

Medicare ESRD Network Organizations Manual

Chapter 5 - Quality Improvement

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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 5-4](#)PP 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.

$RFR = (\% \text{ absolute improvement from baseline} / 100 - \text{baseline rate}) * 100$

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 m² 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 m² 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:

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

$$\text{For Women: } V = -2.097 + 0.2466 * Wt + 0.1069 * Ht$$

Hume method:

$$\text{For Men: } V = -14.012934 + 0.296785 * Wt + 0.192786 * Ht$$

$$\text{For Women: } V = -35.270121 + 0.183809 * Wt + 0.344547 * Ht$$

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:

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

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

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

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 $\text{Kt}/V_{\text{urea}}$ used to measure delivered PD dose; and
- b. Residual renal function (unless negligible*) is assessed by measuring the renal component of $\text{Kt}/V_{\text{urea}}$ ($\text{K}_{\text{ft}}/V_{\text{urea}}$) 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 $\text{Kt}/V_{\text{urea}}$ 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 $\text{Kt}/V_{\text{urea}}$ 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 $\text{Kt}/V_{\text{urea}}$ 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 $\text{Kt}/V_{\text{urea}}$ 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 m² 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 m² 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 least 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 ≥ 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 ≥ 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)