Network for CMS are considered confidential and may not be disclosed to other than the appropriate Network board(s), committee(s), and its administrative staff. As a result of §6219(b) of the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) (December 19, 1989), the confidentiality of data requirements found at 42 CFR 480 also apply to ESRD Networks. Section 1881 specifies that the provisions of §§1157 and 1160 must apply with respect to Networks (including medical review boards). Comply with all applicable CMS confidentiality and disclosure policies and regulations found at 42 CFR Part 480 Subpart B, including 42 CFR 480.101, 480.102(c), 480.103 - 480.109, 480.115, 480.116, 480.120, 480.121, 480.130 - 480.134, 480.135 (a), (b) and (c), 480.137 - 480.143. (See Chapter 3 of this manual.)

80 - Database Management

(Rev. 1, 07-11-03)

ENO 440

Maintain patient and facility databases containing the minimum/critical data elements outlined in SIMS and perform various tasks related to these databases.

80.1 - Patient Database - Minimum/Critical Data Elements

(Rev. 1, 07-11-03)

ENO 440.1

Maintain the critical data elements required by SIMS.

A. General Information

Provide the following information on all ESRD patients:

- Social security number;
- Health insurance claim number;
- Date of birth;
- Sex;

- Race;
- Ethnicity;
- First name;
- Last name;
- State or ZIP code of residence;
- Patient employment status (from medical evidence form); and
- Medical coverage (from medical evidence form).

B. Event(s) Information

An event is a major change in the patient's ESRD history such as modality shift; facility transfer; transplant, first, second; graft failure (failures), first, second; recovered function; discontinued dialysis; death; etc.

1. For All Events - Provide the following information:
    a. Type of event - use the following definitions to determine type of event:
        - Dialysis after transplant - when a patient restarts dialysis therapy after a kidney transplant failure.
        - Discontinue - when a patient discontinues ESRD therapy voluntarily or by physician's recommendation.
        - Loss to follow-up - report a patient's loss to follow-up if the facility is absolutely sure that no provider treats this patient. This event should be used sparingly.
        - Modality shift - when a patient changes his/her modality of treatment (e.g., from in-center hemodialysis to home continuous ambulatory peritoneal dialysis (CAPD)).
        - New ESRD patient - a patient who has been diagnosed with chronic renal disease and has never been on dialysis. A Form CMS-2728 form is initiated for Medicare eligibility as well as registration in the ESRD program. This also includes a transplant patient who never dialyzed prior to transplantation.
        - Recover function - when a patient regains renal function and is able to survive without ESRD therapy.
        - Restart - patient who resumes dialysis after he/she discontinued dialysis and/or recovered kidney function.
        - Transfer in - occurs when a patient, previously dialyzing as an outpatient in another approved renal facility, transfers to a new

facility within or out of the Network area. The transferring unit must provide a copy of the patient's Form CMS-2728 form to the new facility.

- Transfer out - when a patient transfers from one outpatient chronic dialysis facility to another.
- Transfer out for transplant - when a dialysis patient leaves the dialysis unit for a kidney transplant at an approved renal transplant center.
- Transplant - when a patient receives a kidney transplant.
- Transplant failure - when the patient's transplanted kidney no longer functions and there is a need to resume dialysis on a regular basis.

b. Date of event; and

c. Provider at the time event occurred.

2. Patient Transfer Events - For transferred patients, provide the following information: (A patient must be receiving services in the Network area for at least 6 months to be considered a transfer; otherwise, the patient is considered a transient.)

    a. Date of most recent transfer into Network area;

    b. Date of most recent transfer out of Network area; and

    c. Previous State of residence (if known).

3. Historic Information - If the patient began services in one Network (Network A), then transferred to another Network (Network B), then Network B must obtain the information below from the prior servicing Network or from SIMS:

    a. Date regular dialysis began;

    b. Initial provider number (provider at time of onset, if known);

    c. Primary cause of renal failure;

    d. Initial patient residence ZIP code and State; and

    e. Initial modality.

4. Death Information - Provide the following:

    a. Date of death;

    b. Cause of death; and

    c. Provider submitting death information.

C. Physician and Insurance Information

Provide the following information:

1. Dialysis Physician's Universal Physicians Identification Number (UPIN) - Provide the most recent dialysis physician's UPIN (if known); and/or
2. Transplant Physician's UPIN - Provide the most recent transplant physician's UPIN (if known).

80.2 - Patient Database Updates

(Rev. 1, 07-11-03)

ENO 440.2

The Network updates its patient database (or elements in its patient database) on a regular basis to the SIMS central repository.

The CMS may ask the Network to submit its patient database (some or all patients) to its designee for use in selecting patients for the annual Clinical Performance Measures (CPMs) data collection effort. The Network's patient database is due to CMS's designee within 30 calendar days of the request.

80.3 - CMS-Directed Changes to the Network Patient Database

(Rev. 1, 07-11-03)

ENO 440.3

Monthly, if applicable, CMS will notify the Network to make changes to important data elements in its patient database. The Network updates its database with validated changes (e.g., beneficiary name, date of birth, Health Insurance Claim Number and Beneficiary Identification Code) contained in the Social Security Master File, PMMIS, and Provider Certification databases. The CMS will provide these changes to the Network either by hardcopy or electronically through REBUS/REMIS. The Network advises CMS, in writing, of any outstanding discrepancies related to these notifications. (See Exhibit 4-4 for a Sample Notification of Data Element Changes Report.)

80.4 - Facility Database - Minimum Data Elements

(Rev. 1, 07-11-03)

ENO 440.4

At least monthly, the Network maintains and updates in its facility database the following data elements for each facility in its network area that provides dialysis or transplant services:

- Provider number;
- Name, mailing and physical address, and phone number;
- County name where facility is physically located;
- Names of key staff (medical director, administrator, head nurse);
- Facility ownership type (profit, nonprofit);
- Chain organization (Y/N);
- Chain/Corporate affiliation;
- Shifts starting at 5:00 PM or later (Y/N);
- Number of stations (as self reported by the facility); and
- Modalities offered (hemodialysis, peritoneal dialysis, and/or home training; as self-reported by the facility).

80.5 - Submission of Facility Database Elements

(Rev. 1, 07-11-03)

ENO 440.5

Through SIMS, maintain a facility database containing the minimum data elements listed in §80.4. Update the SIMS central repository on an ongoing basis, based upon data or information received from the facilities.

The CMS has the capacity to create data files and labels from the SIMS central repository. Beginning February 2001, CMS will create a monthly file for the "Dialysis Facility Compare" (see http://www.medicare.gov/Dialysis/Home.asp).

Other organizations or individuals may ask the Network to generate and submit mailing labels of facility listings/rosters either electronically or by hardcopy. The Network may negotiate with them the time frame for completion.

By October 31 of each contract year, verify provider data for the "National Listing of Medicare Providers" directly into SIMS. Corrections to provider data for this national listing must be uploaded to the central repository by October 31 of each year.

90 - ESRD Data and Reporting Requirements

(Rev. 1, 07-11-03)

ENO 445

Exhibit 4-5 provides a summary of the data and reporting requirements, and the Network's responsibilities for processing forms and maintaining the data.

100 - CMS ESRD Forms

(Rev. 1, 07-11-03)

ENO 450

Medicare-approved providers of renal services must complete various nonpayment forms that the Secretary of HHS determines are appropriate for collection of data deemed necessary for inclusion in the ESRD PMMIS Database. Other data collection forms may be submitted voluntarily, as indicated on the form.

100.1 - CMS ESRD Program Forms

(Rev. 1, 07-11-03)

ENO 450.1

These forms contain patient specific information necessary for the operation of the national ESRD program. Each ESRD facility and provider in the network area will send the Network the following three CMS forms for use by the Network, CMS, SSA, and the USRDS:

- Form CMS-2728-U3 - ESRD Medical Evidence Report, Medicare Entitlement, and/or Patient Registration (completed on each incident ESRD patient or each patient re-entering the Medicare program);
- Form CMS-2744 - ESRD Facility Survey (completed annually); and
- Form CMS-2746 - ESRD Death Notification or facility generated Death-Notification Form (completed within 30 days after the death of the patient).

Dialysis and/or transplant facilities are required to submit the Medical Evidence Report (Form CMS-2728-U3) to the Network within 45 days from the date a patient is diagnosed with ESRD and either receives a transplant or starts a regular course of dialysis. This

form is also required if a patient loses Medicare coverage and is re-applying for Medicare benefits.

The Death Notification (Form CMS-2746) is due to the Network within 30 days of the date of death of the patient.

100.2 - CMS ESRD Clinical Performance Measures (CPMs) Data Forms

(Rev. 1, 07-11-03)

ENO 450.2

These forms contain patient specific clinical information necessary to calculate the ESRD CPMs. These data are currently collected on a sample of dialysis patients annually on a voluntary basis. Refer to Chapter 5, §60, of this manual for additional information. Selected dialysis facilities in the network area will send the Network the following forms (as applicable) on their patients included in the CPM annual sample:

- Form CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually on a sample of HD patients);
- Form CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually on a sample of PD patients); and
- Form CMS-821-A - Dialysis Facility Clinical Performance Measures Data Collection Form.

100.3 - CMS ESRD Beneficiary Selection Form

(Rev. 1, 07-11-03)

ENO 450.3

The CMS ESRD Beneficiary Selection form is completed by the provider, signed by the patient, and sent directly to the fiscal intermediary.

Form CMS-382 - ESRD Beneficiary Selection (completed only by Medicare patients who are dialyzing at home).

110 - Collection, Completion, Validation, and Maintenance of the ESRD CMS Forms

(Rev. 1, 07-11-03)

ENO 455

Ensure that all CMS ESRD forms listed in §100 are collected, completed, and validated according to the instructions in this section and the "ESRD Program Instruction Manual for Renal Providers" (IMRP). Perform the following tasks in order to fulfill Network data responsibilities for the ESRD forms:

- Provide adequate supplies of the ESRD Death Notification (Form CMS-2746) to providers within the Network's geographical area (unless the Network's facilities/providers are using their own software to generate the Death Notification Form or electronic records).

- Ask providers to obtain supplies of the ESRD Medical Evidence Report, Medicare Entitlement, and/or Patient Registration (Form CMS-2728-U3) through the local SSA field offices.

NOTE: If the facility cannot obtain these forms in a timely manner through its local SSA field office, provide an emergency supply. In addition, the Network may wish to provide start-up supplies to new facilities.

- Send supplies of the blank Facility Survey (Form CMS-2744) to facilities/providers in the network area. Download and print the form, which is in a PDF file format, from the Web site at http://www.cms.hhs.gov/esrd/2.asp. Facilities/providers can also be directed to the Web site. This form is completed once a year.

- Ensure that adequate written instructions for completing the forms, contained in the IMRP, and other information related to the forms are distributed to all providers as they are released from CMS.

- Distribute all CMS revisions to the IMRP to the facilities in its network area.

- Provide guidance, as needed, to the appropriate provider personnel about completion of the forms.

- Process the forms received as instructed in §§110.1-110.3.

NOTE: It is anticipated that the Vital Information System to Improve Outcomes in Nephrology (VISION) project will be rolled out during this contract period, with national implementation during calendar year 2002. Until electronic reporting is required from all dialysis facilities for all patients, it will be on a voluntary basis. The

Network's role in monitoring the accuracy and completeness of reports, and the validation of facility-level patient data are critical in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for crosschecking so facilities can query and detect unreported forms. As VISION is implemented, the activities specified in §§110.1-110.3 will need to be retained in a format that is consistent with migration from hard copy to electronic reporting.

110.1 - Processing Form CMS-2728-U3

(Rev. 1, 07-11-03)

ENO 455.1

Upon receipt of these forms in the Network's office, review the forms for completeness. Each form must provide the following data elements, required by SIMS. Any item not listed in SIMS is not a critical data element. (Critical elements are subject to change.) The data elements are listed by field number and item name.

- The following field numbers with corresponding item names must be completed on all ESRD patients:

    1. Patient's name (Last, First);
    2. Health Insurance Claim (HIC) Number; and/or;
    3. Social Security Number (SSN).

        - If the patient has had a transplant, check the PMMIS database to see if the Organ Procurement and Transplantation Network (OPTN) has assigned a "dummy" number. This number will usually have "9FN" in the first 3 positions. If so, use this number.
        - If a patient does not have a health insurance claim number, or a social security number, AND is not applying for Medicare benefits, and has not received a transplant, issue a "dummy" health insurance claim number and social security number using the following formula:

            Position 1 = X
            Positions 2-7 = Provider number of provider completing form
            Positions 8-9 = Sequential numbering
            Positions 10-11 (of HIC number) = ZZ

        - Use of this "dummy" number should be a rare occurrence and only used, for example, in the case of foreign nationals or

illegal aliens who generally do not have social security numbers.

4. Mailing address;
5. State and ZIP code of residence;
6. Date of birth;
7. Sex;
8. Ethnicity;
9. Race;
10. Medical coverage;
11. Is patient applying for ESRD Medicare coverage?
12. Primary cause of renal failure (ICD-9-CM code plus letter code from back of form);
13. Height, either in inches or centimeters;
14. Weight, either in pounds or kilograms; and
15. Patient employment status.
17. Was pre-dialysis/transplant EPO administered?

18e. Serum creatinine (mg/dl) and date of test; or

18f. Creatinine clearance (ml/min) and date of test.

- The following data elements must be provided if form was prepared in connection with the patient commencement of dialysis:

20. Medicare provider number and provider name;
21. Primary dialysis setting;
22. Primary type of dialysis;
23. Date regular dialysis began; and
24. Date patient started at current facility.

- The following data elements must be provided if form was prepared because the patient received a kidney transplant:

27. Date of transplant;
29. Medicare provider number; and
33. Current status of transplant

- The following data elements must be provided if form was prepared because the patient is applying for waiver of qualifying period based on self-dialysis training provisions of the Social Security Act:

    37. Medicare provider number of training facility;

    38. Date training began;

    39. Type of training;

    40. Patient expected to complete (or has completed) training and will self-dialyze on a regular basis;

    41. Date when patient completed, or is expected to complete, training; and

    43. UPIN of physician personally familiar with patient's training.

- The following data elements must be provided if form was prepared because the patient is applying for Medicare entitlement based on early transplant procedures:

    30. Date patient admitted; and

    32. Provider number.

- The following data elements must be provided for all forms:

    46. UPIN of attending physician;

    47. Attending physician's signature of attestation (stamp is not acceptable.); and

    48. Date physician signed form.

Facilities must submit the Medical Evidence Report within 45 days after either a transplant or the start of a regular course of dialysis (whichever occurs first).

NOTE: The start of a regular course of dialysis is defined as the date of the first dialysis treatment after the physician has determined that the patient has ESRD and has written a prescription for a "regular course of dialysis" regardless of the dialysis setting and regardless of any acute treatments received prior to the implementation of the prescription.

If the critical data described above are not present, return the form to the provider, within one week of receipt, for completion of these data. Prior to returning the form, the Network may key and hold this form in SIMS until all mandatory data have been entered.

Enter the data from the form into SIMS. Subject each form to a clinical algorithm to determine if the patient meets the definition of ESRD.

After data entry of the form is complete, the Network will receive an edit exception report describing the status of this medical evidence form.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, retain these forms for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, for patient privacy purposes, any forms that are patient-specific and are not maintained for the Network's use, or as documentation of actions specified above.

110.2 - Processing Form CMS-2746 (ESRD Death Notification Form)

(Rev. 1, 07-11-03)

ENO 455.2

Upon receipt of these forms in the Network's office, review the forms for completeness. Each form must have the following data elements completed. Any item not listed is not a critical data element.

- The following required data elements are listed by field number and item name:

    1. Patient's last and first name;

    2. Patient's HIC number;

    3. Patient's sex;

    4. Patient's State of residence;

    5. Patient's date of birth;

    6. Patient's date of death;

    8. Provider number; and

    11. Primary cause of death.

Return to the provider, within one week of receipt, forms that are missing information for the critical data items or that contain inaccurate data for the critical data items.

Enter the data from the form into SIMS. Transmit the data on an ongoing basis directly to the CMS Data Center (CMSDC) using SIMS. After the data are transmitted to CMS, they will be added to the PMMIS after passing additional edits.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention

period, retain these forms for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, for patient privacy purposes, any forms that are patient-specific and are not maintained for the Network's use, or as documentation of actions specified above.

110.3 - Processing Form CMS-2744 (ESRD Facility Survey)

(Rev. 1, 07-11-03)

ENO 455.3

Form CMS-2744 is completed annually. Upon receipt of these forms in the Network office, review the forms for completeness. Each form must have all the pertinent data elements completed. Establish a mechanism to ensure that the number of forms submitted to CMS match the number of events reported on Form CMS-2744.

EXAMPLE: If a provider reports five deaths in a given year, the provider should have submitted five Form CMS-2746s or facility/provider generated death notification forms for that year as described in the IMRP.

Enter the data from the forms into SIMS. Transmit the data directly to the HDC using SIMS. After the data is transmitted to CMS, they will be added to the PMMIS after passing additional edits.

Submit hard copies and electronic copies, as directed by CMS, of the completed forms to CMS by the 5th working day of April of each year.

Transmit corrections to the survey data to CMS through SIMS by the third Friday of May of each year.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, such forms are to be retained for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, any forms that are not maintained for the Network's use, or as documentation of actions specified above.

120 - Tracking System for ESRD Forms

(Rev. 1, 07-11-03)

ENO 460

Maintain, through SIMS, a system to track receipt of the CMS ESRD forms from the facilities/providers to ensure that the forms are submitted timely and all critical data

fields, as listed in §110, are completed and are accurate. Instructions for determining timeliness and accuracy are contained in §130.

The Network develops a system to ensure that it can act upon any forms edit reports within two weeks of receipt. The two-week period includes the date(s) the Network returns the edit reports to CMS. The Network develops a system to track all forms that it returns to providers for correction. (See §140 for instructions for resolving discrepant records.)

130 - ESRD Forms Submission Compliance Rates

(Rev. 1, 07-11-03)

ENO 465

Semi-annually, through SIMS, track and profile facility and provider compliance rates for submitting timely, complete, and accurate Medical Evidence (Form CMS-2728-U3) and Death Notification (Form CMS-2746) forms or facility and provider generated death notification reports. Maintain compliance rate information on-site and make it available at CMS's request. The Network documents its attempts to contact providers to obtain missing forms and to correct discrepancies, and reports to the PO any problems encountered with individual provider compliance regarding forms reporting that are not rectified at the Network level.

Acceptable rates for timeliness and completeness/accuracy for each form type are noted below. Follow these instructions for notifying those facilities/providers with unacceptable semi-annual compliance rates and for providing each facility/provider with its annual compliance rates. The Network forwards a copy of the semi-annual and annual notifications to its PO.

A. Medical Evidence (Form CMS-2728-U3)

- Timeliness is defined as 45 days from the date the patient is determined to be end stage and has started regular chronic dialysis at that facility.
- Completeness and accuracy are defined as "all critical data fields are complete and accurate to the extent possible using logic and Network data to determine accuracy."

B. Death Notification (Form CMS-2746) or Facility/Provider Generated Death Notification Forms

- Timeliness is defined as 30 days from the date of death.
- Completeness and accuracy are defined as "all critical data fields are complete and accurate to the extent possible using logic and Network data to determine accuracy."

There are valid reasons why the Medical Evidence (Form CMS-2728) and Death Notification forms may not be submitted in a timely manner. For example, the Medicare ESRD-certified facility submitting Form CMS-2728 receives the patient 45 days after the patient first begins dialysis, or the patient dies outside of the facility's/provider's area and the facility/provider does not learn about the patient's death for more than 30 days after the patient died. Before a facility/provider is considered noncompliant with the timely submission of a form, determine why the form was late.

Timeliness is calculated by dividing the number of forms received late by the total number of forms received from the facility/provider for that month. The calculation only includes those forms that are due for the first time. If the resulting ratio is not within the bounds described below, the facility/provider will be deemed noncompliant.

Completeness and accuracy are calculated by dividing the number of forms that are in error (critical data elements are missing or are inaccurate; the critical data fields are found in §§110.1 and 110.2) by the total number of forms received from the facility/provider for that month. Do not divide by the number of errors on the form. The ratio must be within the bounds described below.

On a semi-annual basis, profile each facility's and provider's compliance rates for timeliness, completeness, and accuracy for each form type. Notify those facilities and providers that have a semi-annual average of greater than three forms (per-form-type) late and/or incomplete/inaccurate or a semi-annual average of greater than 20 percent of the forms (per-form-type) late and/or incomplete/inaccurate that they are at risk of being determined to be out of compliance.

On an annual basis, evaluate each facility's and provider's compliance rates for timeliness, completeness, and accuracy for each form type. Notify each facility/provider of its annual compliance rates.

The annual compliance rate activity is performed during the first quarter of the calendar year for all forms submitted during the prior year for Medicare patients. Each facility and provider is required to maintain an annual average compliance rate of 90 percent for timeliness, completeness, and accuracy.

If a facility and/or provider does not maintain the required annual average compliance rate, provide assistance to the facility to improve its performance. If the Network determines that the facility is not making reasonable attempt to improve its performance, prepare a sanction recommendation to the RO following the instructions in Chapter 7 of this Manual.

140 - CMS ESRD Forms Edit Reports and Data Corrections

(Rev. 1, 07-11-03)

ENO 470

After the Network transmits its monthly ESRD forms data to CMS (see §100), CMS subjects the data to edit checks. The CMS then generates an Edit Report describing any discrepancies found in the data. The Edit Report is sent monthly to the Network for research and resolution of any identified data discrepancies. The Network resolves the data discrepancies and enters the corrections in REBUS/REMIS within 60 calendar days of receipt of the Edit Report.

The CMS may detect other discrepancies when data is merged into the PMMIS. In these cases, CMS will send the Network additional Edit Reports for processing. The Network is responsible for researching and resolving all errors noted in the edit report. Instructions for processing the Edit Reports and resolving the data discrepancies are noted later in this section. If time allows, correct minor errors labeled "warnings." (See Exhibit 4-6 for a sample edit report.)

A. Resolving Discrepant Records

Using SIMS, transmit data from the ESRD CMS forms to the HDC on a regularly scheduled basis. When the data is received in the HDC, it is subjected to various edit checks. If the data from the form does not pass CMS's edit checks, CMS creates an edit report and sends the Network a form letter (see Exhibit 4-7) asking the Network to review, research, and resolve the discrepancies. All of the identifying characteristics on the incoming record must match those on the Medicare master record. Records that do not match are indicated as serious errors on the edit report, along with the statement, "Under investigation by CMS." If CMS's investigation fails to produce a matched record, the edit report will continue to show a serious error with the statement, "To be investigated by Network," until the Network provides the corrected information. For example, if the Network determines that erroneous data was generated because a patient is non-Medicare, enter this information on the appropriate REBUS/REMIS screen, so that the investigation may be terminated.

B. Correcting the Data

When resolving an error, make the changes directly in REBUS/REMIS, using the appropriate "Change Record" screens. Should the personal identifiers need to be modified the REBUS/REMIS "Refile" function should be used.

C. Error Messages

If an error is labeled as a "warning," it is not necessary to correct it. However, if the correct information is available, report it. Serious errors that indicate the record did not

match the Medicare master file, labeled, "To be investigated by Network," must always be investigated and resolved by transmitting the correct identifying information or determining whether the patient was a non-Medicare or non-ESRD Medicare patient.

D. Determining the Correct Medicare HIC Number

If the patient is deceased and was an ESRD patient, the correct Medicare HIC number is still required. In cases where the patient died shortly after the onset of renal failure, it is possible that Medicare entitlement was never established. If this is the case, report the patient as "non-Medicare" on the appropriate REBUS/REMIS screen. In some of these cases, the patient may have been previously enrolled in Medicare due to old age or disability. The CMS also needs to know whether a person was actually an ESRD patient as opposed to an acute renal failure patient (i.e., a patient who was placed on dialysis but who was expected to recover function from his/her native kidney (not a transplanted kidney)). If the person is definitely an ESRD patient, obtain a Medical Evidence Report and key it in on the next monthly REBUS/REMIS submission.

One way of determining a correct name/number is to ask the facility where the patient was, or is, being treated and to contact the billing office to obtain the correct Medicare HIC number, name, or information concerning the patient. The Network may also request the facility to send a copy of the patient's Medicare card to the Network. In the event that the patient is found to be non-Medicare, enter this fact on the appropriate REBUS/REMIS screen.

E. Other Incorrect Data Elements

In addition to the Medicare HIC number, one of several other data elements could be incorrect. All of these data elements are used to match a master record:

- Beneficiary Identification Code (BIC), which is the letter at the end of the claim number;
- Spelling of the surname;
- Date of birth;
- Sex; and
- First initial.

If any of these elements are different from the ones the providers report, enter the correction directly into REBUS/REMIS by using the "refile" function.

150 - Renal Transplant Data

(Rev. 1, 07-11-03)

ENO 475

The Organ Procurement and Transplantation Network (OPTN) is responsible for collecting kidney transplant data. The OPTN transmits data weekly, monthly, and quarterly. Weekly transmissions include data on the donor, renal candidate, transplant recipient, and immunosuppression information. Monthly transmissions include data on the donor, renal candidate, transplant recipient, follow-up information, waitlist information, immunosuppression and histocompatibility information, and deleted records. Quarterly transmissions include the type of data submitted monthly and any additional renal data. Access the transplant data from the OPTN through REBUS/REMIS. Instructions for using REBUS/REMIS are in the REBUS/REMIS Manual. The Network updates its database with the transplant data obtained from the OPTN via REBUS/REMIS. The Network uses this data to maintain status information on patients and in its quality assurance and improvement activities. Follow the instructions below for obtaining the renal transplant data from the OPTN.

The Network accesses the REBUS/REMIS system 60 days after the end of a quarter to obtain transplant data and transplant follow-up data to enter into and update its database.

A. For Transplant Data

The Network may know about transplants that have not been reported to the OPTN. Using the REBUS/REMIS system, the Network reports to CMS those patients known to it for whom the OPTN has not received transplant data. After receipt of unreported transplant information, the Network waits a minimum of 60 calendar days from the end of the quarter in which the transplant event occurred before entering the following basic patient information directly into REBUS/REMIS:

- Name;
- HIC (Medicare) Number;
- Date of transplant (obtained from the dialysis facility);
- Transplant provider number (obtained from the dialysis facility);
- Type of transplant (cadaver or living donor);
- If the patient is not on the CMS Master File, also enter the date of birth, sex, and State of residence. The CMS reports these transplants to the OPTN for research and follow-up; and
- If, when accessing transplant data in PMMIS, the Network notices that a data element is incorrect which may prevent the record from matching the Master File,

enter the correction(s) directly via REBUS/REMIS if possible, using the "Refile" facility.

B. For Transplant Follow-Up Data

The OPTN will attempt to obtain the renal transplant follow-up data for 6 months after the due date of the registration and follow-up report.

- Quarterly, the OPTN will provide the Network with a listing of those renal transplant recipient registration and renal recipient follow-up data forms it has been unsuccessful in obtaining.
- Quarterly, review the list of overdue renal transplant recipient registration and renal recipient follow-up forms and contact the applicable transplant center, in writing, and request that the center submit the missing data electronically to the OPTN. The OPTN will provide a second report of data submitted between each quarterly report of overdue forms.
- Make **one** attempt to request the missing renal transplant recipient registration and renal recipient follow-up form from the transplant center. If the second report of data submitted to the OPTN does not list the required forms, notify the PO of the facility's noncompliance.
- Exhibit 4-8 contains suggested language for inclusion in the letter to the transplant center when requesting an overdue renal transplant candidate registration or renal recipient transplant follow-up form.
- Quarterly, the Network forwards to its PO a copy of the listing of overdue renal transplant recipient registration and renal recipient follow-up forms it has received from the OPTN, annotated with the action(s) taken. For example, the Network indicates if a written request for the form was sent to the transplant center; if the transplant center submitted the delinquent form to the OPTN; or, if after 90 days, it has been unsuccessful in obtaining the delinquent form. The quarterly annotated list may be submitted to the PO with the quarterly progress and status reports (quarterly reports are due in October, January, April, and July).
- The OPTN can only offer corrective action(s) described in the OPTN Charter and Bylaws when they have been approved by the Secretary. For example, failure to submit data within time periods specified in the OPTN policies may result in the following:
    - A warning letter issued by the Membership and Professional Standards Committee (MPSC) or MPSC-Policy Compliance Subcommittee (PCSC), allowing a 60-day period to correct deficiencies and bring all data current. If the violation is not corrected within 75 days after the issuance of the warning letter.
    - Placing the Member on probation. If the violation involves a policy that is designated by the Secretary as covered in §1138 of the Act, and is not corrected within the Member's 30-day probationary period.

- Requesting the Secretary to approve suspension of the Member's membership privileges for 60 days, and to suspend its ability to list patients on the waiting list and to receive organ offers for transplant related services. During this period, the Member's patients will be offered the opportunity to transfer to another Member's waiting list. If the Member fails to demonstrate full compliance by the end of the 60-day suspension period.
- Recommending to the Secretary that the Member be expelled or that other action specifically identified in §121.10(c) of the OPTN Final Rule be taken.

- If the Network finds serious errors or discrepancies in OPTN data, it reports this to CMS for follow-up with the OPTN.

C. For Graft Failure Follow-up Data

The OPTN provides the Network with a list of patients who have had a graft failure and for whom the OPTN has been unable to obtain a follow-up form. (The OPTN follows patients for 2 years after the graft fails.) The Network checks its database and notifies the OPTN of the status of any patient(s) located as alive and back on dialysis, expired, or unknown to it.

160 - Reporting on Continued Status of Medicare ESRD Beneficiaries

(Rev. 1, 07-11-03)

ENO 480

It is the Network's responsibility to reflect current patient status within the SIMS central repository. A patient status is necessary to appropriately identify when Medicare benefits are to be terminated. Any changes to a patient status should be reflected in SIMS no later than 90 days after the change in patient status. The CMS may pull census data from SIMS periodically during the year. This requires the Network to keep its patient database up-to-date.

Each month, respond to either hard copy or electronically downloaded inquiries from CMS regarding the status of specific ESRD beneficiaries, which CMS has been unable to resolve by accessing the central repository in SIMS. Investigate the treatment status of the identified beneficiaries and respond to CMS within 45 days of receipt of the inquiries. The information to be entered includes the current setting and modality of beneficiaries for whom no renal activity has been reported (8 months after dialysis is initiated or 32 months post transplant). All corrections are to be entered into REBUS/REMIS (refer to the REBUS/REMIS Manual for complete instructions). (See Exhibit 4-9, Sample Report of Medicare Beneficiaries Who Will End ESRD Status.) If the Network has trouble entering these data via REBUS/REMIS, it may contact CMS for assistance.

170 - Coordination of Additional Renal Related Information

(Rev. 1, 07-11-03)

ENO 485

A. National Surveillance of Dialysis-Associated Disease Form

The Network distributes the National Surveillance of Dialysis-Associated Disease Form to all ESRD facilities/providers annually. These survey forms are to be completed by the facility/provider on a voluntary basis and returned to the Network for submission to the Centers for Disease Control and Prevention by the fifth working day of April.

B. Veterans Health Administration (VHA)

Process CMS ESRD forms on VHA patients from all VHA facilities. The submission of data to the Network by VHA facilities on their ESRD patients is mandatory. The VHA released VHA Directive 2001-024 on April 23, 2001, to its dialysis and transplant units. This Directive provides instructions for participation in the United States Renal Data System through the completion of ESRD forms.

Supply the VHA units with the Medical Evidence Report and Death Notification forms. The CMS ensures that the Network is supplied with adequate forms to meet the requests from VHA units. Each VHA facility must fill out the ESRD Facility Survey. Follow the instructions below when receiving data on VHA patients:

1. Completion of VHA Forms

Completion of CMS ESRD forms on VHA patients is mandatory on the part of the VHA. VHA facilities may but are not required to participate in Network activities (e.g., meetings, quality improvement projects, committee or Board members).

2. Submission of VHA Forms to CMS

The Network submits VHA patient data with the other CMS forms that are submitted on a monthly basis. If the forms do not pass the critical edits, the Network returns the unaccepted form(s) to the VHA facility, explains the problem, and requests the VHA unit to resubmit the form with the necessary corrections to it. The Network is not required to validate the information supplied by the VHA unit; however, the Network is required to track the VHA unit's compliance with forms submission, resubmission, completion, or accuracy.

VHA units must submit forms on VHA patients using their CMS provider number, which is an "F" number. VHA units should forward to the Network all copies of the ESRD forms that they complete (after they retain one copy for their

files). The Network keeps one copy of each form for its files and destroys all other copies, to protect patient privacy.

If the VHA patient has a Medicare number with a BIC Number, the Network submits this information with the monthly CMS forms it is submitting.

The Network may share information with other Networks if it is discovered that VHA patients who received transplants in other network areas are now located in a new network area. Since information on VHA patients may not be otherwise available, information on the VHA transplant recipient may be the only source for the other Network.

C. Inquiries From Medicare+Choice (M+C) Organizations

The Network responds to permissible inquiries from its area M+C organizations regarding the ESRD status of Medicare beneficiaries who are members of the M+C organizations. Permissible inquiries are for those patients who have been on dialysis for at least 4 months and whose records are not retrievable through other CMS-provided electronic data sources. The CMS provides the Network with a list of the M+C organizations in its network area. M+C organizations receive a differential payment for Medicare enrollees with ESRD. It is important that M+C organizations are correctly paid for their members with ESRD.

NOTE: With the current demonstration project, M+C organizations have access to a CMS-supplied database that provides entitlement status. It is anticipated that this service will be extended to all M+C organizations, thereby replacing the labor-intensive case-by-case look-up and reporting by Networks.

1. Information to be Provided to M+C Organizations

Provide the following types of information to M+C organizations upon written request:

- The patient's current dialysis/transplant functional status;
- The first date of dialysis or date of transplant; and
- The date Form CMS-2728 data were submitted to CMS.

The Network uses its local database or PMMIS database to provide the above information to the M+C organizations.

2. Information Not Required to be Provided to M+C Organizations

The Network is not required to answer any questions regarding the status of a current or pending Medicare entitlement, application, or payment. The M+C organizations have been advised to refer entitlement and/or application questions to the SSA servicing office and to refer payment questions to the CMS RO of

Prepaid Health Care Operations and Oversight. In addition, the Network should not routinely provide M+C organizations with copies of Form CMS-2728. M+C organizations should obtain this information from the servicing dialysis facility.

The Network reports to its PO in the Quarterly Progress and Status Report, the number of inquires received from M+C organizations during the quarter.

180 - Exhibits

(Rev. 1, 07-11-03)

Exhibit 4-1 - Engineering Review Board (ERB) Request Template (Hardware Information)

(Rev. 1, 07-11-03)

HARDWARE INFORMATION

Est. Total Price:

Description of hardware:

Justification for hardware: (Provide a narrative identifying reason for need.)

Narrative must address the following:

- Describe the current process. What are you currently doing that you want to change?
- Describe new process. How would acquiring hardware affect the process?

Manufacturer:

Model:

Number of units:

Number of users: (Identify the number of users, their associated responsibilities, and QIO program/contract where individual's time will be charged.)

Example:	Total 2 Users	1 Statistician	Analysis	CASPRO
		1 Director	Admin	CASPRO

Frequency of use: (Provide the percentage of time the requested hardware will be utilized by the above referenced users.)

Example:	Position A	Statistician	.25	CASPRO	.25	Pilot QIO (.50 QIO)
	Position B	Director	.50	CASPRO	.25	QIO

Method of attachment (e.g., parallel port connection, SDPS LAN):

NOTE: This is the form to be used if:

1. CMS/IFMC has instructed QIOs to submit an ERB Request Form.

*2. A QIO specific hardware (e.g., additional workstations, etc.) need has been identified. Submit the ERB Request Template to the SDPS Help Desk.

*3. Hardware is needed for a "special studies"/project contract (i.e., CASPRO). When ERB Request Template is completed, submit to ERB via the SDPS Help Desk, QIO RO Project Officer, AND a copy to the SDPS Project Officer (with appropriate documentation).

*Will need to attach the contract specialist's approval for hiring additional staff (when request is sent to SDPS Project Officer) as appropriate.

06/15/99

Exhibit 4-2 - Engineering Review Board (ERB) Request Template (Software Information)

(Rev. 1, 07-11-03)

SOFTWARE INFORMATION

Est. Total Price:

Description of software:

Manufacturer:

Name:

Version:

Purpose of software: (Provide a narrative, i.e., an enhancement, automating a manual process, replacing a current software, etc.)

NOTE: Will need to attach SofTrak metering report to verify need if software is currently a part of the SDPS configuration.

Narrative must address the following:

- Describe the current process. What are you currently doing that you want to change?
- Describe new process. How would acquiring software affect the process?

Number of licenses:

License type(e.g., standalone, concurrent, site):

Will SofTrak be used to meter the licenses for this product?

Specific location(s) of where software is installed (hardware platform, directory, i.e., installation on a hard drive for specific workstation or installation on network):

NOTE: This is the form to be used if:

1. CMS/IFMC has instructed QIOs to submit an ERB Request Template.

*2. A QIO specific software (e.g., additional software license, etc.) need has been identified.

*3. Software is needed for a "special studies" contract (i.e., CASPRO). When ERB Request Template is completed, submit to ERB via the SDPS Help Desk, QIO RO Project Officer, AND a copy to the SDPS Project Officer (with appropriate documentation).

*Will need to attach the contract specialist's approval for hiring additional staff (when request is sent to SDPS Project Officer) as appropriate.

06/15/99

Exhibit 4-3 - Application for Access to CMS Computer Systems

(Rev. 1, 07-11-03)

Download a pdf document of this Exhibit.

Exhibit 4-4 - Sample Notification of Data Element Changes Report

(Rev. 1, 07-11-03)

REBUS UNOS.UPLOAD NOTIFICATION OF DATA ELEMENT CHANGES FOR PATIENTS IN NETWORK 3:13 OCT 29 2000

MACHINE READABLE VERSION: MZ00.@AAA2101.NETWORK.NOTIFY.NET

CLAIM	BIC	SURNAME	FIRST NAME	DOB	S	PROV	NT	ST	FIELD: OLD = = > NEW
XXXXXXXX	T	XXXXXXXXXXX	XXXXXX	19430711	M	220028	01		PROVIDER: 220028 = = > 220163
XXXXXXXX	T	XXXXXXXXXXX	XXXXXX	19471203	M		01		PROVIDER: (BLANK) = = >220171
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19481218	F		01		PROVIDER: (BLANK) = = >220110
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19481218	F	220110	01		SETTING: FUNC TX = = > (BLANK)
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19151226	M		01		PROVIDER: (BLANK) = = >222530
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19290412	M	220057	01		DEATH DATE: (BLANK) = = >20000820
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19500418	M	222516	01		PROVIDER: 222516= = >410007
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19500418	M	412300	01		SETTING: IC HEMO = = > FUNC TAX
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19840714	M	222535	01		PROVIDER: 222536 = = >220163
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19180818	F	222535	01		BIC: ZZ = = >A
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19131025	M		01		PROVIDER: (BLANK) = = >302500
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19180304	F	222551	01	MA	BIRTH DATE: 19180304 = = >19170304
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19170304	F	222551	01		BIC: = = >A
XXXXXXXX	TD	XXXXXXXXXXX	XXXXXX	19101110	F		01		PROVIDER: (BLANK) = = >222523
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19481209	M	222551	01		TX STATUS; NO DX = = >FAILED
XXXXXXXX	T	XXXXXXXXXXX	XXXXXX	19431125	F	UNK	01		PROVIDER: UNK = = >220031
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19591214	F	222538	01		PROVIDER: 222538 = = >220077
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19750423	M	222510	01		BIC: ZZ = = >T
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19500114	M	222545	01		PROVIDER: 222545 = = >220071
XXXXXXXX	D	XXXXXXXXXXX	XXXXXX	19160606	F	222543	01		CLAIM NUM: XXXXXXXXX = = > XXXXXXXXX
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	18180602	F	220082	01		BIC: ZZ = = >D
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19151001	M		01		DEATH DATA: (BLANK) = = >19950902
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19151001	M		01		FIRST NAME: (BLANK) = = >LOUIS

REBUS UNOS.UPLOAD NOTIFICATION OF DATA ELEMENT CHANGES FOR PATIENTS IN NETWORK 3:13 OCT 29 2000

MACHINE READABLE VERSION: MZ00.@AAA2101.NETWORK.NOTIFY.NET

CLAIM	BIC	SURNAME	FIRST NAME	DOB	S	PROV	NT	ST	FIELD: OLD = = > NEW
XXXXXXXX	D	XXXXXXXXXXX	XXXXXX	19230917	F	222502	01		CLAIM NUM: XXXXXXXXX = = >XXXXXXXXX
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19191116	F	222502	01		BIRTH DATE: 19191116 = = >19251111
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19251111	F	222502	01	MA	FIRST NAME: CHARLES = = >FRANCES
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19150630	F	220110	01		BIC: ZZ = = >D
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19350730	M	412508	01	RI	STATE CODE: RI = = >FL
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19390707	F	222517	01		PROVIDER: 222517 = = >220086
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19490212	M		01		PROVIDER: (Blank) 222550
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19830205	M		01		TX STATUS: NO INFOR = = >FAILED
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19580718	M	220046	01		PROVIDER: 220046 = = >220077
XXXXXXXX	D	XXXXXXXXXXX	XXXXXX	19301209	F		01		PROVIDER: (BLANK) = = >412510
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19270105	M	222546	01	MA	STATE CODE: MA = = >NH
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19311228	M	220031	01		BIC: ZZ = = >TA
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19270827	F	222506	01	MA	BIRTH DATE: 19270827 = = >19070829
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19410711	F	220036	01		FIRST NAME: (BLANK) = = >MERRIAM
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19410711	F		01		PROVIDER: (BLANK) = = >220036
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19500223	M		01		PROVIDER: (BLANK) = = >412502
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19210224	F		01		PROVIDER: (BLANK) = = >220123
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19500203	F	222534	01		PROVIDER: 222534 = = >220116
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19570417	M		01		FIRST NAME: (BLANK) = = >DANIEL
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19580520	M	222521	01		PROVIDER: 222521 = = >220183
XXXXXXXX	T	XXXXXXXXXXX	XXXXXX	19761019	M	220071	01		SETTING: IC HEMO = = >FUNC TX
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19770212	M		01		PROVIDER: (BLANK) = = >223302
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19300301	M	20003F	01	NE	SURNAME: HENECHE = = >HENECKE
XXXXXXXX	ZZ	XXXXXXXXXXX	XXXXXX	19300301	M	20003F	01		BIC: ZZ = = >A
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19340106	M	222513	01		TX STATUS: NO DX = = >FAILED
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19351206	M	223501	01		PROVIDER: 223501 = = >220071
XXXXXXXX		XXXXXXXXXXX	XXXXXX	19351125	M	220171	01	MA	BIC: (BLANK) = = >ZZ
XXXXXXXX	A	XXXXXXXXXXX	XXXXXX	19351108	M		01		PROVIDER: (BLANK) = = >22010f

Exhibit 4-5 - Summary of Data Requirements

(Rev. 1, 07-11-03)

This exhibit provides a summary of a Network's responsibilities and the actions a Network must take to process forms and ensure the integrity of the data.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
1.	Patient Database Update	SIMS	Schedule system updates for the date file is created. (§80.2)	CMS may request patient database be sent to designee within 30 days.
2.	Monthly Change Notifications	CMS	Update Network database to reflect validated changes made by CMS. Advise CMS of any discrepancies. (§80.3)	Provides listings electronically and hardcopy.
3.	Mailing Labels	Facility/Provider provides data SIMS	Schedule system updates for the date file is created. (§80.5)	CMS to access SIMS. Notifies Network 14 days prior. Uses labels as necessary.
4.	Facility Roster	Facility/ Provider provides data SIMS	Schedule system updates for the date file is created. Submits data to other parties upon request. (§80.5)	CMS to access SIMS. Notifies Network 14 days prior. Distributes data upon request.
5.	Corrections to the Provider Listing	SIMS	Schedule system updates for the date file is created. (§80.5)	CMS to access SIMS. Notifies Network 14 days prior. CMS corrects REBUS/REMIS.
6.	Form CMS-2828 Medical Evidence Form	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; transmits data monthly to CMS data center. Provides emergency and start up supply of forms to facility. (§110.1)	Performs edit checks; matches data against Master File; generates edit reports.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
7.	Form CMS-2746 Death Notification Form	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; transmits data monthly to CMS data center. Provides supply of forms to facility. (§110.2)	Performs edit checks; matches data against Master File; generates edit reports.
8.	Form CMS-2744 Facility Survey Form	Facility/ Provider completes survey form	Sends surveys to facilities; checks forms for completeness; enters into SIMS; transmits data annually to CMS data center and submits hard copies of the forms to CMS. (§110.3)	Notifies Networks of any discrepancies.
9.	Corrections to Form CMS 2744	Information from facility/provider	Submits hardcopies of corrections to CMS. Makes corrections through SIMS. (§110.3)	Ensures corrections have been made after SIMS data is uploaded to PMMIS.
10.	ESRD Form Compliance Rates	SIMS	Semi-annually, notifies facilities of unacceptable compliance rates; provides annual compliance rates to facilities; recommends alternative sanction for non-compliant facilities. (§130)	Processes alternative sanction recommendations, as necessary.
11.	ESRD Forms Edit Reports	Generated by CMS	Makes corrections and enters into REBUS/REMIS. (§140)	Updates PMMIS.
12.	Renal Transplant Data	The Organ Procurement and Transplantation Network (OPTN)	Accesses data quarterly through REBUS/REMIS; updates REBUS/REMIS as necessary on those transplant patients not in PMMIS; obtains follow-up data as requested by OPTN. (§150)	Updates PMMIS with OPTN transplant data; forwards quarterly reports to the OPTN; OPTN notifies Network of the follow-up data to be obtained.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
13.	Reporting the Status of Medicare Beneficiaries	PMMIS	Validates monthly the current setting of beneficiaries for which CMS is unable to resolve by accessing SIMS or for which no renal activity has been reported for 8 months after dialysis has been initiated and 32 months post transplant. Enter corrections via REBUS/REMIS. (§160)	Accesses SIMS for beneficiaries for which no renal activity has been reported (8 months after dialysis has been initiated or 32 months post transplant). Notifies Networks of beneficiaries not identified in SIMS central repository. Updates PMMIS and notifies SSA within 60 days.
14.	National Surveillance of Dialysis - Associated Disease Form	Facility/ Provider completes form	Forwards completed forms to CDC. (§170)	Not applicable.
15.	ESRD Forms on Veterans Affairs (VA) Patients	VA Facility completes forms voluntarily	Enters data into Network database; transmits data monthly to CMS data center. (§170)	Performs edit checks; matches data against Master File; generates edit reports for VA.
16.	Inquiries from M+C organizations	SIMS, REMIS	Provides ESRD functional status information to M+C organizations. (§170)	Not applicable.
17.	CPM Forms	Facility Completes	Forwards to facility; enters data; submits to CMS.	Analyzes and publishes.

Exhibit 4-6 - Sample Edit Report

(Rev. 1, 07-11-03)

REBUS MEDICAL EVIDENCE EDIT REPORT

CLAIM	BIC SURNAME	PHYS SIGN DATE	PROVIDER	NETWORK
XXX-68-5608-ZZ	XXXXNLEE, XXNCEPTION	05/26/1995	030010	15

---------- SERIOUS ERRORS: ---------
THIS DATA HAS NOT YET MATCHED MEDICARE
MASTER FILE (NETWORK SHOULD INVESTIGATE)

-------- ALGORITHM RESULTS: ----------
PATIENT APPROVED
ESTIMATED CREATININE CLEARANCE VALUE IS
LE 15.5 ML/MIN

XXX-18-4046-D	XXXXLLI, XXRNADETTE	01/26/1996	052588	18

---------- SERIOUS ERRORS: ----------
DIALYSIS START: 01/22/1996 DATE MUST
NOT BE AFTER PHYS SIGN DATE: 01/22/1996

THIS DATA HAS NOT YET MATCHED MEDICARE
MASTER FILE (CMS WILL INVESTIGATE)

--------- ALGORITHM RESULTS: ----------
PATIENT APPROVED
SERUM CREATININE VALUE IS GE 8.0 MG/DL

---------- WARNINGS: ----------
TRANSPLANT DATE NOT YET REPORTED BY UNOS

Exhibit 4-7 - Sample Medical Evidence Edit Report Cover Letter

(Rev. 1, 07-11-03)

Date

NOTE TO: End Stage Renal Disease (ESRD) Network Executive Directors/Data Managers

Subject: Monthly Edit Report(s)

Enclosed, you will find the Medical evidence Edit Report for _____.

If you have any questions, please contact me at (phone number). Thank you for your cooperation.

Health Insurance Specialist
ISG/OCSQ

Enclosure

Exhibit 4-8 - Letter to Center Requesting Overdue Follow-Up

(Rev. 1, 07-11-03)

Date

Transplant Center Name & Address

Dear Transplant Provider:

The Organ Procurement and Transplant Network (OPTN) has informed the Network that the renal transplant recipient registration/renal transplant recipient follow-up form(s) for (patient's name) is overdue. Please submit the data within 30 days of the date of this letter. If you use Unet[sm], the electronic data submission tool, log onto **www.unet.unos.org.** If you submit paper forms, send to:

OPTN Clinical Data Systems
720 Moorefield Park Drive, Suite 200
Richmond, VA 23236

Under 42 CFR, Subpart U - Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services, 405.2133, you are required to furnish data and information to the Center for Medicare & Medicaid Services (CMS) for the administration of the ESRD program. Under 405.2134, you are required to participate in Network activities. Failure to comply with these regulations by not submitting the applicable transplant follow-up form(s) to OPTN can result in the recommendation of an alternative sanction to CMS.

If you have any questions, or wish to discuss these issues, please contact _____ at _____.

Sincerely,

Network Executive Director

Address

Exhibit 4-9 - Sample Report of Medicare Beneficiaries Who Will End ESRD Status

(Rev. 1, 07-11-03)

REBUS **STATUS REQUEST: BENES WHO WILL END ESRD THRU: MAR 2001** **5:58 NOV 10, 2000**

GROUP "11" PAGE: 1

						LAST KNOWN						NEW STATUS			
CLAIM	SURNAME	BIRTH	S	NW	ST	AS-OF	PROV	M	S	TERM-DT	RSN	STATUS-DT	MOD	SET	PROV
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	08/24/1956	F	01	NH	03/30/2000	300003	A	A	03/31/2001	B				
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	10/08/1949	F	01	CT	03/04/2000	070035	A	A	03/31/2001	B				
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	06/02/1969	M	01	ME	12/16/1999	200039	A		12/31/2000	B				
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	05/14/1931	F	01	ME	07/03/1996	200034	A		07/31/1997	B				
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	11/09/1935	F	01	ME	03/28/2000	202501	A		03/31/2001	B				
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	08/04/1999	F	01	ME	? ?		G	O	? ?					
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	08/11/1981	M	01	VT	03/31/2000	470003	A	A	03/31/2001	B				
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	10/15/1952	F	01	MA	03/14/2000	220057	A	A	03/31/2001	B				
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	08/20/1944	M	01	MA	03/16/2000	222530	A	A	03/31/2001	B				
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	10/20/1951	M	01	MA	? ?		G	O	? ?					

REBUS **STATUS REQUEST: BENES WHO WILL END ESRD THRU: MAR 2001** **5:58 NOV 10, 2000**

GROUP "11" PAGE: 1

				- - - - - - - - - - - - - - -LAST KNOWN - - - - - - - - - - - - - - -								- - - - - - - - -NEW STATUS - - - - - - - -			
CLAIM	**SURNAME**	**BIRTH**	**S**	**NW**	**ST**	**AS-OF**	**PROV**	**M**	**S**	**TERM-DT**	**RSN**	**STATUS-DT**	**MOD**	**SET**	**PROV**
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	03/21/1989	F	01	MA	? ?	202501	A	F	03/31/2001	B				
XXXXXXXX-T XXXXXXX	XXXXXX, XXXXXX	01/12/1958	M	01	MA	? ?		G	O	? ?					
XXXXXXXX-A XXXXXXX	XXXXXX, XXXXXX	12/08/1989	F		MA	07/25/2000	220116	F	G	03/31/2000	B				

Medicare ESRD Network Organizations Manual

Chapter 5 - Quality Improvement

Table of Contents

10 - Authority

(Rev. 1, 07-11-03)

ENO 500

Section §1881(c)(2)(E) of the Social Security Act (the Act) requires ESRD Network Organizations to perform on-site review of facilities utilizing standards of care established by the Network Organization to assure proper medical care.

20 - ESRD Health Care Quality Improvement Program (HCQIP)

(Rev. 1, 07-11-03)

ENO 505

As stated in CMS's Strategic Plan, HCQIP is a program that supports CMS's mission to assure health care security for beneficiaries. The mission of 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 the quality of care; communicate with beneficiaries, health care providers, and practitioners in order to promote informed health choices; protect beneficiaries from poor care; and strengthening the health care delivery system.

As part of the Network's role in conducting quality improvement activities, the Network should work to improve processes and outcomes of patient care by developing, implementing, and evaluating quality improvement projects in collaboration with ESRD facilities, providers, and other partners. These activities support the ESRD HCQIP.

30 - Responsibilities

(Rev. 1, 07-11-03)

ENO 510

The Network's quality improvement responsibilities include:

- Developing and conducting quality improvement projects based on one or more of the established sets of ESRD Clinical Performance Measures (CPMs) for adequacy of dialysis, anemia management, and vascular access, or other CPMs developed or adopted by CMS;

- Monitoring, tracking, and disseminating regional (Network) and facility-specific (if available) clinical outcomes data (such as the CPM data) to identify opportunities to improve care within the network area or within a specific facility; and

- Upon request of a facility and/or upon identifying poor performance or a specific need, assisting 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.

40 - Quality Improvement Projects (QIPS)

(Rev. 1, 07-11-03)

ENO 515

40.1 - Background and Project Topics

(Rev. 1, 07-11-03)

ENO 515.1

One of CMS's National Performance Review (NPR) goals is that 80 percent of adult in-center hemodialysis patients achieve a delivered dose of dialysis greater than or equal to 65 percent measured by the Urea Reduction Ratio (Hemodialysis (HD) Adequacy CPM III). Therefore, for the Network's first QIP under this contract, the Network must use HD Adequacy CPM III as the primary CPM to measure/improve adequacy. The Network is required to continue conducting QIPs based on this CPM for at least the first contract year. The Network may include in the project design of the Network's first QIP, one or more of the vascular access CPMs I-IV to try to measure and improve; however, these CPMs must be treated as care processes that will lead to improvement in the overall adequacy of dialysis (HD Adequacy CPM III) in its network area.

NOTE: If, after the first contract year, the Network does not meet the 80 percent target for HD Adequacy CPM III, it must continue to conduct QIPs utilizing the HD Adequacy CPM III.

After the first contract year, if the Network reaches or exceeds the 80 percent target for HD Adequacy CPM III, CMS, with input from the Networks, will determine what topics or CPMs the Network's subsequent QIPs will be based on. Potential topics or CPMs for QIPs include the following:

- Adequacy of dialysis (in-center hemodialysis patients) CPMs I-V;
- Adequacy of dialysis (peritoneal dialysis patients) CPMs I-III;
- Anemia management CPMs I-III;
- Vascular access CPMs I-IV; and

- Other standard measures/indicators identified by CMS.

The Network may also propose a QIP not based on one of the CPMs listed in §40.1; however, this must be adequately justified and approved in advance by CMS. The CMS reserves the right to direct its quality improvement project activities, including directing participation in specific projects/special studies, and discontinuing or deferring projects at any time. The choice of other CPMs (topic) on which to conduct a QIP may be based on the analysis of local and/or other data, such as the Core Indicators (predecessor to the CPM) or CPM data, Network resources, patient care improvement needs, and the priorities of the renal community and/or CMS. The Network must, at a minimum, use one or more of the standard CPMs in its QIP. The current standard set of CPMs on which to base QIPs may be found in Exhibit 5-1. Other measures related to the QIP topic that are not part of the current standard set of CPMs may also be included in the QIP as approved by CMS through the Narrative Project Plan (NPP). (See Exhibit 5-4.)

The Network does not research new or suspected relationships between processes and outcome, undertake projects that do not have a strong scientific base, or rest on solid professional consensus, unless directed by CMS.

The evaluation of projects, where possible and feasible, requires similar, comparable data on similar groups of providers/patients that do not experience the intervention. This can be accomplished through appropriate sampling even if the intervention group data is population based (i.e., 100 percent of providers/patients records, etc., are utilized for measurement). These evaluations provide support for observations that interventions directly led to, or contributed to, the improvements observed. The interventions utilized should be based on previous implementation or a good rationale for probability for success, and as such, evaluations are not technically "researching" the effectiveness of the intervention, but evaluating the degree to which a high quality intervention was successfully implemented. Good interventions, if not appropriately and thoroughly implemented, may lead to poor improvements in actual clinical care and outcomes.

The primary purpose of the evaluation is, therefore, to determine the extent to which a good intervention was successfully implemented - not the potential effectiveness of the intervention itself. A high quality QIP with a well documented and implemented intervention may indeed support the observation that a planned and conducted high quality intervention in one setting may not be particularly effective in another, despite the assumptions at the time of project approval. Such outcomes do not constitute project failure; rather they are successful projects that provided important scientifically supported lessons in the developing practice of intervening to improve care for ESRD beneficiaries. The instructions in §40.4.C.4 of the manual and the NPP attempt to maximize the probability that high quality interventions are adequately designed, implemented, and documented so as to minimize situations where intervention data and documentation are not sufficient to assess their contribution to apparently negative outcomes.

40.2 - QIP Frequency, Project Consultant, and Required Reporting

(Rev. 1, 07-11-03)

ENO 515.2

Develop and implement at least one QIP annually, unless directed otherwise by CMS. The Network electronically submits a project idea(s) to its project officer (PO) for approval using the Project Idea Document (PID) (see Exhibit 5-3 prior to developing and implementing the QIP Narrative Project Plan (NPP) (see Exhibit 5-4PP format). Exhibit 5-5 contains the format for the Final Project Report (FPR).

The Network QIP consultant (SOW §C.4.C) must be involved in all phases of the project: planning, analyzing, evaluating, and in preparing the Final Project Report. The project consultant must be identified in the appropriate fields in the PID, NPP, and the FPR.

The Network's first PID is due to its PO as soon as possible, but no later than 60 days after award of the contract. PIDs will be due annually thereafter, unless directed differently by the Network's PO.

Sixty days after CMS approval of the PID, the Network electronically submits a NPP to its PO. The Network's PO and regional office scientific staff may be involved during this stage of the NPP development to provide guidance and assistance. The Network's PO will evaluate proposed QIPs based on the following criteria:

- Feasibility;
- Potential impact on the patient population;
- Project design;
- Cost-effectiveness; and
- Timeliness.

After initiation of the approved NPP, the Network documents all of the project phases and activities through the narrative portion of the Standard Information Management System (SIMS) and reports the status of its QIP in the Quarterly Progress and Status Report (see §40.8). The Network electronically submits any changes to the approved NPP to its PO for review and approval.

NOTE: The Network must also submit its PID, NPP, FPR, and any other modifications of its QIPs via E-mail using Word software to prepare its document until the reporting component of the SIMS software is available and functioning reliably. The CMS will advise the Network when to submit its reports via SIMS. The Network may also submit hard copies of its reports, if necessary.

Within 90 days after completion of the QIP, the Network electronically submits a FPR to its PO that describes and evaluates the project. See instructions in Exhibit 5-5.)

40.3 - Project Idea

(Rev. 1, 07-11-03)

ENO 515.3

In the Network's first contract year, it is required to conduct QIPs based on hemodialysis adequacy CPM III (minimum delivered dose of HD is a URR greater than or equal to 65) until it reaches or exceeds the target of 80 percent of the adult in-center HD patients in its network area meeting this URR level. The Network may include in the project design of its first QIP, one or more of the vascular access CPMs I-IV to try to measure and improve; however, these CPMs must be treated as care processes that will lead to improvement in the overall adequacy of dialysis (HD Adequacy CPM III) in its network area. If, after the first contract year, the Network reaches the 80 percent target for HD adequacy CPM III, CMS, with input from the Networks, will determine what topics or CPMs the Network's subsequent QIPs will be based on. The Network develops its projects in collaboration with its ESRD providers and/or beneficiaries. In addition, the Network may also partner with other Networks, QIOs, State Survey Agencies, national and/or local renal related organizations and ROs when appropriate. The Network QIP consultant must be involved in the development of the Network's project idea.

Surveys to obtain information for project development or implementation must relate to the project being considered. Prior to dissemination, the Network forwards survey questions to its PO for review and approval, and to determine the type of clearance needed, if necessary. The PO or other RO staff will inform the Network of any clearance the survey requires.

The Network assesses the appropriateness of its QIPs using the following general criteria:

- For the first contract year, projects shall be based on HD Adequacy CPM III, until it has met the 80 percent target (as described above).

- In the Network's QIP, it may measure other processes that it believes are associated with achieving adequate dialysis (HD Adequacy CPM III), as approved by CMS. These measures are often useful in determining if the interventions and strategies in the QIP were effective and/or to assess whether the presupposed cause and effect relationships between process and outcome were valid or as strong as suspected.

- Projects should strive to be high-impact/high-feasibility (i.e., the project should result in improved processes of care and outcomes for a large number of the targeted population with a high probability of success). The Network is

encouraged to adopt completed projects of other Networks that have proven to be successful (i.e., where measurable improvement has been demonstrated).

The Network submits its project idea, not exceeding three pages, using the format for the PID in Exhibit 5-3. The first project idea is due to the PO no later than 60 days after award of the contract (approximately September 1, 2000). Subsequent project ideas will be due annually thereafter, unless directed otherwise by the PO.

40.4 - QIP Narrative Project Plan (NPP)

(Rev. 1, 07-11-03)

ENO 515.4

After the approval of the Network's project idea, the Network completes the NPP and submits it to the PO within 60 days. The Network involves its QIP consultant in the development of the NPP. Some of the components of the NPP will have been identified in the PID. It is appropriate to request preliminary review or assistance at any point during the preparation of the NPP. In any event, before the PO officially approves the NPP, the Network's PO or RO scientific staff may ask the Network to include additional information and/or ask for revisions to its NPP. The format for the NPP is found in Exhibit 5-4. Components and instructions for certain sections of the NPP include the following:

A. Network Identification Information - Include the Network number, Network name and contract number.

B. Project Identification Information - Include the following:

1. Project title;

2. Topic (must be a CMS priority CPM (topic area) or preapproved as instructed in §C.2.C of the Network SOW and §40.1 of this manual;

3. Network project contact person;

4. Network Epidemiologic Consultant (must be involved in the PID and NPP as required in the Statement of Work (see §C.4.C) and Chapter 2, §60, of this manual);

5. Regional project officer;

6. Regional scientific advisor;

7. Current date;

8. Initial NPP submission date; and

9. NPP revision number.

C. Objectives of the Project - The project should:

1. State the National ESRD CMS Priority CPM (topic area) - Clearly state the national ESRD CMS priority CPM (topic area) that will be addressed in the project. The CMS has determined that the first project must be based on HD Adequacy CPM III, until the Network has met the 80 percent target as described in §40.1. If the Network's regional office has preapproved a non-priority CPM (topic area) please indicate the measure(s) here.

2. State the Immediate Process and/or Outcome Objectives and Goals - Describe the specific processes and related clinical outcomes to be measured and improved in this project. Describe the long-term goals and impact of the project.

3. List the Quality Indicators - List the CPM(s) to be used in measuring the listed processes and outcomes. List all other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project. These quality indicators must relate directly to the processes and outcomes of this project as found in the previous section.

4. Quantitatively Define "Improvement" in Project-Specific Process and Outcome Indicators - A predetermined target "amount" of improvement helps identify the level of effort and importance of each particular indicator in the overall project, and the importance of targeting interventions for each area of the project where improvement is directly related to expected outcomes.

   Improvement "target" amounts may be expressed in terms of absolute improvement or reduction in failure rates (see examples below). Reaching the target amount of improvement for each quality indicator is not the basis for determining whether a project is "successful". Success is the development and implementation of a sound, high quality plan to measure and improve performance. Measuring the actual amount of improvement for each quality indicator assists in the effort to identify the relationship between the interventions applied to improve specific dimensions of clinical (or patient, where applicable) behavior and the actual improvement in that performance. It is also the key to exploring the relationship between improving clinical performance (process indicators) and the improvements in project-specific outcomes.

EXAMPLES

Absolute Improvement/Process Indicator Example - Time on Dialysis - The target is 20 percent improvement over baseline rates of adherence (as specified in the appropriate quality indicator section, e.g., within 10 minutes of prescribed time). If the baseline rate is 55 percent, and the rate at remeasurement is 73 percent, the absolute improvement is 18 percent and the intervention was apparently effective. There is no penalty for not reaching 20 percent. If the improvement was only 3 percent however, there is an opportunity to explore the relevance and actual conduct (i.e., was the intervention carried out as planned) of the intervention.

Reduction in Failure Rate/Outcome Indicator Example - URR greater than or equal to 65 percent - The Network rate of adherence at baseline is 70 percent. The Network proposes and targets a reduction in failure rate (RFR) of 25 percent. The project was carried out and the rate at remeasurement was 77.4 percent.

RFR = (% absolute improvement from baseline/100-baseline rate)*100

EXAMPLE

(7.4%/30%)*100 = 24.6% (rounded up to 25%) - the failure rate (30%) was reduced by 25%.

D. Background - List:

1. Opportunity for Improvement - Describe the size, severity, and consequences of the problem in the network area. The CMS has identified "improving the percentage of adult in-center hemodialysis patients achieving an adequate delivered dose of dialysis (HD Adequacy CPM III)" as the priority topic for Networks' QIPs. One of CMS's National Performance Review goals is that 80 percent of adult in-center HD patients shall achieve a delivered dose of dialysis greater than or equal to 65 percent. Improvement opportunities may be identified in sub-regions of the entire Network.

2. Potential for Change - What is the current state of practice in the population targeted for improvement? What factors come together to allow and enable the Network to work effectively with the dialysis population and the providers. Which groups are targeted for improvement? Who would need to accept change to improve performance (processes and outcomes)? What factors or prior improvement efforts warrant the expected magnitude of improvement as discussed in the previous section?

3. Prior Projects or Studies - Are there any previous projects (Networks, Quality Improvement Organizations, providers, etc.) that attempted to

improve performance in these areas? What was the magnitude of improvement?

E. Methods

1. Quality Indicators (refer to the CPM definitions in Exhibit 5-1) - Each QIP must include the review of one or more quality indicators or CPMs. A quality indicator is a quantifiable measure of a health care process or outcome that is related to practice guidelines or standards. The focus of the indicators should generally be on processes of care where there is broad consensus on the treatment approach, or there is scientific evidence that the indicators have previously been linked to improved outcomes. Do not research new or suspected relationships between processes and outcome, undertake projects that do not have a strong scientific base, or do not rest on solid professional consensus unless directed by CMS.

    a. Process Measure Indicators - For each process indicator or CPM addressed in the project, provide a clear and succinct statement describing how the indicator or CPM is actually measured in numerator/denominator format that will clearly explain the origins of the numeric data that will be provided in the measurement section of the QIP.

    b. Outcome Measure Indicators - For each outcome indicator or CPM addressed in the project, provide a clear and succinct statement describing how the indicator or CPM is actually measured in numerator/denominator format that will clearly explain the origins of the numeric data that will be provided in the measurement section of the QIP.

2. Project Setting - Describe and enumerate the clinical settings to be included (dialysis centers, physician offices, hospitals, etc.) and the size of population of beneficiaries involved in the project (i.e., experiences the intervention).

3. Study design - Describe the type of study design and the analyses to be used to determine changes or improvements from baseline. Describe control or comparison groups considered or included to help gauge actual impact of interventions versus secular trends.

4. Data - Include the following:

    a. Sources - Describe the specific source of the data, the specific data elements to be utilized in the analyses as described above, details behind the collection of the data, and the accuracy/validity of the data.

b. Collection Methods - Describe in detail the method, tools (existing or developed), and time lines required to collect the data for this project. Indicate proposed pre- and field-testing of data collection instruments. All questionnaires or surveys must be pre-reviewed and approved by CMS.

c. Case selection - Include the definition of cases eligible/ideal for project, and the sample size, sampling frame, sampling strategy, biostatistical power calculations (if sampled). It is important to understand the efficiency introduced by appropriate sampling. Projects that propose to identify and collect data on 100 percent of patients will be scrutinized to assess the costs/benefit of such activities.

5. Intervention

a. Description - Provide a summary of the project's proposed intervention plan, including; description of intervention(s)/intervention arms, indicators used for tracking the actual implementation and progress of the intervention (if different from the project's quality indicators), settings, target population, intervention type, timetable, and intervention evaluation (i.e., was the intervention implemented properly and thoroughly).

b. Objectives for Behavior Changes - Discuss the objectives for behavior changes in various target audiences for this project. Differentiate between the various types of interventions used for the project.

- Target audience interventions are aimed at one or more target audiences whose behavior ultimately should be changed, e.g., physicians, beneficiaries, etc. and which the Network itself implements ("direct" intervention).

- Agent audience interventions are aimed at one or more entities such as, State or local health departments, professional associations, and advocacy groups, which are also working to change the behavior of the target audience. For agent interventions, describe:

    - Expectations (if any) for intervention partners and/or collaborators (e.g., advocacy groups, professional associations, providers, practitioners, plans, State and local health departments);

- Limitations, if any, of targeting one or more agents; and

- The outcomes related to agent behavior desired.

c. Description of Network's and Collaborator's Roles - Describe the Network's and collaborator's roles in the development of interventions and the expected degree of acceptance and implementation. Include in the description:

- The implementation plan (i.e., who is responsible for doing what, when, where, and how);

- How to track and monitor adherence to this plan; and

- Any process assessments that are incorporated and used to track and improve the intervention as it is being implemented where warranted.

6. Feasibility and Risk

- Estimate overall length of time that intervention activities are estimated to require.

- Discuss labor intensity, political sensitivity, resource requirements, and complexity.

- Discuss the potential impact of these issues on the success of the project.

- Estimate the total cost of the project.

- Discuss the potential generalizability of this project to similar target populations.

- Assess the likelihood that the intervention effect is likely to be sustained beyond the implementation period.

F. Results - Upon implementation of the project, include the following:

1. Baseline Measurement Results - Present baseline measurement results for all indicators using appropriate and clear methods (tables, graphs, etc.).

2. Interim Results for All Indicators - Present interim results for all process or outcome indicators that were proposed in the methods section.

3. Follow-Up Measurement Results - Present follow-up measurement results in a manner consistent with the baseline results.

4. Outcome or Impact Evaluation of Project Success - Present an outcome or impact evaluation of project success based on the analyses proposed and the quantitative targets for improvement as found in the proposal. Typically these include two dimensions: (1) absolute or relative improvements (RFRs) from baseline in performance as intended by the planned remeasurement of quality indicators, and (2) comparing these results to the change in quality indicator results from the comparison group(s). These biostatistical analyses must be proposed and explained in the NPP prior to approval.

G. Conclusions and Discussion

1. Conclusions Based on Results - Was the project successful? If not, why not?

2. Limitations of Project Findings - What were the project findings limitations?

3. Overall Evaluation of Project - What was the overall evaluation of the project?

H. Appendices - Include the following:

1. Bibliography.

2. Data collection forms (provide separately, if necessary).

3. Publications or reports.

4. Data collection, abstraction, analysis and evaluation instruments.

5. Other, miscellaneous.

40.5 - Final Project Report (FPR)

(Rev. 1, 07-11-03)

ENO 515.5

Within 90 days after completing the QIP, the Network submits a FPR to its PO using the format in Exhibit 5-5. The Network involves the QIP consultant in the preparation of this report.

40.6 - Disseminating Results

(Rev. 1, 07-11-03)

ENO 515.6

The Network disseminates the results of the project to all providers in its network area, CMS, project partners, and other Networks. The information shared must conform to all Network regulations and or requirements. Protect the identities of individual providers practitioners, plans, and beneficiaries.

40.7 - Identifying Additional Opportunities for Improvement

(Rev. 1, 07-11-03)

ENO 515.7

In this phase of the project, building on experience gained by completing one iteration of the project process, the Network may identify additional intervention strategies or improvement potential within the current project. This final phase of the project process is a checkpoint for the Network to determine how successful the project was in achieving the objectives; whether additional interventions are warranted; and whether the Network should consider the project for exporting and/or expansion within its area (if it was not a Network-wide project).

40.8 - Quarterly Progress and Status Report

(Rev. 1, 07-11-03)

ENO 515.8

The Network documents its project phases/activities on an ongoing basis into the Standard Information Management System (SIMS) and completes its RO reporting requirements. At least quarterly, the Network includes in its Quarterly Progress and Status Report the status of its QIPs, using a format prescribed by its RO. The Network completes a Final Project Report for each completed quality improvement project (see Exhibit 5-5), and it submits the completed project report to the project officer within 90 days after completion of the QIP.

50 - Improvement Plan

(Rev. 1, 07-11-03)

ENO 520

If the Network identifies problems or concerns that could impact the quality of care dialysis patients are receiving, request the facility to complete and initiate an improvement plan to correct the problem. The Network's medical review board will provide guidance as to when the Network should request a facility to initiate an improvement plan.

A request for an improvement plan must be data based and state clearly the issue(s) that warrants improvement. The improvement plan must include the goals/objectives to be achieved, the process/measurements/tools to be used to assess the issue(s) and to measure improvement, and the time frame for accomplishing the improvement plan, including monitoring/documenting improvement. The action to improve the quality of care described in this plan must be sustainable.

60 - Clinical Performance Measures (CPMs)

(Rev. 1, 07-11-03)

ENO 525

Clinical performance measures are methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality. A clinical measure or indicator can be used to identify or direct attention to specific performance issues within a health care organization that should be the subject of more intense review.

Annually, collect data on specific ESRD CPMs by requesting selected dialysis facilities to provide patient-specific data for a sample of ESRD patients in the facilities. The collection of data on CPMs is designed to:

- To describe/analyze the processes (when able) and outcomes of care for the targeted patient population, both at a point in time and over time;

- To describe/analyze conformance to clinical practice guidelines both at a point in time and over time; and

- To provide the facilities/providers with information to stimulate improvement in patient care processes and outcomes for the targeted patient population.

The CMS, working with the Network and the ESRD CPM Quality Improvement (QI) Committee (composed of both Network renal and community representatives), will determine what CPMs to collect and what ESRD patient population(s) to target.

60.1 - CPMs - Network/National Sample

(Rev. 1, 07-11-03)

ENO 525.1

The CPM process is designed to assess the quality of care regarding the CPMs listed in Exhibit 5-5 in a consistent way, on a representative sample of a targeted ESRD patient population in each network area and/or in the United States. Data to calculate the CPMs are collected annually for purposes of:

- Describing and analyzing the care practices for the targeted patient population both at a point in time and over time; and

- Providing the facilities and providers with information to stimulate improvement in patient care processes and outcomes for the targeted patient population.

Report the data collected on the CPMs to CMS or CMS's designee. The CMS will aggregate these results and report Network and/or national profiles of care back to each Network.

60.2 - CPMs - Sampling Method

(Rev. 1, 07-11-03)

ENO 525.2

The CMS or its designee annually selects a targeted patient population of dialysis and/or renal transplant patients. Obtain CPM-related information for these patients, which describes the population and care practices. The level of work effort for this activity remains the same in each contract year.

The CMS or its designee annually selects the patient samples using information from the Network's database. From the Network's databases, CMS or its designee selects a random sample of in-center hemodialysis (HD) patients stratified by the Network, and a national random sample of peritoneal dialysis (PD) patients. The HD patient sample is designed to allow a Network-specific estimate of the prevalence of occurrence of the CPMs within +/- 5 percent accuracy and a 95 percent level of confidence. The aggregate data allows national prevalence estimates with an even tighter accuracy range. The specific sample size for both HD and PD is in the range of 600 to 700 records annually per Network.

Patients are selected from the targeted patient population using a random sampling technique. The CMS over-samples the targeted patient population to compensate for possible non-responses. A non-response could result if the patient's medical record is missing. Do not substitute for patients in the sample.

Each contract year, CMS or its designee provides the Network with the patient listing, data collection forms, and the instructions for completing the form prior to implementing the data collection effort.

NOTE: The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year. The reporting period for PD patients is October, November, and December of each year, and January, February, and March of the following year.

60.3 - CPMs - Data Collection

(Rev. 1, 07-11-03)

ENO 525.3

Staff from each selected dialysis facility will abstract clinical data annually for the CPMs project. Provide the selected facilities with:

- A cover letter explaining the facility staff's abstraction of the CPM data;
- Copies of the CPM data collection form(s); and
- Instructions for completing the data collection forms on the patients selected.

Assume that each dialysis facility in the network area completes a range of 2 to 10 data collection forms per year. The data collection form is preprinted with patient-specific demographic information from the Network's database. The Network must:

- Request that the facility verify the preprinted patient-specific information and enter on the form any corrections to the patient-specific information and the appropriate clinical information for the CPMs from the patient's medical record; and
- Specify the length of time the facility is allotted to complete and return the collection forms. Transmit all data from the completed collection forms to CMS or its designee within 90 calendar days after receipt of the CMS-selected patient sample.

Upon receipt of the CPMs data, CMS or its designee will:

- Merge the data from each Network, conduct edit checks, and aggregate the results; and

- Prepare an annual report that describes the CPMs nationally and at the Network level (when possible), and Network and national profiles of care practices and outcomes of care based on the CPMs data.

60.4 - CPMs - Data Validation

(Rev. 1, 07-11-03)

ENO 525.4

The Network re-abstracts and validates a random 5 percent of the HD and 10 percent of the PD forms completed by facility personnel in its network area. The CMS or its designee will provide the Network with the names of the HD and PD patient records to abstract. This validation activity may be done by the Network's staff conducting onsite record review (if the facility is within 100 miles of the office) or by requesting copies of the pertinent medical records. The Network completes the validation activity, including submitting validation results to CMS or its designee, within 120 calendar days after receiving validation patient samples.

The Network must pay the facility for the costs associated with photocopying medical records for review. Facilities may claim payment for photocopying at the rate of seven cents per page. In addition, the Network must pay the facility for the cost of first-class postage incurred, if records are mailed to it.

60.5 - CPMs - Data Validation Reporting

(Rev. 1, 07-11-03)

ENO 525.5

For each patient in the Network validation sample, enter the CPMs data and any corrections to the patient-specific demographic information into the CMS designated data-entry software program or into SIMS, if available, and transmit to CMS or its designee electronically or on diskette. The CMS or its designee will provide the data-entry software program and instructions for installation. Verify that the correct information has been entered before transmitting the data to CMS or its designee. Annually, the Network transmits data for all patients in its Network sample to CMS or its designee within 120 calendar days after receipt of the Network patient validation samples.

70 - CMS - Compiled Data Reports

(Rev. 1, 07-11-03)

ENO 530

The CMS may develop/compile reports or data files using the CPMs and CMS administrative data to describe the quality of care for ESRD patients. The information on these reports can be used in developing Network QIPs to stimulate facility-specific improvement activities. The CMS will provide these reports or data to the Network (electronically and/or on hard copy).

On occasion, CMS may produce two to three supplemental reports on the CPM data. The CMS or its designee will provide these reports to the Networks as camera-ready copies. The Networks will make these reports available to its facilities and/or providers.

Annually, the Network provides one copy of the CMS ESRD CPM Report, based on the CPMs data, to the medical director, head nurse, and unit administrator of each facility in the network area.

80 - Quality Improvement Projects Versus Research Studies

(Rev. 1, 07-11-03)

ENO 535

Although the Network may use many of the tools and terminology of epidemiological, clinical, or health services research when carrying out QIPs, they should not involve:

- Research efforts to prove that a process of care is effective or ineffective;
- Development of practice guidelines. In general, cooperative projects should rely on a consensus that has already been developed and, where possible, guidelines that have already been written; or
- Development of survey instruments. (A survey is any collection of information or data for any reason from more than ten beneficiaries or from more than ten providers or practitioners except where the collection of data is from medical records for a QIP.)

Surveys to obtain information for project development or implementation must relate to the project being considered. Prior to dissemination, the Network forwards the survey questions to its PO for review and approval, and to determine the type of clearance needed, if necessary. The PO or other RO staff will inform the Network of the type of clearance, if any, the survey requires.

Surveys to obtain information not related to a QIP must be submitted to the Network's PO for review and approval prior to implementation. The PO or other RO staff will inform the Network of the type of clearance necessary for a non-project related survey.

90 - Network Resources to Support the United States Renal Data System (USRDS)

(Rev. 1, 07-11-03)

ENO 540

In addition to the resources and activities the Network conducts to support the ESRD Program Management and Medical Information System (PMMIS) database, which CMS provides to the USRDS, make available Network resources annually to support national and/or regional special studies developed by the USRDS. It is anticipated that the USRDS special study centers will conduct four to five special studies over the 3-year contract period. Assume the following additional Network resources to support USRDS special study activities:

- Staff to conduct activities listed in the assumptions below (staff may be a combination of administrative, data, and quality improvement personnel);
- Postage cost to a 20 percent random sample of facilities in the network area, assume two mailings per year at $10 per mailing; and
- Postage cost to mail completed data collection forms monthly to the national renal registry.

The above annual resource estimate is based on the following:

- A national sample of 5,000 to 7,000 patients per study;
- A patient sample selection per Network that is proportional to the number of patients in each Network (see Exhibit 5-2);
- Staff labor or work effort of one hour per patient; and
- A selection of no more than 20 percent of the facilities in any Network annually.

The Network reports to the CMS PO, using the Quarterly Progress and Status Report, the work conducted to support the USRDS special studies, as appropriate, such as the number of data collection forms completed and the date these forms were mailed to the USRDS.

The CMS, the National Institutes of Health/National Institute of Diabetes, and Digestive and Kidney Diseases (NIH/NIDDK), the Networks, and the USRDS will work together to

design special studies that can be conducted with the resources listed above. Separate technical instructions will be provided to describe the specific activities the Network is to conduct. If additional Network resources or work effort is required by the USRDS to conduct special study activities, additional resources/funding will be provided.

100 - Exhibits

Exhibit 5-1 - ESRD Clinical Performance Measures (CPMs)

(Rev. 1, 07-11-03)

1. Hemodialysis (HD) Adequacy CPM I:

Monthly Measurement of Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 1 - Regular Measurement of the Delivered Dose of Hemodialysis (Evidence). The dialysis care team should routinely measure and monitor the delivered dose of hemodialysis.

HD Adequacy Guideline 6 - Frequency of Measurement of Hemodialysis Adequacy (Opinion). The delivered dose of hemodialysis should be measured at least once a month in all adult and pediatric hemodialysis patients. The frequency of measurement of the delivered dose of hemodialysis should be increased when:

a. Patients are noncompliant with their hemodialysis prescriptions (missed treatments, late for treatments, early sign-off from hemodialysis treatments, etc.).

b. Frequent problems are noted in delivery of the prescribed dose of hemodialysis (such as variably poor blood flows, or treatment interruptions because of hypotension or angina pectoris).

c. Wide variability in urea kinetic modeling results is observed in the absence of prescription changes.

d. The hemodialysis prescription is modified.

Numerator:

Number of patients in denominator with documented monthly adequacy measurements during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample.

2. HD Adequacy CPM II:

Method of Measurement of Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 2 - Method of Measurement of Delivered Dose of Hemodialysis (Evidence). The delivered dose of hemodialysis in adult and pediatric patients should be measured using formal urea kinetic modeling (UKM), employing the single-pool, variable volume model.

Numerator:

Number of patients in denominator for whom delivered HD dose was calculated using formal urea kinetic modeling, or Daugirdas II, or urea reduction ratio (URR) during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample.

3. HD Adequacy CPM III:

Minimum Delivered Hemodialysis Dose.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s)

HD Adequacy Guideline 4 - Minimum Delivered Dose of Hemodialysis (Adults-Evidence, Children-Opinion). The dialysis care team should deliver a Kt/V of at least 1.2 (single-pool, variable volume) for both adult and pediatric hemodialysis patients. For those using the urea reduction ratio (URR), the delivered dose should be equivalent to a Kt/V of 1.2, i.e., an average URR of 65%; however, URR can vary substantially as a function of fluid removal.

Numerator:

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was either Kt/V greater than or equal to 1.2 or URR greater than or equal to 65% during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) HD patients in sample who have been on HD for six months or more.

4. HD Adequacy CPM IV:

Method of Post-Dialysis Blood Urea Nitrogen (BUN) Sampling.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 8 - Acceptable Methods for Blood Urea Nitrogen (BUN) Sampling (Evidence). Blood samples for BUN measurement must be drawn in a particular manner. Pre-dialysis BUN samples should be drawn immediately prior to dialysis, using a technique that avoids dilution of the blood sample with saline or heparin. Post-dialysis BUN samples should be drawn using the Slow Flow/Stop Pump Technique that prevents sample dilution with recirculated blood and minimizes the confounding effects of urea rebound.

Numerator:

Number of facilities in denominator with written policies requiring post-dialysis blood urea nitrogen (BUN) sampling to be done using the slow-flow/stop pump technique (15-60 seconds after slowing or stopping blood flow) during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All dialysis facilities included in sample.

5. HD Adequacy CPM V:

Baseline Total Cell Volume Measurement of Dialyzers Intended for Reuse.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

HD Adequacy Guideline 11 - Baseline Measurement of Total Cell Volume (Evidence). If a hollow-fiber dialyzer is to be reused, the total cell volume (TCV) of that hemodialyzer should be measured prior to its first use. Batch testing and/or use of an average TCV for a group of hemodialyzers is not an acceptable practice.

Numerator:

Facilities in the denominator that during the reporting/study period, pre-volumed 100% of dialyzers intended for reuse. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All facilities in the sample that reuse dialyzers.

6. Peritoneal Dialysis (PD)Adequacy CPM I:

Measurement of Total Solute Clearance at Regular Intervals.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 4 - Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion). Both total weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 11 - Dialysate and Urine Collections (Opinion). Two to three total solute removal measurements are required during the first six months of peritoneal dialysis. (See Guideline 3.) After six months, if the dialysis prescription is unchanged:

a. Perform both complete dialysate and urine collections every four months; and

b. Perform urine collections every two months until the renal weekly K_rt/V_{urea} is <0.1. Thereafter, urine collections are no longer necessary, as the residual renal function contribution to total Kt/V_{urea} becomes negligible. (See Guideline 5.)

Numerator:

Number of patients in denominator with total solute clearance for urea and creatinine measured at least once in a 6 month time period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year, and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

7. PD Adequacy CPM II:

Calculate Weekly Kt/V_{urea} and Creatinine Clearance in a Standard Way.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 4 - Measures of Peritoneal Dialysis Dose and Total Solute Clearance (Opinion). Both total weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} should be used to measure delivered peritoneal dialysis doses.

PD Adequacy Guideline 6 - Assessing Residual Renal Function (Evidence). Residual renal function (RRF), which can provide a significant component of total solute and water removal, should be assessed by measuring the renal component of Kt/V_{urea} (K_rt/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance.

PD Adequacy Guideline 9 - Estimating Total Body Water and Body Surface Area (Opinion).

V (total body water) should be estimated by either the Watson or Hume method in adults using actual body weight.

Watson method:

For Men: V (liters) = 2.447 + 0.3362*Wt(kg) + 0.1074*Ht(cm) - 0.09516*Age(years)

For Women: V = -2.097 + 0.2466*Wt + 0.1069*Ht

Hume method:

For Men: V = -14.012934 + 0.296785*Wt + 0.192786*Ht

For Women: V = -35.270121 + 0.183809*Wt + 0.344547*Ht

BSA should be estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method using actual body weight.

For all formulae, Wt is in kg and Ht is in cm:

DuBois and DuBois method: $BSA\ (m^2) = 71.84*Wt^{0.425}*Ht^{0.725}$

Gehan and George method: $BSA\ (m^2) = 0.0235*Wt^{0.51456}*Ht^{0.42246}$

Haycock method: $BSA\ (m^2) = 0.024265*Wt^{0.5378}*Ht^{0.3964}$

Numerator:

The number of patients in denominator with all of the following:

a. Weekly creatinine clearance normalized to 1.73 m^2 body surface area (BSA) and total weekly Kt/V_{urea} used to measure delivered PD dose; and

b. Residual renal function (unless negligible*) is assessed by measuring the renal component of Kt/V_{urea} (K_ft/V_{urea}) and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance: and

c. Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the DuBois and DuBois method, the Gehan and George method, or the Haycock method of using actual body weight, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

   *negligible = < 200 cc urine in 24 hours.

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

8. PD Adequacy CPM III:

Delivered Dose of Peritoneal Dialysis.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

PD Adequacy Guideline 15 - Weekly Dose of CAPD (Evidence). For CAPD, the delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.0 per week and a total creatinine clearance (C_{Cr}) of at least 60 L/week/1.73 m^2.

PD Adequacy Guideline 16 - Weekly Dose of NIPD and CCPD (Opinion). For NIPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.2 and a weekly total creatinine clearance of at least 66 L/1.73 m^2. For CCPD, the weekly delivered peritoneal dialysis dose should be a total Kt/V_{urea} of at least 2.1 and a weekly total creatinine clearance of at least 63 L/1.73 m^2.

Numerator:

a. For CAPD patients in the denominator, the delivered PD dose was a weekly Kt/V_{urea} of at least 2.0 and a weekly C_{Cr} of at least 60 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

b. For cycler patients in the denominator without a daytime dwell, the delivered PD doses was a weekly Kt/V_{urea} of at least 2.2 and a weekly C_{Cr} of at least 66 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

c. For cycler patients in the denominator with a daytime dwell, the delivered PD doses was a weekly Kt/V_{urea} of at least 2.1 and a weekly C_{Cr} of at least 63 L/week/1.73 m^2 or evidence that the prescription was changed according to NKF-DOQI recommendations, during the reporting/study period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) PD patients in sample.

9. Vascular Access CPM I:

Maximizing Placement of Arterial Venous Fistulae (AVF).

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 29A - Goals of Access Placement-Maximizing Primary Arterial Venous Fistulae (Opinion). Primary arterial venous fistulae (AVF) should be constructed in at least 50% of all new patients electing to receive hemodialysis as their initial form of renal replacement therapy. Ultimately, 40% of prevalent patients should have a native AV fistula. (See Guideline 3, Selection of Permanent Vascular Access and Order of Preference of AV Fistulae.)

Numerator:

a. The number of incident patients in the denominator who were dialyzed using an AVF during their last HD treatment during reporting/study. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of prevalent patients in denominator who were dialyzed using an AVF during their last HD treatment during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

a. Incident adult (greater than or equal to 18 years old) HD patients in sample who were on HD continuously during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. Prevalent adult (greater than or equal to 18 years old) HD patients in sample who were on HD continuously during the reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

10. Vascular Access CPM II:

Minimizing Use of Catheters as Chronic Dialysis Access.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 30A - Goals of Access Placement-Use of Catheters for Chronic Dialysis (Opinion). Less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters as their permanent chronic dialysis access. In this context, chronic catheter access is defined as the use of a dialysis catheter for more than three months in the absence of a maturing permanent access.

Numerator:

The number of patients in the denominator who were dialyzed with a chronic catheter continuously for 90 days or longer prior to the last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) patients in the sample who were on HD continuously during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

11. Vascular Access CPM III:

Preferred/Non-Preferred Location of Hemodialysis Catheters Located above the Waist.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 5B - Type and Location of Tunneled Cuffed Catheter Placement (Evidence). The preferred insertion site for tunneled cuffed venous dialysis catheters is the right internal jugular vein. Other options include: the right external

jugular vein, the left internal and external jugular veins, subclavian veins, femoral veins, or translumbar access to the inferior vena cava. Subclavian access should be used only when jugular options are not available. Tunneled cuffed catheters should not be placed on the same side as a maturing arterial venous access, if possible.

Vascular Access Guideline 6D - Acute Hemodialysis Vascular Access-Noncuffed Catheters (Evidence). The subclavian insertion site should not be used in a patient who may need permanent vascular access.

Numerator:

a. The number of patients in denominator who used a jugular vein catheter as dialysis access at their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of patients in the denominator who used a subclavian vein catheter as dialysis access at their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

Denominator:

All adult (greater than or equal to 18 years old) patients who were on HD continuously during reporting/study period and who were dialyzed through a catheter during their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

12. Vascular Access CPM IV:

Monitoring Arterial Venous Grafts for Stenosis:

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Vascular Access Guideline 10 - Monitoring Dialysis AV Grafts for Stenosis (Evidence/Opinion).

Physical examination of an access graft should be performed weekly and should include, but not be limited to, inspection and palpation for pulse and thrill at the arterial, mid, and venous sections of the graft (Opinion). Dialysis arterial venous graft accesses should be monitored for hemodynamically significant stenosis. The DOQI Work Group recommends an organized monitoring approach with regular assessment of clinical parameters of the arterial venous access and dialysis adequacy. Data from the monitoring tests, clinical assessment, and dialysis adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each dialysis center as part of a Quality Assurance/

Continuous Quality Improvement (QA/CQI) program (Opinion). Prospective monitoring of arterial venous grafts for hemodynamically significant stenosis, when combined with correction, improves patency and decreases the incidence of thrombosis (Evidence). Techniques, not mutually exclusive, that can be used to monitor for stenosis in arterial venous grafts include:

a. Intra-access flow (Evidence)

b. Static venous pressures (Evidence)

c. Dynamic venous pressures (Evidence)

Other studies or information that can be useful in detecting arterial venous graft stenosis include:

d. Measurement of access recirculation using urea concentrations (See Guideline 12.) (Evidence)

e. Measurement of recirculation using dilution techniques (nonurea-based) (Evidence)

f. Unexplained decreases in the measured amount of hemodialysis delivered (URR, Kt/V) (Evidence)

g. Physical findings of persistent swelling of the arm, clotting of the graft, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft (Evidence/Opinion)

h. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow (Evidence/Opinion)

i. Doppler ultrasound (Evidence/Opinion)

Persistent abnormalities in any of these parameters should prompt referral for venography(Evidence).

Numerator:

The number of patients in the denominator whose AV graft was routinely monitored (screened) for the presence of stenosis during reporting/study period by one of the following methods and with the stated frequency:

a. Color-flow Doppler at least once every 3 months;

b. Static venous pressure at lease once every 2 weeks;

c. Dynamic venous pressure every HD session;

d. Dilution technique at least once every 3 months.

Denominator:

All adult (greater than or equal to 18 years old) patients who were on HD continuously during reporting/study period and who were dialyzed through an arterial venous graft during their last HD session during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

13. Anemia Management CPM I:

Target Hemoglobin for Epoetin Therapy

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 4 - Target Hemoglobin (hgb) for Epoetin Therapy (Evidence/Opinion). The target range for hemoglobin should be 11 g/dL - 12 g/dL (Evidence). This target is for Epoetin therapy and is not an indication for blood transfusion therapy (Opinion).

Numerator:

Number of patients in denominator with documented mean hgb of 11-12gm/dL during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year; and for PD patients, October, November, and December of each year and January, February, March of the following year.)

Denominator:

All adult (greater than or equal to 18 years old) HD or PD patients in sample, exclude patients with mean hgb greater than or equal to 12 who are not prescribed Epoetin at any time during reporting/study period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year; and for PD patients, October, November, and December of each year and January, February, March of the following year.)

14. Anemia Management CPM IIa:

Assessment of Iron Stores among Anemic Patients or Patients Prescribed Epoetin.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 5 - Assessment of Iron Status (Evidence). Iron status should be monitored by the percent transferrin saturation (TSAT) and the serum ferritin.

Anemia Management Guideline 6A - Target Iron Level (Evidence). Chronic renal failure patients should have sufficient iron to achieve and maintain a hgb of 11 to 12 g/dL.

Anemia Management Guideline 7A - Monitoring Iron Status (Opinion). During the initiation of Epoetin therapy and while increasing the Epoetin dose in order to achieve an increase in hematocrit/hemoglobin, the TSAT and the serum ferritin should be checked every month in patients not receiving intravenous iron, and at least once every 3 months in patients receiving intravenous iron, until target hematocrit/hemoglobin is reached.

Anemia Management Guideline 7B - Monitoring Iron Status (Opinion). Following attainment of the target hematocrit/hemoglobin, TSAT and serum ferritin should be determined at least once every 3 months.

Numerator:

a. The number of HD patients in the denominator with at least one documented TSAT and ferritin result every 3 months.

b. The number of PD patients in the denominator with at least two documented TSAT and ferritin result every 6 months.

Denominator:

a. All adult (greater than or equal to 18 years) HD patients included in sample, excluding patients with hgb > 12 for all 3 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. All adult (greater than or equal to 18 years) PD patients included in sample, excluding patients with hgb > 12 for all 6 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.) [Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

15. Anemia Management CPM IIb:

Maintenance of Iron Stores-Target.

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 6B - Target Iron Level (Evidence). To achieve and maintain target hgb of 11-12 g/dL, sufficient iron should be administered to maintain a transferrin saturation (TSAT) of 20%, and a serum ferritin level of 100 ng/mL.

Numerator:

a. The number of HD patients in the denominator with at least one documented TSAT result 20% and at least one documented ferritin result 100 ng/mL during a 3 month period.

b. The number of PD patients in the denominator with at least one documented TSAT result 20% and at least one documented ferritin result 100 ng/mL during a 6 month period.

Denominator:

a. All adult (greater than or equal to 18 years old) HD patients included in sample, excluding patients with hgb > 12 for all 3 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. All adult (greater than or equal to 18 years old) PD patients included in sample, excluding patients with hgb > 12 for all 6 months during reporting period and not prescribed Epoetin at any time during reporting period. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.) [Note: Not directly comparable to Numerator "a", but most feasible given probable frequency of visits for PD patients.]

16. Anemia Management CPM III:

Administration of Supplemental Iron

NKF-DOQI Clinical Practice Guideline(s) Name(s) and Number(s):

Anemia Management Guideline 8A - Administration of Supplemental Iron (Evidence). Supplemental iron should be administered to prevent iron deficiency and to maintain adequate iron stores so that chronic renal failure patients can achieve and maintain a hgb of 11 to 12 g/dL in conjunction with Epoetin therapy.

Anemia Management Guideline 8C - Administration of Supplemental Iron (Evidence/Opinion).

The adult pre-dialysis, home hemodialysis, and peritoneal dialysis patient may not be able to maintain adequate iron status with oral iron. Therefore, 500 to 1000 mg of iron dextran may be administered intravenously in a single infusion, and repeated as needed, after an initial one-time test dose of 25 mg.

Anemia Management Guideline 8D - Administration of Supplemental Iron (Opinion/Evidence). A trial of oral iron is acceptable in the hemodialysis patient, but is unlikely to maintain the transferrin saturation (TSAT) $\geq$ 20%, serum ferritin $\geq$ 100 ng/mL, and hgb at 11-12 g/dL.

Anemia Management Guideline 8G - Administration of Supplemental Iron (Opinion/Evidence). Most patients will achieve a hgb 11 to 12 g/dL with TSAT and serum ferritin levels < 50% and < 800 ng/mL, respectively. In patients in whom TSAT is 50% and/or serum ferritin is 800 ng/mL, intravenous iron should be withheld for up to three months, at which time the iron parameters should be re-measured before intravenous iron is resumed. When the TSAT and serum ferritin have fallen to 50% and 800 ng/mL, intravenous iron can be resumed at a dose reduced by one-third to one-half.

Anemia Management Guideline 8H - Administration of Supplemental Iron (Opinion). It is anticipated that once optimal hematocrit/hemoglobin and iron stores are achieved, the required maintenance dose of intravenous iron may vary from 25 to 100 mg/week for hemodialysis patients. The goal is to provide a weekly dose of intravenous iron in hemodialysis patients that will allow the patient to maintain the target hematocrit/hemoglobin at a safe and stable iron level. The maintenance iron status should be monitored by measuring the TSAT and serum ferritin every three months.

Numerator:

a. The number of HD patients in denominator prescribed intravenous iron in at least one study/reporting month. (The reporting period for HD patients in CMS's CPM Project is October, November, and December of each year.)

b. The number of PD patients in denominator prescribed intravenous iron in at least two study/reporting months. (The reporting period for PD patients in CMS's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

a. All adult (greater than or equal to 18 years old) HD patients included in sample if first monthly hgb < 11 g/dL for at least 1 month out of 3 month period or prescribed Epoetin at any time during reporting/study period regardless of hgb level, with at least one TSAT < 20% or at least one ferritin < 100 ng/mL. **EXCLUDE** patients with TSAT $\geq$ 50% or ferritin $\geq$ 800 ng/mL and **EXCLUDE** patients in first 3 months of dialysis and prescribed oral iron.

b. All adult (greater than or equal to 18 years old) PD patients included in sample if first monthly hgb < 11 g/dL for at least 1 month out of 3 month period or prescribed Epoetin at any time during reporting/study period regardless of hgb level, with at least one TSAT < 20% or at least one ferritin < 100 ng/mL. **EXCLUDE** patients with TSAT $\geq$ 50% or ferritin greater than or equal to 800 ng/mL and **EXCLUDE** patients in first three months of dialysis and prescribed oral iron.

Exhibit 5-2 - Annual Estimate of Patient Sample Per Network for USRDS Special Studies

(Rev. 1, 07-11-03)

Network	Number of Patients
1	326
2	658
3	390
4	440
5	521
6	742
7	515
8	498
9	532
10	389
11	500
12	289
13	359
14	664
15	328
16	202
17	412
18	637

Exhibit 5-3 - ESRD Network - Project Idea Document (PID) Format

(Rev. 1, 07-11-03)

ESRD Network Number:

ESRD Network Name:

Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a CMS priority area or preapproved as instructed in the Network SOW §C.2.C and §40.1 in this manual).

C. Network Project Contact Person

D. Network Epidemiologic Consultant (must be involved in project idea document and narrative project plan according to Network SOW §C.4.C) and §40.2 in this manual).

E. Regional Project Officer

F. Regional Scientific Advisor

G. Current Date

H. Initial Project Idea Document (PID) Submission date

I. PID Revision Number _____

II. Objectives (see §40.3 for additional information and instructions for completing the Project Idea Document - please limit the PID to 3 pages maximum).

A. Clearly state the national ESRD CMS priority topic that will be addressed in the project.

B. Outline:

1. The immediate process and/or outcome objectives and goals;

2. The clinical processes and the related clinical outcomes to be measured and improved in this project; and

3. The long term goals and impact of the project.

C. List:

1. The quality indicators;

2. The CPM (s) to be used in measuring the listed processes and outcomes; and

3. All other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project.

III. Background

Opportunity for improvement - outline the size, severity and consequences of the problem in the Network. Identify sub-regions affected. Outline the potential for change. Which groups are targeted for improvement? Who would need to accept change in behavior to improve performance for both processes and outcomes? In general, what magnitude of improvement is expected? Indicate if prior projects or studies exist. Indicate the magnitude of improvement realized.

IV. Methods (refer to §40.1 for topics to highlight)

Summarize:

- The methods to be utilized;
- The data to be used;
- The interventions to be used;
- The comparison or control group to be used, and
- The feasibility and risks.

V. Results

Summarize the expected results.

VI. Appendices

A. Bibliography

B. Description of potential data collection, abstraction, analysis, and evaluation instruments

C. Other, miscellaneous information

Exhibit 5-4 - ESRD Network - Narrative Project Plan (NPP) Format

(Rev. 1, 07-11-03)

ESRD Network Number:

ESRD Network Name:

Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a CMS priority area or preapproved as instructed in the Network Statement of Work (SOW) §C.2.C and §40.1 in this manual).

C. Network Project Contact Person

D. Network Epidemiologic Consultant (must be involved in project idea document and narrative project plan according to Network SOW §C.4.C. and §40.2).

E. Regional Project Officer

F. Regional Scientific Advisor

G. Current Date

H. Initial Narrative Project Plan (NPP) Submission Date

I. NPP Revision Number ____

II. Objectives (see §40.4 for additional information and instructions for completing the Narrative Project Plan (NPP)).

A. Clearly state the national ESRD CMS priority topic that will be addressed in the project. If the regional office has preapproved a non-priority project area please indicate here.

B. Immediate Process and/or Outcome Objectives and Goals - describe the specific clinical processes and the specific related clinical outcomes to be measured and improved in this project. Describe the long term goals and impact of the project.

C. Quality indicators - list the CPM (s) to be used in measuring the listed processes and outcomes. List all other (non-CPM) project-specific process or outcome quality indicators required or utilized in the project. These quality indicators must relate directly to the processes and outcomes of this project as found in §II.B.

D. Define "improvement" in quantitative terms as they relate to each project-specific process and outcome indicator.

III. Background

A. Opportunity for improvement - describe the size, severity and consequences of the problem in the network area.

B. Potential for change - what factors come together to allow and enable the Network to work effectively with the dialysis population and the providers for this project. Which specific groups are targeted for improvement? Who would need to accept change in behavior to improve performance for both processes and outcomes? In general, what magnitude of improvement is expected?

C. Prior projects or studies - are there any previous projects (Networks, Peer Review Organizations, providers, etc.) that attempted to improve performance in these areas? What was the magnitude of improvement?

IV. Methods

A. Quality Indicators (please refer to the CPM definitions in Exhibit 5-1.)

1. Process measure indicators (formulas)

a. Numerator

b. Denominator

2. Outcome measure indicators (formulas)

a. Numerator

b. Denominator

B. Project Setting

1. Describe and enumerate the clinical settings to be included (dialysis centers, physician offices, hospitals, etc.).

2. Describe the size of population of beneficiaries involved in the project (i.e., experiences the intervention).

C. Study design

1. Describe the type of study design and the analyses to be used to determine changes or improvements from baseline.

2. Describe control or comparison groups considered or included to help gauge actual impact of interventions versus secular trends.

D. Data

1. Sources - describe the specific source of the data, the specific data elements to be utilized in the analyses as described above, details behind the collection of the data, and the accuracy/validity of the data.

2. Collection methods - describe in detail the method, tools (existing or developed), and timelines required to collect the data for this project. Indicate proposed pre- and field-testing of data collection instruments. All questionnaires or surveys must be pre-reviewed and approved by CMS.

3. Case selection

a. Definition of cases eligible/ideal for project;

b. Sample size, sampling frame, sampling strategy, biostatistical power calculations (if sampled).

E. Intervention

1. Description - provide a summary of the projects proposed intervention plan, including;

a. General description of intervention(s)/intervention arms;

b. Indicators used for tracking the progress of the intervention (if different from the project's quality indicators);

c. Settings;

d. Target population;

e. Intervention type;

f. Timetable; and

g. Evaluation (i.e., was the intervention implemented properly).

2. Discuss the objectives for behavior changes in various target audiences for this project.

F. Feasibility and Risk

1. Estimate overall length of time that intervention activities are estimated to require.

a. Discuss labor-intensity, political sensitivity, resource requirements, and complexity;

b. Discuss the potential impact of these issues on the success of the project.

2. Estimate the total cost of the project.

3. Discuss the potential generalizability of this project to similar target populations. Assess the likelihood that the intervention effect is likely to be sustained beyond the implementation period.

V. Results (to be entered as project is implemented)

A. Present baseline measurement results for all indicators using appropriate and clear methods (tables, graphs, etc.).

B. Present interim results for all process or outcome indicators that were proposed in the methods section.

C. Present follow-up measurement results in a manner consistent with the baseline results.

D. Present an outcome or impact evaluation of project success based on the analyses proposed and the quantitative targets for improvement as found in the proposal. Typically these include two dimensions.

1. Absolute or relative improvements (RFRs) from baseline in performance as intended by the planned remeasurement of quality indicators; and

2. Comparison of these results to the change in quality indicator results from the comparison group(s). These biostatistical analyses shall be proposed and explained in the NPP prior to approval.

VI. Conclusions and Discussion

A. Conclusions based on results (see §V of the NPP). Was the project successful - if not, why not.

B. Limitations of project findings. What were these limitations?

C. Overall evaluation of project.

VII. Appendices

A. Bibliography.

B. Data collection forms (provide separately, if necessary).

C. Publications or reports.

D. Data collection, abstraction, analysis, and evaluation instruments.

E. Other, Miscellaneous.

Exhibit 5-5 - ESRD Network - Final Project Report Format

(Rev. 1, 07-11-03)

This report should be prepared much like an article for publication. Please limit to 6 pages, single spaced lines (unless otherwise directed).

Sections:

- Organization and authors of report/project staff
- Abstract or Executive Summary of entire project (maximum one page)
- Introduction and objectives (specify quality indicators and targeted improvements)
- Methods (describe analyses and other evaluations)
- Results (see §V of the NPP, describe changes in QIs and contrast results from comparison or control group)
- Conclusions (see §VI of the NPP, describe the extent of success, and likely causes of deviations from target goals and objectives)

Medicare ESRD Network Organizations Manual

Chapter 6 - Community Information and Resources

Table of Contents

10 - Introduction

(Rev. 1, 07-11-03)

ENO 600

The Network coordinates and participates in activities with the renal community in the network area. The Network's role is to provide informational material, technical assistance and guidance, and/or referrals to the appropriate resources, to the facilities/providers and to the patients to improve the quality of care and the life of ESRD patients. The Network assumes a proactive role in the prevention, facilitation, and resolution of complaints and grievances, including implementing educational programs that will assist facility staff in handling difficult situations. The Network must be sensitive to the local needs of the renal community and continually familiarize that community, including organ procurement organizations, with its role.

20 - Provision of Educational Information

(Rev. 1, 07-11-03)

ENO 605

To ensure that the renal community is apprised of the activities in its network area, the Network distributes, at least annually, the following informational and/or educational materials to its facilities/providers:

- ESRD program goals and Network activities to meet these goals;
- The Network's plan for monitoring facility compliance with the goals;

- Regional patterns or profiles of care as provided in the Clinical Performance Measures Annual Report;

- The Network's annual report;

- Results of the Network's quality improvement projects;

- Special mailings (assume two per year and 5-10 pages per mailing) as directed by CMS, including duplicating the materials, as necessary;

- Other materials (such as journal articles or pertinent research information) that facilities/providers can use in their quality improvement programs;

- The process for reporting and resolving patient grievances;

- Treatment options and new ESRD technologies available for patients;

- State/regional vocational rehabilitation programs available in the network area; and

- At a minimum, a letter of introduction to each new ESRD patient in the network area that includes:

    1. Information on the grievance procedure;

    2. Network specific information;

    3. A way to request/obtain additional educational materials on ESRD, patient care, treatment options, and services; and

    4. Information about the function of the Network's State agency, its address and phone number, and the fact that it receives and investigates complaints.

  NOTE: The information to be distributed to new ESRD patients is subject to change by CMS in response to recommendations from the workgroup established to examine the creation of a national new ESRD patient orientation package.

The Network must comply with laws that prohibit excluding or denying individuals with disabilities an opportunity to receive the same information and assistance provided other ESRD patients who want to attend the Network-sponsored educational programs.

The Network establishes and/or maintains a user-friendly toll free number to facilitate communications with beneficiaries within its network area. At a minimum, the toll free

number must be advertised to patients through the New Patient Package letter of introduction, patient brochures, and on the Network's Web site.

The Network develops and/or maintains a Web site that follows CMS standards and guidelines. The Network's Web site must include at a minimum:

- The Network's grievance process;
- The location of the Network;
- Toll free number for patients to contact the Network;
- Current completed Annual Report;
- Network goals; and
- A link to the Medicare.gov Dialysis Facility Compare site (http://www.medicare.gov/Dialysis/Home.asp).

The Network directs the facilities/providers in the network area to make the information available to its patients or to inform patients about contacting them to obtain this information. The above materials can be distributed by mailings, handouts at meeting(s), newsletters, etc.

The Network reports quarterly to its project officer (PO) through the Quarterly Progress and Status Report the activities conducted to distribute the above types of material. If more resources than allocated are needed to conduct these activities, the Network contacts its PO for guidance in prioritizing work activities.

30 - Provision of Technical Assistance

(Rev. 1, 07-11-03)

ENO 610

Upon request, the Network provides technical assistance, guidance, and/or appropriate referrals to facilities/providers and patients in the network area. At a minimum, the Network notifies facilities/providers annually that it is available to assist them in these areas:

- Identifying available providers for patients seeking ESRD services (including transient patients);

  NOTE: The Network's role is complementary to the efforts of the local facility staff in making transient dialysis arrangements for the facility's patients.

- Assisting providers/facilities in the development of local disaster plans that include planning for such emergencies as floods, earthquakes, hurricanes, etc.;

- Assisting providers/facilities in the development of community and patient education programs;

- Assessing the functional status of patients through the dissemination of established tools designed specifically for that purpose;

- Promoting patient education regarding kidney transplantation and self-care home dialysis;

- Encouraging and assisting providers/facilities to do timely patient assessments and appropriate referrals for evaluation of kidney transplant;

- Addressing impediments to referrals and/or transplantation, as appropriate and feasible; and

- Defining or establishing rehabilitation goals for referring suitable candidates to vocational rehabilitation programs.

The Network is required to assist facilities/providers and patients (or provide the appropriate referral) upon request. If the Network is unable to assist all or some requestors because of resource limitations, the Network contacts its PO to discuss the situation(s) and obtain guidance for prioritizing work activities.

The Network reports quarterly to its PO through the Quarterly Progress and Status Report the activities or assistance it conducted or provided.

40 - Resolution of Difficult Situations and Grievances

(Rev. 1, 07-11-03)

ENO 615

Assume a proactive role in the prevention, facilitation, and resolution of complaints and grievances, including implementing educational programs that will assist facility staff in handling difficult situations. Conduct trend analysis of reported situations to detect patterns of greater concern. The Network is responsible for, but not limited to, the following activities:

- Implementing educational programs designed to provide facility staff with an understanding of the issues and skills to prevent, intervene, or mitigate difficult patient and/or facility situations;

- Upon request, assisting in the resolution of patient, provider, and/or facility complaints, before they become formal grievances by providing education, and/or facilitating solutions and/or making referrals, which address the issue(s) involved;

- Describing and reporting in the Quarterly Progress and Status Report, patient and facility concerns/grievances and Network actions and interventions in a narrative format;

- Annually analyzing facility-specific data to identify patterns of concern at the facility or the Network level, and opportunities to improve;

- Implementing interventions aimed at reducing grievances and/or the numbers of difficult situations;

- Collecting and appropriately categorizing inquiries/complaints/grievance data using the Standard Information Management System (SIMS); and

- Utilizing grievance data to plan new training modules, provide facilities with feedback and/or make recommendations to CMS.

See Chapter 7 of this manual for evaluating, resolving and reporting patient grievances and facility concerns. Refer immediate and serious grievances to the appropriate CMS regional office and State survey agency, within 24 hours of receipt. Upon request, assist the State survey agency with the investigation of a complaint.

Report on these activities in the Quarterly Progress and Status Report as required in Chapter 2, §70.

Medicare ESRD Network Organizations Manual

Chapter 6 - Community Information and Resources

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- Assisting providers/facilities in the development of community and patient education programs;

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- Promoting patient education regarding kidney transplantation and self-care home dialysis;

- Encouraging and assisting providers/facilities to do timely patient assessments and appropriate referrals for evaluation of kidney transplant;

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40 - Resolution of Difficult Situations and Grievances

(Rev. 1, 07-11-03)

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- Implementing educational programs designed to provide facility staff with an understanding of the issues and skills to prevent, intervene, or mitigate difficult patient and/or facility situations;

- Upon request, assisting in the resolution of patient, provider, and/or facility complaints, before they become formal grievances by providing education, and/or facilitating solutions and/or making referrals, which address the issue(s) involved;

- Describing and reporting in the Quarterly Progress and Status Report, patient and facility concerns/grievances and Network actions and interventions in a narrative format;

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See Chapter 7 of this manual for evaluating, resolving and reporting patient grievances and facility concerns. Refer immediate and serious grievances to the appropriate CMS regional office and State survey agency, within 24 hours of receipt. Upon request, assist the State survey agency with the investigation of a complaint.

Report on these activities in the Quarterly Progress and Status Report as required in Chapter 2, §70.

Medicare ESRD Network Organizations

Chapter 7 – Sanctions and ESRD Complaints and Grievances

Table of Contents

Sanctions

Grievances

Sanctions

10 - Authority

(Rev. 1, 07-11-03)

ENO 700

If a facility or provider fails the requirement in §1881(c)(3) of the Social Security Act (the Act) to cooperate in achieving the goals and plans of the Network of ESRD facilities to which it belongs, and that failure does not jeopardize patient health and safety, the CMS Regional Office (RO), the Secretary's designee, may impose sanctions as an

alternative to terminating coverage of ESRD services furnished by that supplier. (See 42 CFR 405.2181.)

20 - Network's Role Prior to Initiating Sanction Recommendations

(Rev. 1, 07-11-03)

ENO 705

The Network must have a plan for monitoring facilities'/providers' compliance with Network goals. The plan for monitoring facility/provider compliance with Network goals must be distributed to CMS and to all facilities/providers in the network area. The Network must use its monitoring plan to identify facilities/providers, which consistently fail to cooperate with Network plans and goals or to follow the recommendation of the Medical Review Board (MRB).

If the Network identifies a facility that is not cooperating in meeting goals and objectives and the Network is considering recommending a sanction to the RO serving the involved facility, discuss the situation with your CMS project officer (PO). The Network consults its PO or Survey and Certification Branch for guidance if it is uncertain whether it has enough documentation to proceed with the sanction recommendation. If after 3 months, the Network has exhausted all reasonable efforts to gain facility compliance, and has documented that the facility has failed to cooperate with Network goals and objectives, the Network may recommend to the RO the imposition of an alternative sanction. (See 42 CFR 405.2181.) Alternative sanction recommendations must be facility focused, not physician focused. However, physicians who fail to comply with the Network performance goals to such a degree that they are considered to be failing to meet their obligation to provide quality care must be referred to the Quality Improvement Organization (QIO) or the Office of the Inspector General and/or the Board of Examiners for Physicians. Before the Network submits an alternative sanction recommendation to the PO, the Network must document the details of the situation and that the facility is still not in compliance with Network goals and plans, including the following deficiencies:

- Consistently fails to cooperate with and meet performance expectations in regards to Network plans or goals as specified in the contract with CMS;
- Consistently fails to follow recommendations of the MRB;
- Fails to permit the Network MRB, without just cause, to conduct an on-site review; or
- Fails to submit data as required so that you can prepare your Network Annual Report.

All fraud and abuse cases should be referred to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse in the Medicare or Medicaid programs. (See 42 CFR 480.137.)

30 - Written Documentation Requirements for Sanction Recommendations

(Rev. 1, 07-11-03)

ENO 710

To support its recommendation that an ESRD facility should be recommended for an alternative sanction, the Network must provide the RO with the following written documentation. The documentation can be in the form of written correspondence between the facility and the Network, written notes, and/or contact reports documenting telephone conversations:

- Documentation that the facility was notified in writing of your goals and objectives;
- Documentation of the goal, objective, or plan that the facility has failed to meet;
- Actions the Network took to inform the facility that it was not complying with your goals, objectives, or plans;
- Documentation that the facility was given an opportunity to make corrections;
- Follow-up actions taken to resolve the problem (e.g., documentation of phone calls to the facility asking for specific information) which demonstrate the Network attempts to work with the facility to resolve the problem; and
- Documentation of the facility's failure to submit an action plan, or the submission of an unacceptable action plan, if applicable.

If the facility's failure to meet the Network's goals, plans, etc., causes the Network to fail to meet your statutory contractual obligations, the Network must take action. The Network uses its professional judgment in deciding when it has provided enough assistance to the facility. A maximum time of three months is allowed for the facility to meet the Network's goals, plans, etc.

40 - Forwarding Sanction Recommendations

(Rev. 1, 07-11-03)

ENO 715

The Network alerts its RO Project Officer (PO) of its intent to recommend a sanction after the Network has fully documented, in writing, the facility's failure to comply with your goals and objectives. The Network submits two copies of your documentation and a cover letter addressed to the appropriate Associate Regional Administrator (ARA) through your RO PO and include:

- The name, address, and Medicare provider number of the facility;
- The Network goal or objective with which the facility failed to comply;
- A brief summary of the basis for the sanction recommendation;
- An outline of what documentation and action the facility must submit and follow in order to remove the sanction;
- The individual in the Network whom the RO can contact for further information and assistance; and
- The name and phone number of the Network's PO.

The Network organizes the information in notebook form with a chronological summary and a table of contents

NOTE: Appropriate RO is defined as the RO that services the State where the facility is located.

50 - Project Officer's (PO) Role in Sanction Procedures

(Rev. 1, 07-11-03)

ENO 720

The RO PO forwards the sanction recommendation for processing to the ARA of the RO that services the State where the facility is located. The PO will also alert CMS CO of a potential sanction action against an ESRD facility.

60 – Regional Officer (RO) Role in Sanction Procedures

(Rev. 1, 07-11-03)

ENO 725

The RO (Survey and Certification Branch) has the responsibility for implementation of an alternative sanction recommendation. When an alternative sanction recommendation is received, the RO will:

- Review the sanction recommendation for completeness, and determine if there is sufficient information to process the sanction recommendation and the type of sanction to impose;

- Notify the RO Survey and Certification Branch and the State Survey Agency of the potential sanction action to determine if there has been any State action past or pending;

- Select the mechanism that provides the most effective means to encourage the facility to come into compliance with the requirement; and

- Review the sanction recommendation and make the final determination whether or not to sanction a facility.

If additional information and/or assistance is needed to process the case, the RO will contact the Network.

70 – RO Role in Notice and Appeal Rights

(Rev. 1, 07-11-03)

ENO 730

The RO Survey and Certification Branch notifies the facility of the alternative sanction and its effective date. The effective date of the sanction is at least 30 days after the date of the notice.

When the RO proposes to apply an alternative sanction, the facility is given written notice of the proposed sanction and 15 days in which to request a hearing. Unless the facility requests a hearing within 15 days, the RO notifies the Network and the public about the reasons for the sanction and when it will take effect. If the facility requests a hearing, the RO will provide an informal hearing by an official who was not involved in making the sanction decision. During the informal hearing, the facility:

- May be represented by counsel;

- Has access to the information on which the allegation was based; and

- May present oral or written evidence and documentation to refute the finding of failure to participate in Network activities and pursue Network goals.

If the written decision, based on the informal hearing, supports application of the alternative sanction, the RO, at least 30 days before the effective date of the sanction, will provide the facility with a second written notice that specifies the effective date of and the reasons for the sanction. The RO will notify the Network and the public of the sanction.

80 - Duration and Removal of Alternative Sanctions

(Rev. 1, 07-11-03)

ENO 735

An alternative sanction remains in effect until the facility is in substantial compliance with the requirements to participate in your Network's activities and pursue the Network's goals, or the facility is terminated from the Medicare program by the CMS RO for lack of compliance. The RO will remove the alternative sanction when the facility demonstrates and documents that the reason for the sanction is eliminated. The RO may ask for the Network for its assistance in verifying the facility's compliance with the requirements.

When a sanction is based on failure to participate in Network activities (see 42 CFR 405.2134) and pursue Network goals, the sanction action can b/200e removed when CMS finds that the supplier of ESRD services is making a reasonabl0e effort to comply with the statutory requirement.

90 – Quality of Care Referrals

(Rev. 1, 07-11-03)

ENO 740

If at any time while conducting Network contract activities, the Network identifies situations or collects information which indicates that a physician may be failing to meet his/her obligation to provide quality care, the Network refers the issue to the appropriate QIO for peer review or Office of Inspector General and the Board of Examiners for Physicians for follow-up. Concurrently, advise the Network PO of the situation and its actions.

ESRD Complaints and Grievances

100 – Definitions for the ESRD Complaint and Grievance Process

(Rev. 1, 07-11-03)

1. **Closed** – A complaint or grievance has been handled to the extent available to Network resources. (See §140.1.)

2. **Complaint** – A written, verbal, or electronic request for assistance initiated by or on behalf of an ESRD patient(s) regarding concern(s) about ESRD issues including but not limited to care, treatment, or providers.

3. **Complainant** – An individual who expresses a concern by filing a complaint.

4. **Grievance** – A request for a formal investigation of a complaint, or a serious complaint involving a facility, physician, or other provider.

5. **Grievant** – An individual who expresses a concern through a formal process by filing a grievance.

6. **Inquiry** – A written, verbal, or electronic request from individuals or facilities for information, advice, referral, or educational materials that usually does not require problem resolution.

7. **Medicare Beneficiary** – An individual who, due to age, disability, or end stage renal disease, is entitled to receive benefits under Medicare.

8. **Personal Representative** – An individual designated to represent another individual for a designated reason and a specific length of time. (See §170.)

9. **Referred** – The complainant or grievant has been sent to the agency or individual that can most appropriately respond to the complaint or grievance. Or the complainant/grievant has been given the appropriate contact information for the best agency or individual to assist him/her with the concern and will make the contact himself/herself. (See §130.6 and §140.3).

10. **Reopened** – A previously closed inquiry, complaint, or grievance that has reoccurred. (See §140.4.)

11. **Resolved** - The complaint or grievance has been explained, corrected, or settled by the Network so that the complainant is in agreement with the determination or outcome. (See §140.2.)

110 – ESRD Complaints and Grievances

(Rev. 1, 07-11-03)

ENO 755

The Network must implement procedures for evaluating and resolving patient grievances as required in §1881(c)(2)(D) of the Act and CMS regulations at 42 CFR 405.2112(g). In addition the Omnibus Budget Reconciliation Act amended the Act in 1989 to provide ESRD Networks with confidentiality in the medical review process (see §1160 of the Act) and a limitation on the Network's liability. (See §1157 of the Act.)

It is the responsibility of the Network to assure that an impartial review of grievances by Network staff and the MRB occurs without conflict of interest. (See §180.)

120 - Role of Network in a Complaint/Grievances

(Rev. 1, 07-11-03)

ENO 760

The Network's role in resolving a complaint, grievances, or inquiry will vary, depending upon the situation. The following are examples of different roles that the Network may assume:

A. Expert Investigator

The Network may assume the role of an expert investigator, when the quality of care provided to a patient(s) is an issue, the investigation's focus is the individual complaint and any overall patterns of care within the facility related to the complaint. For example, if a patient complains about the procedures used to initiate dialysis, the Network s potentially affected patients.

B. Facilitator

When communication between the patient and the facility is problematic, the Networks role may be to facilitate communication and the resolution of differences.

C. Advocate

Networks advocate for individual patient's rights and/or the rights of all patients at a facility, depending on the situation. A Network acts for greater good when the situation involves a threatening or **violent patient**.

D. Referral Agent

Issues that are not specifically ESRD Network issues, such as staff safety, fraud, and compliance with the Conditions for Coverage (CfC), should be handled by SAs or other local, State, or Federal agencies. Each Network must maintain a current list of appropriate local, State, and Federal resources to use as referrals for beneficiaries and/or complainants in need of assistance. (See §130.6)

E. Coordinator

Where potentially serious quality of care concerns and/or CfC issues are involved, the Network alerts the appropriate RO and your RO PO immediately and coordinate its investigation with the SA to avoid duplication of effort and conflicting outcomes. (See §130.8.)

F. Educator

The Network acts as an educator providing information and/or a referral to an appropriate resource when patients, families or facility staff request or require information/ education about ESRD, treatment of ESRD, or appropriateness of care.

130 - ESRD Complaint and Grievance Process

(Rev. 1, 07-11-03)

ENO 765

The Network is responsible for implementing a procedure for receiving, evaluating, and resolving complaints and grievances by determining the appropriate action(s) needed to assist the complainant/grievant and to resolve the concern. (Refer to §110.) Document all complaints and grievances in SIMS. It is expected that most complaints will be resolved quickly and will not become a formal grievance.

In resolving a complaint involving patient care, gather information on the telephone, by letter/email, by conducting on-site reviews, or by performing other investigative activities concerning care provided by a facility or a provider as appropriate (as determined by the MRB and 42 CFR 405.2112). In making a determination, the Network should utilize recognized standards of care to assure proper treatment for ESRD patients.

If resolution of the complaint through the Network's intervention as an advocate, facilitator, or educator is possible, the informal complaint process may be used and the formal grievance process is not required. However, if the Network is requested by the beneficiary to conduct a formal review and evaluation, or if a formal process is the best way to address a complaint, the formal grievance process should be initiated. (See Exhibit 7-1, ESRD Network Complaint Process and Exhibit 7-2, ESRD Network Grievance Process.)

130.1 – Facility Awareness of the Complaint/Grievance Process

(Rev. 1, 07-11-03)

ENO 765.1

The Network provides all new ESRD patients in its jurisdiction with information about patient's rights and how to file a complaint or grievance with the Network and with the State survey agency. The Network provides its toll-free number. In addition, the Network assures each facility is aware of its responsibility to inform its patients of the facility's grievance procedure (in accordance with 42 CFR 405.2138(e).

130.2 – Use of Facility Complaint/Grievance Process

(Rev. 1, 07-11-03)

ENO 765.2

All ESRD patients should be informed about the facility complaint/grievance process and encouraged to use it before requesting Network assistance. However, there may be instances when the patient does not wish to approach the facility staff or the provider. It is not mandatory that patients utilize the facility grievance process before contacting you.

EXAMPLE

A patient, who expresses concern about the attitudes of the staff at the facility, and is afraid to approach the facility staff for fear of retribution, asks for the Network's assistance without discussing the problem with facility staff. In this instance, the Network may investigate and resolve the problem. If the problem is severe or the facility is resistant to correcting the problem, the Network should refer the complaint to the SA and/or coordinate your activities with the SA and notify its RO PO. The Network must work with the SA to settle the complaint/grievance, ensure that the facility is in compliance and that the problem is closed.

All complaints or grievances directed to the Network require some type of action by the Network. The Network is not expected to monitor web sites for quality of care issues.

130.3 – Determination of Network Involvement

(Rev. 1, 07-11-03)

ENO 765.3

The Network has the authority under §1881(c)(2)(D) of the Act to act on all complaints/grievances regarding a Medicare certified facility or made by a Medicare

beneficiary alleging a facility's failure to provide care and services to which beneficiaries are entitled. All complaints alleging a situation that could affect the health or safety of beneficiaries should be investigated immediately by the Network or referred to the SA or other appropriate authority. Whether a case should be referred may be determined by the Network in a confidential conversation with the SA or other appropriate authority. The SA has the authority and responsibility to act on complaints within the scope of the Conditions for Coverage. State law enforcement agencies, SAs, and CMS Regional Office have the authority to investigate cases of alleged Medicare fraud and abuse.

It is important for you to determine if the complaint is an issue appropriately handled by the Network or if it should be referred. The Network make a preliminary determination when the complaint is first received. Then the makes final determination after you have gathered information about the complaint/grievance. The Network may refer a complaint or grievance at any time during the complaint/grievance process.

130.4 - Receiving a Complaint/Grievances

(Rev. 1, 07-11-03)

ENO 765.4

The Network may receive a written or verbal inquiry, complaint, or grievance from an ESRD patient, a personal representative (See §170), a family member, a friend, a facility employee, a physician, a Federal or State agency, a patient advocate, or a concerned individual. In addition, other sources, such as the media, may make the Network aware of quality of ESRD care issues that should prompt an investigation. The Network may be requested to investigate certain cases by its PO. The Network may also receive referrals of complaints affecting or made by ESRD patients from Quality Improvement Organization(s) (QIOs), SAs, other ESRD Networks, the Medicare 1-800 Hotline, and Medicare fiscal intermediaries. Networks are not expected to monitor web sites for quality of care issues.

The Network receives and acknowledges all complaints and grievances directed to you. Complaints or grievances may be made anonymously. A complainant's or grievant's identity must remain confidential unless specific permission is given by the complainant or grievant to use or release his/her name. The Network always asks the complainant/grievant if his/her name can be revealed before the Network begins its investigation. The Network documents the complainant's position on maintaining confidentiality and when possible obtains a written authorization. The Network does not wait for written authorization before beginning its investigation.

When written or verbal complaints/grievances are received, they should be documented by entering them into SIMS. The Network should keep supporting documents and related correspondence in a confidential file. There may be occasions when a complaint/grievance recurs, and a closed case needs to be reopened because of a further need for review, investigation, and/or action. When the Network reopens a case, it counts

it as a new case, but is linked to the previous case so that you can watch for patterns. If a case is linked to another case or there are multiple complainants, the Network document the linkage in the SIMS Contact section until SIMS is able to automatically link related cases.

When a complainant contacts the Network with a problem, there are three options for handling any given situation:

1. **Informal complaint process**

   An informal complaint process allows the Network to communicate with the facility/practitioner by phone, letter, fax, email, or in person. This process does not require a formal written report to the complainant. The Network will work with the involved parties to shepherd a workable solution.

2. **Formal grievance process**

   A formal grievance process usually a longer process involving a CMS-specified investigation process, a grievance determination, due process for the involved parties and a final written report.

3. **Referral**

   A referral to an appropriate agency or entity, is made when the issue falls under that agency's or entity's authority (e.g., failure to meet a Condition for Coverage would be referred to the State survey agency for action.)

The Network can recommend one of the above options to the complainant, but you must present all options. The Network uses the complaint handling option that the complainant prefers. A grievance automatically initiates the formal process. Regardless of whether a formal or informal process is used initially, the process used may be changed latter.

Within five days of receipt, the Network acknowledges all written complaints either in writing or by phone. The Network writes a letter to a complainant state the complaint, explains the options for handling the situation, and provides a Network contact person and a toll-free phone number. All grievances should be acknowledged in writing within 5 working days of receipt. (See Exhibit 7-4, Model Response Letter of Acknowledgement for a Written Complaint/Grievance)

The Network explains in writing the disclosure provisions that will govern your final grievance response, and advise that the final response will include as much information as you are permitted to disclose under those provisions.

1. The Network advises that in a grievance/complaint it will not reveal the grievant's complainant's identity during your investigation/review process without his/her consent. However, explain that because of the small patient

population in dialysis facilities, identification by the provider/involved practitioner may occur, even when confidentiality is maintained;

2. The Network advises anonymous complainants or grievant that their complaint will be investigated but you will be unable to report back to them without their name and address. Explain that because of the small patient population in dialysis facilities, identification by the provider/involved practitioner may occur, even when anonymity is maintained;

3. The Network advises that the complainant or grievant needs to inform the Network, either by telephone or in writing, of his/her decision regarding the use of his/her name in the investigation/resolution process. . (See Exhibit 7-4, Model Response Letter of Acknowledgement for a Written Complaint/Grievance, and Exhibit 7-5, Consent to Disclose Identity – Model Form);

4. The Network advises the grievant only that once your review is completed, you are required to advise the provider/involved practitioner of your determination and solicit comments prior to the release of your response to the grievant. Thirty days are allowed for the submission of comments;

5. The Network advises the complainant/grievant, that information which explicitly or implicitly identifies the practitioner, is confidential and cannot be disclosed without the practitioner's consent (see 42 CFR 480.133(a)(2)(B)(iii)); and that none of the confidential information in the grievance response letter may be used in litigation. (See 42 CFR 480.107); and

6. The Network assures the complainant/grievant that regardless of whether his/her name remains confidential, the Network will investigate the complaint/grievance and you will act on the findings. If the case is investigated as an anonymous complaint, and there is no contact information the Network will be unable to provide him/her with a final report.

130.5 - Request of Grievance in Writing

(Rev. 1, 07-11-03)

ENO 765.5

Whenever possible, a grievance received via telephone or in person should be confirmed by the grievant in writing; however, **a written confirmation is not required.** Once a grievance is received/initiated, the Network starts its investigation of the grievance immediately. For a potential life-threatening situation refer the complaint to the SA and immediately notify its RO and the RO responsible for the state in which the dialysis facility is located. (See §130.9)

130.6 – Referring Complaints and Grievances

(Rev. 1, 07-11-03)

ENO 765.6

The Network is responsible for reviewing the issue(s) raised by a complaint or grievance and determining the action required (e.g., investigation or referral). If there is a question as to whether or where a complaint or grievance should be referred, the Network seeks direction from its RO PO. If the Network and its RO PO determine that a complaint or grievance concerns an issue that would more appropriately be handled by another agency, organization, or licensing board, advise the complainant/grievant and either provide the referral information to the complainant/grievant or make the referral to:

1. Carrier, Fiscal Intermediary (FI), and RO Medicare Coordinator

If the grievance concerns a payment or denial of services, refer the complainant to the appropriate carrier or intermediary or to the RO representative who works with carriers or intermediaries.

2. State Survey Agency (SA)

Life threatening situations should be referred immediately to the SA (See §130.9). If the complaint/grievance is not life threatening but involves Conditions for Coverage coordinates its activities with the SA or refer the complaint. Networks may provide quality improvement (QI) assistance whether or not the complaint has been referred to SA. QI assistance may also be provided when the facility requests it as a result of a SA investigation.

3. Quality Improvement Organization (QIO)

Refer complaints or grievances involving hospital inpatient stays, nursing homes, home health agencies, and ambulatory surgical centers to the QIO for peer review in the State where the hospital or service provider is located whether or not the complaint/grievance is specifically related to ESRD treatment or services. The complaint may involve care or services for comorbid conditions.

EXAMPLE

An ESRD patient complains that he failed to receive diabetic foot care while in the hospital. The lack of care resulted in a gangrenous heel ulcer and his foot being amputated. You should refer this complaint to the QIO responsible for the area where the physician and hospital is located.

EXAMPLE

A dialysis facility staff person complains that several ESRD patients with pneumonia had been discharged prematurely from a particular hospital and have had to be readmitted within a few days of discharge due to serious complications. The complaint should be referred for review to the QIO responsible for the state in which the hospital is located.

4. CMS Regional Office

Refer complaints/grievances that are potential or alleged fraud or abuse cases to the CMS RO. Refer to the CMS web site for the most recent Associate Regional Administrator (ARA) list.

EXAMPLE

A Medicare ESRD patient alleges that a provider is submitting charges to Medicare for treatments and services that were not rendered. You should refer this complaint to your CMS RO.

5. State Licensing Boards

Refer complaints/grievances about a physician or other provider services furnished in private offices, clinics or other ambulatory settings to the appropriate QIO for review, investigation and a determination as to whether the complaint/grievance should be referred to an accreditation, licensing, or certification agency.

EXAMPLE

A relative of an ESRD patient complained that her father's doctor failed to treat his decubitus ulcer, which became infected and resulted in a fatal septicemia. Since the alleged lack of care resulted in the death of the complainant's father, you should refer the case to the QIO for peer review and discuss the case with the RO PO to determine whether or not the case should also be referred to the State Physicians' Licensing Board.

6. Managed Care Organization (MCO)

If the patient is a known managed care patient, refer complaints/grievances about services furnish contractually for the MCO's department for patient complaints. If the complaint is about the MCO itself, refer the complaint to the CMS RO repsonsible for the state in which the HMO is located.

EXAMPLE

A patient complained that their MCO is preventing them from receiving a transplant by requiring them to use an out-of-state transplant center when a local Medicare certified center is available. The patient should be referred to the CMS RO.

130.7 - Written Acknowledgment of Grievance

(Rev. 1, 07-11-03)

ENO 765.7

When a formal grievance is received, written acknowledgement should be provided to the grievant within five business days. The letter of acknowledgement must:

- State the grievance;
- Advise that the Network will look into the issues raised by the grievant;
- Explain the disclosure provisions that will govern your final response; (See §130.5.)
- Explain the review process and provide approximate time frames;
- Explain that you will notify the grievant of any delays;
- Advise that additional information/documentation can be submitted at any time;
- Advise the grievant if the grievance is more appropriately handled by another agency. If the grievance is referred, provide a contact person and the name, address, and phone number of the agency receiving the referral; and
- Provide the Network's name, address, and toll-free telephone number and a contact person who the grievant should contact to provide additional information about his/her grievance or to check on the progress of the investigation.

130.8 – Investigation of Complaints and Grievances

(Rev. 1, 07-11-03)

ENO 765.8

The Network focuses its investigation on gathering information objectively in order to determine the validity of the allegation stated in the grievance or complaint. The Network starts its investigation by obtaining as much information as is available and/or necessary in order to fully understand the issue(s). Information may be gathered from the

complainant/grievant, and/or facility by phone, letter, fax, e-mail, in person, or on-site visit. During the investigation of a grievance the Network staff and/or the MRB may interview the complainant/grievant, patients, or facility staff and may review medical records or other records to make determinations about the quality of care provided. If in gathering information about the complaint or grievance, the Network observes a situation which it believes poses a substantial risk to public health, not related to the complaint/grievance, the Network should advise the facility to report the problem to SA or the Network reports for them.

130.9 – Life-Threatening Situations

(Rev. 1, 07-11-03)

ENO 765.9

If the complaint or grievance appears to present an immediate and serious threat to patient health and safety, forward it immediately (within 24 hours of receipt or determination) to the appropriate SA and RO ARA or ARA designee, which services the state/SA where the facility is located. The Network keeps your RO PO informed. Although initial contact with the appropriate RO may be via telephone, immediately follow the call with a written confirmation of the situation either by e-mail or FAX. If the RO requests the Network's assistance, the Network makes itself available to consult and/or begin the investigation immediately. If the RO asks the Network to investigate the complaint/grievance, the Network reports its findings to the RO as soon as possible.

130.10 – Challenging Patient Situations

(Rev. 1, 07-11-03)

ENO 765.10

If a complaint or grievance involves discharge of a disruptive, abusive, or violent patient, the Network investigates the situation by obtaining information from all involved parties. In all cases, the safety of all patients and/or staff should be the primary concern during the resolution process. The Network tries to determine what the facility and the patient have done to resolve the problem. The facility should upon admission advise the patient of the facility rules and discharge policy and should, when possible, make an effort to work with the patient toward a successful outcome. The Network may facilitate communication between the patient/complainant and the facility staff, but the Network should not provide services that are the responsibility of the facility and the facility social worker (e.g., finding placement in another facility). If on investigation, the facility may be in violation of the Conditions for Coverage (CfC), refer the case to the SA (See 42 CFR 405.2138).

Upon request, assist facilities in developing policies and procedures that are in compliance with Medicare regulations. If a facility's policy or procedure contradicts/does not comply with the CfC, the Network advises the facility and refers the case to the SA.

130.11 – Advocating for Patient Rights

(Rev. 1, 07-11-03)

ENO 765.11

The Network advocates for patient rights with the understanding that the patient is responsible for his/her behavior. Patient rights are found at 42 CFR 405.2138. If attempts to resolve the complaint/problem(s) fail and the facility wants to discharge the patient, you may request that the facility provide advance discharge notice preferably 30 days before discharge. The facility should also be notified that they are required to assist with alternate placement. Whenever possible the patient's nephrologist should be involved in the discharge and transfer planning. If the patient requests, the Network provides the patient with a list of facilities. If a patient has been discharged from a unit and the unit was unable to place the patient in another outpatient dialysis facility and the patient is no longer being followed by a dialysis facility social worker, the Network may assist the patient if requested by the patient. It is not the responsibility of the Network to place patients in dialysis facilities. The Network evaluates its involvement on a case-by-case basis with consultation from its RO PO and the SA as appropriate.

130.12 – Addressing a Complaint or Grievance

(Rev. 1, 07-11-03)

ENO 765.12

The Network addresses complaints and grievances as described in §120. The Network assists in the resolution of the complaint or grievance by acting in the appropriate capacity between the complainant/grievant and the facility, physician, provider, or supplier. The Network advises the facility and practitioner that you will be responding to the grievant or complainant. When appropriate, a complaint or grievance may be resolved by requiring the facility to develop and implement an improvement plan (IP). The Network should monitor the progress the facility makes to correct or improve the problem. A complaint/grievance may be closed on the completion of the improvement plan. If on completion of the improvement plan, the facility has failed to adequately address/correct the identified problem, the Network can ask that a revised improvement plan be carried out or the Network may refer the complaint/grievance.

130.13 – Follow-Up of a Grievance

(Rev. 1, 07-11-03)

ENO 765.13

After addressing a grievance, the Network may want to follow-up with the grievant if you have concerns about the correction or recurrence of the problem. In following up on a grievance try to determine if the outcome of the grievance process met the needs of the grievant/patient. Grievant satisfaction is desired, not required.

130.14 – Conclusion of a Grievance Investigation

(Rev. 1, 07-11-03)

ENO 765.14

As required at §1154(a)(19) of the Act, advise the facility, physician and/or involved practitioner of your findings and recommendations. At least 30 days prior to reporting your final determination to the grievant, the Network provides the involved physician and/or practitioner with an opportunity to submit additional information or comments relating to the initial grievance determination. Comments must be made in writing before a final Network determination is made and the letter to the grievant is written.
(See 42 CFR 480.105)

1. Afford the involved practitioner 15 calendar days (within the 30 day time period prior to sending the response letter to the grievant) to respond. Advise the physician and the facility that you will be sending a final report to the grievant. Advise the physician that his/her response, if there is one, must be received prior to the release of the report to the grievant if it is to be included in the response letter.

2. Send a letter containing a grievance report (See§130.15) to all of the involved parties, the grievant/patient representative, provider and facility. Protect the confidentiality of the grievant and the practitioner, unless the grievant and/or the practitioner have agreed to the release of his/her name (See §160). The Network should conclude a formal grievance within 90 calendar days of receipt of the grievance. In those instances where more than 90 days are required for the determination to be made and the grievance process to be completed, notify all parties including the RO PO, of the reason for the delay and the anticipated date for the conclusion of the activity.

3. In concluding a grievance investigation, advise the grievant to contact the Network if the problem is not resolved or if it occurs again. If the problem is a recurring one at the involved facility, the Network should follow-up by checking

with the grievant and/or the facility to make sure the problem was actually resolved and remained resolved.

130.15 – Report and Letter to the Grievant

(Rev. 1, 07-11-03)

ENO 770

The Network's report to the grievant should be contained in a summary letter that includes the following:

- A brief description of the grievance and the investigation;
- The extent to which the problem described in the grievance was verified;
- If the situation resulted in Network recommendations to the facility; and/or
- If the situation has been or is being corrected by the facility; and whether the facility in implementing an Improvement Plan (IP) and will be monitored to assure correction/improvement is made. (See Exhibit 7-7, Final Response to Grievant Model Letter.)

If the Network has facilitated a resolution of the grievance, list the agreed upon actions and remedies (facility, physician/provider and grievant/patient responsibilities) as well as information on how to contact the Network and a person at the facility that will be in charge of implementing the facility's actions.

The Network's report to the grievant should be of a general nature and should not detail all the specifics of the investigation. Do not identify the practitioner, without the consent of the practitioner(s) at issue. (See 42 CFR 480.133(a). Do not use the name of another patient without his/her permission. In the grievance report, a Network may disclose facility-specific information concerning the grievance. (See §160 below and 42 CFR 480.133)

If the Network's MRB is involved in the grievance process, the deliberations of the MRB are considered predecisionary and confidential and are not to be released.

In addition, the letter should include a detailed explanation of other options and contacts for those options, such as referral to the SA or the appropriate RO, which the grievant may pursue if he/she is not satisfied with the Network grievance process including the outcome. (See Exhibit 7-7, Final Response to the Grievant Model Letter)

140 – Potential Outcomes of Complaint/Grievance Process

(Rev. 1, 07-11-03)

ENO 775

There are several possible outcomes for beneficiary complaints and grievances.

140.1 - Complaint/Grievance Is Closed

(Rev. 1, 07-11-03)

A case is closed and the Network complaint/grievance activities may be suspended when the complaint or grievance has been referred, investigated, or acted on by another agency or when no further action can be taken or required of the Network. The following situations are examples of when it is unnecessary for a Network to continue its investigation or to make a determination:

1. Complainant died and the complaint became moot because it only pertained to that person and the complaint was not related to the death, e.g., the complainant wanted to dialyze on a different shift; or

2. The provider is no longer in business, and the Network is unable to pursue an investigation.

In both of these situations, the Network keeps its RO PO informed about the situation. The complainant/grievant may be dissatisfied with the results of the investigation because the Network is:

1. Unable to confirm the alleged problem; or

2. Unable to modify facility activity to the extent that the complainant/grievant desires. (In some instances, although the Network has identified a situation that is problematic for the complainant, there may be no regulatory requirement that the provider change their policies, procedures or behaviors in the problematic area.)

EXAMPLE

The facility's hours of operation did not allow the beneficiary to schedule dialysis at a convenient time for his/her job. Although it is preferred that facilities accommodate their patients' work schedules, there is no requirement in the CfC. If the facility cannot adjust the patient's treatment times and if the patient requests the Network's assistance, the Network should assist the patient in identifying alternative options, such as a nearby facility with the desired treatment hours.

140.2 - Complaint/Grievance Is Resolved

(Rev. 1, 07-11-03)

The complaint is considered to be resolved when:

1. The complaint/grievance has been explained, corrected or settled by the Network so that the complainant/grievant is in agreement with the determination and/or the outcome, or

2. The involved parties comply with the desired outcome.

A complainant/grievant may be in agreement with the outcome are:

EXAMPLES

A. The Network's assistance with communications between the complainant/grievant and the facility staff results in a satisfactory outcome for the complainant/grievant;

B. The investigation determines that it is appropriate for the facility to implement changes and an acceptable improvement plan is developed and carried out, and resulting in satisfactory facility changes; or

C. An explanation/educational effort resolves the complainant's/grievant's concern.

140.3 - Complaint/Grievance Is Referred

(Rev. 1, 07-11-03)

A complaint or grievance may be referred when a complainant makes a request for referral or when you determine that the concern/grievance falls under the authority or jurisdiction of another entity or agency, or if the complainant/grievant is dissatisfied with the Network's determination. A complaint or grievance can be referred so that it may be assessed by another appropriate entity. (See §130.6.)

140.4 - Complaint/Grievance Is Reopened

(Rev. 1, 07-11-03)

A complaint or grievance is reopened when a complaint/grievance, that had previously been resolved, becomes an issue again. The case is opened as a new case but is linked to the original case so that the Network can have the benefit of the original case work and determine if a pattern exits. The Network documents the linkage as a narrative in the SIMS - Background section. (See §130.4)

150 – Improvement Plans

(Rev. 1, 07-11-03)

ENO 780

The Network requests an IP if you have determined that a single situation of or a pattern of substandard care exists which has, or may have, an impact on the health or well-being of one or more Medicare beneficiaries. The intervention designed should correct the problem(s) identified. The facility or provider develops the intervention and the Network approves it. However, if requested, the Network should assist the facility with the intervention development. When the Network requires an IP to be developed, the Network informs the RO PO and enters the IP and related activities into SIMS. Facility IPs may be shared with the RO and SA on request.

150.1 – Content of Improvement Plans (IPs)

(Rev. 1, 07-11-03)

ENO 780.1

A facility must submit their IP in writing or electronically. The IP should:

- Identify and confirm an opportunity for improvement;
- Describe the implementation of an intervention activity to correct the problem;
- Describe the staff and material resources that will be dedicated to the intervention;
- Provide an expeditious timetable including all interim steps and a final completion date; and
- Propose a methodology, which will allow you to periodically monitor the intervention activities and outcomes to ensure that the problem has been corrected and that it does not recur.

150.2 – Time Period for Review and Acceptance/Rejection of IPs

(Rev. 1, 07-11-03)

ENO 780.2

The facility has 15 calendar days to submit an IP after you requested by the Network and the Network has up to 30 days to accept or reject the IP. An IP must be finalized and implemented within 60 calendar days of notification (within 15 days of Network approval of the IP). If possible the IP should be completed within one to three months.

150.3 – IP Tracking System

(Rev. 1, 07-11-03)

ENO 780.3

The Network should develop an internal tracking system to ensure adherence to the improvement plan scope and time line until the capability is in SIMS. The Network should also contact the facility at least once a month to offer assistance and support.

150.4 – Conclusion of IP

(Rev. 1, 07-11-03)

ENO 780.4

At the conclusion of the approved time period (usually one to three months) for completion of the IP, determine whether the facility has complied with the plan and if the problem has been adequately addressed. The determination may be made by onsite inspection, off-site review of material provided by the facility, or by a conference call with the involved parties, or any combination of the three.

150.5 – Non-Compliance With IP

(Rev. 1, 07-11-03)

ENO 780.5

If the Network determines that the facility has not complied with the IP, after timely Network internal reviews, a decision will be made by the Network whether to amend the existing IP, or recommend a sanction to the RO, and/or refer the situation to the SA. The Network should notify its PO of the facility's non-compliance and the action that will be taken.

160 – Confidentiality and Disclosure of Information

(Rev. 1, 07-11-03)

ENO 785

A patient's/complainant's/grievant's identity is confidential information and may not be revealed unless the patient/complainant/grievant or personal representative (See Exhibit 7-5, Consent to Disclose Identity – Model Form) has specifically authorized release of his/her name. The Network is subject to §1160 of the Act and

42 CFR Part 480 and should comply with these disclosure requirements. Title 42 CFR Part 480 permits disclosure of the patient's identity to the SA on request of the SA.

The Network maintains all complaint investigation/resolution correspondence and documentation (not captured in SIMS) in a confidential file in a locked cabinet. On request, provide the RO PO with the complaint/grievance file and SIMS documentation for on-site review. The RO PO will advise the ARA or the ARA designee at the appropriate RO about the grievance when the situation requires ARA involvement.

160.1 – Identity of Complainant

(Rev. 1, 07-11-03)

ENO 785.1

The Network asks the complainant/grievant if they may be identified during the investigation and resolution process. Verbal consent for the release of the complainant's/grievant's identity should be obtained during the first contact. The Network must document the complainant's/grievant's consent or lack of consent. The Network is not required to wait for written authorization before taking action

Consult with the complainant/grievant throughout the complaint/grievance process. If the Network is unable to pursue resolution of the complaint/grievance without releasing the complainant's/grievant's identity, the Network advises the complainant/grievant immediately. The complainant/grievant may reconsider and authorize the release of his/her name. If the patient still does not wish the Network to release/use his/her name the Network may act on or refer the complaint as an anonymous complaint. If the complaint/grievance becomes irresolvable due to confidentiality issues, the Network advises the complainant/grievant in writing that the process cannot be continued, and outline any other available alternatives (refer CfC issues to the SA). A potentially irresolvable complaint/grievance can occur when a patient's refusal to authorize release of his/her name, prevents the facility from focusing its corrective action. Occasionally, however, the problem may be resolved with out the release of his/her name, if by raising the concern, the facility becomes sensitive to the issue and makes an effort to improve or correct the situation generally. (See Exhibit 7-5, Consent to Disclose Identity – Model Form.)

160.2 – Request of Grievance in Writing

(Rev. 1, 07-11-03)

ENO 785.2

The identity of a practitioner should not be revealed in the grievance report letter without the consent of the practitioner at issue. (See 42 CFR 480.133 (a)(2)(iii).)

160.3 – Facility Identity

(Rev. 1, 07-11-03)

ENO 785.3

The identification of a facility and disclosure of facility information may occur upon request by Federal and State enforcement agencies, licensing and certification bodies, State and local public health officials. (See 42 CFR 480.135 through 480.138 for disclosure provisions.) In addition, it is acceptable to release aggregate statistics about the number and types of complaints/grievances as long as individual patients/complainants/grievants cannot be identified implicitly or explicitly.

170 – Personal Representative

(Rev. 1, 07-11-03)

ENO 790
A personal representative is an individual designated by a court of competent jurisdiction or by the beneficiary, as evidenced by a document signed by such beneficiary, to act on his/her behalf. An individual/patient/beneficiary may designate whomever he/she chooses as his/her personal representative. An individual may designate a representative by executing a Power of Attorney, a Durable Power of Attorney, or a signed and dated proxy statement. The patient representative may act for the person they represent in any capacity that the person authorizes (e.g., financial actions, health care decisions, or advocacy that may be limited to a single transaction or an ongoing responsibility). The court may appoint a Guardian of the Person or a Representative Payee if the individual is deemed incompetent. The appointment may be for a single action/transaction or it may last for the life of the individual. The names of the involved parties, the duration of the appointment and the extent of the power should be stated in the court document. Whenever a third party acts as a representative of an adult patient in the filing of a complaint/grievance, the Network obtains a copy of the document appointing them as representative before releasing any confidential information or the results of Network activities. (See Exhibit 7-6, Designation of a Representative – Model Form.)

A third party can, however, file a complaint or grievance on behalf of a patient without being a lawfully appointed personal representative. Even though a third party may file a complaint, they would not be authorized to receive a report of findings that contained any confidential information (information that would implicitly or explicitly identify a patient or a practitioner) unless they obtained legal appointment or personal designation in writing by the patient and provided the Network with a copy of the document.

180 – Conflict of Interest

(Rev. 1, 07-11-03)

ENO 795

The Network ensures that a conflict of interest or potential conflict of interest does not exist among members of a complaint/grievance committee, a MRB committee, or a board of directors handling a grievance. Any individual, who has direct involvement with the complainant/grievant or the provider under investigation, whether it is a financial, professional or personal relationship, should be excluded from participation in the investigation and resolution of the complaint/grievance. (See §1881(c) of the Act)

190 – Exhibits

(Rev. 1, 07-11-03)

Exhibit 7-1 - ESRD Complaint Process

(Rev. 1, 07-11-03)

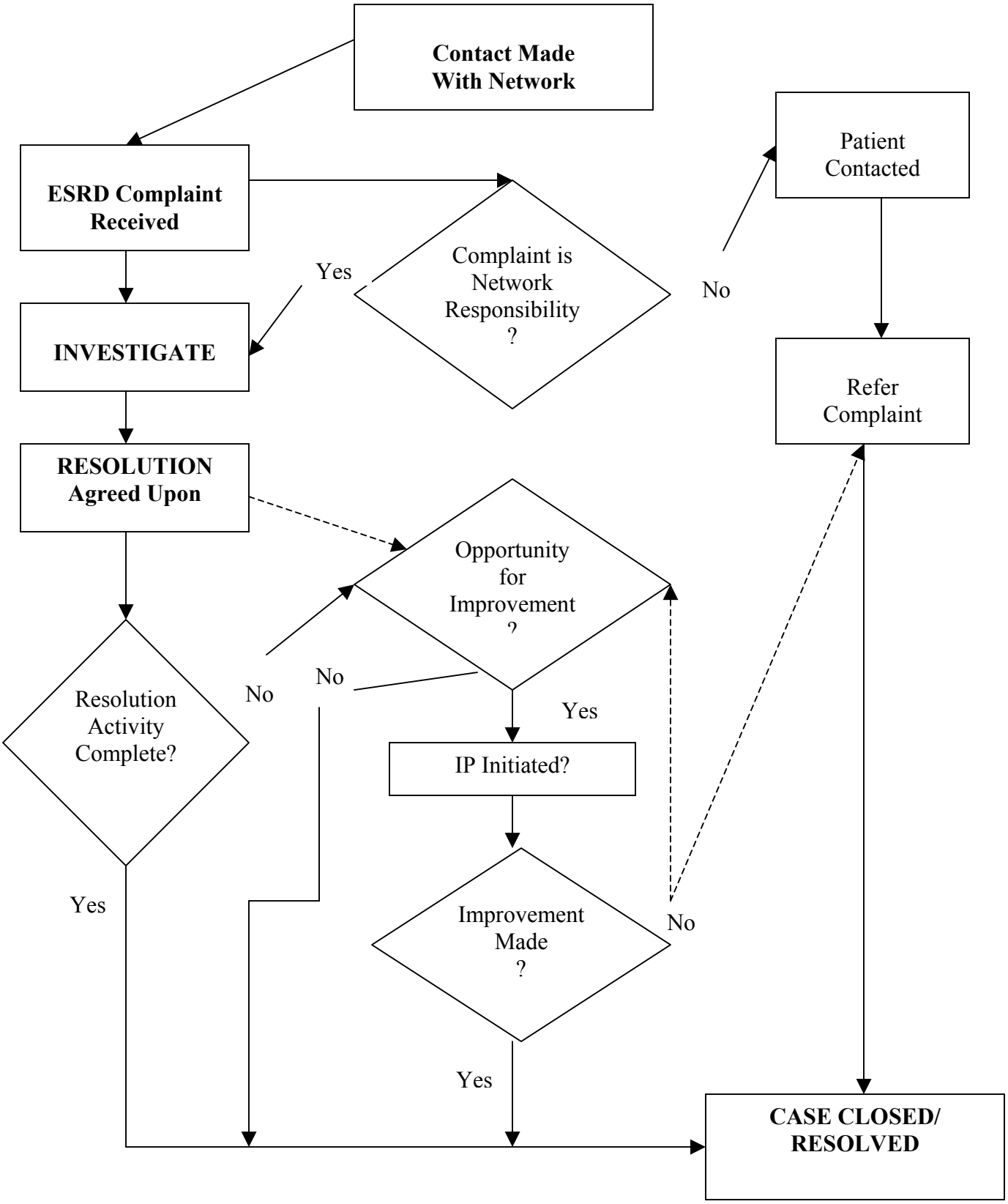

Exhibit 7-2 - ESRD Grievance Process

(Rev. 1, 07-11-03)

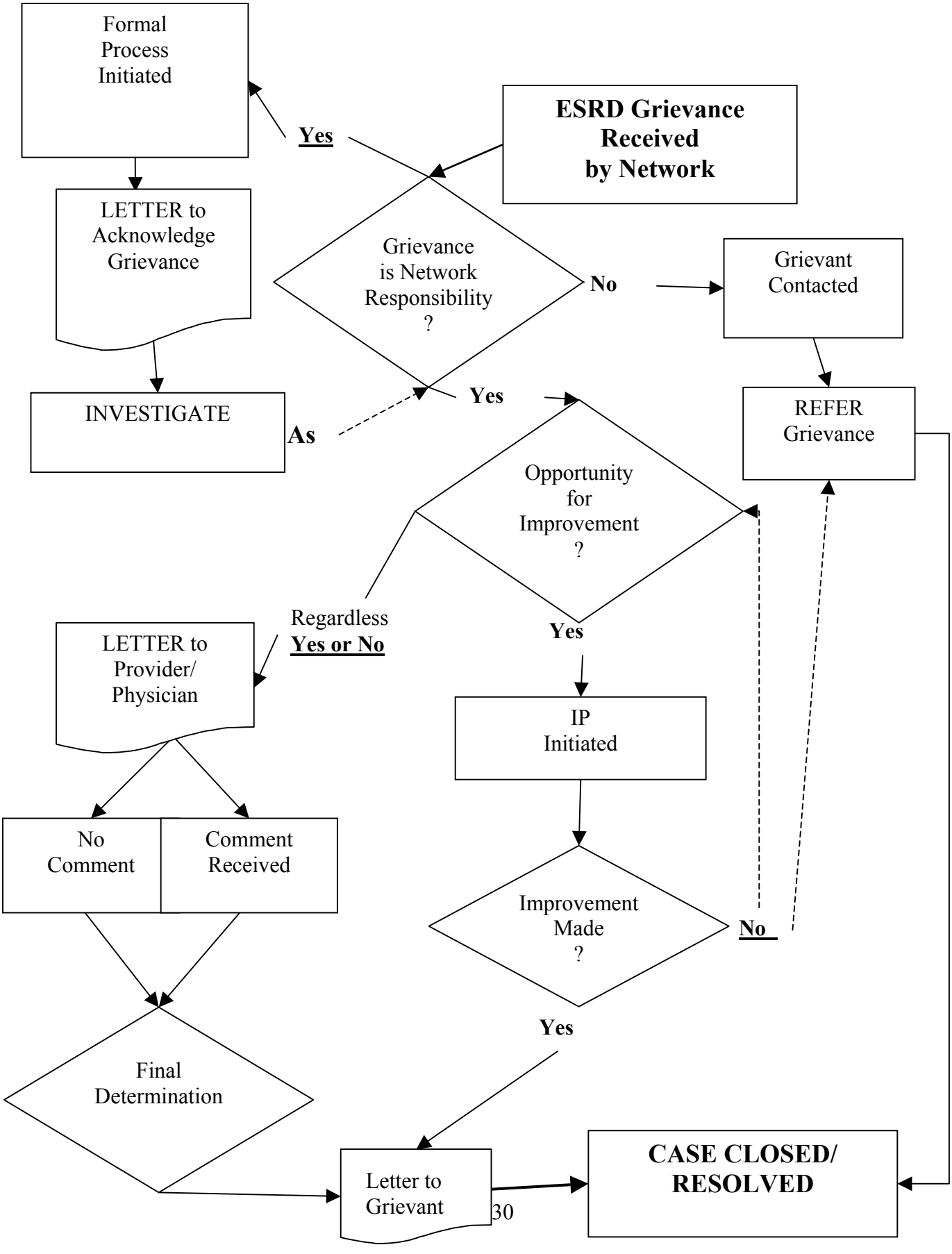

Exhibit 7-3 - ESRD Inquiry Process

(Rev. 1, 07-11-03)

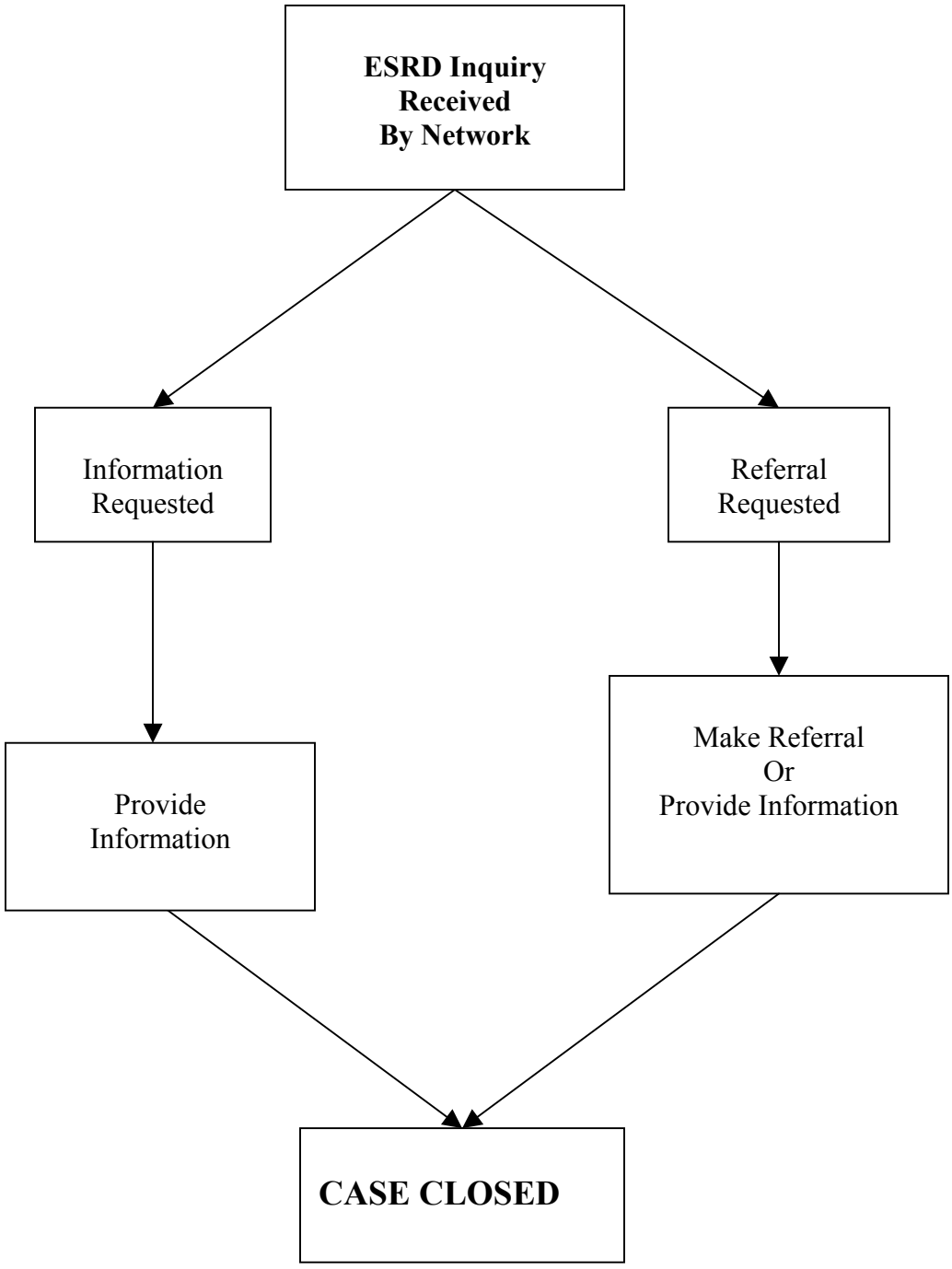

Exhibit 7-4 - Time Table for Complaints and Grievances

Contact Type	Acknowledge Complaint	Investigation, Review, and Make Initial Determination	Notice of Disclosure to Provider & Request for Provider Comment	Final Report/ Letter	Total Days
Complaint (verbal)	Acknowledge Complaint & describe complaint/grievance process during first contact	Gather information & try to resolve the complaint as quickly as possible	Letter **not** required.	Follow-up by phone or letter as appropriate	Usually 1 – 90 days plus follow-up as necessary
Complaint (written)	Letter of or call acknowledgement Sent within 5 business days from receipt of complaint letter.	Gather information &try to resolve the complaint as quickly as possible	Letter **not** required.	Follow-up by phone or letter as appropriate	Usually 1 – 90 days plus follow-up as needed.
Complaint becomes a grievance	Letter of acknowledgement sent within 5 business days from the time a complaint becomes a grievance	Up to 50 calendar days for intake and resolution	30 days (includes response time from the provider)	5 days after 30 day response time – letter sent to grievant	Up to 90 days plus follow-up as needed
Grievance	Letter of acknowledgement sent within 5 business days from receipt of grievance	Up to 50 calendar days for intake and resolution	30 days (includes response time from the provider)	5 days after 30 day response time – letter sent to grievant	Up to 90 days plus follow-up as needed
Life Threatening Situation	Forward to SA within 24 hours of receipt or determination and notify complainant/ grievant	If unsure of complaint validity gather information and make referral if appropriate	N/A	N/A	24 Hours
	Plan Submission	**Network Approval**	**Plan Implementation**	**IP Completed & Evaluated**	**Follow-up**
Improvement Plan	15 Calendar days from determination of need	Up to 30 Calendar days	Within 15 calendar days of approval	Usually 30 calendar days after implementation	1-3 months As appropriate

All complaints should be handled as quickly as possible. Whenever possible the time frame should be shortened, with the exception of the time allowed for the notice of determination to the provider. Do not shorten the time allowed for the provider/facility response, unless a response is received prior to the end of the 30-day period and no follow-up is needed.

Exhibit 7-5 – Model Response Letter of Acknowledgement of a Written Complaint/Grievance

(Your Letterhead)

(Date)
(Name of Complainant/Grievant)
(Address)
(City, State, and Zip Code)

Dear (Name of Complainant/Grievant):

We have received your (complaint or grievance) of (date) concerning (restate the complaint/ grievance). We will begin our investigation. However, we need to know whether we have your permission to use your name while investigating and trying to resolve your complaint. We have enclosed a consent form. Please complete all sections indicated on the form and return it to us using the enclosed addressed envelope. You may also call us with the requested information. The Network phone number is (Network phone number). Please contact us as soon as possible either by phone or in writing. If you choose to complete the sections indicated on the form, be sure to sign and date the form before returning it to us.

The (Network Name) is the End Stage Renal Disease Network Organization authorized by the Medicare Program to receive, investigate, and when possible resolve complaints and grievances made by or on behalf of Medicare beneficiaries in the State(s) of (name state(s)). The Network responsibilities include collecting the available information to determine the nature and extent of a problem and/or whether the services you received met medically acceptable standards. When quality of care concerns are identified, we either request the facility to correct the problem or we ask the State Survey Agency to look into the problem and take appropriate action.

If you have any questions or would like assistance in filling our the enclosed form, please contact us at:

(Network Contact Person)
(Network Name)
(Network Address)
(Network Telephone Number)
(Include toll-free number, if different)

Sincerely,

Exhibit 7-6 - Consent to Disclose Identity – Model Form

(To Be Used If Verbal Authorization Has Not Been Given)

CONSENT TO DISCLOSE YOUR IDENTITY

(Name of Requesting Network) will not reveal your name to the facility, doctor or provider involved in your (complaint or grievance as appropriate) without your consent. Your (complaint or grievance) will be handled as an anonymous (complaint or grievance) if we cannot use your name. An anonymous (complaint or grievance) is more difficult to investigate, and may prevent your concerns from being fully addressed. However, the choice is yours.

It is important for you to know that it is unlawful for a facility or its staff to retaliate against a patient or complainant for filing a complaint or grievance. If at any time you should feel that you are being discriminated against, please contact us (your Network name) or your State survey agency immediately.

Insert wording below if this form is being sent to a grievant:

When our inquiry is complete, before we send you our final response explaining our findings; we are required by law to:

1. Send a copy of those findings to the involved facility, doctor and/or provider for their review and comment; and

2. Obtain permission from the doctor to use his/her name in the letter that we write to you.

To avoid having your identity revealed, you can choose to receive a general response from us stating that we have completed our review. This general response would not discuss the outcomes of the review, but would serve to protect your identity.

---------- Cut on this line ----------

Please use a check mark below to indicate either YES or NO:

(_) YES, my identity may be revealed during the investigation of my (complaint or grievance). (If this consent form is in response to a grievance add: Please send me a grievance report letter).

(_) NO, I do NOT want my identity revealed during the investigation of my (complaint or grievance). (If this consent form is in response to a grievance add: Please send me a general notice.)

(Signature) (Date)

(Print Your Name) (Date)

Exhibit 7-7 - Designation of a Representative – Model Form

(The Network may use this form to inform an inquirer that the beneficiary may designate him or her as a personal representative. (See §170))

If you are acting as a personal representative of a living beneficiary and wish to file a complaint or grievance with (name of the ESRD Network) (known as the Network) on behalf of that beneficiary, the Network must receive written authorization from the beneficiary designating you as his/her personal representative or you may provide a copy of a court order designating you as Guardian. You may send the Network a copy of the document appointing you the beneficiary's representative or the completed form below with the beneficiary designating you as his/her representative.

I,_____ designate_____
(Beneficiary's Name – Print) (Personal Representative's Name – Print)

who is my _____,
(State Relationship to Beneficiary)
to represent me in the matter stated below. I understand that once I designate a personal representative he/she will communicate with the Network and will act on my behalf in regards to the complaint/grievance that I have made concerning:

_____

(State the complaint/grievance)

_____

_____

_____

_____

I understand that, if I file a complaint and use the informal process that the Network will communicate with my personal representative. If I file a grievance, the outcome letter written in response to my grievance will be sent to my personal representative. It will be the responsibility of my personal representative to share the outcome letter with me.

_____

(Beneficiary's Signature) and (Date)

_____

(Witness' Name) and (Date)

Exhibit 7-8 - Final Response to Grievant – Model Letter

YOUR LETTERHEAD

Date of Final Report:

Name of Beneficiary or Personal Representative:

Address:

City, State, and Zip Code:

Dear (Name of Beneficiary or Personal Representative):

The (Network Name) is the End Stage Renal Disease (ESRD) Network Organization authorized by the Medicare Program to receive and to the extent possible, resolve grievances lodged by or on behalf of Medicare ESRD patients in the State of _____. We look into complaints and grievances about the quality of dialysis and transplant services and care provided to Medicare patients or in Medicare certified facilities. Our responsibilities include discussing the grievance with the involved party or parties, reviewing dialysis facility records, as necessary, and making a determination as to whether the grievance was confirmed and the appropriate action to be taken. Where quality of care concerns are identified, we provide education and feed back to practitioners and physicians, and may require a quality improvement plan to be developed and carried out by the facility. In addition, we may refer the grievance to the State Survey Agency, which assures the care that dialysis facilities give meets Medicare standards.

Based on your grievance received on (date), the Network has investigated your grievance regarding the (care/services) (you or the name of the beneficiary as appropriate) received on (date) at (name of the dialysis facility). You were concerned about (Restate the grievance. Include issues raised by the grievant.)

Insert A or B below:

A. Involved Practitioner/Physician Does Not Consent to Disclosure to the Inquirer, include the following:

   We have carefully examined your concern(s) and conducted a thorough review of the relevant records and information pertaining to the grievance (you or the name of the beneficiary as appropriate) raised. Federal regulations prohibit us from releasing information about our review without the consent of the involved physician. Because your physician/practitioner did not give (his or her) consent, we are unable to release specific information about the results of our review. This does not necessarily mean that we found a problem with the services (you or the name of the beneficiary) received. However, if warranted by our review, we will take further action to address our findings.

B. Involved Practitioner/Physician Consents to Disclosure to the Inquirer, include the following:

Before reaching our decision, we gave (name of the involved practitioner/physician) an opportunity to review our findings concerning the services (you or the name of the beneficiary) received and (he/she) consented to the use of (his/her name). (If appropriate, include: "He/she responded to our determination letter to (him/her) with (additional information or comments). Attached is a copy of (his/her) comments.").

C.1. If the Network finds the grievance was unsubstantiated, insert the following:
After a thorough review of (your or name of the beneficiary) information and the information that we gathered regarding the grievance, we have determined that the grievance you made was not substantiated. Specifically: (Give a summary of the grievance findings keeping in mind that you can not implicitly or explicitly identify the MRB reviewer(s), another practitioner, or another patient without their consent.).

C.2. If the Network found the grievance to be substantiated, insert the following:

We were able to confirm your grievance about (the quality of services or situation) (you or the name of the beneficiary) (received or experienced) and will initiate the following action: (Summarize the Network's action in handling the grievance and the resulting responsibilities of the involved parties. Keep in mind that you cannot implicitly or explicitly identify the MRB reviewer(s), another practitioner, or another patient without their consent)

D. If the physician's/practitioner's name is used close with:

Please note that this letter and the information concerning (name of the practitioner and/or physician) contained in this letter is confidential and cannot be given to anyone else, unless the practitioner/physician gives (his, her, or their) consent to the disclosure.

If (you or the name of the beneficiary) have/has other concerns regarding this matter, please contact:

Name of the Network Complaint Contact Person
Name of the Network
Network Address (include zip code)

Telephone Number (include toll-free number, if different)

If you have been dissatisfied with the grievance process or the outcome of the process you may contact the State Agency, which is responsible for making sure that the care provided at your facility is safe and in compliance with Medicare requirements.

Name of a Complaint Contact Person
Name of the appropriate State Survey Agency
Address (include zip code)

Telephone number (including toll-free number, if possible)

You may also contact the Assistant Regional Administrator (ARA) at the Regional Office of the Center for Medicare & Medicaid Services. The address is:

Name of your ARA
Centers for Medicare & Medicaid Services Region (Region Number)_
Address (including zip code)

Telephone Number (toll free- if possible)

Sincerely yours,

Executive Director

(Name of Network)

Enclosures: (Include involved practitioner(s)/physician(s)'s and/or provider's comments and informational material, when applicable and appropriate.)

Medicare ESRD Network Organizations Manual

Chapter 8 - Publication Policy

Table of Contents

10 - Background

(Rev. 1, 07-11-03)

ENO 800

The mission of the Health Care Quality Improvement Program (HCQIP) is to promote the quality, effectiveness, and efficiency of health care services to Medicare beneficiaries by:

- Monitoring and improving the quality of care;
- Strengthening the community of those committed to improving quality;
- Communicating with beneficiaries and health care providers in order to promote informed health choices;
- Protecting beneficiaries from poor care; and
- Strengthening the health care delivery system.

The Centers for Medicare & Medicaid Services (CMS) supports ESRD Network publications to the extent of describing documented results of HCQIP activities and contributing to the achievement of the program's mission.

20 - Definition

(Rev. 1, 07-11-03)

ENO 810

In the following instruction, the term "publication" refers to any peer-reviewed, referenced, and/or referred document which a Network submits on its own behalf to a professional or trade journal, and which results from a CMS-funded quality improvement activity. "Publication" does not refer to press releases, newsletters, brochures, pamphlets, or letters to the editor (with the exception of letters to the editor that include CMS data that has not previously been published elsewhere). When the Network is unsure if a document falls under the definition of "publication," the Network's regional office (RO) project officer has the discretion to decide whether a document requires CMS review. Project officers may also expand the definition of "publication" if they believe such action is justified. The same criteria outlined in this instruction apply to abstracts submitted for publication or for presentation at professional meetings (excluding CMS, Network, and/or Network Forum sponsored meetings), although RO review time is shortened. (See §30.3.)

30 - Requirements

(Rev. 1, 07-11-03)

ENO 820

The Network's publication must meet the following requirements:

30.1 - Confidentiality

(Rev. 1, 07-11-03)

ENO 820.A

All Network publications must meet the confidentiality requirements specified at 42 CFR Part 480, §1160 of the Social Security Act, and Chapter 3 of this manual.

30.2 - Disclaimer

(Rev. 1, 07-11-03)

ENO 820.B

All Network publications (except abstracts) must include the following disclaimer:

> The analyses upon which this publication is based were performed under Contract Number 500-xx-xxxx entitled End Stage Renal Disease Networks Organization for the State (Commonwealth) of _____, sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. The author assumes full responsibility for the accuracy and completeness of the ideas presented. This article is a direct result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Ideas and contributions to the author concerning experience in engaging with issues presented are welcomed.

Any deviation from the above legend must be approved in writing by the contracting officer.

30.3 - CMS Certification

(Rev. 1, 07-11-03)

ENO 820.C

The Network provides CMS with manuscripts for publication prior to submitting them for publication, and sends the manuscript to its RO project officer, who is responsible for reviewing the manuscript and certifying that the manuscript meets the requirements listed above. Project officers have 30 calendar days from the date of receipt of the manuscript to provide a response to the Network. The Network considers RO review time in relation to any deadlines imposed upon it by the journal or any other publication. In the case of abstracts, the project officer has 10 calendar days to respond to the Network. On an individual basis, the Network can request a more rapid reply from the project officer (for either manuscripts or abstracts). The project officer has the discretion to honor or reject such requests. The Network works with its project officer to establish a process for prompt and efficient review and comment on draft publications (e.g., method of

submitting draft publication to the project officer, begin and end dates of project officer review time).

Project officers and/or other RO staff may provide the Network with substantive changes to the manuscript. The Network considers these substantive changes just as it would similar changes suggested by other peer reviewers. The Network must address any confidentiality and/or disclaimer issues raised by the project officer. Once the Network has addressed these issues and the project officer has certified that they have been adequately addressed, the Network may submit the manuscript for publication.

If the Network does not receive certification from the project officer within 30 days of receipt of the manuscript (or within 10 days in the case of the abstract), assume certification and proceed with the publication.

30.4 - Revisions to Original Manuscript

(Rev. 1, 07-11-03)

ENO 820.D

Project officers will review the version of a manuscript which the Network will initially submit for publication. In situations where revisions to a manuscript are made between the time it is first submitted to a journal or other publication and when it is actually published, the Network is responsible for informing the project officer of any changes to the manuscript which relate to Network data and/or CMS policy. The project officer may decide to review revisions of the manuscript. However, project officers are not required to do so. Ultimately, the Network is responsible for the manuscript as published. The Network is liable for any breaches of confidentiality or misrepresentation of CMS policy that results from the publication of a revision of the original manuscript and will be subject to any penalties that may be imposed for doing so.

30.5 - Published Article

(Rev. 1, 07-11-03)

ENO 820.E

The Network must provide a copy of the article, as published, to its project officer.

40 - Disagreements

(Rev. 1, 07-11-03)

ENO 830

Disagreements with the project officer's determinations regarding the manuscript will be resolved by the contracting officer.

Medicare ESRD Network Organizations Manual

Chapter 9 - Information Collection

Table of Contents

10 - Background

(Rev. 1, 07-11-03)

ENO 900

Under the Health Care Quality Improvement Program (HCQIP), one of the Network's responsibilities is to measurably improve the quality of ESRD patient care and outcomes. To meet this responsibility, the Network conducts improvement projects. The CMS encourages the Network to develop innovative approaches that include collaborative efforts with the renal community, communication with ESRD beneficiaries and providers, and monitoring of the health care services furnished to ESRD beneficiaries. The use of survey data collection methods to support and evaluate improvement projects is an innovative option that the Network may consider to be worthwhile. However, the Network must meet all applicable CMS statutory and regulatory requirements before implementing a survey.

NOTE: This instruction applies to all Network projects, regardless of whether they are conducted as a part of the Network's Statement of Work requirements or part of a special study. This instruction does not apply to medical record abstraction that the Network conducts as a part of a quality improvement project. This instruction also applies to any information collection instruments directed towards 10 or more **persons** as defined in §40

of this chapter. Therefore, this instruction applies to information collection activities directed towards beneficiaries, providers of all types, organizations, etc.

20 - CMS/Office of Clinical Standards and Quality (OCSQ) Requirements

(Rev. 1, 07-11-03)

ENO 910

In order to maintain the integrity of the information collection capabilities, it is imperative that the Network gives careful consideration to the need for every distinct information collection activity that the Network proposes to conduct, the use of the information that the Network intends to collect, and the quality of the instrument the Network proposes to use to collect that information. The Network should only use surveys if the Network cannot obtain that information from any other source. Any proposed information collection activity must meet the following CMS/OCSQ requirements:

- The instrument must be an integral part of a specific cooperative improvement project;

- The Network must explain the extent to which it has sought to verify that the information that the Network proposes to collect is not available from any other source (e.g., peer-reviewed published literature, Medicare claims data, Clinical Data Abstraction Center chart reviews, Behavioral Risk Factor Surveillance System, National Health Interview Survey, Medicare Current Beneficiary Survey, Health Plan Employer Data and Information Set, other Network projects/surveys, etc.); and

- The Network data collection to support the Network HCQIP activities must be approved by the Network PO.

30 - Statutory and Regulatory Requirements

(Rev. 1, 07-11-03)

ENO 920

Surveys and any other information that the Network collects must comply with the provisions of the Paperwork Reduction Act (PRA) of 1995 (Public Law 104-13). These provisions generally prohibit an agency from conducting or sponsoring a collection of information (as that term is defined in the PRA) unless, in advance thereof, the agency reviews the collection of information, publishes a 60-day notice in the Federal Register, evaluates comments received pursuant to such notice, and receives approval and a control number from the Office of Management and Budget (OMB). (See 44 U.S.C. 3506 and

3507.) Regulations at 5 CFR Part 1320 implement the provisions of the PRA. These regulations require OMB approval for a collection of information on identical or similar questions from 10 or more public respondents by means of a standardized format prior to implementation. The provisions of the PRA apply to information collected through oral interviews and information collected in writing.

In the regulations at 5 CFR Part 1320, some items are not deemed to be "information" under the PRA, and thus do not require OMB clearance. Refer to 5 CFR Part 1320 for information on the additional PRA requirements. This manual provision addresses the requirement for OMB clearance. (See §50 of this chapter, which describes the process for seeking regular OMB clearance, and §60, which details those items pertinent to Network information collection activities.)

40 - Definitions

(Rev. 1, 07-11-03)

ENO 930

Items in the PRA have very specific definitions. Those used for this instruction are defined here as they are at 5 CFR Part 1320. (See the PRA regulation text for complete definitions.)

"**Burden** means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. A collection of information conducted or sponsored by a Federal agency that is also conducted or sponsored by a unit of State, local, or tribal government is presumed to impose a Federal burden except to the extent that the agency shows that such State, local, or tribal requirement would be imposed even in the absence of a Federal requirement." (5 CFR 1320.3(b)(1),(3))

"**Information** means any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media." (5 CFR 1320.3(h))

"**Collection of information** means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to an agency, third parties, or the public of information by or for an agency by means of identical questions posed to, or identical reporting, record keeping, or disclosure requirements imposed on ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. A collection of information may be in any form or format, including the use of report forms; questionnaires; surveys; reporting or record keeping requirements; interview guides; oral communications; telegraphic or telephonic requests; automated, electronic, mechanical, or other technological collection techniques; standard questionnaires used to monitor compliance with agency requirements; or any other

techniques or technological methods used to monitor compliance with agency requirements." (5 CFR 1320.3(c))

"**Person** means an individual, partnership, association, corporation, business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision." (5 CFR 1320.3(k))

"**Practical utility** means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third-party or public disclosure) in a useful and timely fashion. In the case of record keeping requirements or general purpose statistics, practical utility means that the actual uses can be demonstrated." (5 CFR 1320.3 (l))

50 - Office of Management and Budget (OMB) Clearance

(Rev. 1, 07-11-03)

ENO 940

Unless a survey would not be subject to the PRA under the regulations, the Network must have prior OMB approval to conduct, or engage someone else to conduct, a survey that is part of the Network's Medicare contract. If the proposed survey requires OMB approval, the Network must submit Form OMB 83-I, "Request for OMB Review", a supporting statement, and related materials to the Network's project officer. The Network's project officer will then submit the Request to OMB through CMS' Reports Clearance Officer (RCO). The Network may initiate the survey only after the Network has secured proper approval from OMB through the RCO. The Network can contact its project officer for the Form OMB 83-I, supporting statement outline, and checklist of related materials.

60 - Items Not Subject to OMB Clearance

(Rev. 1, 07-11-03)

ENO 950

The Federal government has specified certain categories of items that generally do not constitute "information" for purposes of the PRA and, as such, are not subject to the general OMB clearance requirement at 5 CFR 1320. In planning a project, the Network will discuss with the Network's project officer the potential applicability of these categories to the Network's project and any information collection activities planned for the project. Only those categories likely to be applicable to the Network's projects are listed below. For a complete list of the categories, refer to 5 CFR 1320.3(h).

5 CFR 1320.3(h)(5) - "Facts or opinions obtained initially or in follow-up requests from individuals (including individuals in control groups) under treatment or clinical examination in connection with research on or prophylaxis to prevent a clinical disorder, direct treatment of that disorder, or the interpretation of biological analyses of body fluids, tissues, or other specimens, or the identification or classification of such specimens."

NOTE: The OMB has delegated to the National Institutes of Health (NIH) its authority to determine whether a proposed collection of information falls outside the definition of "information" as a clinical exemption under 5 CFR 1320.3(h)(5). In cases where CMS' RCO deems it appropriate (e.g., longitudinal studies or studies of a sensitive nature), the RCO may refer a Network's project to NIH for such a determination.

5 CFR 1320.3(h)(8) - "Facts or opinions obtained or solicited at or in connection with public hearings or meetings."

5 CFR 1320.3(h)(9) - "Facts or opinions obtained or solicited through nonstandardized follow-up questions designed to clarify responses to approved collections of information." Moreover, 5 CFR 1320.4(a) lists certain collections of information that are not subject to the PRA, including the following:

5 CFR 1320.4(a)(2) - "Collections of information during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities."

70 - Request for Exception From OMB Review

(Rev. 1, 07-11-03)

ENO 960

The authority within CMS to decide whether a Network project falls outside the definition of "information," or is otherwise not subject to the requirements of the PRA, resides with CMS' RCO in Central Office. The OMB has the ultimate authority to determine whether a Network project is subject to the PRA. The RO must endorse a project before the RCO will consider whether an item is exempt from OMB clearance under 5 CFR 1320.3 or 5 CFR 1320.4. If a project is not subject to 5 CFR Part 1320, then any information collection activities that the Network conducts to support that project would be exempt from OMB review. All other information requests are subject to formal OMB clearance as described in §50. If the RCO determines that the project must be cleared by OMB, the Network should work with its project officer to submit the appropriate documentation for formal clearance to OMB (through the RCO).

Based on the provisions in the PRA, CMS developed criteria and a process for reviewing projects to determine whether OMB clearance is necessary. Follow this process for each project in which the Network intends to incorporate an information collection activity.

In order for CMS to determine whether the Network's project requires OMB clearance, the Network must submit electronically to the RCO (through its project officer) a Request for Exception from OMB Review. Any deviations from an electronic submission must be approved by the project officer. There is no specific format for the Request. The only requirement is that the Request must include sufficient information (as described below) for the RCO to determine whether the intent and concept of the **project** falls into one or more of the categories described in §60. The Network should not submit to the RCO specific information on the actual survey instrument(s) to be used in the project unless specifically requested by the RCO. The request should only discuss the project intent and concept, and it must include the following elements:

A. Opportunity for Improvement

The Network should be sure to include information on the data source used to identify that an opportunity for improvement exists (e.g., CMS administrative data, national renal registry data, core indicators, etc.). Information collection instruments cannot be used to identify an opportunity for improvement; rather, they are used to provide useful information to assist the Network in designing and implementing effective interventions and/or to measure improvement.

B. Planned Intervention Strategy for the Project

The Network should include discussion on the proposed interventions for the project. Also, the Network should discuss whether it intends to use the information obtained through the survey to design and/or implement intervention strategies.

C. Project Evaluation and Documentation of Results

The Network must describe the method it will use to evaluate the impact of the project. If the Network plans to use the survey instrument as a part of the evaluation process, it must discuss the role of the survey in that process. The Network must also discuss how it intends to document the results of the project.

NOTE: The Network is encouraged to use information submitted in its Network Quality Improvement Project Report to complete its Request. The Network may attach a copy of the Project Report to its Request, but CMS will not accept the Project Report as a substitute for its formal Request for Exception from OMB Review.

Once the project officer receives the Network's Request for Exception from OMB Review, the project officer and RO scientific staff will have15 business days to initially review the Request and provide comments on its submission. The RO may ask to submit additional information. The RO will then have an additional 15 business days from the

date of the resubmission to review the Request. If the project officer and scientific staff agree with the intent and concept of the project, the project officer will submit the Request electronically to the RCO. The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between the Network, the project officer, and/or the RO scientific staff on the project concept or design. The RCO will have 15 business days to review the Request and determine whether the proposed project is subject to OMB clearance. The RCO will express his/her decision in writing (e-mail is preferred; fax or hard copy letter is acceptable) to the project officer, who will in turn notify the Network in writing (again, e-mail is preferred; fax or hard copy letter is acceptable) of CMS' decision. As directed by the RCO (through the project officer), the Network must submit additional supporting documentation to assist the RCO in making this determination.

80 - Survey Justification and Methods

(Rev. 1, 07-11-03)

ENO 970

The Network is encouraged to begin work on the survey instrument and supporting documentation at the same time that the Network's project proposal is under review by the RO and the RCO. If the RCO determines that the project is subject to the requirements of 5 CFR Part 1320, and the Network chooses to submit its project to OMB for formal review, the Network will be required to include the information described below in its submission to OMB. The Network must work with the RO and the RCO to prepare a Request for OMB Review, supporting statement, and related materials.
If the RCO determines that the project does not require OMB clearance, the Network will still be required to work with the project officer and the RO scientific staff in designing the information collection instrument(s) to be used in the project. Supply the following information to the project officer:

A. Survey Justification

The Network:

- Shows how, by whom, and for what purpose the survey information is to be used. States the purpose of the study. Describes what questions the survey is designed to address. Describes the subject population. Explains the circumstances that make the survey necessary.

- Provides documentation describing the process it used to verify that the information to be collected is not available through any other source (e.g., peer-reviewed published literature, Medicare claims data, ESRD Program Management and Medical Information System database, Networks' projects/surveys, etc.). The Network describes efforts to identify similar information collection activities previously conducted itself or by another entity. Shows specifically why any

similar information already available cannot be used or modified for use for the purposes described above. The Network describes whether it has imported the project concept or survey design from another Network, or other entity.

- Describes any use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology that may reduce burdens.

- Indicates situations in which it project and/or survey results may be used at an aggregate level (e.g., regional, national, etc.)

- Explains any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

- Describes procedures it, its subcontractors, and its consultants will employ to maintain respondents' confidentiality.

NOTE: All survey activities must meet the confidentiality requirements specified at 42 CFR Part 480, §1160 of the Social Security Act, and Chapter 3 of this manual. Survey activities must also comply with the data requirements specified in sections G and H of the ESRD contract.

- The Network provides the following language, which must be included in the introduction of the survey collection instrument:

    1. The information provided by the respondent is voluntary.

    2. The identity of the respondent and the information provided by the respondent are confidential.

    3. The respondent's decision whether or not to participate in the survey will not affect his or her Medicare (or Medicaid, where applicable) benefits or reimbursements.

    4. An estimate of the total time it will take the respondent to answer the questions.

    5. The name of company or foundation requesting the information.

    6. A way in which the respondent may contact the requestor (toll free/collect phone number, or name and address) if he/she has questions or wants further information about the survey.

- The Network provides justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. Follow the guidelines outlined in OMB Directive

No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting, and the subsequent revisions to that Directive, when asking questions related to race and ethnicity. The Network can obtain these documents through the Internet or from its project officer.

- The Network provides estimates of the cost to the Federal government of the survey. (Annualize the cost if applicable.)
-

B. Survey Methods

The Network:

- Describes the sampling accuracy needed for the purpose described in §80.A. and any unusual problems requiring specialized sampling procedures. Provides a description of the sampling methodology, including how interviewees will be selected. Addresses whether proxies will be interviewed and any exclusion criteria used for interviewees.

- Describes who will conduct the surveys or whether they will be self-administered. If a subcontractor will be used, provides a resume or description of the subcontractor, including survey experience.

- Describes how the information collection instrument has been or will be field-tested.

- Describes expected response rates for the collection as a whole, and upon what evidence this estimate is based. Includes the actual response rates if any entity has previously conducted the collection.

- Describes methods to maximize response rates and to deal with issues of non-response. Shows that the accuracy and reliability are expected to be adequate for intended uses. Provides justification for any collection that will not yield reliable and valid data that can be generalized to the units studied.

- Provides an exact copy of the entire proposed survey questionnaire. Includes a description of any tests of procedures or methods to be undertaken to assess reliability and validity of questions to be developed.

NOTE: The Network is strongly encouraged to use measures that have already been developed and tested and are in the public domain rather than creating a new survey for a project. The Network is also encouraged to use an experienced consultant when developing new questions. The RO may request to see the resumes of any consultants used.

- Briefly discusses the qualifications of the individuals who will design statistical aspects of the project, data collection, and analysis.

NOTE: The Network is encouraged to consult with individuals or organizations with specialties in designing, collecting, and analyzing survey data.

The Network submits this information electronically to its project officer for review. The project officer and RO scientific staff must approve the information collection instrument(s) and the supporting documentation prior to implementation of the instrument(s). The project officer will have 15 business days to review the documentation and the instrument(s), and to provide the Network with a decision on its submission. The RO may ask the Network to submit additional information. The RO will then have another 15 business days from the date of resubmission to review its documentation and to provide the Network with a decision.

The RO Associate Regional Administrator for Clinical Standards and Quality will resolve any disagreements between the Network, the project officer, and/or the RO scientific staff on the documentation provided to support the information collection activity and the actual instrument(s).

90 - Additional Considerations

(Rev. 1, 07-11-03)

ENO 980

The Network **must** include the following items in its information collection activity:

A. Beneficiary Notification Letter

Before contacting a beneficiary to participate in a survey (either by mail or by phone), notify the beneficiary in writing of the possibility of his/her being contacted. The letter, which must go out over the Regional Administrator's signature, must:

- Identify the Network (e.g., the State's quality improvement organization for Medicare's ESRD program);
- Describe the nature of the survey (e.g., whether it is a mail or phone survey, the purpose of the survey, etc.);
- Inform the beneficiary that he/she is under no obligation to respond to the survey;
- Assure the beneficiary that the decision to respond or not to respond will not affect the beneficiary's Medicare (or Medicaid, where applicable) benefits; and
- Assure the beneficiary that his/her identity and the responses provided by him or her are confidential and that all information provided is protected by the Privacy Act.

The letter must be dated and must include a toll-free or collect phone number with the name of a contact person at the Network that the beneficiary can call if he/she has additional questions about the survey or prefers not to participate in the survey. Beneficiary Notification Letters must be received by the beneficiary at least fifteen (15) calendar days prior to the implementation of the survey.

The project officer must review and approve the content and format of the Beneficiary Notification Letter prior to its being mailed to the beneficiaries. The Network work with its Network project officer to secure the proper CMS authorization and signature for the letter. The letter must be written on CMS letterhead and may be mailed in an envelope using the Network's return address. The Network is encouraged to model its Beneficiary Notification Letter after previously approved letters, to expedite the review and clearance processes. Consider the time required for this review and clearance when planning its information collection activity.

The RO review of the Beneficiary Notification Letter may occur simultaneously with the RCO's review of the Network's Request.

B. Beneficiary No-Contact List

During the course of its work, the Network may encounter beneficiaries who indicate that they prefer not to participate in surveys that the Network conducts. The Network must maintain a list (including name, Health Insurance Claim (HIC) number, address, and date of birth) of these beneficiaries and **must not** contact any of these beneficiaries to participate in a survey. Before sending a Beneficiary Notification Letter, the Network consults its Beneficiary No-Contact List to determine whether any of the beneficiaries that the Network intends to contact are on that list, and remove those beneficiaries from the survey sample. At such time that CMS may request it, the Network must provide to CMS the name, HIC number, address, and date of birth of all beneficiaries on its Beneficiary No-Contact List.

100 - Documentation for CMS

(Rev. 1, 07-11-03)

ENO 990

The Network submits a copy of the Beneficiary Notification Letter and the final survey instrument to its project officer before implementation of the survey.

Medicare ESRD Network Organizations
List of Commonly Used Acronyms

AAKP -- American Association of Kidney Patients

AHRQ -- Agency for Healthcare Research and Quality

AKF -- American Kidney Fund

ANNA -- American Nephrology Nurses Association

BOD -- Board of Directors

BUN -- Blood Urea Nitrogen

CMS -- Centers for Medicare & Medicaid Services

CMSDC -- CMS Data Center

CO -- Central Office (CMS)

CPM -- Clinical Performance Measure

CQI -- Continuous Quality Improvement

CROWN -- Consolidated Renal Operations in a Web-Enabled Network

EC -- Executive Committee of the Network

EDEES -- ESRD Data Entry and Editing System (CMS)

EPO -- Erythropoietin

ESRD -- End Stage Renal Disease

FPR -- Final Project Report

HCQIP -- Health Care Quality Improvement Program

HCT -- Hematocrit

HD -- Hemodialysis

HIC -- Health Insurance Claim

IMRP -- Instruction Manual for Renal Providers

MRB -- Medical Review Board

NC -- Network Council

NCC -- Network Coordinating Council

NIDDK -- National Institute of Diabetes, and Digestive and Kidney Diseases

NIH -- National Institutes of Health

NIP -- National Improvement Project

NKF -- National Kidney Foundation

NPP -- Narrative Project Plan

NRAA -- National Renal Administrators Association

OCSQ -- Office of Clinical Standards and Quality

ODIE -- Online Data Input and Edit

OGC -- Office of General Counsel (CMS)

OIC -- Opportunity to Improve Care

OIG -- Office of the Inspector General (CMS)

OPO -- Organ Procurement Organization

OPTN -- Organ Procurement and Transplantation Network

OSCAR -- Online Survey Certification and Reporting

PD -- Peritoneal Dialysis

PID -- Project Idea Document

PIP -- Performance Improvement Plan

PMMIS -- Program Management and Medical Information System

PO -- Project Officer

QA -- Quality Assurance

QI -- Quality Improvement

QIO -- Quality Improvement Organization

QIP -- Quality Improvement Project

REBUS -- Renal Beneficiary and Utilization System

REMIS -- Renal Management Information System

RO -- Regional Office (CMS)

ROPO -- Regional Office Project Officer

RPA -- Renal Physicians Association

SA -- State Agency/State Survey Agency

SIMS -- Standard Information Management System

SOW -- Statement of Work

SSA -- Social Security Administration

SSN -- Social Security Number

TQE -- Total Quality Environment

UNOS -- United Network for Organ Sharing

USRDS -- United States Renal Data System

VHA -- Veterans Health Administration

VISION -- Vital Information System to Improve Outcomes in Nephrology

Medicare ESRD Network Organizations

Glossary

Abstraction -- Abstraction is the collection of information from the medical record via hardcopy or electronic instrument.

Albumin -- One of a class of simple proteins in the blood. The level of albumin may reflect the amount of protein intake in food.

Algorithm -- An algorithm is a rule or procedure containing conditional logic for solving a problem or accomplishing a task. Guideline algorithms concern rules for evaluating patient care against published guidelines. Criteria algorithms concern rules for evaluating criteria compliance. Algorithms may be expressed in written form, graphic outlines, diagrams, or flow charts that describe each step in the work or thought process.

Anemia -- A condition occurring when the blood is deficient in red blood cells and/or hemoglobin which decreases the oxygen-carrying capacity of the blood.

Benchmark -- A benchmark is sustained superior performance by a medical care provider which can be used as a reference to raise the mainstream of care for Medicare beneficiaries. The relative definition of superior will vary from situation to situation. In many instances, an appropriate benchmark would be a provider that appears in the top 10 percent of all providers for more than a year.

Blood Urea Nitrogen (BUN) -- The term, blood urea nitrogen, refers to the substance urea, which is the major breakdown product of protein metabolism and is ordinarily removed by the kidneys. During kidney failure, urea accumulates in proportion to the degree of kidney failure and to the amount of protein breakdown. The symptoms of uremia correspond roughly to the amount of urea in the bloodstream.

Cadaveric Transplant -- The surgical procedure of excising a kidney from a deceased individual and implanting it into a suitable recipient.

Carriers -- Carriers are organizations/entities which contract with CMS to process claims submitted by beneficiaries, physicians, suppliers, and other individuals/entities that are not associated with an institutional provider under the Part B program.

Case Mix -- Case mix is the distribution of patients into categories reflecting differences in severity of illness or resource consumption.

Chronic Maintenance Dialysis -- Dialysis that is regularly furnished to an ESRD patient in a hospital-based, independent (non-hospital-based), or home setting.

Clinical Performance Measure (CPM) -- A clinical performance measure (CPM) is a method or instrument to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to practice guidelines, medical review criteria, or standards of quality.

CMS Agent -- Any individual or organization, public or private, with whom CMS has a contractual arrangement to contribute to or participate in the Medicare survey and certification process. The State survey agency is the most common example of a "CMS agent," as established through the partnership role the State agency (SA) plays in the survey process under the provisions of §1864 of the Act. A private physician serving a contractual consultant role with the SA or the CMS regional office as a part of a survey and certification activity is another example of a "CMS agent."

CMS-Directed Improvement Projects -- A CMS-directed improvement project is any project where CMS specifies the subject, size, pace, data source, analytic techniques, educational intervention techniques, or impact measurement model. These projects may be developed by CMS in consultation with the Networks, the health care community, and other interested groups.

Cohort -- A population group that shares a common property, characteristic, or event, such as a year of birth or year of marriage. The most common one is the birth cohort, a group of individuals born within a defined time period, usually a calendar year or a 5-year interval.

Continuous Ambulatory Peritoneal Dialysis (CAPD) -- A type of dialysis where the patient's peritoneal membrane is used as the dialyzer. The patient dialyzes at home, using special supplies, but without the need for a machine. (See Peritoneal Dialysis.)

Continuous Cycling Peritoneal Dialysis (CCPD) -- A type of dialysis where the patient generally dialyzes at home and utilizes an automated peritoneal cycler for delivering dialysis exchanges. (See Peritoneal Dialysis.)

Continuous Peritoneal Dialysis -- A regimen where peritoneal dialysate is present in the peritoneal cavity continuously seven days per week. Short interruptions between infrequent exchanges do not disqualify the regime as continuous if the interruptions do not exceed 10 percent of the total dialysis time. (See Peritoneal Dialysis.)

Continuous Quality Improvement (CQI) -- A process which continuously monitors program performance. When a quality problem is identified, CQI develops a revised approach to that problem and monitors implementation and success of the revised approach. The process includes involvement at all stages by all organizations which are affected by the problem and/or involved in implementing the revised approach.

Criteria -- Expected levels of achievement or specifications against which performance can be assessed.

Department of Health and Human Services (DHHS) -- DHHS administers many of the "social" programs at the Federal level dealing with the health and welfare of the citizens of the United States. It is the "parent" of the Centers for Medicare & Medicaid Services.

Dialysate -- Dialysate or dialysate fluid is the solution used in dialysis to remove excess fluids and waste products from the blood.

Dialysis -- Dialysis is a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semi-permeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

Dialysis Center (renal) -- A hospital unit that is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis) furnished directly or under arrangement.

Dialysis Facility (renal) -- A unit (hospital-based or free-standing) which is approved to furnish dialysis services directly to ESRD patients.

Dialysis Station -- A portion of the dialysis patient treatment area which accommodates the equipment necessary to provide a hemodialysis or peritoneal dialysis treatment. This station must have sufficient area to house a chair or bed, the dialysis equipment, and emergency equipment if needed. Provision for privacy is ordinarily supplied by drapes or screens.

Durable Medical Equipment (DME) -- DME are items covered under the Medicare program such as oxygen equipment, wheelchairs, and other medically necessary equipment prescribed by a physician for a patient's in-home use.

End Stage Renal Disease (ESRD) -- That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Facility -- A facility which is approved to furnish at least one specific ESRD service. These services may be performed in a renal transplantation center, renal dialysis center, renal dialysis facility, self-dialysis unit, or special purpose renal dialysis facility.

ESRD Network -- All Medicare-approved ESRD facilities in a designated geographic area specified by CMS.

ESRD Network Organization -- The administrative governing body of the ESRD Network and liaison to the Federal government.

ESRD Patient -- A person with irreversible and permanent kidney failure who requires a regular course of dialysis or kidney transplantation to maintain life.

ESRD Service -- The type of care or service furnished to an ESRD patient. Such types of care are: transplantation; dialysis; outpatient dialysis; staff-assisted dialysis; self-dialysis; home dialysis; and self-dialysis and home dialysis training.

Guidelines -- Guidelines are systematically developed by appropriate groups to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances.

Health Care Quality Improvement Program (HCQIP) -- HCQIP is a program which supports the mission of the Centers for Medicare & Medicaid Services to assure health care security for beneficiaries. The mission of HCQIP is to promote the quality, effectiveness, and efficiency of services to Medicare beneficiaries by strengthening the community of those committed to improving quality, monitoring and improving quality of care, communicating with beneficiaries and health care providers, practitioners, and plans to promote informed health choices, protecting beneficiaries from poor care, and strengthening the infrastructure.

Hematocrit -- A measurement of red blood cell volume in the blood.

Hemodiafiltration (Also called high flux hemodiafiltration and double high flux hemodiafiltration) -- Simultaneous hemodialysis and hemofiltration which involves the removal of large volumes of fluid and fluid replacement to maintain hemodynamic stability. It requires use of ultra pure dialysate or intravenous fluid for volume replacement.

Hemodialysis -- A method of dialysis in which blood from a patient's body is circulated through an external device or machine and then returned to the patient's bloodstream. Such an artificial kidney machine usually is designed to remove fluids and metabolic end products from the bloodstream by placing the blood in contact with a semi-permeable membrane which is bathed on the other side by an appropriate chemical solution referred to as dialysate.

Hemofiltration -- Fluid removal

Home Patients -- Medically-able individuals who have their own dialysis equipment at home and, after proper training, perform their own dialysis treatment alone or with the assistance of a helper.

Improvement Plan -- A plan for measurable process or outcome improvement. This plan is usually developed cooperatively by a provider and the Network. The plan must address how and when its results will be measured.

Incidence -- The frequency of new occurrences of a condition within a defined time interval. The incidence rate is the number of new cases of specific disease divided by the number of people in a population over a specified period of time, usually 1 year.

Indicator -- A key clinical value or quality characteristic used to measure, over time, the performance, processes, and outcomes of an organization or some component of health care delivery.

Intermediaries -- Intermediaries are entities that contract with CMS to perform Medicare administrative services for institutional providers (i.e., hospitals, SNFs, HHAs, and hospices) and all ESRD providers, and to determine and make Medicare payments for Part A or Part B benefits.

Intermittent Peritoneal Dialysis -- An intermittent (periodic), supine regimen, which uses intermittent flow technique, automated, assisted manual, or manual method in dialysis sessions 2 to 4-times weekly.

Living Donor Kidney Transplant -- The surgical procedure of excising a kidney from a living donor and implanting it into a suitable recipient.

Managed Care Organizations -- Managed care organizations are entities that serve Medicare or Medicaid beneficiaries on a risk basis through a network of employed or affiliated providers.

Measurement -- The systematic process of data collection, repeated over time or at a single point in time.

Medicare+Choice (M+C) Organization -- An M+C organization is a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the M+C contract requirements.

Medicare+Choice (M+C) Plan -- An M+C plan means health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.

Medicare Eligibility Requirements -- To qualify for Medicare under the renal provision, a person must have ESRD and either be entitled to a monthly insurance benefit under title II of the Act (or an annuity under the Railroad Retirement Act), be fully or currently insured under Social Security (railroad work may count), or be the spouse or dependent child of a person who meets at least one of these last two requirements. There is no minimum age for eligibility under the renal disease provision. An Application for Health Insurance Benefits Under Medicare For Individuals with Chronic Renal Disease, Form CMS-43 (effective October 1, 1978), must be filed.

Medicare Handbook -- The Medicare Handbook provides information on such things as how to file a claim and what type of care is covered under the Medicare program. This handbook is given to all beneficiaries when first enrolled in the program.

Modality -- Methods of treatment for kidney failure/ESRD. Modality types include transplant, hemodialysis, and peritoneal dialysis.

Monitoring -- A planned, systematic, and ongoing process to gather and organize data, and aggregate results in order to evaluate performance.

Morbidity -- A diseased state, often used in the context of a "morbidity rate," i.e., the rate of disease or proportion of diseased people in a population. In common clinical usage, any disease state, including diagnoses and complications, is referred to as morbidity.

Morbidity Rate -- The rate of illness in a population. The number of people ill during a time period divided by the number of people in the total population.

Mortality Rate -- The death rate, often made explicit for a particular characteristic, e.g., gender, sex, or specific cause of death. Mortality rate contains three essential elements: (1) the number of people in a population group exposed to the risk of death (the denominator); (2) a time factor; and (3) the number of deaths occurring in the exposed population during a certain time period (the numerator).

National Improvement Projects -- HCQIP projects developed by a group consisting of representatives of some or all of the following groups: CMS, Public Health Service, Networks, renal provider, and consumer communities. The object is to use statistical analysis to identify better patterns of care and outcomes and to feed the results of that analysis back into the provider community to improve the quality of care provided to renal Medicare beneficiaries. Each project will have a particular clinical focus.

Organ -- Organ means a human kidney, liver, heart, lung, or pancreas.

Organ Procurement -- The process of acquiring donor kidneys in the ESRD program.

Organ Procurement Organization (OPO) -- An organization that performs or coordinates the retrieval, preservation, and transportation of organs and maintains a system of locating prospective recipients for available organs.

Outcome -- The result of performance (or nonperformance) of a function or process.

Outcome Indicator -- An indicator that assesses what happens or does not happen to a patient following a process; agreed upon desired patient characteristics to be achieved; or undesired patient conditions to be avoided.

Part A of Medicare -- Part A is the hospital insurance portion of Medicare. It was established by §1811 of title XVIII of the Social Security Act of 1965, as amended, and covers inpatient hospital care, skilled nursing facility care, some home health agency services, and hospice care.

Part B of Medicare -- Part B is the supplementary or "physicians" insurance portion of Medicare. It was established by §1831 of title XVIII of the Social Security Act of 1965, as amended, and covers services of physicians/other suppliers, outpatient care, medical equipment and supplies, and other medical services not covered by the hospital insurance part of Medicare.

Pattern Analysis -- The clinical and statistical analysis of data sets. Frequently used ESRD data sets include the PMMIS, USRDS, the core indicators, Network files, or CMS analytic files.

Performance -- The way in which an individual, group, or organization carries out or accomplishes its important functions or processes.

Performance Assessment -- Involves analysis and interpretation of performance measurement data to transform it into useful information for purposes of continuous performance improvement.

Performance Measure -- A gauge used to assess the performance of a process or function of any organization.

Peritoneal Dialysis -- A procedure that introduces dialysate into the abdominal cavity to remove waste products through the peritoneum (a membrane which surrounds the intestines and other organs in the abdominal cavity). It functions in a manner similar to that of the artificial semi-permeable membrane in the hemodialysis machine. Three forms of peritoneal dialysis are continuous ambulatory peritoneal dialysis, continuous cycling peritoneal dialysis, and intermittent peritoneal dialysis.

Prevalence -- The number of existing cases of a disease or condition in a given population at a specific time.

Process -- A goal-directed, interrelated series of actions, events, mechanisms, or steps.

Process Improvement -- A methodology utilized to make improvements to a process through the use of continuous quality improvement methods.

Process Indicator -- A gauge that measures a goal-directed, interrelated series of actions, events, mechanisms, or steps.

Profiles -- Data aggregated by specific time period (e.g., quarterly, annually) and target area (e.g., facility, State) for purposes of identifying patterns.

Program Management and Medical Information System (PMMIS) -- An automated system of records that contains records primarily of current Medicare-eligible ESRD patients, but also maintains historical information on people no longer classified as ESRD patients because of death or successful transplantation or recovery of renal function. The PMMIS contains medical information on patients and the services that they received

during the course of their therapy. In addition, it contains information on ESRD facilities and facility payment. Beginning January 1, 1995, the PMMIS collects information on all dialysis and kidney transplant patients.

Quality -- Quality, as defined by the Institute of Medicine, is the degree to which health services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge.

Random Sample -- A random sample is a group selected for study which is drawn at random from the universe of cases by a statistically valid method.

Regional Office (RO) -- CMS has 10 ROs that work closely together with Medicare contractors in their assigned geographical areas on a day-to-day basis. Four of these ROs monitor Network contractor performance, negotiate contractor budgets, distribute administrative monies to contractors, work with contractors when corrective actions are needed, and provide a variety of other liaison services to the contractors in their respective regions.

Rehabilitation (as distinguished from Vocational Rehabilitation) -- A restorative process through which an individual with ESRD develops and maintains self-sufficient functioning consistent with his/her capability.

Renal Transplant Center -- A hospital unit that is approved to furnish transplantation and other medical and surgical specialty services directly for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement.

Self-dialysis -- Dialysis performed with little or no professional assistance (except in emergency situations), by an ESRD patient who has completed an appropriate course of training, in a dialysis facility or at home.

Staff-assisted Dialysis -- Dialysis performed by the staff of the renal dialysis center or facility.

State Survey -- Under §1864 of the Act, CMS has entered into agreements with agencies of State governments, typically the agency that licenses health facilities within the State health departments, to conduct surveys of Medicare participating providers and suppliers for purposes of determining compliance with Medicare requirements for participation in the Medicare program.

Survey and Certification Process -- The activity conducted by State survey agencies or other CMS agents under the direction of CMS and within the scope of applicable regulations and operating instructions and under the provisions of §1864 of the Act whereby surveyors determine compliance or noncompliance of Medicare providers and suppliers with applicable Medicare requirements for participation. The survey and certification process for each provider and supplier is outlined in detail in the State Operations and Regional Office Manuals published by CMS.

Systematic -- Pursuing a defined objective(s) in a planned, step-by-step manner.

Transient Patients -- Patients who receive treatments on an episodic basis and are not a part of a facility's regular caseload (i.e., patients who have not been permanently transferred to a facility for ongoing treatments).

Transplant -- The surgical procedure that involves removing a functional organ from either a deceased or living donor and implanting it in a patient needing a functional organ to replace their non-functional organ.

Vocational Rehabilitation (VR) -- The process of facilitating an individual in the choice of or return to a suitable vocation. When necessary, assisting the patient to obtain training for such a vocation. Vocational rehabilitation can also mean preparing an individual regardless of age, status (whether U.S. citizen or immigrant), or physical condition (disability other than ESRD) to cope emotionally, psychologically, and physically with changing circumstances in life, including remaining at school or returning to school, work, or work equivalent (homemaker).

ESRD Network Organization Crosswalk

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1	10.3	ENO-Foreword	ESRD Network Organizations Manual Revisions
1	10.4	ENO-Foreword	Acronyms and Glossary
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1	30	ENO115	Requirements For ESRD Network Organizations
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1	50	ENO125	Health Care Quality Improvement Program (HCQIP)
1	60	ENO130	Goals
1	70	ENO135	Network Organization's Role in HCQIP
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2	20.1	ENO205A	Establishing the NC
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