SECTION C – STATEMENT OF WORK

C.1. BACKGROUND

A. Statutory Mandate

This Statement of Work (SOW) is based upon Title XI of the Social Security Act, Part B (hereinafter referred to as The Act) as amended by the Peer Review Improvement Act of 1982. This legislation established the Utilization and Quality Control Peer Review Organization Program -- the Quality Improvement Organization (QIO) Program. As a result of legislative mandates and CMS's experience in administering the Program, CMS has identified the following requirements of the QIO program:

1. Improve quality of care for beneficiaries by ensuring that beneficiary care meets professionally recognized standards of health care;

2. Protect the integrity of the Medicare Trust Fund by ensuring that Medicare only pays for services and items that are reasonable and medically necessary and that are provided in the most appropriate (e.g., economical) setting;

3. Protect beneficiaries by expeditiously addressing individual cases such as beneficiary complaints, provider-issued notices of non-coverage (HINNs), EMTALA violations (dumping), and other statutory responsibilities.

B. Contract Purpose

The purpose of this 7th Scope Contract is to satisfy the requirements of the QIO Program as defined throughout this statement of work in order to achieve successful performance.

C. Technical Considerations

QIOs shall consider their experiences and the findings under previous QIO contracts in determining their approaches to the 7th Scope Contract requirements.

C.2. REQUIREMENTS

A. Contractual Requirements

The Contractor, acting independently and not as an agent of the Federal Government, shall furnish the necessary personnel, materials, services, facilities (except as otherwise specified in the contract), and otherwise do all things necessary for, or incident to the performance of the work as set forth in the SOW.

B. Other Requirements

The QIO shall be subject to the following requirements as they apply to the specific Tasks described in Section C.3.

1. Data Plan

   The QIO shall deliver a Standard Data Processing System (SDPS) Data Management Plan following the format detailed in Part 8 of the PRO Manual (Attachment J-4). The Plan is to be delivered not later than 30 days after the effective date of the contract.

   For multi-state contracts, if all elements for all sections of the SDPS Data Management Plan are the same across States, then only one document shall be kept on file. If any element differs across States, a separate SDPS Data Management Plan shall be maintained for each State.

   The QIO shall update its SDPS Data Management Plan as necessary (i.e. whenever an element changes) throughout the Seventh Scope Contract.

2. Hardware/Software

   The SDPS Contractor will provide each QIO with the necessary hardware/software for the purpose of SDPS according to a formula (See Attachment J-16, SDPS Site Plan). In the event that the Contractor requires additional equipment, a request must be processed through the SDPS ERB process (see Section G.14.) and paid for from QIO contract funds.

3. Reporting Requirements

   The QIO shall report to CMS as identified in Section F and the appropriate portions of the PRO Manual referenced below. The QIO shall use all components of the SDPS Data Collection and Reporting Systems to manage and report work done under the current Statement of Work. (See Reference Document for a list of mid-level reporting requirements. Further detail will be provided in the SDPS PROvantage Users Guide to be available prior to August 1, 2002.)

4. Coordination

   The QIO shall coordinate its activities with other stakeholders in its State working on comparable improvement efforts or interested in teaming with the QIO. This coordination may include creating, joining, and/or supporting partnerships with organizations with similar goals and objectives, or facilitating ongoing discussion among the various stakeholders. Specific guidance for this coordination is included in individual task descriptions. The goal of such coordination is to utilize

resources efficiently and avoid duplication of effort and inconsistencies, which are burdensome to providers and practitioners.

5. Communication

The planning, development and implementation of a broad range of communication and intervention materials and of outreach strategies are essential to the effective performance of many aspects of QIO work. The QIO shall conduct marketing, communications, and outreach activities only to support the Tasks outlined in Section III below. Any marketing and communications activities that do not support Tasks 1, 2 or 3 must be approved as a Special Study, as described in Task 4.

CMS requires QIOs to manage their communications and marketing resources as efficiently and effectively as possible to accomplish the goals of the QIO Program. CMS expects QIOs to share and utilize existing, non-copyrighted materials and resources to the extent possible when undertaking similar communications activities. Prior to embarking on development of new strategies and intervention materials in support of any Task in this SOW, the QIO shall consult the relevant information clearinghouse (if one is available) maintained by the Quality Improvement Organization Support Contractor (QIOSC) and/or CMS. If suitable production files or materials are available through the clearinghouse, the QIO is expected to utilize and/or adapt these materials for local use. In addition to the materials available in the clearinghouse, the QIO shall seek and consider already-developed materials available for use or modification from other experts. (This may include web-based materials.) The QIO may modify these materials (with documented permission from the owner) as needed) if such modification is required for the QIO's communications strategy with local audiences and partners.

If new materials are needed but not readily available, the QIO may develop such materials using the most efficient and effective methods possible. The QIO does not need prior review and approval by CMS to modify existing materials or to develop new materials. However, the QIO shall provide a copy of all newly-developed or significantly modified materials as well as non-copyrighted materials borrowed from other experts but not yet in the clearinghouse, in file formats specified by CMS, to the relevant QIOSC prior to distribution. The QIO shall also provide to the QIOSC a brief explanation describing why it determined it necessary to develop new materials or to significantly modify existing materials.

a. Publications (Peer-Reviewed)

QIOs which seek to publish reports on results of specific activities in technical or professional journals or to present

such results at technical or professional meetings shall follow the procedures included in sections 16300-16330 of the QIO Manual, TOPS 2000-28 (attached at J-4) and any other administrative directives.

b. Publications (Outreach Materials)

All QIO-printed outreach material must conform to the DHHS/CMS standards provided at http://www.cms.hhs.gov/contracts/outreach and any other administrative directives.

See above, for additional requirements related to the development of outreach materials.

c. Use of Web Technology

In addition to the activities described in the preceding sections, the QIO may consider engaging in other activities that involve innovative and cost-effective ways of educating beneficiaries and providers/practitioners. If a QIO creates or maintains a website(s) where information regarding the QIO's Medicare contract activities appears, the QIO shall adhere to the following for its Medicare contract-related information on that site(s):

Follow the Contractor Website Standards and Guidelines outlined at http://www.cms.hhs.gov/about/web/contrsng.htm. (See Section H.16 for additional information on requirements for QIO websites.) The QIO shall refer to this website on an on-going basis for the most up-to-date standards and guidelines, as the standards and guidelines may be updated or revised periodically;

Refer to TOPS 2000-23, TOPS 2001-05, and any other administrative directives; and

Follow the Accessibility and Section 508 Requirements at http://www.cms.hhs.gov/about/web/section508/default.asp (providing equivalent alternatives to auditory and visual content meeting the Americans with Disabilities Act requirements).

6. Internal Quality Control

The objectives of the internal quality control (IQC) program are to support and foster continuous quality improvement within the QIO in support of each of the Tasks. Quality improvement enables QIOs to maximize the effectiveness and efficiency of their activities.

Within 60 days of the contract effective date, the QIO shall submit a comprehensive IQC Plan to its Project Officer for review. This Plan shall include the elements set forth in section 13000 to 13030 (attached at J-4). While each IQC plan will be independently developed, a template containing a standard set of major requirements will be provided by CMS at the beginning of the contract. The QIO shall implement this Plan such that it identifies opportunities for improvement in relation to each Task, and makes revisions to its process which are likely to result in improved QIO performance. The Project Officer will monitor activities resulting from implementation of the Plan.

Collaboration with other QIOs in implementing these IQC plans is encouraged. The QIO shall share what it learns regarding these IQC activities with other QIOs using the mechanisms available to it, including QIO conferences, newsletters, and databases.

7. Workplan

Within 60 days of the contract effective date, the QIO shall submit a Workplan that includes the major activities and milestones with a timeline for progress on the Tasks. While each Workplan will be independently developed, a template containing the expected fields for recording major activities and milestones will be provided by CMS at the beginning of the contract. Throughout the course of the contract period, the QIO will provide updates to the Workplan on no less than a quarterly basis to reflect achievement of milestones and, as opportunities for improvement are identified as part of the IQC Plan, appropriate revisions of tasks and timeframes. The template will support this updating and revision.

The Project Officer will review the Workplan and its updates. Failure to update the Workplan, failure to meet contract requirements, or inability to develop or modify the Workplan so as to meet contract performance expectations, will result in submission of a Performance Improvement Plan (PIP) or other appropriate action by CMS.

8. Confidentiality

The QIO shall adhere to the confidentiality and disclosure requirements set forth in section 1160 of the Act, 42 CFR Part 480, 45 CFR Parts 160 and 164 as they pertain to "oversight" agencies, Section H of the contract, the PRO Manual, and other administrative directives.

9. Information Collection Activities

QIOs which seek to conduct information collection activities (including surveys) as a part of any of the Tasks included in Section III shall do so in accordance with the Paperwork Reduction Act (see Section H), the PRO Manual (see sections 16200 - 16290 provided in Attachment J-4), and other administrative directives. All information collection activity is subject to the approval of the project officer prior to implementation. Project officer approval of a project plan does not constitute approval of an information collection activity described in that plan.

10. Government Data

A specific list of the data to be supplied by CMS and the schedule in which they will be provided appears in Attachment J-5. In general Part A data will be available from the Data Warehouse. The Quality Improvement Organization Support Contractors (QIOSCs) will create state level measurement and analytic datasets for distribution to QIOs. QIO requests for additional data or analytic datasets will be reviewed and approved by the Government Task Leader (GTL) for distribution to the QIOs. A preliminary list of the types of information to be supplied by the various QIOSCs appears in Reference Document. The SDPS contractor will be responsible for the delivery of the datasets.

11. Personnel and Core Competencies

Within 30 calendar days of the contract effective date, the QIO shall employ a Chief Executive Officer/Executive Director or equivalent (CEO). The CEO is responsible for leading the organization and obtaining the staff and resources necessary to effectively manage the contract. The QIO CEO must have had experience in managing a quality improvement organization, QIO-like entity, or other similar type organization.

A replacement for the person identified in this position must be done in accordance with the Key Personnel portion of Section G.

The QIO shall also have available the professional and technical expertise required to meet performance expectations described in this Statement of Work. Such core competencies include but are not limited to:

a. medicine, nursing and related medical/clinical disciplines including expertise in the nursing home, home health, hospital, physician office settings and managed care;

b. health education, health promotion, social marketing and formative research, public relations, market research, media, web design, and related communications disciplines;

c. diagnostic coding expertise;

d. quality of care and performance improvement disciplines;

e. epidemiology, statistics, survey research, data analysis, information systems, computer science, and related empirical and analytic disciplines;

f. social and behavioral science disciplines; and

g. expertise in the administrative and clinical aspects of case review including the use of mediation to resolve complaints and case management.

[NOTE: For SDPS hardware and software support refer to the PRO Manual Section 8005 - Staffing Functions (See Attachment J-4)].

12. Clinical Data Abstraction Centers (CDAC) Subcontracts

The QIO shall sign a subcontract with both CDACs. The first subcontract shall be with the CDAC that provided services to the QIO in the State under the previous QIO contract. This CDAC will remain the "prime" CDAC for each respective QIO and will provide the majority (and possibly all) of the services under this contract. The QIO shall sign a second subcontract with the other CDAC that did not provide services to the QIO under the previous contract. (This is necessary in order to provide workload flexibility under the Seventh Round Contract. Under this arrangement, QIOs will have the necessary authority to work with both CDACs, and CMS will have the flexibility to shift workload from one CDAC to another should that prove necessary.)

Under the subcontracting arrangements, the QIO is to obtain whatever external data abstraction/entry services it requires from the CDAC(s), as prescribed in the standard subcontract. The QIO shall work directly with

the CDAC on records management activities; i.e., the CDAC will request medical records on behalf of the QIO, will work with the QIO to track which medical records have been received and will maintain, track and report to the QIO on all photocopying and mailing costs incurred by providers or practitioners and may pay the pass-through costs if the QIO so chooses.

The QIO may choose to subcontract additional functions to the CDAC. However, these subcontracting arrangements must be handled separately from the data abstraction agreement and must be individually negotiated between the QIO and the CDAC.

C.3. TASKS

A. General Guidelines

Under this contract, the QIO shall be responsible for completing the specific Tasks, which follow.

1. Task 1: Improving Beneficiary Safety and Health Through Clinical Quality Improvement

    a. Nursing Home
    b. Home Health
    c. Hospital
    d. Physician Office
    e. Underserved and Rural Beneficiaries
    f. Medicare + Choice Organizations (M+COs)

2. Task 2 – Improving Beneficiary Safety and Health Through Information and Communications

    a. Promoting the Use of Performance Data
    b. Transitioning to Hospital-Generated Data
    c. Other Mandated Communications Activities

3. Task 3 – Improving Beneficiary Safety and Health Through Medicare Beneficiary Protection Activities

    a. Beneficiary Complaint Response Program
    b. Hospital Payment Monitoring Review Program
    c. All Other Beneficiary Protection Activities

4. Task 4 – Improving Beneficiary Safety and Health Through Developmental Activities

Terms used in Section C are defined in the Glossary at Attachment J-1.

B. (Reserved)

C. Task 1 – Improving Beneficiary Safety and Health Through Clinical Quality Improvement

One goal of the QIO program is to improve the quality of care for Medicare beneficiaries. QIOs achieve this goal by working with providers, practitioners, M+COs, beneficiaries and other stakeholders to implement quality improvement projects. QIO quality improvement projects typically focus on care processes known to improve patient outcomes and/or specific preventive services. Quality of care measures are measures of how often these critical processes or services are performed or how often desired outcomes are achieved.

1. General Requirements

To improve the clinical health outcomes of Medicare beneficiaries and to prevent clinical disorders in the areas described in this Task, the QIO shall:

a. use data provided by CMS and information the QIO collects, to identify opportunities to improve performance on the quality of care measures listed below for each sub-Task (e.g. Task 1a, Task 1b, etc.) of Task 1;

b. develop and implement quality improvement projects (see Section 16025 of the PRO Manual attached at J-4), distributing contract resources within each sub-Task to achieve the maximum feasible amount of improvement on the quality of care measures listed within each sub-Task. Thus, the QIO will determine the type, level, duration and intensity of support to offer in its state within the budget constraints of each sub-Task, with exceptions noted under sub-Tasks below;

c. build upon materials and information provided by CMS, other QIOs and/or the QIO Support Contractor (QIOSC) and actively share with other QIOs (via the QIOSC when feasible) its own processes for implementing quality improvement activities, interventions, materials, and any other information likely to help other QIOs to improve care for beneficiaries in their States (see Part 16 of PRO Manual attached at J-4):

d. respond to *ad hoc* information requests either from CMS directly or from a QIOSC when so authorized by CMS;

e. invite all M+COs in the State to work with the QIO on Tasks 1a through 1e: and

f. utilize resources efficiently and reduce burdens on providers, plans and practitioners while improving care for the greatest possible

number of beneficiaries throughout the state. Methods for accomplishing this goal include:

(i) working with other stakeholders (e.g., establishing new relationships or joining in already existing efforts) to improve care. Stakeholders are organizations with common goals and may include providers' membership associations; healthcare alliances and professional associations; clinical specialty organizations; State licensing, certification and survey agencies; State and local health departments; accreditation organizations; payers; beneficiary advocacy groups; Medicare suppliers, State Medicaid agencies; ESRD Networks; etc.; and/or;

(ii) facilitating simultaneous work (e.g., through joint/group meetings and/or workgroups) with multiple providers, M+COs, practitioners, and other QIOs.

2. General Support

To support this Task, CMS will create Task Action Teams (TATs) of CMS Central and Regional Office staff to help guide and support QIOs' quality improvement work. CMS also will contract with QIO Support Contractors (QIOSCs) (approximately one for each of the sub-Tasks under Task 1) to assist CMS staff and the QIO in achieving quality improvement. A Reference Document contains a list of the types of materials that may be supplied by the various QIOSCs and the currently estimated date of their availability. The QIOSCs will facilitate QIO activities by:

a. providing materials and information to the QIO for use in assisting providers/practitioners to improve the quality of care, such as implementing systems' changes/approaches and following clinical practice guidelines;

b. initiating collaboration, coordination, and communication within the QIO community;

c. assisting with the development of national-level partnerships and providing information to assist QIOs with cooperative, coordination and communication activities between the QIO and its State stakeholders;

d. assisting with analyzing and interpreting data; convening expert groups; working with national partners; and providing individual and group consultation;

e. providing information on clinical topics and care processes, quality improvement, and other areas relevant to QIO quality improvement projects; and

f. providing information on management systems' approaches, processes, tools and techniques.

3. Changes in Quality of Care Measures

CMS reserves the right to discontinue, change, and/or add measures if CMS determines it is necessary. If this occurs, CMS will, after discussions with the QIO and all other interested parties, amend the contract and evaluation strategy in such a way as to hold the QIO harmless from effects of indicator changes. In particular, CMS anticipates changing measures to ensure consistency with measures promulgated by the National Quality Forum.

4. General Evaluation

See Attachment J-7

D. Specific Tasks

1. Task 1a - Nursing Home Quality Improvement

a. Background

CMS is committed to publicly reporting on the quality of care provided to Medicare beneficiaries in nursing homes (NHs) by October 2002. This effort will provide information to Medicare beneficiaries, their families and others involved in their care which can be used for selecting a nursing home, for better understanding care in nursing homes, and for improving NH care. QIO quality improvement efforts will focus on the care areas reflected in the CMS publicly reported NH quality of care measures. Prior to the start of the 7th SoW contract period, CMS will finalize the publicly reported NH quality of care measures. It is expected that there will be approximately 10-15 NH quality of care measures derived from the Minimum Data Set (MDS).

b. Task Description

In addition to the general Task requirements listed in C.3.C.1, the QIO shall:

(i) undertake interventions to improve the quality of care in NHs in relation to publicly reported quality of care measures at the Statewide and nursing home level;

(ii) develop and implement a plan to partner with the relevant nursing home stakeholders, i.e., State Survey and Certification Agency, State Medicaid Agency, Fiscal Intermediary (FI), for-profit and not-for-profit trade organizations, clinical and professional groups, local service organizations and patient advocacy groups;

(iii) participate in the NH Support QIOSC training, use its standard models, methodology and materials, and utilize the NH QIOSC for individual consultation to address QIO NH technical and data specific concerns or problems;

(iv) Or, if after participating in the training, the QIO wishes to use a different approach, discuss its reasons for wanting to do so and the approach that it proposes to take with its Project Officer. If, after that discussion, it then elects to take an alternate approach, it must:

provide its models, methodology, and materials to the QIOSC, and

acknowledge that support from the QIOSC for the approach that it has chosen will be limited.

(v) offer information to all nursing homes in the state about systems based approaches to improve care and outcomes related to all of the CMS publicly reported NH quality of care measures using the material developed and provided by the NH QIOSC;

(vi) In consultation with relevant stakeholders, select 3-5 of the publicly reported measures on which to focus its efforts to improve NH quality of care. The QIO shall not be allowed to change these measures once it has reported the selected set to CMS. The selected measures shall be reported to CMS via QIO/Provider Activity Reporting Tool not later than December 15, 2002;

(vii) No later than February 3, 2003, provide a list of the identified participant nursing homes. The target participation rate is at least 10% of the nursing homes in the State or, in States with less than 100 nursing homes, at

least 10 facilities. (See Glossary at J-1 for definition of identified participant); and

(viii) provide technical assistance to the identified participant nursing homes in its state to improve the NHs' organizational quality systems and clinical systems related to the selected measures.

c. Support

In addition to the general coordination assistance described above and the specific materials described in the Reference Document, the NH QIOSC will:

(i) provide detailed technical information and reports about CMS's publicly reported NH quality of care measures;

(ii) provide train the trainer and other educational materials regarding the NH culture, regulatory/compliance environment, MDS, and NH systems approaches;

(iii) provide step by step project implementation and training material as well as other template project material;

(iv) provide ongoing technical assistance and consultation to QIOs in the areas of:

helping nursing homes improve their organizational quality systems and clinical systems related to the selected measures; and

queries about working in the NH setting;

(v) provide information for QIO use in assisting NHs to understand the discrepancies between the publicly reported data and other CMS NH quality reports (e.g. State Survey Agency results);

(vi) provide guidelines and criteria for the QIO to use in determining which nursing homes in their State will be recruited as identified participants;

(vii) provide structured communication among QIOs working with nursing homes; and

(viii) assist CMS to develop and maintain a Nursing Home Information Clearinghouse. All QIOs and all NHs will have access to the NH Information Clearinghouse. The Clearinghouse is a web site database of clinical outcome enhancement techniques, successful systems changes, best practices, change concepts, interventions, and guidelines that facilities can incorporate into their quality improvement interventions. The Clearinghouse is based on findings presented in the literature, the experience of the QIOs and nursing homes.

d. Changes in Quality of Care Measures

See Section C.3.C.3 above

e. Evaluation

See Attachment J-7

f. Deliverables

See Attachment F.2

2. Task 1b: Home Health Quality Improvement

a. Background

CMS is committed to publicly reporting on the quality of care provided to Medicare beneficiaries by home health agencies (HHAs). This effort will provide information to Medicare beneficiaries, their families and others involved in their care, which can be used for selecting a home health agency. QIO quality improvement efforts will focus on the care areas reflected in the CMS publicly reported OASIS quality of care measures. It is expected, but not yet decided, that there will be approximately 10-15 publicly reported OASIS quality of care measures derived from the OASIS outcome measures.

b. Task Description

In addition to the general Task requirements listed in C.3.C.1, the QIO shall:

(i) improve the quality of care in HHAs in relation to the publicly reported OASIS quality of care measures Statewide;

(ii) develop and implement a plan to cooperate with the relevant home health stakeholders, e.g., State Survey and Certification Agency, State Medicaid Agency, Regional Home Health Intermediary (RHHI), trade organizations, home health clinical and professional groups, State OASIS Education Coordinators and patient advocacy groups;

(iii) attend and complete Home Health Outcome Based Quality Improvement (HH OBQI) training within 3 months from the effective date of the contract;

(iv) use the HHA QIOSC provided standard models, methodology and materials, and utilize the HH QIOSC for individual consultation to address QIO HH technical and data specific concerns or problems;

(v) offer education and training to all HHAs in the state on HH OBQI methodology and techniques to improve care and outcomes related to OASIS quality of care measures, using the HH OBQI training materials developed and provided by the HH QIOSC;

(vi) Or, if after participating in the training, the QIO wishes to use a different approach, discuss its reasons for wanting to do so and the approach that it proposes to take with its Project Officer. If, after that discussion, the QIO then elects to take an alternate approach, it must:

If requested, provide its models, methodology, materials to the QIOSC, and

acknowledge that support from the QIOSC for the approach that it has chosen will be limited:

(vii) Within 6 months of the contract effective date, provide a list of the identified participant HHAs. The target participation rate is at least 30% of the HHAs in the State…(See Glossary at J-1 for definition of identified participant.);

(viii) provide technical assistance to identified participant HHAs in their state with the implementation of the HH OBQI System (HH OBQI SoW available at http://www.hcfa.gov/quality/11c2.htm). The specific agencies constituting the participating group may change throughout the contract cycle. The QIO will report the

number of participating HHAs monthly in TQIP; However, only those agencies listed as identified participants within 6 months of the contract effective date will be considered for evaluation purposes; and

(ix) review and use CMS OASIS quality of care measures, CMS OASIS reports, and other information provided by HH QIOSC for statewide, group and individual provider quality improvement efforts.

c. Support

In addition to the general coordination assistance described above, the HH QIOSC will:

(i) provide detailed technical information and reports about OASIS outcome measures and the CMS publicly reported OASIS quality of care measures;

(ii) provide HH OBQI training and materials to QIOs;

(iii) provide technical assistance and consultation to assist QIOs in helping HHAs implement the HH OBQI system; and

(iv) maintain and further develop a Home Health Information Clearinghouse. QIOs and HHAs will have access to the HH Information Clearinghouse. The Clearinghouse is an interactive web site that includes a database of clinical outcome enhancement techniques, successful systems changes, change concepts, best practices, interventions, and guidelines that agencies can incorporate into their quality improvement plans of action. The Clearinghouse is based on findings presented in the literature and the experience of the QIOs and home health agencies. The Clearinghouse is also an interactive resource where QIOs can download training materials, share information with other QIOs and HHAs, and obtain expert answers to frequently asked questions.

d. Changes in Quality Measures

See Section C.3.C.3 above.

e. Evaluation

See Attachment J-7

f. Deliverables

See Attachment F.2

3. Task 1c - Hospital Quality Improvement

a. Background

This Subtask builds upon work to improve quality in acute care hospitals (now including Critical Access Hospitals) begun under the 4th SoW.

b. Task Description

In addition to the general Task requirements listed in C.3.C.1, the QIO shall:

(i) implement quality improvement projects (defined in Part 16 of the PRO Manual) designed to:

reduce medication (and other) systems failures for hospitalized cardiovascular and pneumonia patients; and

prevent surgical infections;

(ii) work with hospitals, M+COs and others to improve care for hospitalized Medicare beneficiaries, measured by the following quality of care measures, which have been endorsed by CMS and others. (Where CMS and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have similar measures, the two organizations have worked to make their measure specifications and data definitions identical wherever feasible. CMS and JCAHO will continue to work together to develop identical measures in the future.

Topic	Quality of Care Measures

Reduce medication (and other) systems failures for hospitalized cardiovascular and pneumonia patients	<u>Acute myocardial infarction:</u> 1. Early administration of aspirin 2. Aspirin at discharge 3. Early administration of beta blocker 4. Beta blocker at discharge 5. ACE inhibitor at discharge for patients with systolic dysfunction 6. Time to initiation of reperfusion therapy 7. Smoking cessation counseling
	<u>Heart Failure:</u> 1. Evaluation of left ventricular function before or during hospitalization. 2. ACE inhibitor at discharge for patients with systolic dysfunction. 3. Discharge instructions 4. Smoking cessation counseling
	<u>Pneumonia:</u> 1. Blood culture before antibiotics 2. Time to initial antibiotic administration [NOTE: target time is currently 8 hours, but is likely to change to 4 hours reflecting expected evidence-based revision of specialty society guidelines.] 3. Administration of antibiotics consistent with current guidelines 4. Pneumococcal (PPV) immunization (inpatient) 5. Influenza immunization (inpatient) 6. Oxygenation assessment within 24 hours of hospital arrival 7. Smoking cessation counseling
Prevent surgical infections	1. Correct prophylactic antibiotic 2. Correct timing of antibiotic administration 3. Correct duration of antibiotic administration

The QIO shall use data provided by CMS (see "statewide improvement on quality of care measures in Attachment J-7) to identify opportunities to improve care. The QIO may determine that it needs to collect additional hospital-specific data during the contract period through (1) hospital-generated data, (2) CDAC abstraction services, or (3) its own data abstraction and collection efforts. See Task 2b for guidance on hospital-specific data abstraction, collection, analysis and related activities.

c. Changes in Quality of Care Measures

See Section C.3.C.3 above.

d. Evaluation

See Attachment J-7

g. Deliverables

See Attachment F.2

4. Task 1d Physician Office Quality Improvement

a. Background

This Subtask will expand and build on work to improve quality in physician office settings begun under the 6th Scope.

b. Task Description

In addition to the general Task requirements listed in A, the QIO shall:

(i) implement quality improvement projects (defined in Part 16 of the PRO Manual)(Attached at J-4);

(ii) work with physicians and others (e.g., State health department based Diabetes Control Programs) to improve care for Medicare beneficiaries, measured by the following quality of care measures:

Topic	Quality of Care Measures
Care for Chronic Disease	
Diabetes	1. Biennial retinal exam by an eye professional 2. Annual HbA1c testing 3. Biennial testing of lipid profile
Preventive Services	
Cancer Screening	Biennial screening mammography
Adult immunizations	1. Influenza immunization [full state Medicare population] 2. Pneumococcal (PPV) immunization [full state Medicare population]

(iii) Within 6 months of the contract effective date, provide a list of the "identified participant" physicians. The target is to include identified participants who treat at least 10% of the beneficiaries in the State for each topic area.. (See Glossary at J-1 for definition of identified participants.)

(iii) implement a focussed effort with identified participants in the State using specific interventions that will lead to improved beneficiary care for the topics listed above; and

(iv) initiate and/or support statewide/regional/local collaborative quality improvement activities by acting as a convener, facilitator, collaborator and/or clearinghouse for the QAPI projects required of M+COs on the topics listed above.

c. Changes in Quality of Care Measures

See C.3.C.3 above.

d. Evaluation

See Attachment J-7

e. Deliverables

See Attachment F.2.

5. Task 1e - Underserved and Rural Beneficiaries Quality Improvement

a. Background

In the 6th SoW, every QIO was required to work on a project to eliminate health disparities. Currently, 52 projects to eliminate health disparities are in progress. In the 7th SoW, QIOs are expected to build on lessons from those projects to further reduce disparities.

b. Task Description

In addition to the general task requirements listed in Section C.3, the QIO shall work to eliminate health disparities between certain medically underserved populations and the general beneficiary population. In doing

so, the QIOs shall use the groups and definitions as described in the Glossary (attached at J-1).

The disparity shall be identified using one of the quality of care measures listed in Tasks 1(c) or 1(d). During the pre-contract award phase, the CMS Project Officer and Central Office staff will have determined which of the following approaches the QIO shall follow:

(i) The QIO will continue implementing their approved 6th SoW disparities project.

QIOs continuing a 6th SoW project under b.i above shall continue to perform their projects in accordance with the approved project plan in effect on the completion date of the 6th SoW contract. A copy of the approved project plan shall be submitted to the CMS Project Officer within 10 days of the 7th SoW contract effective date.

OR

(ii) The QIO will start a new project selecting one quality of care measure from Subtask 1c or 1d in one underserved population defined in the Glossary attached at J-1.

(iii) A QIO that has been directed to continue implementing its approved 6th SoW disparities project may also work on an additional project to eliminate health disparities in rural beneficiary populations.

A QIO starting a new project under b.i or b.ii above shall submit a project idea document to its CMS Project Officer within 90 days of contract effective date for noncompetitive procurements and within 120 days of contract effective date for competitive procurements. The QIO shall submit a project plan by the date negotiated, upon approval of the project idea document by the CMS Project Officer.

The QIO shall also initiate and/or support statewide/regional/local quality improvement activities by acting as a convener, facilitator and/or clearinghouse for the required Quality Assurance and Performance Improvement (QAPI) projects to reduce clinical health care disparities (CHCD), the Year 2003 National QAPI Project as

described in OPL2001.133. (Available at http://www.cms.hhs.gov/medicare/mdgcar/.htm)

NOTE: For projects to eliminate health disparities in immunizations, the QIO may use a CMS-approved data source for baseline and remeasurement other than the data source specified in Task 1d for influenza or pneumococcal immunization.

c. Changes in Quality of Care Measures

See Section C.3.C.3 above

d. Coordination:

See C.3. above.

e. Evaluation

See Attachment J-7

f. Deliverables

See Attachment F.2

6. Task 1f - Medicare+Choice Organizations (M+COs) Quality Improvement

a. Background

QIOs are specifically required by statute to undertake an equivalent level of effort for the review of services provided to beneficiaries enrolled in M+CO plans as that devoted to those beneficiaries in FFS Medicare. CMS requires M+COs to implement Quality Assessment and Performance Improvement (QAPI) projects to improve health outcomes and enrollee satisfaction for beneficiaries enrolled in an M+CO. (For information on QAPI see http://www.com/hhs.gov/medicare/mdgcar/.htm) The purpose of this subtask is to improve care for beneficiaries enrolled in M+COs while assuring that QIOs meet the statutory obligation, support M+COs in meeting QAPI requirements, and reduce burden for practitioners and providers by encouraging consistent approaches to quality improvement activities among the M+COs in the state. In almost all cases, any project authorized under this sub-Task will not involve inpatient care.

b. Task Description

In addition to the general Task requirements listed in C.3., the QIO shall:

(i) invite all M+COs in the state to join quality improvement projects on Tasks 1a to 1e. Within 60 days of the contract effective date, the QIO shall submit a plan describing the methods it will use to accomplish this requirement;;

(ii) initiate and/or support statewide/regional/local quality improvement activities by acting as a convener, facilitator and/or clearinghouse for the required QAPI projects not covered by 1(d) or (e); and,

(iii) Resources permitting, offer technical assistance to M+COs for quality improvement activities that may not be related to national QAPI clinical requirements.

E. Task 2 – Improving Beneficiary Safety and Health Through Information and Communications

In addition to integrating communications, outreach, and marketing strategies into other tasks of this contract (See C.2.B.4), there are specific communications and information activities in which the QIO must engage that will contribute to the overall execution of the contract. These include:

1. Task 2a - Promoting the Use of Performance Data

The purpose of this task is to stimulate improvement in clinical performance indicators in specific provider and practitioner settings through communication between QIOs, providers/practitioners, beneficiaries, and those who assist beneficiaries with their health care choices by using CMS-directed and/or QIO-initiated methods. Initially, implementation of this activity will be carried out through modification to the QIOs' 6th Round Contract. However, it is possible that during the period of the 7th Round Contract, CMS may direct all QIOs to conduct certain activities to further this goal.

2. Task 2.b - Transitioning to Hospital-Generated Data

a. Background

Individual hospital generation of quality of care measurement data is advancing on three fronts. In a small number of States, hospitals are, or soon will be, required by law to report hospital level indicators. Nationally, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is creating a set of quality of care measures that hospitals must report as part of the accreditation process. Since the 6th SOW, CMS has been collecting quality of care measures at the State level for reporting purposes and is working with JCAHO to achieve consistency

between the indicators used by the two organizations. As a consequence of these activities, many hospitals have begun to voluntarily abstract and collect quality of care measures, both in anticipation of coming reporting requirements and for internal quality improvement processes. In the future, it is expected that hospitals will report on a standard set of quality of care measures.

In addition, Under Task 1c, the QIO must use statewide hospital quality of care measures to identify opportunities to improve care. Hospitals may ask the QIO to abstract additional data, specific for that hospital, to help improve their internal processes of care. As a transitional step, and to the degree that QIO and/or CDAC resources are available, the QIO may assist in this way. In this case, priority should be given to the small hospitals or others with the fewest internal resources. However, it is expected that by the end of the contract, the QIO will have the largest number of hospitals possible collecting its own measures.

The purpose of this task is to transition to self-generated data. The QIO will assess the current reporting capabilities of hospitals in each State; build the capacity to provide technical assistance to hospitals as they take on this responsibility; lay the foundation for a data validation mechanism once a hospital engages in abstracting its own data; use a data base management system to confidentially collect the measures reported by the hospitals; and have the largest number of hospitals possible collecting and reporting quality of care measures. From these activities, CMS will consolidate data for State level reporting of quality of care measures and the QIO will provide feedback to the hospitals for quality improvement. During the transition to electronic self-reporting by hospitals, CMS will continue to maintain the current system whereby QIOs request paper copies of medical records for review and abstraction.

During this SOW, CMS will periodically report data aggregated at the state level on the progress of this effort. We do not require in this task that hospital-specific reported data will be released to the public. However, under Task 4 CMS is planning to conduct pilot studies in the small number of states that already have (or are close to) mandatory reporting to investigate a data collection and public reporting effort which will inform a national strategy for public reporting by hospitals.

b. Task Description

(i) Assessing Hospital Status

The QIO shall determine the extent to which individual hospitals are prepared to collect and disseminate quality of care measures information. This assessment would include third party vendors

contracted to abstract for a hospital. CMS will provide a list of information that it requires about the ability and capacity of each hospital to collect and report quality of care measure information. Each QIO will make an initial determination for each hospital by collecting and maintaining the required information. The QIO will insure that the information for each hospital is current for each quarter. The QIO will maintain the information in the SDPS system. CMS will periodically create reports based upon this data. Any information collection/survey activities conducted by the QIO must be done in accordance with Section C.2.B.7.

(ii) Provide Technical Assistance on Data Abstraction Tools

The QIO shall make available and demonstrate as requested to each hospital the CMS approved data abstraction tool. The QIO shall respond to hospital requests for assistance to implement a data abstraction system using the CMS data abstraction tool to abstract quality of care measures.

The QIO shall provide training on the use of the CMS data abstraction tool; its on-going maintenance as changes of the tool occur; troubleshooting support for facilities installing the software; and assistance on reporting results of the abstraction and transmitting the data or information to a designated recipient.

Should a hospital choose to use a data abstraction tool other than that approved by CMS, the QIO shall assure that the hospital uses standard file definitions and abstraction protocols equivalent to the CMS data abstraction tool.

(iii) Data Validation on Hospital Reported Measures

The QIO shall determine the accuracy of the reported hospital quality of care measures by re-abstracting a sample of Medicare cases known to have been abstracted and submitted by the hospitals in their State.

The QIO shall use the results of the data validation samples to improve a hospital's performance and provide feedback on process changes. Hospitals that consistently perform below 90 percent reliability (as evidenced by the last data validation sample) will be required to provide hardcopy versions of charts when data are requested by QIOs, CDACs or other lawful requests for charts from CMS. Those hospitals performing at or above 90 percent reliability will be allowed to submit electronic versions of abstracted data when requested.

The QIO shall participate, as directed by CMS, in inter-QIO data reliability projects. Participation includes submitting abstracted test data and conducting training or other activities necessary to improve abstraction accuracy based on the results of the data reliability projects.

(iv) Assistance on Collecting and Reporting Hospital Data

The QIO shall be responsible for the data sets provided by each hospital that is abstracting and reporting quality of care measures. For hospitals that are reporting measures using computer software other than the CMS data abstraction tool, the QIO shall assure that the reported data conforms to standard file definitions and abstraction protocols as defined by CMS.

The QIO shall be the point of contact for each hospital and shall serve as the technical support for importing hospital collected measurement data into the CMS SDPS data collection system. The QIO may also use this data for benchmarking and aggregate reporting back to a hospital to assist quality improvement projects.

The QIO may assist a hospital in its data abstraction, as a feedback mechanism to improve the quality of care process, by either abstracting the hospital's data internally or providing services through the CDAC. Priority for offering these services should go to small hospitals and those lacking adequate internal resources to abstract data. It is expected that these services will be more limited as the contract progresses and as many hospitals as possible should be abstracting and reporting their own data by the end of the contract.

c. Support

Support for the CMS data abstraction tool will be provided by a QIOSC. This QIOSC will also supply the standard file definitions and the standard abstraction protocols developed by CMS.

3. Task 2c – Other Mandated Communications Activities

a. Background

In addition to integrating communications, outreach, and marketing strategies into other tasks of this contract (See C.2.B.4) and the possible activities in Subtask 2a, there are specific communications activities in which the QIO must engage that will contribute to the overall execution of the contract.

b. Task Description

(i) Consumer Representation

The QIO shall establish a Consumer Advisory Council (CAC) for the purpose of advising it regarding consumer-oriented activities. For those QIOs with a Beneficiary Liaison Committee (BLC), the QIO may expand the membership and purpose of the BLC to meet the requirements of the CAC (as described below). However, the QIO shall not maintain both a CAC and a BLC for the 7th Round Contract.

Within 30 days of the contract effective date, the QIO shall propose to the project officer the structure and size of its CAC, including a list of prospective organizations and/or individuals that it plans to invite to join the CAC. CAC membership must include representatives from community and business organizations. Such organizations might include advocacy groups, provider associations, health care purchasers, information intermediaries, community-based organizations, media/public relations experts, and academicians with expertise in quality improvement or consumer information. More than half of the CAC members must be from organizations whose primary responsibility is protecting the interest of Medicare beneficiaries. Upon project officer approval of the proposed structure and size, the QIO shall select an initial meeting location and date (no later than three months after the beginning of the contract). CACs will meet as often as the members who attend the initial meeting decide to meet, but no less than quarterly.

The QIO shall expand consumer membership on its Board of Directors. See PRO Manual Section 2200-2230, attached at J-4, for information on beneficiary representation on QIO Boards of Directors.

(ii) Helpline

The QIO shall maintain and staff a Medicare helpline to facilitate communications pursuant to all Tasks within this SoW. The QIO shall provide timely and appropriate response to all calls to this helpline. It shall refer all requests for assistance not covered in this SoW to other

appropriate entities (e.g., FIs, Social Security District Offices, State Agencies, etc.).

It shall enter and track information regarding its performance using an instrument provided by SDPS. In planning its beneficiary rights activities, the QIO shall consider information from beneficiary complaints and requests for coverage review (notices of non-coverage) as well as the results of those reviews.

(iii) Annual Report

The QIO shall publish an Annual Report following the publication deadlines, content and format requirements outlined in PRO Manual Section 12400-12440, attached at J-4, as well as any other administrative directives. Any Annual Reports posted to a QIO website must follow the requirements on the Use of Web Technology, found at C.2.0.B.5.

(iv) Implementation of Practitioner, Provider, and Beneficiary Outreach Activities

The QIO shall conduct provider, practitioner, and beneficiary outreach activities in support of Tasks 1, 2, and 3 of this contract.

As it relates to Tasks 1, 2, or 3 of this contract, the QIO shall ensure that the providers, practitioners, and beneficiaries understand the QIO's role in protecting beneficiary rights, conducting quality improvement projects, and protecting the fiscal integrity of the Medicare trust fund.

In accordance with Section 1154(a)(6)(B)(i) of the Act, the QIO shall offer to send a physician representing its organization to meet with medical and administrative staff of each hospital whose services it reviews.

F. Task 3 - Medicare Beneficiary Protection Program

1. Background

By Federal statute and regulations, QIOs are required to conduct a number of activities to ensure protection of beneficiary's safety and health: response to beneficiary complaint, HINN/NODMAR review, EMTALA case review, review for hospital payment monitoring, other kinds of individual case reviews and post-case reviews. These activities and their purposes are discussed below.

2. Requirements

a. Task 3a- Beneficiary Complaint Response Program

As set forth under section 1154(a)(14) of the Social Security Act and as specified in PRO Manual instructions at Part 5 (Attachment J-4), the QIO shall review all written quality of care complaints from Medicare beneficiaries or their designated representatives. QIO review activities include the following:

As further described in Attachment J-4, the QIO shall utilize a case management approach.

When directed by CMS, the QIO shall offer mediation if voluntarily accepted by the beneficiary and provider/practitioner to resolve the complaints, as described in Attachment J-4. Prior to implementation of mediation activities, the QIO shall participate in training sessions and in other related activities sponsored by CMS.

The QIO shall use concerns discovered through these activities to identify issues for which providers and practitioners would benefit from conducting quality improvement activities and to address and seek to resolve beneficiary concerns. In deciding whether to pursue these opportunities, the QIO shall weigh the probable benefit against benefits from other investment of resources.

Where the QIO makes a recommendation that a provider and/or practitioner develop and implement a plan for improvement, the QIO shall follow up to evaluate whether improvement has occurred.

The QIO shall inform beneficiaries or their designated representatives of the final disposition of the review. And,

The QIO shall respond to other complaints that do not meet the 1154(a)(14) statutory requirements by conducting a review of the complaint and/or referring the complainants or complaint to other entities when appropriate, as specified in Part 5 of the PRO Manual (Attachment J-4).

b. Task 3b-Hospital Payment Monitoring Review Program

The QIO shall review all cases referred by the CDACs as part of a random sample to produce national and statewide error rates for coding and medical necessity for estimating the payment error rate for inpatient PPS services. The payment error rate shall be monitored and reported for each State.

The QIO shall review services provided to Medicare beneficiaries under the Medicare program to determine whether: 1) such services are reasonable and medically necessary, 2) services are provided efficiently in the most appropriate setting, and 3) such services support the validity and diagnosis of medical information supplied by the provider. Subsequently, the QIO shall make an initial determination that may result in approval or denial of payment and/or DRG changes. The QIO shall review these cases following the procedures specified in Parts 4 and 7 of the PRO Manual (Attachment J-4).

The QIO shall monitor the hospital admission and coding patterns in its area by conducting hospital profiling and trend monitoring/target identification activities. To supplement other information that the QIO has available to it, CMS will supply the QIO with periodic monitoring reports, specific to all hospitals in the State. The QIO shall analyze these reports and, coupled with information independently developed through analysis of case review data (and other appropriate sources), determine the potential for errors and inappropriate utilization by providers.

The QIO shall develop project proposals to address identified and potentially significant inappropriate utilization and aberrant coding patterns and submit them to its Project Officer for approval. The QIO shall report and disseminate the results of its monitoring and project activities as specified in Part 11 of the PRO Manual (attached J-4). The development and implementation of any project must be well documented and supported by the results of the QIO's monitoring activities of hospital admission and coding patterns. Additionally, CMS may direct the QIO to conduct specific error prevention projects. Projects directed or approved by CMS will be funded under Task 4 as Special Studies.

c. Task 3c - Other Beneficiary Protection Activities

HINN/NODMAR Review

As described in Part 7 of the PRO Manual (see Attachment J-4), the QIO shall respond to beneficiaries' (and when applicable, to providers') requests for immediate QIO review to ensure that HINNs/NODMARs given to Medicare beneficiaries or their designated representatives are correct and that those beneficiaries are not discharged prematurely from care. For such review, the QIO shall:

Make an initial determination and, on request, conduct a reconsideration of that determination.

Follow the HINN/NODMAR review procedures and time frames as specified in Part 7 of the PRO Manual (attached at J-4).

Monitor the content of the HINN and the accuracy of the hospital's determination including appropriate interventions to correct any identified deficiencies no less than every 6 months as specified in Part 7 of the PRO Manual (attached at J-4).

EMTALA Review

The QIO shall conduct a 5-day medical advisory review upon request from the appropriate CMS RO for a (physician) medical assessment of a potential EMTALA violation case as specified in Part 9 of the PRO Manual (Attachment J-4). The Federal statute and regulations do not mandate the 5-day review; however, the RO may use this review as a resource in making a compliance determination, rather than simply determining the merits of the complaint.

Under sections 1867(d)(3) of the Act and 42 CFR 489.24(g), the QIO shall conduct a 60-day review upon receipt of a completed EMTALA case sent to OIG for possible civil monetary penalty or exclusion sanction as outlined in Part 9 of the PRO Manual.

All Other Case Review Activities

The QIO shall review individual cases received from a variety of sources. The QIO shall make medical necessity, quality of care, and/or DRG validation determinations (applicable to the kind of case under review) as specified at Part 4 of the PRO Manual (Attachment at J-4). These activities include all hospital-requested higher weighted DRG assignment cases accepted by the fiscal intermediaries (FIs), coverage decision referrals from FIs and any other review required by PRO Manual instructions at Part 4.

Additionally, the QIO shall monitor the hospital's compliance of securing physician acknowledgment statements.

Post Review Activities

The QIO shall exercise its authority to reopen initial determinations and DRG changes when necessary and within the time frames specified at 42 CFR 476.96.

As specified in Parts 4 and 7 of the PRO Manual, the QIO shall conduct the following post review activities:

Reopening of technical denials for lack of medical records.

Rereviews of DRG assignment changes.

Rereviews of confirmed quality concerns.

Reopenings of cases in accordance with 42 CFR 476.

When directed by CMS, the QIO shall conduct other activities related to the preparation of the QIO's initial determination claim file for release to the appropriate organization responsible for conducting further appeals (See Attachment J-4).

3. Support

CMS will contract with a Medicare Beneficiary Protection QIOSC (MPB QIOSC) to provide technical leadership, develop training tools and conduct the necessary training to assist the QIO in implementing certain task activities. As directed by CMS, the QIO will cooperate and coordinate its effort with the MPB QIOSC to achieve the greatest efficiency and cost-effectiveness in accomplishing certain requirements of this Task.

1. Evaluation

See Attachment J-7.

2. Deliverables

See Attachment F.2.

G. Task 4-- Improving Beneficiary Safety and Health Through Developmental Activities (Special Studies)

1. Background

CMS reserves the right to direct the QIO, or approve an application from the QIO, to initiate a special study not currently defined under this SOW.

2. Task Description

A special study is defined as work that CMS directs a QIO to perform or work that a QIO elects to perform with CMS approval which is not currently defined in Tasks 1 - 3 of the SOW but falls within the scope of the contract and Section 1154 of the Act. The term “special studies” is interchangeable with the terms “special projects” and “special work.”

3. Evaluation

All special studies approved under this task will be evaluated individually, based on study-specific evaluation criteria. The QIO's success or failure on a special study will not be factored into the evaluation of the QIO's work under Tasks 1 - 3, as described in Attachment J-7.