CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

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

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NEW/REVISED MATERIAL - EFFECTIVE DATE: June 29, 2003

Section 2000 - Background

Section 2010 - Eligibility

Section 2020 - Competing For a QIO Contract

Section 2030 - Additional Requirements for a Physician-access or Physician-sponsored Organization

Section 2200 - Responsibilities of the Board

Section 2210 - Health Care Affiliate Limitations

Section 2220 - Consumer Representative adds additional requirements with regard to all new consumer representatives appointed or reappointed to the QIO board as required under section 2220.

Section 2230 - Prohibition Against Sanctioned Board Members

Section 2300 - Background

Section 2310 - Renewal

Section 2320 - Determination

Section 8000 - Introduction informs the QIO of its minimum requirements and responsibilities in using the Standard Data Processing System (SDPS).

Section 8005 - Staffing Functions instructs the QIO to have adequate Information Systems staff to fulfill the requirements of the QIO programs.

Section 8010 - Mandatory System Use informs the QIO of its requirement to use all components of SDPS and to use the same software, hardware, and procedures to conform to the entire SDPS.

Section 8015 - Operations contains information on the various systems, operations and processes that the QIO must carry out on a periodic basis.

Section 8020 - Communication informs the QIO of the various ways communication will be carried out between the QIO and CMS, and the QIO community.

Section 8025 - Confidentiality of System instructs how the QIO must transmit confidential data through the Wide Area Network (WAN) that CMS has in place exclusively for the QIO community.

Section 8030 - Applicable Documentation informs the QIO that documentation to support the SDPS community will be provided as necessary.

Section 8035 - Process for Moving instructs the QIO that prior to moving offices or major SDPS equipment, it must contact the SDPS Help Desk to make arrangements to have the government telecommunication lines moved.

Section 8040 - Standard Data Processing System (SDPS) Engineering Review Board (ERB) Process-Approved Software and Hardware instructs the QIO to submit an SDPS ERB request to the SDPS Help Desk prior to purchasing any equipment for its SDPS system.

Section 8045 - Hardware Maintenance Process instructs the QIO to contact the SDPS Help Desk for maintenance on most SDPS equipment.

Exhibit 8-1 - Standard Data Processing System (SDPS) Data Management Plan is an exhibit of the SDPS Data Management Plan format that the QIO must use to document the policies and procedures it develops when using the SDPS.

Throughout Chapter 13, all references to Health Care Financing Administration (HCFA) are changed to Centers for Medicare and Medicaid Services (CMS), and all references to Peer Review Organization (PRO) are changed to Quality Improvement Organization (QIO). All references to Payment Error Prevention Program (PEPP) are changed to Medicare Beneficiary Protection Program (MBPP). Finally, all references to 42 CFR 476

are changed to 42 CFR 480, references to 42 CFR 466 are changed to 42 CFR 476, and references to 42 CFR 473 are changed to 42 CFR 478.

Section 13000 - Purpose and Objectives of the Internal Quality Control (IQC) Program adds improving reliability, accuracy, consistency and timeliness of "case review process and decisions" to the objectives of the IQC program.

Section 13010 - IQC Program Requirements instructs the QIO to have an IQC program that encompasses the Statement of Work (SOW) tasks/subtasks and other major activities.

Section 13020 - IQC Control Process instructs the QIO to implement an IQC program that identifies tasks and subtasks, monitors performance, implements improvement actions, and determines successful improvement actions. The QIO must analyze performance annually and make adjustments as needed.

Section 13030 - Analysis and Reporting Requirements instructs the QIO to document and make available measures/monitoring plans, results, and improvement actions for all major activities.

Section 15100 - Background reference to Peer Review Organization (PRO) is deleted and replaced with Quality Improvement Organization (QIO).

Section 15110 - Provisions of the Notice deletes reference to a separate Statement of Work (SOW) and evaluation criteria for Medicare + Choice Organizations.

Section 15120 - Uses of Evaluation Criteria deletes reference to the PRO Monitoring Protocol and Tracking System (PROMPTS).

Section 15200 - Background deletes reference to the Peer Review Organization Evaluation Process (PREP).

Section 15210 - Purpose describes the purpose of the current Contract Evaluation Process and deletes reference to the PREP.

Section 15220 - Timing is revised to clarify that Project Officers continually monitor the QIO performance throughout the contract period.

Section 15230 - Methods of Evaluation describes the methods of evaluating QIO contract performance.

Section 15240 - Report of Findings is deleted in its entirety.

Section 15400 - Background is revised to clarify that the Project Officer, and in some instances the Contracting Officer, can request a Performance Improvement Plan.

Section 15410 - Monitoring Responsibilities is deleted. Information contained in that section has been incorporated in §15400 and §15420.

Section 15420 - Performance Plan Expectations, formerly entitled "PIP Format," is renamed and identifies the elements of a successful performance improvement plan.

Section 15510 - Grounds for Termination deletes reference to HCFA and contains minor editorial revisions.

Section 15520 - Recommendation to Initiate Termination specifies the elements of a recommendation to terminate.

Section 15530 - Notice of Intent to Terminate Contract deletes reference to the time frame to submit additional information to CMS for review in order to continue or cease with the proposed termination process.

Section 15540 - Termination Panel editorial revisions made.

Section 15550 - Termination Decision CMS may terminate a QIO contract within 90 days of the panel's report, or with concurrence from the QIO, amend the Statement of Work to modify the QIO functions or otherwise change the contract.

Section 15600 - Statutory Requirements this information was included in the Renewal/Non-renewal section and is now being deleted.

Section 15610 - Renewal/Non-renewal Procedures has been renumbered to §15600 and advises the QIO that one of the purposes of the evaluation process is to make a determination as to whether the QIO is eligible for non-competitive contract renewal.

Section 15700 - Introduction contains minor editorial revisions.

Section 15710 - Boxing of Records - General contains minor editorial revisions.

Section 15720 - Boxing of Review Records deletes reference to the Uniform Clinical Data Set System Reports.

Section 15740 - Boxing of Miscellaneous Records references to HCFA are deleted.

Section 15750 - Retention of Financial Records clarifies that deliverables are contained in Section F of the QIO contract.

Workload and Costs: These instructions do not represent an increase in workloads or costs.

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

Quality Improvement Organization Manual

Chapter 2 - Eligibility

TABLE OF CONTENTS (Rev. 1, 05-23-03)

2000 - Background - (Rev. 1, 05-23-03)

Every organization performing medical review and conducting quality improvement activities as a Quality Improvement Organization (QIO) must either be sponsored by a significant number of physicians actively practicing in the QIO area, or must have available to it the services of a sufficient number of area physicians to assure adequate peer review.

Any organization submitting a bid to perform QIO review in a QIO area is required to demonstrate that it meets the requirements of physician-access or physician-sponsorship in order to be eligible to compete for the bid.

2010 - Eligibility - (Rev. 1, 05-23-03)

A. Physician-sponsored -- To be eligible as a physician-sponsored organization, the organization must meet the following requirements:

- Be composed (have physicians as owners or members) of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State (e.g., at least 20 percent of the practicing physicians in the State are owners of the QIO, or the QIO is owned by an entity which includes at least 20 percent of the practicing physicians in the State as members); or

- Be composed (have physicians as owners or members) of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the State, and demonstrate through means (e.g., letters of support from physicians or physician organizations) acceptable to CMS that the organization is representative of an additional 10 percent of the practicing physicians in the State; and

- Not be a health care facility, health care facility association, or health care facility affiliate.

B. Physician-access -- To be eligible as a physician-access organization, the organization must meet the following requirements:

- Have arrangements with doctors of medicine or osteopathy, licensed and practicing in the State, to conduct review for the organization;

- Have available at least one physician, licensed in the State, from every generally recognized specialty and subspecialty who is in active practice in your review area; and

- Not be a health care facility, health care facility association, or health care facility affiliate.

2020 - Competing for a QIO Contract - (Rev. 1, 05-23-03)

To be eligible to compete for a QIO contract, you must demonstrate in your proposal that your organizational structure meets the definition of either a physician-access or a physician-sponsored organization. The Request for Proposal (RFP) issued by CMS defines the terms of an offeror's bid to compete as a QIO, and states the obligations of the offeror to provide documentation supporting its status as a physician-access or physician-sponsored organization.

A. Competing as a Physician-sponsored Organization -- The RFP stipulates the requirements of an organization claiming eligibility as a physician-sponsored organization. The requirements include:

- Submitting written certifications or a statement of the number of actively practicing physicians in your area who support you as a QIO; and

- Having documentation on file that substantiates the support of individual physicians in your area.

B. Competing as a Physician-access Organization -- The RFP stipulates the requirements of an organization claiming eligibility as a physician-access organization. The requirements include:

- Submitting written certification or a statement that you have available, by arrangement or otherwise, the services of a sufficient number of physicians practicing in your review area to assure adequate peer review of services provided by the various medical specialties and subspecialties in your area.

NOTE: All certificates and statements of physician support are subject to audit by CMS and other government agencies. False certifications or statements are grounds for not awarding or terminating the contract.

C. Priority Status of Competing Physician-sponsored Organizations -- Priority in awarding contracts under a competitive procurement is given to physician-sponsored organizations. Physician-sponsored organizations receive additional points during the proposal evaluation process.

2030 - Additional Requirements for a Physician-access or Physician-sponsored Organization - (Rev. 1, 05-23-03)

An organization proposing to perform review on the basis that it is a physician-sponsored or physician-access organization must include written certification that it is not a health care facility in the QIO area, that it is not an association of health care facilities in the QIO area, or that it is not a health care facility affiliate.

- A "health care facility" is defined as an institution that directly provides or supplies health care services for which payment may be made in whole or in part under title XVIII of the Social Security Act. For example, a health care facility may be a hospital, skilled nursing facility, home health agency, freestanding ambulatory surgical center, or any other entity that provides or supplies direct care to Medicare beneficiaries.

- A "health care facility affiliate" is defined as an organization that has a board on which more than 20 percent of the members are also either a governing board member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the QIO area.

NOTE: These requirements do not apply to a payer organization if CMS determines that there is no other eligible organization available to perform QIO review.

2200 - Responsibilities of the Board - (Rev. 1, 05-23-03)

Each Quality Improvement Organization (QIO) must have a governing board that performs certain duties to assure the efficient and effective management of the organization. Outline these duties in the proposal to perform review, which you submit to CMS prior to the award of the contract. The duties detailed in your contract must conform to the minimal standards established by CMS in the Request for Proposal (RFP) and this manual.

CMS does not mandate a specific process for selecting board members (e.g., endorsement from community organizations). Thus, you have the flexibility to establish your own methodology for determining who will serve (except as provided below in §2220), how long they will serve, and what services they will perform as a member of your board.

2210 - Health Care Affiliate Limitations - (Rev. 1, 05-23-03)

Federal regulations require that QIO boards cannot be composed of a significant number of individuals with health care facility affiliations. Regulations at 42 CFR 475.105 require that you not have more than 20 percent of the members of your governing body affiliated with a health care facility or association of health care facilities located in the area in any of the following capacities:

- A governing member;
- An officer;
- A partner;
- An owner of five percent or more; or
- A managing employee.

NOTE: The prohibition does not apply to a payer organization if CMS determines that no other eligible organization is available.

2220 - Consumer Representative - (Rev. 1, 05-23-03)

With regard to all new consumer representatives appointed or reappointed to the QIO board as required under §2220 below, appointees shall meet the following appointment criteria in addition to all other requirements as set forth in §2220:

- Understand, or be willing to learn, the specific responsibilities of the QIO;
- Understand, or be willing to learn, the specific requirements of the Statement of Work (SOW) in effect at the time of the appointment; and
- Be willing to persevere in an ongoing process of learning about and developing contacts with major religious, community service, civic, union, consumer, public

service, and other organizations in their state that have an interest in health care delivery and health care policy, including organizations that represent disadvantaged communities, rural, and non-English speaking populations.

In addition, appointees shall meet at least four (4) of the following five (5) criteria in order to be eligible for appointment as a consumer representative:

- Have a track record of advocacy in behalf of furthering consumer interests, especially in the area of health care;

- Be knowledgeable about the organizations representing or advocating for seniors in the state;

- Be knowledgeable about the needs and concerns of the diverse groups of Medicare beneficiaries and their caregivers in their state;

- Have a basic understanding of the Medicare program; and

- Have previous experience serving on the governing board of a business, religious organization, union, consumer organization, community service organization, community hospital, school board, or other type of service organization; or have previous experience serving on a governmental or non-governmental policy level commission or advisory council; or have held a governmental or non-governmental management position that involved working with boards or advisory committees or commissions.

In addition, the board must be composed of a diverse group of members so as to reflect, in terms of gender, race, ethnicity, rural/urban, and socio-economic status, the Medicare population of the state. If the current governing board does not meet this criterion, then the QIO must develop a written plan to reconstitute the board within three years to meet the requirements set forth in the previous sentence.

§9353(b) of the Omnibus Budget Reconciliation Act of 1986 amended §1152 of the Social Security Act (the Act) to require you to have at least one consumer representative on your governing board. As a member of the QIO governing board, the consumer representative must live in a State represented by the board. Therefore, if the board is a single State board, the consumer representative must live in the State. If, however, the board is a joint board of two or more States (in the case of multi-State QIO contracts), the consumer representative may live in any State represented by the board.

QIOs must have a minimum of one consumer representative on each QIO governing board (regardless of the number of QIO areas governed by the board). Therefore, a joint board of two or more States is required to have a minimum of one consumer representative on the joint board. The consumer representative must meet the requirements listed below:

- The consumer representative must be a Medicare beneficiary (fee-for-service or managed care); and

- The consumer representative must not be: (1) a practicing or retired physician or (2) a governing board member, officer, partner, owner of more than five percent interest in a health care facility, or managing employee of a health care facility or association of health care facilities.

A nurse or other non-physician health care practitioner may serve as the consumer representative if he/she meets the other requirements.

QIOs that have a fee-for-service and managed care contract must ensure that each Medicare beneficiary population is adequately represented in QIO matters. Therefore, these QIOs must have a minimum of one consumer representative from the beneficiary population that is not included on the board as a permanent member of at least one appropriate committee/group. In the case of a joint board, there must be a managed care Medicare consumer representative from each QIO area (on the board or on a committee/group) because managed care plans differ from State to State.

Afford the consumer representative the same responsibilities as other non-physician board members. For example, if other non-physician board members participate in the sanction process and vote on sanction actions, then the consumer representative must be allowed to participate in the sanction process and to vote as well. You must assure that Medicare beneficiaries have a voice in the Health Care Quality Improvement Program. Representation on the board is one approach.

Create other positions on your board such as a health care ombudsman or a provider representative, as appropriate.

2230 - Prohibition Against Sanctioned Board Members - (Rev. 1, 05-23-03)

Organizations, which have sanctioned individuals on their boards, are excluded in almost all cases from obtaining contracts as QIOs. §1128 of the Act permits the Secretary to exclude sanctioned entities or entities controlled by sanctioned individuals when the person has direct or indirect ownership interest or controls a five percent or more interest in the entity. §1128, when read in conjunction with §1124(a)(3) of the Act, excludes those entities having a sanctioned individual:

- As an officer or director, if the entity is organized as a corporation; or

- As a partner in the entity, if the entity is organized as a partnership.

Sanctioned entities or individuals include the following:

- Those who, under the Medicare program or under a State health care program, have been:

- Convicted of a criminal offense related to the delivery of a health care item or service;

- Excluded from participation; or

- Assessed a civil monetary penalty in regard to the abuse of the rules and procedures under §1128A.

➢ Those convicted under Federal or State law:

- Of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service;

- Of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to any act of omission in a program operated by or financed in whole or in part by any Federal, State, or local Government agency; or

- In connection with the interference with or obstruction of any investigation into any criminal offense described above.

➢ Those convicted under Federal or State law of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

2300 - Background - (Rev. 1, 05-23-03)

§1153(i)(3) of the Social Security Act (the Act) defines an in-State organization as an organization that has its primary place of business in the State in which review will be conducted or that is owned by a parent corporation the headquarters of which is located in that State. A geographic contract region comprising a territory or other area not defined by the boundaries of a State (e.g., the District of Columbia) is considered to be the equivalent of a State for the purpose of applying the in-State provision of §1153 of the Act to QIO contracts.

Primary place of business is determined as follows:

➢ If you are designated in only one geographic contract region, then the location of your corporate headquarters, Board of Directors, day-to-day management of your contracts, and place of performance for all contracts determines your primary place of business.

- If, as a single corporate entity, you are designated in more than one geographic contract region, then the location of your corporate headquarters determines your primary place of business.

- If you are a corporate entity subsidiary to another corporate entity, you may qualify as an in-State organization in the State in which you have your primary place of business, regardless of your parent corporation's headquarters location, and regardless of whether the parent may also be designated in-State in the geographic contract region where it maintains its primary place of business. Subsidiary corporate entity's primary place of business is determined according to the criteria set forth above for an organization designated in only one geographic contract region, provided the subsidiary corporation (not the parent corporation) is the entity that holds, and has bound itself to perform, the contract.

2310 - Renewal - (Rev. 1, 05-23-03)

A. Statutory Restriction -- §1153(i) of the Act prohibits renewal of any QIO contract not held by an in-State organization, requiring CMS to provide to potential in-State bidders notice and opportunity to compete for such QIO contracts.

B. Notification Procedures -- Before CMS can renew a QIO that does not meet the requirements to be considered "in-State," CMS must:

- Publish an advance notice in the Federal Register announcing when the QIO's contract will expire and requesting a statement of interest from any in-State organizations interested in competing for the contract. The Federal Register notice must:

    - Be published no later than six months before the date the current QIO contract expires; and

    - Specify the period of time during which an in-State organization may submit a statement of interest for the contract.

NOTE: For purposes of this notice, your status in terms of being considered in-State or out-of-State is assumed to be the same as it was when your current contract was awarded, unless you submit acceptable evidence that you have changed your status (e.g., you are now an in-State organization). Send such evidence to the Contract Officer (CO) and the Project Officer (PO) no later than one year before the date of expiration of your contract to provide sufficient review time.

- Give in-State organizations 21 days from the date of publication of the Federal Register notice to submit a statement of interest to the CO (Office of Acquisitions & Grants) in order to compete for the contract.

NOTE: An interested organization must demonstrate that it meets the definition of an in-State organization at the time it responds to the notice and that it is otherwise an eligible organization in accordance with §§1152 and 1153 of the Act.

- Once an in-State organization expresses an interest in a given QIO contract, CMS must provide for competitive procurement for that contract, and any organization (in-State or out-of-State) may respond to the Request for Proposal.

2320 - Determination - (Rev. 1, 05-23-03)

The CO and the Director of the Office of Clinical Standards and Quality will make a formal decision as to whether the organization:

- Meets the definition of an in-State organization;

- Has submitted an adequate statement of interest within the 21-day timeframe; and

- Has demonstrated that it meets, or will meet, the requirements as a physician-sponsored organization or physician-access organization by the date the contract is signed, as specified in 42 CFR 475.102 and 42 CFR 475.103.

Quality Improvement Organization Manual

Chapter 8 - Data Management

TABLE OF CONTENTS (Rev. 1, 05-23-03)

8000 - Introduction - (Rev. 1, 05-23-03)

This section describes the minimum requirements and responsibilities of the Quality Improvement Organizations (QIOs), formerly the Peer Review Organizations (PROs) in using the Standard Data Processing System (SDPS). The QIOs must document the policies and procedures they develop to conduct these requirements in a SDPS Data Management Plan. The SDPS Data Management Plan should follow the format in Exhibit 8-1.

8005 - Staffing Functions - (Rev. 1, 05-23-03)

A. Staffing

CMS' SDPS provides you with hardware and software tools to enable your personnel to fulfill the requirements of the QIO programs. You are responsible for adequately staffing the functions described in this section and associated references to other documentation. This includes, but is not limited to, knowledgeable personnel to perform:

- Timely updates;
- Routine maintenance procedures; and
- Local troubleshooting for SDPS workstations, printers, fileservers, routers, and database servers.

Make the necessary business decisions within your organization to ensure Information Systems (IS) staff are adequately hired, maintained, managed, and trained to continue effective operation of the SDPS system in its current environment. If you are unable to fulfill the functions described in this manual section and/or as described in your SDPS Data Management Plan and associated references to other documentation due to staffing changes, immediately notify your project officer and the SDPS Help Desk.

B. Responsibilities and Descriptions

Security Staff -- Personnel with responsibility to make decisions about access to databases and the network for staff at their QIO. These individuals should have sufficient business knowledge to determine the access that would be appropriate for SDPS applications and the databases with which they are associated.

Technical Staff -- Personnel with a basic understanding of relational databases with emphasis on Oracle. Ability to follow directions provided by SDPS Memos and the SDPS Help Desk, as well as supporting local analysis efforts. Technically capable of coding and reviewing code run against large databases such as the National Data Warehouse.

QIO RS/6000 Systems Administrator -- This qualification should include 3 - 4 years of experience in working with IBM AIX. AIX Systems Administration Certification is a plus but not a requirement. Ability to follow directions provided by SDPS Memos and the SDPS Help Desk, as well as supporting local analysis efforts. This administrator will follow the guidelines in the Systems Administrator Guide. This administrator will be required to:

- Perform normal systems maintenance
- Daily backups of the AIX file server
- Support the local user population
- Report any problems in the local SDPS environment to the SDPS Help Desk for resolution
- Follow instructions provided by the SDPS Engineers for changes to the local SDPS environment
- Use the Remedy system to provide information on the local SDPS environment to CMS and the SDPS Help Desk
- Keep abreast of any SDPS memos or Technical Alerts posted to the SDPS Intranet

QIO LAN Administrator -- This qualification should include 3 - 4 years of experience in working with the Novell network operating system and user/workstation support. Novell CNE certification is a plus but not a requirement. Ability to follow directions provided by SDPS Memos and the SDPS Help Desk, as well as supporting local analysis efforts. This administrator will follow the guidelines in the Systems Administrator Guide. This administrator will be required to:

- Perform normal systems maintenance
- Daily backups of the Novell file server
- Support the local user population
- Report any problems in the local SDPS environment to the SDPS Help Desk for resolution
- Follow instructions provided by the SDPS Engineers for changes to the local SDPS environment
- Use the Remedy system to provide information on the local SDPS environment to CMS and the SDPS Help Desk

- Keep abreast of any SDPS memos or Technical Alerts posted to the SDPS Intranet

C. Security

Password Change Notification -- Each QIO is required to notify the SDPS Help Desk any time they change the RS/6000's root password. Each QIO is required to maintain a list of root passwords they have used in the past and keep the effective date and date the password was changed in the event the SDPS Help Desk would need to restore from an old MKSYSB tape.

Employee Resignation and Termination -- In the event of a QIO employee either leaving or being terminated, the QIO is required to remove or disable the users login account on the local RS/6000 and in the Oracle database, and they must notify the SDPS Help Desk that the user is no longer employed at the QIO. In addition, the QIO is required to notify the SDPS Help Desk to disable any accounts for national Quality Net access. This will serve as a way to remove/disable any accounts that the particular user may have on either Quality Net complex 1 or 2 SP's.

8010 - Mandatory System Use - (Rev. 1, 05-23-03)

CMS-approved systems are the standard for the SDPS community. SDPS is the Office and Division of Clinical Standards and Quality (central and regional offices), the Clinical Data Abstraction Center, and the Quality Improvement Organizations data system for communications. It is also the standard platform for data and for accessing the data. The components of the SDPS include, but are not limited to, file servers, workstations, database servers, commercial off the shelf (COTS) products, custom written software (e.g., including, but not limited to PROvantage, PRS, PATS, CATS, SDPS Infonet reports, and SEFF), and video conferencing. All QIOs are required to use the same software, hardware, and procedures to conform to the entire SDPS. You are required to use all components of SDPS and SDPS Developed Applications (e.g., PROvantage, PRS, PATS, CATS, SEFF, MedQuest), and other new components, when implemented, to manage and report work done under the current Statement of Work (SOW). Enter information according to the QIO Manual and applicable SDPS reporting requirements.

8015 - Operations - (Rev. 1, 05-23-03)

A. Monthly Merge -- The SDPS databases located at the QIO site have periodic load processes that you are required to run by the 5th calendar day of each month. This load process is referred to as the Monthly Merge. The Monthly Merge is a set of processes you perform to load and merge claims, beneficiary, reference, physician, Health Services Providers, Health Maintenance Organizations, and other files that are needed on a regularly scheduled basis into the Oracle database. (See the SDPS Data Base Administrator (DBA) Guide for specific instructions.) Until the SDPS applications are moved to a national database, this Monthly Merge process must be kept current. Prior

merges not run, need to be caught up to keep the data accurate. Problems regarding the monthly data merge process should be directed to the SDPS Help Desk as soon as they are identified.

B. Capacity Metering -- Monitor the capacity of the SDPS. Perform and collect periodic capacity analysis. Capacity analysis includes disk utilization and system performance. (See the DBA Guide for more specific instructions.) Clean up system disk areas on a regular basis. The SDPS Team may periodically access the QIO SDPS to monitor disk space and volume capacity to determine future needs of the QIO.

C. Backups -- Perform regular backups as required in the Backup and Recovery Guide referenced as an appendix to the DBA Guide.

- AIX Systems Backups -- Complete AIX Database Server Backups must be completed as specified in the AIX Systems Administrator Guide. QIOs should follow the AIX Systems Administrator Guide as to purchasing the specific quantity and brand of backup tapes. QIOs should allocate an annual budget for tape replacement.

- AIX MKSYSB Backups -- A MKSYSB must be completed at least once a month. We suggest the first Monday of the month for performing the MKSYSB. See the AIX Systems Administrator Guide for how to perform the MKSYSB.

- Novell File Server Backups -- Complete backups of the Novell file server are to be performed each night as specified in the SDPS LAN Administrator Guide. The QIO is responsible for purchasing and having on hand the backup media required to maintain the backup schedule as specified in the SDPS LAN Administrator Guide.

- Offsite Tape Storage -- Each QIO must participate in a qualified off-site tape storage program. See the AIX Systems Administrator Guide and the SDPS LAN Administrator Guide for the requirements.

D. System Upgrades -- The SDPS team provides periodic systems upgrades, which are released to the QIO community. You are responsible for installing them in a 30-day timeframe according to the instructions provided. Future system upgrades are based on the fact that prior upgrades have correctly been installed. If problems arise in this area, contact the SDPS Help Desk immediately.

E. Producing Required Data/Reports -- CMS requires you to enter data timely. You are required to meet this schedule and ensure that the data and information are accurate and complete (e.g., reflects current status of QIO performance). This information may be generated from the SDPS-provided software.

F. Ad Hoc Data Requests -- QIOs wanting access to CMS data that is not accessible to them may request it through the process outlined in the Ad Hoc attachment to the SDPS

DBA Guide. As additional data sources become available, they are documented and provided to you through this Ad Hoc process.

G. Quality Assurance/Data Integrity of QIO Generated Data -- You are responsible for implementing processes to routinely monitor the quality and integrity of data which is generated by your staff and collaborators when performing Seventh Statement of Work activities. Policies, results, analysis, and corrective actions should be documented and kept on file.

H. Insurance Issues -- Unless otherwise specified, if a contractor uses Government-furnished property, the Government acts as a self-insurer. If the contractor exercises reasonable care and custody, we will replace any damaged or stolen equipment.

I. QIO/Clinical Data Abstraction Center (CDAC) Interaction -- CDACs will perform data abstraction for all national projects. You are encouraged to use the CDACs to perform data abstraction for any of your local projects. If this option is used, develop and provide specifications to the CDACs based on CMS standards.

8020 - Communication - (Rev. 1, 05-23-03)

A. SDPS Memos -- SDPS Memos are issued routinely to inform the QIO community of CMS and SDPS issues. SDPS Memos are sent by e-mail from the SDPS Help Desk to the appropriate SDPS Points of Contact (e.g., DBA Point of Contact, Review Point of Contact, etc.). Copies of the SDPS Memos are also stored on the SDPS Infonet as a reference. Distribute the memos to appropriate QIO staff and act on the instructions in a timely manner.

B. Internet -- The SDPS provides Internet access and e-mail on the World Wide Web for use by the QIO community for business-related work. QIOs are responsible for educating Internet users as to appropriate business use. The SDPS Help Desk monitors use of this service.

C. CMS Newsletters -- The SDPS Newsletter is published monthly by the SDPS team and distributed to CMS and the QIO community. Route the SDPS Newsletter to the appropriate QIO staff. The SDPS Newsletter is distributed on the 15th of each month via e-mail from the SDPS Help Desk and is also posted on the SDPS Infonet.

D. Infonet -- The SDPS Infonet is set up on the Wide Area Network (WAN) to provide information via the SDPS Newsletter, SDPS Memos, newsgroups, release notes, release executables, user documentation, and training documentation. This setup provides efficient distribution of materials for your use. The Infonet has zones set up with limited access to provide security for the information posted. You need a password to access the secured areas of the Infonet. Routinely access the Infonet server to obtain information on the latest changes in the SDPS. Workgroup activity and other information are located in the Newsgroups section of the Infonet, which is helpful to the end users.

E. Periodic Data Issues Conference Calls -- The SDPS team provides a periodic Data Issues call as published in the SDPS Newsletter. Provide a representative to participate in the latest activities related to the SDPS.

F. Training -- The SDPS provides training on SDPS Developed Applications (including but not limited to PROvantage, PRS, PATS, CATS, and SEFF) and new features of SDPS (e.g., using reporting tools) via Quality Net e-University. Hands-on training is provided at the Quality Net User's Group Conference. You are responsible for having appropriate personnel attend these sessions.

G. Point of Contact (POC)/ SDPS Help Desk -- The SDPS provides a Help Desk accessible to you via e-mail, fax, or telephone. Assign a designated POC with the SDPS Help Desk. This information should be kept current. Any changes to the POC list should be reported to the SDPS Help Desk immediately. The SDPS Help Desk is used to facilitate questions, problems, suggestions, Engineering Review Boards (ERBs), and maintenance issues. The SDPS Help Desk may be contacted at 1-888-432-2737, or you may fax them at 1-888-329-7377, or you may send a GroupWise message to the SDPS Help Desk in the IA-DEV Public Group. QIOs are required to contact the SDPS Help Desk in the event of any system problem or issue. QIOs should only use the designated SDPS Help Desk Support Number to report problems or issues and should refrain from contacting the support staff directly without an issue ticket being created. Only the designated QIO Point of Contact is to call the SDPS Help Desk.

H. QIO Use of the Remedy System -- The Remedy system is used by the SDPS Help Desk to track changes and problems within the SDPS environment. Each Remedy user must have his or her own username and password. Only the approved Remedy users are to have access to the username and password for the Remedy system. The QIOs are required to use the Remedy system to provide information to CMS and to the SDPS Help Desk. This information will include, but will not be limited to the following:

- SDPS hardware inventory
- SDPS software inventory
- ERB submission and tracking
- Tracking of changes to the SDPS environment
- Any additional information relevant to the operation of the local SDPS environment

I. SDPS Workgroups -- There are several SDPS Workgroups designed to provide input to CMS and the SDPS team for enhancements and suggestions for improvement. The SDPS Workgroups are divided into specific focus areas. Information about the Workgroups is available on the SDPS Infonet in the Newsgroups area. QIOs are urged to participate in the SDPS Workgroups.

8025 - Confidentiality Of System - (Rev. 1, 05-23-03)

To maintain system confidentiality, CMS has a WAN in place that is exclusive to the QIO community. Information retrieved and/or transmitted within this system is protected from outside invasion. Do not transmit confidential data through the Internet without prior written permission from CMS. In addition, DO NOT connect or install external systems, applications, or procedures without prior approval by CMS and the SDPS team. You may request potential changes to the SDPS infrastructure through the ERB request process. If you fail to obtain prior approval, you may be disconnected from the SDPS WAN without warning.

8030 - Applicable Documentation - (Rev. 1, 05-23-03)

The SDPS community is provided with documentation (e.g., guides and manuals) to support the activities of the SDPS system. A Users Guide and a list of updates accompany each release of the SDPS-developed software applications (including but not limited to PROvantage, PRS, PATS, CATS, and SEFF). A Data Model to chart the tables and associations of data and an SDPS Data Dictionary with extensive definitions for the various components of the Data Model are also provided by SDPS. Other documentation is released to inform QIOs of procedures, processes, and system maintenance. This documentation is as follows:

- Users Guides;
- SDPS Data Model Poster;
- PDF Version of the SDPS Data Model;
- SDPS DBA Guide;
- The InfoMaker Master Library; and
- The SDPS Data Dictionary.

Copies of SDPS documentation can be obtained from either the SDPS Infonet or by contacting the SDPS Help Desk.

8035 - Process For Moving - (Rev. 1, 05-23-03)

If you plan to move offices and/or major SDPS equipment (fileservers, database servers, etc.), you must contact the SDPS Help Desk immediately. It takes approximately 54 business days for the phone service companies to move the FTS2000 government telecommunication lines. In addition, properly package and insure all equipment to protect against damages during the move.

8040 - Standard Data Processing System (SDPS) Engineering Review Board (ERB) Process -- Approved Software And Hardware - (Rev. 1, 05-23-03)

The SDPS Team provides a list of standard hardware and software. Periodically, the SDPS Team adds additional items to the list of approved SDPS items. Prior to purchasing approved SDPS items or having external non-SDPS procedures, connections, or applications integrated with the SDPS system, submit an SDPS ERB request on the AR System ERB Database. The SDPS ERB Team evaluates and coordinates the purchase of approved, denied, or returned for additional documentation based on the determination of the SDPS ERB Team and CMS. When you receive an approved SDPS ERB request involving software or hardware, pay the vendor directly from your invoice. Once the hardware or software is received, you need to update the AR System hardware or software inventory database.

QIOs are required to submit an ERB request to the SDPS Help Desk and wait for approval before making any changes to the RS/6000 system or its peripherals. All requests will be properly evaluated before a request can be implemented. All ERB requests submitted must benefit the entire QIO community before they will be approved.

QIOs are required to submit an ERB request to the SDPS Help Desk and wait for approval before making any changes to the Novell file server, workstations, or any peripherals. All requests will be properly evaluated before a request can be implemented. All ERBs will be submitted online using the Remedy system.

Hardware and software approved by the Engineering Review Board and CMS must be purchased and installed within 45 days of the notification to the QIO that the ERB was approved. Any information relevant to the ERB (e.g., hardware or software serial numbers or license certificates) must be communicated to the SDPS Help Desk.

8045 - Hardware Maintenance Process - (Rev. 1, 05-23-03)

The SDPS provides for maintenance on most SDPS equipment. Hardware maintenance issues are called in to the SDPS Help Desk. The information is entered into an SDPS tracking system. The SDPS Help Desk coordinates with the maintenance vendor to resolve the issue. Once resolved, notify the SDPS Help Desk to complete the tracking of the issue.

IBM CE Support -- Under no circumstance should any QIO allow an IBM CE or any other person posing as a support technician to perform any service or maintenance to the RS/6000 or its peripherals without an SDPS Help Desk AIX Systems Administrator being on the phone or having direct knowledge of the case at hand.

Hardware Replacement (Warranty) Notification -- QIOs are required to notify the SDPS Help Desk any time there is a physical serial number change to the RS/6000 or any of its peripherals due to maintenance or hardware failure.

Database Server -- System Updates (AIX, Oracle, Mlink, SAS, PowerChute) – QIOs are not to install any unauthorized software on the RS/6000. In the event the QIO is required to perform any updates to the system without the SDPS Help Desk being present, the QIO must submit a Statement of Completion form to the SDPS Help Desk.

Novell File Server Support -- Under no circumstance should any QIO personnel or any other person posing as a support technician perform any service or maintenance to the Novell file server's hardware or its peripherals without a SDPS Engineer being on the phone or having direct knowledge of the case at hand. Any changes to the Novell file server's hardware or software configuration must be directed by a SDPS memo and formal instructions. The changes must be recorded when complete using the Remedy system (mentioned above), and any documentation or files requested by the SDPS Engineering team must be sent to the SDPS Help Desk. All changes released by the SDPS Engineers by way of an SDPS memo and formal instructions must be implemented within 45 days of the release of the SDPS memo unless otherwise directed by an SDPS Engineer. QIOs are not to install any unauthorized software or hardware on the Novell file server.

Workstations -- The LAN Administrator is to maintain the standard SDPS workstation image on the workstations at all time unless directed by an SDPS Engineer. Unauthorized software or hardware is not to be installed on the workstations. Any changes must be approved by an ERB.

Exhibit 8-1 - (Rev. 1, 05-23-03)

STANDARD DATA PROCESSING SYSTEM (SDPS)
DATA MANAGEMENT PLAN

QIO Organization:
Applicable State(s):

SDPS Data Management Plan Section:

A. Process -- Describe, in detail, your process for ensuring that the required activity in each Section of the SDPS Interface Document is fulfilled within your organization. Include how coordination with other activities will occur, if warranted.

B. Primary -- Indicate the staff person (e.g., job title) who has primary responsibility for conducting the process described in (A):

C. Secondary -- Indicate the staff person (e.g., job title) who has secondary responsibility for conducting the process described in (A) (e.g., this is the backup to the primary, so it must be someone other than the primary listed in (B)):

D. Frequency -- Indicate the frequency which the process described in (A) is performed:

E. Criteria -- Describe the criteria used to determine when an intervention is required:

F. Intervention -- Describe the intervention(s) which may be taken if warranted:

G. Notes -- Additional notes:

Listed below are the sections to be plugged into the final SDPS Data Management Plan document:

I. Staffing Functions

- A. Staffing
- B. Responsibilities and Descriptions
- C. Security

II. Mandatory System Use

III. Operations

- A. Monthly Merge
- B. Capacity Metering
- C. Backups
- D. System Upgrades
- E. Producing Required Data/Reports
- F. Ad Hoc Data Requests
- G. Quality Assurance/Data Integrity of QIO Generated Data
- H. Insurance Issues
- I. QIO/CDAC Interaction

IV. Communication

- A. SDPS Memos
- B. Internet
- C. CMS Newsletters

D. Infonet

E. Periodic Data Issues Conference Calls

F. Training

G. POC/SDPS Help Desk

H. QIO Use of Remedy System

I. SDPS Workgroups

V. Confidentiality of System

VI. Applicable Documentation

VII. Process for Moving

VIII. SDPS Engineering Review Board (ERB) Process - Approved Software & Hardware

IX. Hardware Maintenance Process

Quality Improvement Organization Manual

Chapter 13 - Management

TABLE OF CONTENTS (Rev. 1, 05-23-03)

13000 - Purpose And Objectives of the Internal Quality Control (IQC) Program - (Rev. 1, 05-23-03)

The objectives of the IQC program are to:

- Support and foster continuous quality improvement within the QIO in support of the Health Care Quality Improvement Program (HCQIP), the Medicare Beneficiary Protection Program (MBPP), and other Statement of Work (SOW) activities;
- Develop and implement a plan that ensures all aspects of QIO activities run efficiently, comply with the contract, and are consistent with CMS' goals and objectives for the HCQIP, MBPP, and the SOW;

- Maintain QIO activities within a permissible range of deviation with minimum effort;

- Ensure the financial integrity of the contract by actively monitoring and staying within the total estimated cost and indirect cost ceilings of the contract;

- Improve the reliability, accuracy, consistency, and timeliness of data processing, data reports, and case review process and decisions; and

- Ensure the support, understanding, and participation of all beneficiaries, practitioners, providers, and other constituencies that are affected by QIO activities.

13010 - IQC Program Requirements - (Rev. 1, 05-23-03)

You must have an IQC program that encompasses the SOW tasks, subtasks, and other major activities including administrative functions such as financial management.

13020 - IQC Control Process - (Rev. 1, 05-23-03)

You must implement an IQC program that includes the following elements:

- Identify tasks/subtasks and/or activities that are included;

- For each of the tasks/subtasks and/or activities, identify measures/monitors of performance;

- Develop a plan for how you will meet goals/targets;

- Use measures that enable you to determine if performance is proceeding acceptably during the course of the contract to enable you to meet goals or targets that you have set for identified tasks/subtasks and/or activities;

- At least annually, or more often as performance indicates, or as otherwise directed, use measures, results, and other information to assess whether you are likely to meet goals/targets. Analyze any causes of failure, and project changes in the process that you believe will improve performance;

- Improve your process; and

- Determine whether improvements were successful, and make further adjustments to the process as needed.

13030 - Analysis and Reporting Requirements - (Rev. 1, 05-23-03)

You must document and make available on request by CMS your documentation of measurements/monitoring, plan, results, and improvement actions for all subtasks and major activities.

13100 - Introduction - (Rev. 1, 05-23-03)

Maintain complete and accurate documentation of all review activities in a manner that ensures that:

- Review activities can be validated during auditing procedures;

- Documentation is available to verify performance of all reviews; and

- Review activities and documentation are handled in a manner that ensures the confidentiality of all QIO data in accordance with 42 CFR Part 480.

13110 - QIO Review Documentation - (Rev. 1, 05-23-03)

A. General Documentation Requirements -- At a minimum, your review documentation must include:

- Case identifiers (e.g., Health Insurance Claim (HIC) number);

- Determinations (outcomes) of each review (e.g., approval, denial, coding decision, quality concern);

- Medical review criteria used in the review;

- Verification that appropriate review was performed;

- Name and title of each reviewer who contributed to the determination (e.g., review coordinator, physician advisor);

- Dates of each review function that demonstrate compliance with review timeframes (e.g., date case was identified for review, dates records requested and received, dates review initiated and completed, dates notices issued, if applicable); and

- Any referrals to other QIO departments or external agencies.

B. Denial Determinations, Diagnostic Related Group (DRG) Assignment Changes, and Confirmed Quality Concerns -- In addition to the general documentation required in §13110.A, if your determination results in an initial or technical denial, DRG assignment change, or confirmed quality concern, your review documentation must also include:

- The detailed basis (e.g., all documentation already in your possession for the case) for the denial determination (including limitation on liability determinations and documentation errors), DRG assignment change, or confirmed quality concern;

- A copy of the notice that was sent to all parties, identification of each party, and the date the notice was mailed or delivered; and

- The returned envelope and notice, if the notice was subsequently returned as undeliverable or receipt refused.

C. Reconsideration and Re-review Determinations -- In addition to the general documentation required in §13110.A, if you conduct a reconsideration or re-review, your review documentation must also include:

- A copy of the reconsideration/re-review request;

- The detailed basis for the reconsideration (including the limitation on liability determination) or re-review determination;

- A copy of the reconsideration or re-review notice that was sent to all parties, identification of each party, and the date on which the notice was mailed or delivered; and

- The returned envelope and notice, if the notice was subsequently returned as undeliverable or receipt refused.

D. Format of QIO Review Documentation -- Retain review documentation in an easily retrievable format such as hard copy, computer entry, imaging/CD ROM, or microfilm.

13115 - Timeframes For Retaining QIO Review Documentation – (Rev. 1, 05-23-03)

Retain copies of your review documentation as follows:

A. Approved Reviews -- Retain your review documentation for 12 months from the date review is completed.

B. Negative Determinations -- In accordance with regulations at 42 CFR 476.94(e), retain your review documentation of initial denial determinations and DRG assignment changes for 6 years from the date the services in question are furnished. In addition, retain your review documentation of confirmed quality concerns for 6 years from the date the services in question are furnished.

C. Re-review Determinations -- Retain your review documentation of quality and DRG assignment change re-review determinations for 6 years from the date the services in question are furnished.

D. Reconsideration Determinations -- In accordance with regulations at 42 CFR 478.36, retain your review documentation of reconsideration determinations for 4 years after the date on the notice of your reconsidered determination, or until litigation is completed and the time period for filing all appeals has passed, whichever is later.

E. Regional Office (RO) Reviews -- The RO retains pertinent records at least until the QIO contract is no longer in effect.

F. Audits -- Ensure that the documentation is readily retrievable within 10 working days for any auditing process that may be required by CMS. If an audit is conducted by CMS, retain your review documentation for 3 years from the date of the audit or date specified in §13115.A, B, C, or D, whichever is later.

13120 - Medical Records - (Rev. 1, 05-23-03)

See §7520.A.1 for a listing of documents contained in a medical record.

13125 - Timeframes for Retaining Medical Records - (Rev. 1, 05-23-03)

Retain copies of medical records as follows:

A. Approved Reviews -- Retain medical records for at least 90 days from the date review is completed.

B. Negative Determinations -- Retain medical records for initial denial determinations, DRG assignment changes, and confirmed quality concerns for 12 months from the date review is completed.

C. Re-review Determinations -- Retain medical records for quality and DRG assignment change re-review determinations for 12 months from the date the re-review is completed.

D. Reconsideration Determinations -- Retain medical records for 12 months from the date the reconsideration is completed.

13130 - Electronic Data Retention Requirements - (Rev. 1, 05-23-03)

Retain for 18 months, records of any sampling universe records electronically supplied by CMS. Sampling records include the universe for sampling, identification of each sample selected for review with information sufficient to identify an individual case, and the category of review for which the case was selected.

13140 - Contractor Records Retention - (Rev. 1, 05-23-03)

In addition to SOW requirements, the Federal Acquisition Regulations (FAR) require that all other documents (e.g., outreach activities) related to contracts entered into by negotiation be retained for 3 years after final payment under the contract.

The Comptroller General of the United States or duly authorized representatives from the General Accounting Office (GAO) have access to and the right to examine directly any of the contractor's pertinent books, documents, papers, or other records involving transactions related to the contract.

For any subcontracts under a negotiated contract, the GAO has access to and the right to examine any of the subcontractor's pertinent books, documents, papers, or other records involving transactions related to the subcontract for 3 years after final payment under the subcontract. Subcontracting records do not include purchase orders not exceeding $10,000 and subcontracts or purchase orders for public utility services.

13150 - Disposal Of Records - (Rev. 1, 05-23-03)

Ensure that confidential records are destroyed when appropriate. In accordance with 42 CFR 480.115(e), destroy and dispose of records in a manner that ensures that confidential information cannot be retrieved.

If you subcontract with a private company to destroy records, use prudent business standards.

13200 - Purpose Of Data Exchange Reports - (Rev. 1, 05-23-03)

Produce data exchange reports as specified in §13220. Produce reports monthly, quarterly, or as you or the Centers for Medicare and Medicaid Services (CMS) determine is necessary. Modify and/or expand reports to meet changing needs and requirements.

13210 - Reporting Requirements - (Rev. 1, 05-23-03)

A. Submission of Reports -- Submit reports to CMS concerning QIO/intermediary exchange of information as required by your contract. Develop a specific set of reports to meet your needs. The reports detailed in §13220 should be submitted in accordance with your Project Officer's (PO) instructions.

B. PO Approval -- Produce these reports for PO approval no later than 90 days after the effective date of the contract. Reflect the same time periods as reported to CMS in the QIO Report Files. This not only assists you in knowing what is being reported to CMS, but also reflects the data CMS uses to evaluate your performance. Once approval is obtained, produce reports for your staff on an ongoing basis. When necessary, produce and provide your PO with requested copies.

13220 - QIO/Intermediary Data Exchange Reports - (Rev. 1, 05-23-03)

Produce a report for PO approval no later than 90 days after the effective date of the contract. Thereafter, produce and electronically submit an adjustment report monthly (at a minimum) to the PO and to each intermediary listed on the report. Design this report to monitor the status of adjustment records. Be cognizant of the number of adjustments generated, forwarded, pending, and returned from the intermediary. Make sure that the report identifies the overall status of the adjustment process to facilitate prompt corrective action when necessary. Quality Improvement Organization Manual

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Chapter 15 - Performance Evaluation

TABLE OF CONTENTS (Rev. 1, 05-23-03)

15100 - Background - (Rev. 1, 05-23-03)

The Omnibus Budget Reconciliation Act of 1987 amended §1153 of the Social Security Act (the Act) by adding subsection (h)(2) that requires the Secretary to publish in the Federal Register (FR) the general criteria and standards used for evaluating the performance of QIO contract obligations and to provide an opportunity for public comment with respect to such criteria and standards. A 60-day comment period is provided.

15110 - Provisions Of The Notice - (Rev. 1, 05-23-03)

The FR notice contains a brief legislative history of the QIO program and the statutory requirement for publication. It presents a description of the CMS process for measuring QIO performance and specifically solicits comments on the evaluation criteria. The

notice also addresses each of the major areas of the Statement of Work (SOW) and specifies which contract requirements are considered in evaluating QIO performance.

15120 - Uses Of Evaluation Criteria - (Rev. 1, 05-23-03)

CMS routinely uses evaluation criteria in a variety of ways designed to formally appraise and monitor QIO performance and capability. Evaluation criteria are also used to determine whether or not a contract should be renewed on a non-competitive basis. QIO contractor performance monitoring provisions are included in each contract as part of the negotiated agreement. Criteria and standards for evaluating performance common to all contracts are developed based on the SOW. As the SOW is changed, its evaluation criteria and standards are updated, as necessary, to coincide with the SOW requirements.

Evaluation criteria are used in the following ways to monitor and assess contractor performance:

- CMS Regional Offices (ROs), which are responsible for the daily oversight of QIO operations, use the criteria to:
    - Monitor QIO performance;
    - Identify deficiencies in performance; and
    - Request and evaluate corrective action plans to eliminate deficiencies.
- On the basis of the performance assessment findings, CMS determines whether a QIO contract should be renewed non-competitively or awarded through competitive bidding. The performance assessment protocol is consistent with the evaluation criteria and standards, and within the requirements of your contract. Performance is one factor in determining if it is in the best interest of the government to non-competitively renew contracts; and
- To determine if a QIO with a performance-based contract is eligible for a cash award.

15200 - Background - (Rev. 1, 05-23-03)

§1153(c)(2) of the Social Security Act (the Act) authorizes CMS to monitor the performance of Utilization and Quality Control Quality Improvement Organizations (QIOs) to ensure that these organizations meet all contract requirements.

§1153(h)(2) of the Act requires CMS to publish in the Federal Register (FR) the general criteria and standards used for evaluating the efficient and effective performance of QIO contract obligations and to provide the opportunity for public comment on these criteria and standards (See §15100-15120). These criteria are published whenever there are significant changes.

15210 - Purpose - (Rev. 1, 05-23-03)

An assessment of QIO performance is based on performance results, data from the management information system (Standard Data Processing System), and information collected from observation and site visits. The performance-based components of the QIO evaluation are based upon objective measurement of target indicators. For other components, the RO is responsible for performing this assessment. The combination of the factors mentioned above is designed to provide a basis for determining whether your contract should be renewed on a non-competitive basis. These results are used by CMS:

- To evaluate your overall performance;
- As a resource tool for future contract procurement decisions (e.g., whether an incumbent QIO is eligible to have its contract renewed on a non-competitive basis); and
- To nationally recognize QIOs who demonstrate the capability of developing and implementing innovative processes/approaches to make the QIO program more efficient and effective.

15220 - Timing - (Rev. 1, 05-23-03)

RO Project Officers (POs) continually monitor QIO performance throughout the contract period. As new review activities or changes are made to the contract requirements, the evaluation process is revised to reflect these changes.

15230 - Methods Of Evaluation - (Rev. 1, 05-23-03)

Substantial elements of QIO contracts are performance-based, where a QIO is assessed relative to specific performance measures established in the contract. Performance on these measures can be used to objectively make determinations about non-competitive renewals and/or be used as objective criteria in competitive procurements. Additionally, ROs assess QIO performance based on on-site visits, regularly scheduled teleconferences, data analysis, and off-site reviews of QIOs. Specifically, the on-site visit permits the RO POs and/or Scientific Officers (SOs) to have a face-to-face meeting and allow CMS an opportunity to understand all of the QIO activities within the context of their state. This process entails the evaluation of QIO project activities and data reports, interviews with QIO staff, and an examination of other pertinent records.

Ongoing monitoring will be accomplished by telephone and videoconferencing between the PO and the QIO, on-site visits and analysis of information reported in project plans, routine written reports, and review of contract deliverables.

The findings that result from on-site visits are compiled into formal summaries that describe the QIO's progress and performance. If the PO identifies major deficiencies, a

Performance Improvement Plan (PIP) will be requested. In the event a QIO is unsuccessful at correcting the deficiencies contained in the PIP, CMS will consider terminating the contract. RO POs would continue to perform ongoing monitoring of other aspects of the contract. These include:

- QIO proposed information collection activities (e.g., surveys), abstracts or articles submitted to non-CMS sponsored peer reviewed publications or meetings;
- Subcontract arrangements;
- QIOs' internal quality control process;
- QIOs' case review requirements;
- Communication requirements (Web site, physician/provider outreach, annual reports, etc.);
- Requests related to quality improvement projects (including ad hoc data requests, CDAC requests, and approval of locally developed projects);
- Confidentiality requirements;
- Board membership and structure; and
- QIO resource allocation/utilization and management (and other financial information).

15400 - Background - (Rev. 1, 05-23-03)

When you fail to meet contract requirements, CMS generally requires that you submit a Performance Improvement Plan (PIP) to ensure that you will take appropriate steps to remedy contract performance deficiencies.

The role of the Project Officer (PO) in Federal contracts is to monitor your progress and make known to the Contracting Officer potential problems that threaten performance so that corrective measures may be taken. It is in the best interest of the Government that you make progress toward completing the requirements specified in your contract, adhere to contract clauses, and maintain sound financial status.

If your performance is unsatisfactory, the PO will act to correct unsatisfactory performance or to protect the Government's interest in the event of actual contract default. The actions may include:

- By letter or through a meeting, bring the particular deficiency to your attention and obtain a commitment for appropriate corrective action;

- Extend the contract schedule if you have excusable delays in performance;

- Withhold contract payments in cases where you fail to comply with delivery or reporting provisions of the contract; or

- Terminate the contract for default (all or part of the work).

Within the QIO contract, the PO is responsible for determining whether the services/activities conform to the contract requirements. In the event that work is considered unsatisfactory, the PO (and in some instances, the Contracting Officer) will typically notify the QIO of the deficiencies in writing and request an acceptable PIP (typically within 10 working days of the QIO's receipt of the request) to not only remedy the deficiency, but also to prevent its re-occurrence. The Central Office will be notified in the event of an issuance of a PIP. Once the PIP is approved, the PO monitors the QIO's progress on the corrections outlined in the PIP. Once the QIO has corrected the deficiency, the PO formally (in writing) notifies the QIO (with copy to the Contracting Officer) before closure of the PIP.

The following steps are typical:

- Identification of unsatisfactory performance via on-site visit, monitoring of reports/deliverables, or other monitoring tools.

- Formal notification of the deficiencies and request for PIP developed and signed by PO (with a copy to the Contracting Officer). If other than the QIO program requirements (e.g., Federal Acquisition Regulations (FAR) requirements, Section G and Section H requirements), the Contracting Officer may sign the formal notice.

- Formal response of acceptability to QIO. If unacceptable, the PO will notify the QIO/ESRD Steering Committee regarding next steps.

- If final PIP resolution is greater than 30 days, PO continues to monitor progress on the accepted PIP over the course of the PIP on a monthly basis.

- When QIO has successfully completed the PIP, PO formally closes the PIP and continues monitoring for sustained correction. Copies are provided to Central Office.

- If QIO is unsuccessful in completing the PIP, the PO notifies the RO DCSQ Associate Regional Administrator and Contracting Officer of the continued deficiency.

- The QIO/ESRD Steering Committee may be contacted regarding steps with this QIO.

15420 - Performance Plan Expectations - (Rev. 1, 05-23-03)

A fully acceptable PIP:

- Is responsive to all identified issues;
- Is measurable by the QIO and the RO;
- Identifies the source of the problem;
- Addresses what modifications in processes/procedures the QIO will accomplish;
- Addresses what new/additional Internal Quality Control processes/procedures the QIO will employ to monitor future performance;
- Addresses what immediate and ongoing staff training the QIO will provide to assure that corrections are sustained; and
- If the corrective action extends beyond 30 days, include a timeline with milestones delineating the QIO progress toward PIP completion with an estimated completion date.

The PO request for the PIP should clearly identify the specific deficiency in contract performance. It should:

- Specify how and when the deficiency was identified;
- Specify how the deficiency adversely affects the QIO contract performance;
- Specify the authority that requires correction (e.g., Social Security Act, Code of Federal Regulations, Statement of Work, QIO Manual);
- Specify that if the total estimated costs of the contract are increased by the correction proposed, the QIO must submit a contract modification request with the PIP;
- Allow the QIO the latitude to develop a PIP that meets the needs of the QIO; and
- Does not instruct on how to correct the deficiency (but may inform the QIO of a specific action, if required, so that the QIO can comment on its feasibility).

The PIP request must include a statement that notifies the QIO that if a fully acceptable PIP is not submitted by the QIO within 10 working days (or a negotiated alternate date) the PO may initiate a recommendation to the CMS Steering Committee and Contracting Officer to take further action. If the QIO is unsuccessful at fulfilling the activities of the

PIP, the PO may also make a recommendation to the CMS Steering Committee and Contracting Officer.

When the PO requests a PIP, the information provided by the QIO may contain proprietary information. Proprietary information is defined as "information the release of which would cause substantial harm to your competitive position." The PO, in his/her PIP request, will instruct you to identify any proprietary data contained in your response.

15500 - Statutory Basis - (Rev. 1, 05-23-03)

In accordance with §1153(c)(6) of the Social Security Act (the Act), upon 90 days notice to you, the Secretary may terminate your contract prior to its expiration if it is determined that you:

- Do not substantially meet the eligibility requirements of §1152 of the Act;
- Have failed substantially to carry out the provisions of the contract; or
- Are carrying out the contract in a manner inconsistent with efficient and effective administration.

15510 - Grounds For Termination - (Rev. 1, 05-23-03)

Grounds for termination include, but are not limited to:

- Failure to maintain physician-sponsored or physician-access eligibility requirements;
- Failure to perform one or more contract tasks or subtasks;
- Failure to implement and/or maintain a data system sufficient to fulfill the requirements of the contract;
- Failure to make correct and appropriate decisions;
- Failure to meet reporting requirements;
- Failure to obtain/retain staff and resources necessary to conduct the contract;
- False reporting of activities;
- Delays in conducting reviews resulting in substantial backlogs;
- Failure to take timely corrective action to remove conflicts of interest;

- Inability or unwillingness to take CMS required corrective actions within reasonable timeframes;
- Failure to satisfy the requirements for peer reviewers;
- Failure to cooperate with CMS evaluation assessments;
- Failure to comply with the requirements of the Paperwork Reduction Act;
- Failure to meet contract implementation requirements timely;
- Failure to comply with CMS publication policy;
- Failure to comply with confidentiality requirements; and
- Failure to request CMS approval for certain activities when approval is required.

15520 - Recommendation To Initiate Termination - (Rev. 1, 05-23-03)

The RO submits a recommendation to initiate termination and a preliminary Notice of Intent to Terminate (NIT) your contract to the Contracting Officer through the Office of Clinical Standards and Quality. The recommendation explains the basis for the proposed termination action. It should include the following elements:

- The specific grounds for termination;
- Actions taken by the PO to bring you into compliance (e.g., Performance Improvement Plans (PIPs), withholding of contract payments); and
- QIO performance with respect to PIPs.

15530 - Notice Of Intent To Terminate Contract - (Rev. 1, 05-23-03)

The Contracting Officer sends you the preliminary NIT, which includes a complete list of deficiencies that justify termination. This is your formal notification of CMS's intent to terminate your contract.

In accordance with §1153(c)(6)(B) of the Act - where it is determined that the QIO has failed to substantially carry out the contract or is carrying out the contract in a manner that is inconsistent with effective and efficient administration - you are entitled to an opportunity to submit data (additional information) to be reviewed by a panel as described below.

If you choose not to submit the additional information, CMS proceeds with the termination after providing you 90 days notice.

In accordance with §1153(c)(6)(A) of the Act - where it is determined that the QIO does not substantially meet the eligibility requirements of §1152 of the Act - you are not entitled to an opportunity to submit data, interpretations of data, and other information pertinent to your performance, nor is there a review by a panel.

15540 - Termination Panel - (Rev. 1, 05-23-03)

If the decision is to continue with the termination process based on §1153(c)(6)(B), a panel is appointed by CMS in accordance with §1153(d) of the Act. The purpose of the panel is to review data, interpretations of data, and other performance-related information that you submit in response to the NIT. The panel is required to prepare and submit a report of its findings to CMS in a timely manner. CMS shall make a copy of the report available to the QIO.

15550 - Termination Decision - (Rev. 1, 05-23-03)

CMS may or may not accept the findings of the panel. After the panel has submitted its report, CMS may, with concurrence of the QIO, amend the Statement of Work (SOW) to modify the QIO's functions or otherwise change the contract. Also, CMS may elect to terminate the QIO's contract upon 90 days notice after submission of the panel's report or earlier if the QIO agrees. In accordance with §1153(f) of the Act, any determination by the Secretary to terminate a contract shall not be subject to judicial review.

From the time CMS receives the panel's report and gives the notice of intent to terminate, CMS may transfer review responsibilities of the QIO under the contract being terminated to another Utilization and Quality Control QIO, or to an intermediary or carrier having an agreement under §1816 of the Act or a contract under §1842 of the Act until CMS enters into a contract with another QIO.

15600 - Renewal/Non-renewal Procedures - (Rev. 1, 05-23-03)

One of the purposes of the evaluation process is to make determinations on whether QIOs are eligible for non-competitive contract renewals. Details of the renewal/non-renewal process can be found in the QIO contract.

15700 - Introduction - (Rev. 1, 05-23-03)

From the beginning of the contract a QIO should conduct its business in a manner that will facilitate an orderly transition, should the QIO later be replaced by a successor. Therefore, QIOs should arrange to receive mail not directly related to the QIO contract(s) at a separate location or box number. To avoid consumer, provider, or practitioner confusion, QIOs should also consider doing business as (DBA) the ___ QIO, where the blank contains the State's two-position postal abbreviation (e.g., MD). A QIO's toll-free telephone services should also be listed this way. If requested by CMS, you should allow any successor QIO to use these telephone numbers.

If you cease to perform your responsibilities under your current contract for any reason, you must:

- Turn over to another review entity or appropriate custodian, as directed by the Contracting Officer (CO) or his designated property officer, all medical records and other appropriate data;

- Turn the data over in a form usable to CMS;

- Continue to work on the cases selected for review until the end of your contract unless CMS determines that the new QIO will complete the cases already selected for review;

- Maintain a telephone hotline service as required by your contract and as directed by the Project Officer (PO) until you are notified by the CO that this activity is no longer required; and

- Provide the name of a knowledgeable person who will be available, on a daily basis, to assist CMS during the transition process.

The CO will provide you with the name and address of the individual in CMS with whom to arrange for the disposal of Government-acquired property.

15710 - Boxing Of Records - General - (Rev. 1, 05-23-03)

All materials should be organized and boxed for shipment to other entities unless otherwise instructed by CMS.

Box Medicare + Choice Organization (M+CO) work separately from fee-for-service work.

Box the materials by type of work and status of activity (e.g., works in progress should be boxed separately from medical records not yet reviewed and those where review has been completed). Label each box on the outside with a list of contents. Include an inventory list in each box and clearly indicate the type and date of the materials.

15720 - Boxing Of Review Records - (Rev. 1, 05-23-03)

The following types of review records should be identified and boxed as follows:

- "Live cases" (cases open) include:

    - Medical records, worksheets and case decision abstracts for all cases awaiting additional medical record information;

- Medical records, worksheets and case decision abstracts for all documents awaiting review by a physician advisor;

- Medical records, worksheets and case decision abstracts for all cases where the physician advisor has determined that further action is necessary (e.g., initial determination was made), but such action has not yet been taken (e.g., final notification has not been issued);

- Files on quality improvement activities in process (includes provider's/practitioner's improvement plans under case review activities) including a list of contacts that you are working with on quality improvement activities;

- Files on beneficiary complaint cases awaiting the beneficiary's response of the provider's medical records;

- Files on beneficiary immediate review requests of provider-issued notices of non-coverage awaiting receipt of the medical records;

- A listing of all quality improvement activities in place by physician, provider, etc., along with the basis for this activity;

- Case files, including medical records, for all cases with confirmed quality problems (this is not considered a "live case" unless the notification has not been sent, or is awaiting the 60-day period for a re-review request, or the case involves a matter that is being addressed under a sanction in progress). Cases awaiting the expiration of the 60-day period for a right to re-review are different from the one below where the case is pending;

- Cases pending re-review and re-consideration (after a request was received);

- Sanction cases in all stages of development, beginning with the first notice;

- Case files for all cases under evaluation for a determination to initiate sanction proceedings;

- Fraud and abuse case review referrals (by OIG, CMS, etc.) in progress;

- M+CO cases for targeted review; and

- Administrative law judge's request for case files in progress.

➢ "Old cases" (cases closed) include:

- Files pertaining to hospital adjustments (e.g., changes in DRGs);
- Quality review logs and cases;
- Documentation (including medical records in the possession of the QIO) related to cases denied within the last 6 years;
- Documentation related to cases approved where there has been an action within the last year;
- Reconsiderations and technical denials; and
- Re-review cases involving potential quality issues from CMS.

The inventory of reviews and medical records should include the following information:

- Beneficiary name;
- Health Insurance Claim Number (HICN);
- Reason for selection;
- Name of hospital, facility, or M+CO;
- Type of review it requires (e.g., fee-for-service or M+CO review); and
- Status of cases (e.g., completed, pending physician review, or pending data entry).

15730 - Boxing Of Data - (Rev. 1, 05-23-03)

The following types of data should be identified and boxed:

- All aggregate statistical information and profiles on M+CO, institutions, and physicians;
- All special study reports or summaries, including files and work papers, conducted on any area of the program during the contract period;
- All periodic (e.g., monthly, quarterly) data reports completed as required under the contract;
- The database of completed reviews, denials, adjustments, and reversals, as well as cases selected where the review has not yet been completed;
- All management information files and tracking system files (where proprietary systems are used, output files must be text files);

- All relevant specifications and documentation; and
- The list of M+CO enrollees and deaths used to determine the current review sample.

NOTE: "All" means data collected during the current contract.

15740 - Boxing Of Miscellaneous Records - (Rev. 1, 05-23-03)

The following types of miscellaneous records should be boxed:

- Written beneficiary complaints received directly or through CMS;
- A schedule of any remaining speaking engagements of the community outreach program;
- Action plans in progress;
- A list of designated rural providers;
- A list of providers/physicians identified for educational feedback and the supporting documentation;
- Copies of all Memoranda of Understanding/Memoranda of Agreement with Medicare providers, facilities, M+CO, Fiscal Intermediaries (FIs), and carriers;
- Copies of all technical denials and the reasons for denial;
- Documents pertaining to sanction cases; and
- Any other documents, materials, cases, and work now the responsibility of the new contractor.

You should contact the PO and/or the Contracting Officer if you question whether or not to box an item or discard it.

15750 - Retention Of Financial Records - (Rev. 1, 05-23-03)

All financial records and supporting documents are to be retained for 3 years by a designated, responsible individual of the outgoing contract or in accordance with Government contract requirements. If any litigation claims or audits are begun before the expiration of the 3-year period, all records shall be retained until the completion of the action or until the end of the regular 3-year period, whichever comes last. The 3-year period begins on the date the outgoing contractor submits its final deliverables, as listed in Section F of the QIO contract, to CMS.

The name, address, and telephone number of the designated individual responsible for retaining records should be given to the PO.