Medicare
End Stage Renal Disease Network Organizations Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: September 1, 2000*

Sections 505, ESRD Health Care Quality Improvement Program (HCQIP), and 510, Responsibilities, have been revised grammatically to make the sentences easier to read.

Section 515, Quality Improvement Projects (QIPs), previously titled Quality of Care Improvement Projects.

Section 515.1, Background and Project Topics, previously titled Components of QIPs, is revised to require you to use Hemodialysis (HD) Adequacy Clinical Performance Measure CPM III in your QIP for the first year of your contract.

Section 515.2, QIP Frequency, Project Consultant, and Required Reporting, previously titled Developing and Planning the Project, instructs you to involve your QIP consultant in all phases of your project and advises you of the time frame for your QIP reporting.

Section 515.3, Project Idea, previously titled Identifying and Confirming an Opportunity to Improve Care, informs you that for the first year of your contract, you must conduct QIPs based on adequacy and involve your QIP consultant when developing your project idea.

Section 515.4, QIP Narrative Project Plan (NPP), previously titled Developing a Network Intervention Activity, advises you that the NPP must be completed and submitted to your project officer within 60 days of approval of your project idea.

Section 515.5, Final Project Report (FPR), previously titled Measuring Impact and Project Evaluation, advises you that you have 90 days to submit your final report and requires you to involve your QIP consultant prior to submitting your report to your project officer.

Section 515.7, Identifying Additional Opportunities for Improvement, is revised to advise you that you may identify additional intervention strategies or improvement potential within the current project.

Section 515.8, Quarterly Progress and Status Report, previously titled Project Reporting System, is revised to change the exhibit number for the final report to Exhibit 5-5.

Section 525, Clinical Performance Measures (CPMs), previously titled ESRD Clinical Indicators, clarifies that CPMs 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.

Section 525.1, CPMs - Network/National Sample, is revised to inform you that data to calculate the CPMs are collected annually and you are required to report the data collected on the CPMs to HCFA or HCFA's designee.

Section 525.2, CPMs - Sampling Method, advises you that from your databases, HCFA or its designee selects a random sample of in-center hemodialysis (HD) patients stratified by Network, and a national random sample of peritoneal dialysis (PD) patients.

Section 525.3, CPMs - Data Collection, is revised to assume that each dialysis facility in your network area will complete a range of 2 to 10 data collection forms per year.

Section 525.4, CPMs - Data Validation, is revised to have you re-abstract and validate a random 5 percent of the HD and 10 percent of the PD forms completed by facility personnel in your network area.

Section 525.5, CPMs - Data Validation Reporting, requires you to enter the CPMs data and any corrections to the patient-specific demographic information into the HCFA designated data-entry software program or the Standard Information Management System (SIMS), if available, and transmit your Network patient validation samples to HCFA or its designee within 120 calendar days after receipt of samples.

Section 530, HCFA - Compiled Data Reports, is revised to inform you that HCFA may develop/compile reports or data files using the CPMs and that HCFA or its designee will provide these reports to the networks as camera-ready copies.

Section 540, Network Resources to Support the United States Renal Data System (USRDS), is revised to instruct you to 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 4-5 special studies over the 3-year contract period.

Exhibit 5-1, ESRD Clinical Performance Measures (CPMs), defines the 16 quality indicators or CPMs.

Exhibit 5-2, Annual Estimate of Patient Sample Per Network For USRDS Special Studies, provides estimates of patient samples for your Network for the USRDS special studies.

Exhibit 5-3, ESRD Network - Project Idea Document (PID) Format, provides you with the PID format when doing your QIPs.

Exhibit 5-4, ESRD Network - Narrative Project Plan (NPP) Format, provides you with the NPP format following the project officer's approval of your PID.

Exhibit 5-5, ESRD Network - Final Project Report (FPR) Format, provides you with the FPR format for your final QIP report.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previous published in the manual and is only being reprinted.

PART 5

QUALITY IMPROVEMENT

500. AUTHORITY

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.

505. ESRD HEALTH CARE QUALITY IMPROVEMENT PROGRAM (HCQIP)

As stated in HCFA's Strategic Plan, HCQIP is a program that supports HCFA'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 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 your role in conducting quality improvement activities, you 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.

510. RESPONSIBILITIES

Your 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 HCFA;

- 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.

515. QUALITY IMPROVEMENT PROJECTS (QIPs)

515.1 Background and Project Topics.--One of HCFA's National Performance Review (NPR) goals is that 80% of adult in-center hemodialysis patients achieve a delivered dose of dialysis $\geq$ 65% as measured by the Urea Reduction Ratio (Hemodialysis (HD) Adequacy CPM III). Therefore, for your first QIP under this contract, you must use HD Adequacy CPM III as the primary CPM to measure/improve adequacy. You are required to continue conducting QIPs based on this CPM for at least the first contract year. You may include in the project design of your 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 your network area.

NOTE: If, after the first contract year, you do not met the 80% target for HD Adequacy CPM III, you must continue to conduct QIPs utilizing the HD Adequacy CPM III.

After the first contract year, if you reach or exceed the 80% target for HD Adequacy CPM III, HCFA, with input from the Networks, will determine what topics or CPMs your 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 HCFA.

You may also propose a QIP not based on one of the CPMs listed in §515.1; however, this must be adequately justified and approved in advance by HCFA. HCFA reserves the right to direct your 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, your Network resources, patient care improvement needs, and the priorities of the renal community and/or HCFA. You must, at a minimum, use one or more of the standard CPMs in your 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 HCFA through the Narrative Project Plan (NPP). (See Exhibit 5-4.)

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 HCFA.

Evaluation of projects, where possible and feasible, require 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% 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 §515.4.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.

515.2 QIP Frequency, Project Consultant, and Required Reporting.--Develop and implement at least one QIP annually, unless directed otherwise by HCFA. Electronically submit a project idea(s) to your 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 for the NPP 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.

Your first PID is due to your 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 your PO.

Sixty days after HCFA approval of the PID, electronically submit an NPP to your PO. Your PO and regional office scientific staff may be involved during this stage of the NPP development to provide guidance and assistance. Your PO will evaluate proposed QIPs based on the following criteria:

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

After initiation of the approved NPP, document all project phases and activities through the narrative portion of the Standard Information Management System (SIMS) and report the status of your QIP in the Quarterly Progress and Status Report (see §515.8). Electronically submit any changes to the approved NPP to your PO for review and approval.

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

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

515.3 Project Idea.--In your first contract year, you are required to conduct QIPs based on hemodialysis adequacy CPM III (minimum delivered dose of HD is a URR $\geq$ 65) until you reach or exceed the target of 80% of the adult in-center HD patients in your network area meeting this URR level. You may include in the project design of your 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 your network area. If, after the first contract year, you reach the 80% target for HD adequacy CPM III, HCFA, with input from the Networks, will determine what topics or CPMs your subsequent QIPs will be based on. Develop your projects in collaboration with your ESRD providers and/or beneficiaries. In addition, you may also partner with other Networks, PROs, State Survey Agencies, national and/or local renal related organizations and ROs when appropriate. Your Network QIP consultant must be involved in the development of your project idea.

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

Assess the appropriateness of your QIPs using the following general criteria:

- For the first contract year, projects shall be based on HD Adequacy CPM III, until you have meet the 80% target (as described above).

- In your QIP, you may measure other processes that you believe are associated with achieving adequate dialysis (HD Adequacy CPM III), as approved by HCFA. These measures are often useful in determining if the interventions and strategies in your QIP were effective and/or to assess whether the pre-supposed 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). You are encouraged to adopt completed projects of other Networks that have proven to be successful (i.e., where measurable improvement has been demonstrated).

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

515.4 QIP Narrative Project Plan (NPP).--After the approval of your project idea, complete the NPP and submit it to your PO within 60 days. Involve your QIP consultant in the development of the NPP. Some of the components of the NPP will have been identified in your PID. It is appropriate to request preliminary review or assistance at any point during the preparation of the NPP. In any event, before your PO officially approves your NPP, your PO or RO scientific staff may ask you to include additional information and/or ask for revisions to your 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 your Network number, Network name and contract number.

B. Project Identification Information.--Include the following:

- Project title;

- Topic (must be a HCFA priority CPM (topic area) or pre-approved as instructed in §C.2.C. of the Network SOW and §515.1 of this manual;

- Network project contact person;

- Network Epidemiologic Consultant (must be involved in the PID and NPP as required in your Statement of Work (see §C.4.C) and §225 of this manual);

- Regional project officer;

- Regional scientific advisor;

- Current date;

- o Initial NPP submission date; and
- o NPP revision number

C. Objectives of the Project.--Your project should:

1. State the National ESRD HCFA Priority CPM (topic area).--Clearly state the national ESRD HCFA priority CPM (topic area) that will be addressed in the project. HCFA has determined that your first project must be based on HD Adequacy CPM III, until you have meet the 80% target as described in §515.1. If your regional office has pre-approved 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 pre-determined 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% 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%, and the rate at remeasurement is 73%, the absolute improvement is 18% and the intervention was apparently effective. There is no penalty for not reaching 20%. If the improvement was only 3% 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 > 65%.--The Network rate of adherence at baseline is 70%. The Network proposes and targets a reduction in failure rate (RFR) of 25%. The project was carried out and the rate at remeasurement was 77.4%.

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

E.g., (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. HCFA 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 HCFA's National Performance Review goals is that 80% of adult in-center HD patients shall achieve a delivered dose of dialysis $\geq$ 65%. 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, Peer Review 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 HCFA.

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 HCFA.

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% 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 your project.

o Target audience interventions are aimed at one or more target audiences whose behavior you ultimately want to change, e.g., physicians, beneficiaries, etc. and which the Network itself implements ("direct" intervention).

o 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 your description:

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

o How you will 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.--

- o Estimate overall length of time that intervention activities are estimated to require.
- o Discuss labor-intensity, political sensitivity, resource requirements, and complexity.
- o Discuss the potential impact of these issues on the success of the project.
- o Estimate the total cost of the project.
- o 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 your 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 your project findings limitations; and

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

H. Appendices.--Include the following:

- o Bibliography
- o Data collection forms (provide separately, if necessary)
- o Publications or reports
- o Data collection, abstraction, analysis and evaluation instruments
- o Other, miscellaneous

515.5 Final Project Report (FPR).--Within 90 days after completing your QIP, submit a FPR to your PO using the format in Exhibit 5-5. Involve your QIP consultant in the preparation of this report.

515.6 Disseminating Results--Disseminate the results of your project to all providers in your network area, HCFA, 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.

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

515.8 Quarterly Progress and Status Report.--Document your project phases/activities on an ongoing basis into the Standard Information Management System (SIMS) and complete your RO reporting requirements. At least quarterly, include in your Quarterly Progress and Status Report the status of your QIPs, using a format prescribed by your RO. Complete a Final Project Report for each completed quality improvement project (see Exhibit 5-5). Submit the completed project report to your project officer within 90 days after completion of the QIP.

520. IMPROVEMENT PLAN

If you identify 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. Your medical review board will provide guidance as to when you 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.

525. CLINICAL PERFORMANCE MEASURES (CPMs)

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.

HCFA, working with you 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.

525.1 CPMs - Network/National Sample.--The CPM process is designed to assess the quality of care regarding the CPMs listed in Exhibit 5-1 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:

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

- o 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 HCFA or HCFA's designee. HCFA will aggregate these results and report Network and/or national profiles of care back to each Network.

525.2 CPMs - Sampling Method.--HCFA 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.

HCFA or its designee annually selects the patient samples using information from your database. From your databases, HCFA or its designee selects a random sample of in-center hemodialysis (HD) patients stratified by 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. HCFA 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, HCFA or its designee provides you 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 HCFA'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.

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

- o A cover letter explaining the facility staff's abstraction of the CPM data;

- o Copies of the CPM data collection form(s); and

- o Instructions for completing the data collection forms on the patients selected.

Assume that each dialysis facility in your 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. You are to:

- 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 to you. Transmit all data from the completed collection forms to HCFA or its designee within 90 calendar days after receipt of the HCFA-selected patient sample.

Upon receipt of the CPMs data, HCFA 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.

525.4 CPMs - Data Validation.--Re-abstract and validate a random 5 percent of the HD and 10 percent of the PD forms completed by facility personnel in your network area. HCFA or its designee will provide you with the names of the HD and PD patient records to abstract. This validation activity may be done by your staff conducting onsite record review (if the facility is within 100 miles of the office) or by requesting copies of the pertinent medical records. Complete the validation activity, including submitting your validation results to HCFA or its designee, within 120 calendar days after receiving your validation patient samples.

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

525.5 CPMs - Data Validation Reporting.--For each patient in your Network validation sample, enter the CPMs data and any corrections to the patient-specific demographic information into the HCFA designated data-entry software program or into SIMS, if available, and transmit to HCFA or its designee electronically or on diskette. HCFA 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 HCFA or its designee. Annually, transmit data for all patients in your Network sample to HCFA or its designee within 120 calendar days after receipt of your Network patient validation samples.

530. HCFA - COMPILED DATA REPORTS

HCFA may develop/compile reports or data files using the CPMs and HCFA 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. HCFA will provide these reports or data to you (electronically and/or on hard copy).

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

Annually, provide one copy of the HCFA ESRD CPM Report, based on the CPMs data, to the medical director, head nurse, and unit administrator of each facility in your network area:

535. QUALITY IMPROVEMENT PROJECTS VERSUS RESEARCH STUDIES

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

- o Research efforts to prove that a process of care is effective or ineffective;
- o 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
- o 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, forward the survey questions to your PO for review and approval, and to determine the type of clearance needed, if necessary. The PO or other RO staff will inform you of the type of clearance, if any, the survey requires.

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

540. NETWORK RESOURCES TO SUPPORT THE UNITED STATES RENAL DATA SYSTEM (USRDS)

In addition to the resources and activities you conduct to support the ESRD Program Management and Medical Information System (PMMIS) database, which HCFA 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 4-5 special studies over the 3-year contract period. Assume the following additional network resources to support USRDS special study activities:

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

The above annual resource estimate is based on the following:

- o A national sample of 5,000 to 7,000 patients per study;
- o A patient sample selection per Network that is proportional to the number of patients in each Network (see Exhibit 5-2);
- o 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.

Report to your HCFA PO, using the Quarterly Progress and Status Report, the work conducted to support the USRDS special studies, as appropriates, such as the number of data collection forms completed and the date these forms were mailed to the USRDS.

HCFA, 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 you are 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.

EXHIBIT 5-1

ESRD CLINICAL PERFORMANCE MEASURES (CPMs)

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 HCFA's CPM Project is October, November, and December of each year.)

Denominator:
All adult (≥ 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 HCFA's CPM Project is October, November, and December of each year.)

Denominator:
All adult (≥ 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 $\geq$ 1.2 or URR $\geq$ 65% during the reporting/study period. (The reporting period for HD patients in HCFA's CPM Project is October, November, and December of each year.)

Denominator:
All adult ($\geq$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 HCFA=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 HCFA's CPM Project is Octoberober, 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 HCFA's CPM Project is October, November, and December of each year, and January, February, March of the following year.)

Denominator:
All adult (≥ 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 HCFA'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 (≥ 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 HCFA'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 HCFA'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 HCFA's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

All adult (≥ 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 HCFA'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 HCFA's CPM Project is October, November, and December of each year.)

Denominator:

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

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

Denominator:
All adult (≥ 18 years old) patients in the sample who were on HD continuously during reporting/study period. (The reporting period for HD patients in HCFA'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 HCFA'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 HCFA's CPM Project is October, November, and December of each year.)

Denominator:
All adult (≥ 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 HCFA'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 (≥ 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 HCFA'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 HCFA'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 (≥ 18 years old) HD or PD patients in sample, exclude patients with mean hgb > 12 who are not prescribed Epoetin at any time during reporting/study period. (The reporting period for HD patients in HCFA'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 (≥ 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 HCFA's CPM Project is October, November, and December of each year.)

b. All adult (≥ 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 HCFA'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 (≥ 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 HCFA's CPM Project is October, November, and December of each year.)

b. All adult (≥ 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 HCFA'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) > 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 HCFA'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 HCFA's CPM Project is October, November, and December of each year and January, February, March of the following year.)

Denominator:

a. All adult (≥ 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 ≥ 50% or ferritin ≥ 800 ng/mL and **EXCLUDE** patients in first 3 months of dialysis and prescribed oral iron.

b. All adult (≥ 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 ≥ 50% or ferritin ≥ 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

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

ESRD Network Number:
ESRD Network Name:
Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a HCFA priority area or pre-approved as instructed in the Network SOW §C.2.C and §515.1 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 §515.2 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 §515.3 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 HCFA 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 §515.1 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

ESRD Network Number:
ESRD Network Name:
Contract Number:

I. Project Identifiers

A. Project Title

B. Topic (must be a HCFA priority area or pre-approved as instructed in the Network Statement of Work (SOW) §C.2.C and §515.1 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 §515.2).

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 §515.4 for additional information and instructions for completing the Narrative Project Plan (NPP)).

A. Clearly state the national ESRD HCFA priority topic that will be addressed in the project. If your regional office has pre-approved 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 HCFA.

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

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)