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PART I
SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. DESCRIPTION OF SERVICES

This is a contract with a Utilization and Quality Control Peer Review Organization (hereinafter referred to as a Quality Improvement Organization (QIO)) in accordance with Section 1154 of the Social Security Act. Performance of the requirements of Section C, Statement of Work (SOW) focuses on successful achievement of the following requirements for the QIO Program:

- Improve quality of care for beneficiaries;
- Protect the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and medically necessary and that are provided in the most appropriate setting; and
- Protect beneficiaries by expeditiously addressing individual complaints, notices and appeals, such as beneficiary complaints; provider-based appeals; Emergency Medical Treatment and Labor Act (EMTALA) violations; and other related statutory QIO responsibilities.

B.2. TYPE OF CONTRACT

This contract contains cost-plus-award-fee (CPAF) and cost-plus-fixed-fee (CPFF) type requirements. All requirements contained in Section C SOW, with the exception of information systems and special projects, shall be performed on a CPAF basis. Section C.8. Special Projects (SP) and Information Systems (IS) shall be performed on a CPFF basis.

B.3. FEES

A. Core Contract Themes

Payment of fee will be made based upon the requirements of Section B, Section C theme evaluation criteria and Section J, Attachment J-2 Award Fee Plan. The fees available under this contract are as follows:

Fixed Base Fee = $_____ (to be determined (TBD)) (excluding pass-thru and Section C.8. Special Project costs) associated with the three core Themes: Beneficiary Protection, Patient Safety, and Prevention. The fixed base fee will be reimbursed on a monthly basis.

Performance Award Fee = $_____ (TBD) (excluding pass-thru and Section C.8. Special Project costs) associated with the three core Themes: Beneficiary Protection, Patient Safety, and Prevention for which the QIO receives a rating of "pass" in accordance with the requirements specified in Section C.6. and elsewhere in the SOW.

Fixed Fee = $_____ (TBD) for Information Systems (IS)
Section C.8. Special Project Fixed Fee will be negotiated on individual Special Projects at the time of issuance. The special project fixed fee will be reimbursed on a monthly basis.

B. Directed Sub-National Requirement (Prevention Disparities)

Fixed Base Fee = $_____ (TBD) (excluding pass-thru) fixed base fee will be reimbursed on a monthly basis.

Performance Award Fee = $_____ (TBD) (excluding pass-thru) for which the QIO receives a rating of "pass" in accordance with the requirements specified in Section C.7. and elsewhere in the SOW.

C. Optional Sub-National Requirement (Patient Pathways)

Fixed Base Fee = $_____ (TBD) (excluding pass-thru) fixed base fee will be reimbursed on a monthly basis.

Performance Award Fee = $_____ (TBD) (excluding pass-thru) for which the QIO receives a rating of "pass" in accordance with the requirements specified in Section C.7. and elsewhere in the SOW.

D. Optional Sub-National Requirement (Chronic Kidney Disease)

Fixed Base Fee = $_____ (TBD) (excluding pass-thru) fixed base fee will be reimbursed on a monthly basis.

Performance Award Fee = $_____ (TBD) (excluding pass-thru) for which the QIO receives a rating of "pass" in accordance with the requirements specified in Section C.7. and elsewhere in the SOW.

B.4. CONSIDERATION AND PAYMENT

A. Total Contract Amount

The total estimated cost-plus-fixed fees (TEC+Award, Base and Fixed Fee) is $_____

> **Note:** Special Projects (SP) will be incorporated into the contract by issuance and execution of a formal contract modification (see Section B.5.). Upon issuance of a SP contract modification, Section B.4.A., entitled, "Total Contract Amount" and Section B.4.B., entitled, "Table of Total Estimated Cost and Associated Fees," will be modified accordingly.

B. Table of TEC and Associated Fees

The QIO shall provide the necessary personnel, materials, services, facilities and supplies (except as may be otherwise specified in the contract) and otherwise do all things necessary for, or incident to, the performance of the work as set forth in Section C, SOW. In consideration of successful performance in accordance with the evaluation criteria set forth in Section C and Section J-2 Award Fee Plan, the QIO will be reimbursed as stated in the Table of TEC and Associated Fees on the following pages:

Theme	Estimated Cost	Base Fee	Award Fee	Fixed Fee IS and SP
Theme 6.1 Beneficiary Protection				
Theme 6.2 Patient Safety (Total)				
6.2.1 Pressure Ulcers				
6.2.2 Physical Restraints				
6.2.3 Surgical Care Improvement Project				
6.2.4 Methicillin-resistant Staphylococcus Aureus (MRSA)				
6.2.5 Drug Safety				

6.2.6 Poorly Performing Nursing Homes				
Theme 6.3 **Core Prevention**				
Directed Sub-National **Theme 7.1** Prevention: Disparities				
Optional Sub-National **Theme 7.2** Patient Pathways (Care Transitions)				
Optional Sub-National **Theme 7.3** Prevention: Chronic Kidney Disease				
Section C.8 **Special Projects**				
IS				
Pass-Thru 6.1				
Pass-Thru(6.2 & 6.3)				
Pass-Thru Directed Sub-National Theme 7.1				
Pass-Thru Optional Sub-National Theme 7.2				
Pass-Thru Optional Sub-National Theme 7.2				
TOTALS				

C. Schedule for Payment of Base Fee and Fixed Fee

Payment of the fixed base fee and other fixed fees (IS and SP) will be made in accordance with the schedule provided below. As authorized under FAR 52.216-8, after payment of 85% of these fixed fees, CMS may elect to withhold 15% or $100,000 (whichever is less).

Month	Payment/Month	Total
1-35	$_____	$_____
36	$_____	$_____
Total	$_____	$_____

Note: Regardless of the period of performance of a SP, the associated fixed fee shall be allocated across the remaining months of the contract period (not period of performance for the SP). Therefore, as SPs are incorporated into the contract, the Section B.4.C. Schedule of Payment of Base Fee and Fixed Fee will be modified accordingly.

D. Reallocation of Costs

Costs provided in Table B.4.B are estimates only. During contract performance, the QIO may move funding at any time to ensure successful contract performance as follows:

1. Theme 6.2 Patient Safety and 6.3 Core Prevention funds may be moved within Themes 6.2 and 6.3 components and associated pass-thru costs.

2. Theme 6.1 Beneficiary Protection **cannot** be utilized for the performance of any other work.

3. Directed Sub-National Theme 7.1 Prevention Disparities funding **cannot** be utilized for performance of any other work.

4. Optional Sub-National Theme7.2 Patient Pathways funding **cannot** be utilized for performance of any other work.

5. Optional Sub-National Theme 7.3 Chronic Kidney Disease funding **cannot** be utilized for performance of any other work.

6. IS funding **cannot** be utilized for performance of any other work.

B.5. SPECIAL PROJECTS

A. Special Projects

As provided under Section C.8. and in accordance with the procedures contained in Section G.20, CMS reserves the right to direct the QIO to initiate a SP not currently defined under the SOW or to approve an application from a QIO to conduct a SP. SPs will be awarded on a CPFF basis. The table provided below will be completed (through execution of a formal contract modification) as SPs are incorporated into this contract.

SP Number	FIVS Number	CAN`	SP Title	Period of Performance	Funded Amount

B. Reallocation of Funds for Special Projects

Funds associated with Section C.8 SP **cannot** be redirected for performance of any other work. Additionally SP funding **cannot** be reallocated from one SP to another.

B.6. CEILINGS

A. General

The cost limitations addressed in this Section apply to the total contract ceiling amount of the contract. The QIO is advised that all costs associated with this contract, either directly or indirectly, are subject to audit.

B. Medical Records Photocopying/Pass-Thru Costs

The QIO will be paid for a properly certified invoice/voucher for medical records photocopying costs at a rate of **$.12 per page** for reproduction of PPS provider records and **$.15 per page** for reproduction of non-PPS institutions and practitioner records, plus first class postage. Specifically, hospitals and other providers (such as critical access hospitals) under a Medicare cost reimbursement system, receive no photocopying reimbursement from the QIO. Capitation providers such as HMOs and dialysis facilities receive **$.12 per page**.

All other photocopying costs are to be directly charged to the theme to which they apply and shall be reimbursed on the basis of the costs that are allowable. In order for a cost to be determined allowable, the cost must be allocable and reasonable.

C. Overnight Mail

Contract deliverables shall not be submitted utilizing overnight mail. All other overnight mailings (e.g., provider-based discharge appeals, etc.) shall be at the discretion of the QIO and are subject to the Contracting Officer's determination of reasonableness.

D. Indirect Cost Rates

The indirect cost rate ceiling(s) for this contract is/are:

Overhead:	_____%TBD*
Fringe Benefits:	_____%TBD*
Other:	_____%TBD*

(*To Be Determined)

B.7. TRANSITION SERVICES

In the event that CMS requires transition services from an incumbent QIO to a successor QIO, CMS will request a separate technical and business proposal for these services (see Section H.21.). These services will be incorporated into the contract if applicable.

B.8. INCREMENTAL FUNDING

Due to funding limitations, CMS will partially fund the three-year contract award amount. CMS anticipates that the contract will be fully funded in Fiscal Year 2009 up to the three-year estimated cost plus-fixed fee ceiling amount. Accordingly, the following will apply:

(a) It is CMS's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds, as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover a portion of contract performance. CMS intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modification.

However, the Government is not obligated to reimburse the QIO for costs incurred in excess of the periodic allotments nor is the QIO obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in Section I, Contract Clauses.

SECTION C – SCOPE OF WORK

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C.5.	OVERALL EVALUATION
C.6.	THEME REQUIREMENTS AND EVALUATION Theme 6.1. Beneficiary Protection Theme 6.2. Patient Safety - Pressure Ulcers - Physical Restraints - Surgical Care Improvement Project - Methicillin-resistant Staphylococcus aureus - Drug Safety - Poorly Performing Nursing Homes Theme 6.3. Prevention
C.7.	SUB-NATIONAL REQUIREMENTS Theme 7.1. Prevention: Disparities (Directed) Theme 7.2. Patient Pathways (Care Transitions) (Optional) Theme 7.3. Prevention: Chronic Kidney Disease (Optional)
C.8.	SPECIAL PROJECTS
C.9.	TRANSITION FROM INCUMBENT QIO TO SUCCESSOR QIO

SECTION C. SCOPE OF WORK

C.1. BACKGROUND AND OVERVIEW

The statutory authority for this Scope of Work (SOW) is found in Part B of Title XI of the Social Security Act (hereinafter referred to as the Act), as amended by the Peer Review Improvement Act of 1982. The Act established the Utilization and Quality Control Peer Review Organization Program, now known as the Quality Improvement Organization (QIO) Program.

The statutory mission of the Program, as set forth in Section 1862(g) of the Act, is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries.

Based on statutory language and the experience of the Centers for Medicare & Medicaid Services (CMS) in administering the Program, CMS has identified the following requirements for the QIO Program:

- Improve quality of care for beneficiaries;

- Protect the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and medically necessary and that are provided in the most appropriate setting;

- Protect beneficiaries by expeditiously addressing individual complaints, such as beneficiary complaints; provider-based notice appeals; Emergency Medical Treatment and Labor Act (EMTALA) violations; and other related statutory QIO responsibilities.

This SOW contains a number of quality improvement initiatives that are authorized by various provisions in the Act. The most relevant ones are described here. As a general matter, Section 1862(g) of the Act mandates that the Secretary enter into contracts with QIOs for the purpose of determining that Medicare services are reasonable and medically necessary, and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under Medicare. CMS interprets the term “promoting the quality of services” to involve more than QIOs reviewing care on a case- by-case basis, but as covering a broad range of proactive initiatives that will promote higher quality. CMS has, for example, included in the SOW Tasks in which the QIO will provide technical assistance to Medicare-participating providers and practitioners in order to help them improve the quality of the care they furnish to Medicare beneficiaries. Additional authority for these activities appears in Section 1154(a)(8) of the Act, which requires that QIOs perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by the Medicare statute. CMS regards these activities as appropriate if they will directly benefit Medicare beneficiaries.

In addition, Section 1154(a)(10) of the Act specifically requires that the QIOs "coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations, including other public or private review organizations as may be appropriate." CMS regards this as specific authority for QIOs to coordinate and operate a broad range of collaboratives and community activities among private and public entities, as long as the predicted outcome will directly benefit the Medicare program. In addition, Section 1156(c) of the Act states that it is the duty of each QIO to use such authority or influence as it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over healthcare practitioners or entities furnishing services in its area, in assuring that each practitioner or entity shall comply with all obligations imposed on them under Section 1156(a). Under these obligations, providers and practitioners must assure that they will provide services of a quality that meets professionally recognized standards of care.

C.2. CONTRACT PURPOSE

This SOW aims to improve the quality of care and protect Medicare beneficiaries through the following four Themes:

- Beneficiary Protection
- Patient Pathways
- Patient Safety
- Prevention

C.3. TECHNICAL CONSIDERATIONS

The contractor (hereinafter referred to as "QIO") undertaking this SOW shall comply with all technical requirements outlined in this contract.

The QIO may meet the experience and expertise requirements for this SOW by documenting access to persons with relevant knowledge, skills, and abilities either within its own staff or by subcontracting with others, including expert consultant(s).

C.4. GENERAL REQUIREMENTS

The QIO, acting independently and not as an agent of the federal government, shall furnish the necessary personnel, materials, services, facilities, and supplies (except as may be otherwise specified in the contract) and otherwise do all things necessary for, or incident to, the performance of the work as set forth in this SOW.

The QIO shall adhere to the following requirements as they apply to the specific Themes described in Section C.6.

1. Infrastructure Operations Support and Data Management:

Unless otherwise directed by CMS, the QIO shall adhere to the most current version of the policies and procedures outlined and posted on QIONET. These include the QIO Infrastructure Operations and Support Manual, the QIO Information Technology (IT) Administrator Manual, the SDPS Database Systems Administrator Guide, and the QualityNet System Security Policy, QualityNet Incident Response Procedures. Additional Policies and Procedures may be released requiring the QIO to comply.

The QIO shall maintain all necessary documentation that meets or exceeds the performance standards and deliverables specified in Chapter 8, Infrastructure Operations Support and Data Management, of the *QIO Manual* and Section F – QIO Schedule of Deliverables.

2. Hardware/Software:

CMS, either directly or through a CMS contractor, will provide each QIO with a file/print server and a workstation for each 0.5 or greater full-time equivalent (FTE) employee. The file/print server and each workstation will be equipped with a standard operating system and a software suite approved by CMS. If a QIO requires additional equipment and software, the QIO must receive approval from
the Engineering Review Board (ERB) (see Section 2 of the QIO Infrastructure Operations and Support Manual; Attachment J-6 Engineering Review Board [ERB] User's Guide; and G.17. Purchase Request Users Guide for Obtaining Additional Hardware/Software) and must pay for the additional equipment and software out of QIO contract funds.

3. Security

3.1 Certification by Information's System Security Officer (ISSO) for Compliance with CMS Systems Security Requirements

The QIO designated ISSO equivalent, also referred to as the Security Point of Contact (SPOC) shall certify compliance with CMS' Office of Clinical Standards and Quality's Quality Improvement Program (QIP) systems security requirements.

3.2 Administer Security Program

- The QIO shall comply with all CMS security program requirements as specified within the Internet-Only Manual (IOM) Pub. 100-17 (Business Partner System Security Manual [BPSSM] –

http://www.cms.hhs.gov/InformationSecurity/13_Policies.asp#TopOfPage), the CMS Information Security (IS) "Virtual Handbook", which is the collection of all CMS policies, procedures, standards and guidelines which implement the CMS Information Security Program found at www.cms.hhs.gov/informationsecurity and the QualityNet Security Policy and Procedures found at http://www.cms.hhs.gov/manuals/downloads/qio110c08.pdf.

- The QIO shall adhere to all deadlines and formats outlined in official CMS communications (e.g., Joint Signature Memoranda or JSMs).
- The QIO shall comply with the CMS Policy for the Information Security Program (PISP) and all CMS methodologies, policies, standards, and procedures contained within the CMS PISP unless otherwise directed by CMS in writing.
- The QIO shall comply with the Federal Information Security Management Act of 2002 (FISMA) requirements set forth in the e-Government Act of 2002.
- The QIO shall fully cooperate with (including the timely installation of CMS test software on the QIO systems) CMS audits, reviews, evaluations, tests, and assessments of QIO systems, processes, and facilities.
- The QIO shall visit the CMS security website (www.cms.hhs.gov/informationsecurity) and the QualityNet security website (http://qionet.sdps.org/training_resources/qnet_security.shtml) at least monthly for updates. Refer to the CMS (IOM Pub. 100-17) (Business Partner System Security Manual [BPSSM] – http://www.cms.hhs.gov/InformationSecurity/13_Policies.asp#TopOfPage) and related QIO program materials (http://qionet.sdps.org) for updates. The QIO shall visit the QualityNet Conference website (http://www.qualitynetonline.com/) annually for QualityNet Program and Security briefings and training opportunities. The QIO shall participate in the CMS Security Best Practices conferences and audio conferences as directed by CMS.
- The QIO shall document is compliance with CMS security requirements and maintain such documentation in the Systems Security Profile as directed by CMS.

3.3 Correct Deficiencies

- The QIO shall correct any security deficiencies, conditions, weaknesses, findings, or gaps identified by all audits, reviews, evaluations, tests, and assessments, including but not limited to, Office of the Inspector General (OIG) audits, self-assessments, QIO management review, QIO security audits, and vulnerability assessments in a timely manner.
- The QIO shall develop, in conjunction with CMS, Corrective Action Plans (CAPS) for all identified weaknesses, findings, gaps, or other

deficiencies in accordance with IOM Pub. 100-17 (BPSSM) or as otherwise directed by CMS.

- The QIO shall validate and document that corrective actions have been implemented and demonstrated to be effective.
- The QIO shall provide CAPs and quarterly progress reports to CMS as directed by CMS.

3.4 Corrective Action Attestation

The QIO shall provide attestation of corrective actions to CMS upon request.

3.5 Security Review and Verification

- The QIO shall comply with the CMS Certification and Accreditation (C&A) methodology, policies, standards, procedures, and guidelines for contractor facilities and systems (http://www.cms.hhs.gov/InformationSecurity/14_standards.asp#TopOfPage).
- The QIO shall conduct or undergo an independent evaluation and test of its systems security program in accordance with CMS Reporting Standard for Information Security (IS) Testing (http://www.cms.hhs.gov/InformationSecurity/14_Standards.asp#TopOfPage). The report should follow the template as prescribed in CMS Reporting Standard for Information Security (IS) Template (http://www.cms.hhs.gov/InformationSecurity/14_Standards.asp#TopOfPage).
- The QIO shall support CMS validation and accreditation of contractor systems and facilities in accordance with CMS' C&A methodology.
- The QIO shall provide annual certification in accordance with C&A methodology that certifies it has examined the management, operational, and technical controls for its systems supporting the QIO contract function and considers these controls adequate to meet CMS' security standards and requirements.

4. Reporting Requirements:

The QIO shall report to CMS as directed in Section F – QIO Schedule of Deliverables and the sections of the *QIO Manual* referenced in this SOW. The QIO shall use all components and adhere to all procedures of the Standard Data Processing System (SDPS) data collection and reporting systems (including those outlined in the SDPS User's Guide and Section F – QIO Schedule of Deliverables) to manage and report work performed under this SOW.

5. Confidentiality:

The QIO shall adhere to the privacy, confidentiality and disclosure requirements set forth in Section 1160 of the Act, and in Section 42 of the Code of Federal Regulation (CFR) Part 480; Section H of this contract, which limits uses and disclosures when the QIO is acting as a business associate of CMS and contains the business associate agreement required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy and Security Rules; the *QIO Manual*; and other applicable federal laws, regulations and administrative directives.

The business associate agreement requirement applies if the QIO conducts any activities on behalf of CMS' Medicare fee-for-service health plan function involving the use or disclosure of protected health information or electronic protected health information such as for payment or health care operations. The business associate agreement in Section H applies only where the QIO is serving as a HIPAA business associate of CMS' Medicare FFS health plan function, which includes conducting payment or health care operations activities. The business associate agreement does not apply when the QIO is not serving as a HIPAA business associate of CMS' Medicare FFS health plan function such as when the QIO is providing health oversight activities as defined by the Act, based on the grant of authority provided to it by CMS to conduct authorized health oversight activities.

6. Government Data:

A listing of data to be supplied by CMS and the schedule by which they will be provided appears in Section J, Attachment J-5 - Data Supplied by CMS. In general, Part A reported data will be available from the CMS Data Warehouse. CMS support contractors will create and deliver to CMS state/jurisdiction-level measurement and analytic datasets for distribution to the QIO. A QIO request for additional data or analytic datasets will be reviewed and approved by the Project Officer (PO).

7. Clinical Data Abstraction Center Subcontract:

The QIO shall sign a subcontract with the Clinical Data Abstraction Center (CDAC) and shall work directly with the CDAC on records management activities. The CDAC will (1) request medical records on behalf of the QIO; (2) work with the QIO to track which medical records have been received; and (3) track and report to the QIO on all photocopying and mailing costs incurred by providers or practitioners. The CDAC may pay the pass-through costs if the QIO chooses to include this as a provision of its subcontract with the CDAC.

The QIO may choose to subcontract additional functions to the CDAC, as it would to any other potential subcontractor. However, these subcontracting arrangements shall be handled separately from the data abstraction

subcontract and shall be individually negotiated between the QIO and the CDAC and subject to approval by the Contracting Officer (CO).

8. Coordination with Stakeholders:

The QIO may coordinate certain of its activities with those of stakeholder organizations in its state/jurisdiction working on comparable improvement efforts or interested in teaming with the QIO. Stakeholders are organizations that have common goals with those of the QIO and may include fiscal intermediaries (FIs), Carriers, Medicare Administrative Contractors (MACs), Recovery Audit Contractors (RACs), Medicare provider membership associations; health care alliances; 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; and End-Stage Renal Disease (ESRD) Networks. Coordination with stakeholders may involve creating, joining, and supporting partnerships with organizations with similar goals and objectives, or facilitating ongoing discussion among the various stakeholders. The nature of the activity to facilitate coordination must be consistent with the terms of the contract and may require advance approval from the CO.

9. Communications:

For communications activities, the QIO may use Attachment J-3 *QIO Communications Handbook* as a resource.

The QIO shall manage its resources as efficiently and effectively as possible. In this regard, CMS recognizes three major sources from which the QIO can obtain marketing materials and resources: (1) other CMS contractors, (2) the ESRD Networks, and (3) other external sources that provide non-copyrighted materials and resources. In addition, the QIO may develop its own materials.

The QIO shall make available to the general QIO community (1) any CMS-approved new materials developed by the QIO, and (2) any CMS-approved substantial adaptations by the QIO of CMS- or CMS contractor-developed materials. The QIO shall provide a copy of such materials in a file format specified by CMS to the PO.

The QIO shall adhere to review requirements with regard to media activities and/or materials supporting high-profile events and national initiatives. Once a submitted document has been approved and any required changes made, the QIO shall provide a copy of the final version to the PO.

The QIO shall adhere to the following requirements in conducting its communications activities:

a. Publications–Peer-Reviewed:

A QIO that seeks 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 CMS-issued procedures.

b. Publications–Outreach Materials:

All QIO-printed outreach material shall conform to the Department of Health and Human Services (DHHS)/CMS standards issued through CMS.

c. Use of Web Technology:

The QIO may create or maintain a website(s) on which communications pursuant to the QIO's Medicare contract activities appear. The QIO shall adhere to the following in presenting its Medicare contract-related communications on that site(s):

i. Follow the CMS Contractor Website Guidelines as specified in www.cms.hhs.gov/AboutWebsite/13_contractorwebguidlines.asp. The QIO shall refer to this website regularly for the current standards and guidelines;
ii. Follow the Accessibility and Section 508 Amendment to the Rehabilitation Act of 1973 Requirements;
iii. Follow the Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," promulgated on June 12, 2002
iv. Follow the HHS guidance promulgated on August 4, 2003 "Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons"
v. Follow any other CMS directives.
vi. Only use the website for informational purposes, no application design usage unless approved by CMS as described in section C.4.16.

d. Emergency Preparedness

Medicare beneficiaries would likely be affected in the event of many kinds of emergency situations, such as a pandemic flu outbreak. When emergency situations occur, the QIO shall assist CMS' public health efforts by disseminating information and messages as directed by CMS. CMS will utilize the QIO's relationship with providers, including its partnerships and collaborations to serve as additional channels for

communications. The QIO, in working with its state or jurisdiction's health department, shall ensure that the QIO has established point(s) of contact with the Immunization Bureau or others at the health department to assure effective dissemination of DHHS and CMS information. The QIO may, as needed, work actively within its state/jurisdiction performing activities such as:

1. Assist the health department in provider education/information;
2. Participate in the state's/jurisdiction's disaster planning process (the QIO is encouraged to establish contacts and make sure information on existing contacts remains current to ensure coordination in advance of any disaster);
3. Participate in the state's/jurisdiction's Pandemic Readiness Committee(s) as necessary to help bridge communications and mobilize physician practices (PPs), hospitals, nursing homes, home health agencies and ESRD Networks;
4. Subscribe to established listservs for emergencies/disasters and pandemics, as appropriate, to ensure consistency with message and status for pandemic readiness.

10. Education, Information and Outreach:

In performing the work of the four core Themes (Beneficiary Protection, Patient Pathways, Patient Safety and Prevention) the QIO shall incorporate various tactics in its effort to stimulate widespread positive changes in the attitudes and behavior of various target audiences such as providers and Medicare beneficiaries. To create broad impact and significant improvement in the Theme areas, a QIO is encouraged to engage in health promotion campaigns utilizing any of the tactical approaches below or its own creative strategies.

In conducting education, information and outreach, a QIO must make available to CMS a marketing (or communications) plan with specific strategies and other details for outlining the intended approach within each Theme. A QIO shall include recruitment efforts in its marketing/communications plan and is encouraged to utilize efficiencies in product development by maximizing the use of CMS-available materials.

In developing its own local products, a QIO must effectively manage adherence to CMS policy requirements and agency and Departmental directives. In addition, a QIO must utilize social marketing theories in its development of strategies and products to ensure that content, design, and dissemination appropriately conform to target audience(s).

QIO work in supporting these Themes may include but is not limited to the following:

- Promoting dialogue among providers around the discharge and receiving of patients;
- Assisting providers in meeting the communication needs of individuals who do not speak English as their primary language (i.e., are limited-English-proficient) or who are deaf or hard of hearing). Individuals are patients or potential patients (rather than hospital employees or others);
- Improving methods of communications with patients and families in various health care settings, such as the hospitals;
- Influencing community leadership to promote buy-in and community ownership in quality improvement efforts;
- Developing and supporting provider workgroups to focus more specifically on specific inter-provider transitions;
- Developing strategies and materials to improve networking with partners/stakeholders for leveraging awareness;
- Managing public recognition, including announcements of provider participation;
- Monitoring public inquiries and stimulating relations with media to help build awareness and value of the Program;
- Developing and utilizing multimedia campaigns to increase provider and/or beneficiary awareness of the Program and QIO services;
- Influencing providers and other audiences through promotion of QIO accomplishments;
- Providing tools and training to support provider changes in practice;
- Marketing and disseminating training programs that assist providers;
- Marketing materials to convey Theme messages in specific settings, such as in hospitals for use on the day of discharge;
- Identifying and developing tactical products, such as tip sheets and checklists to help empower beneficiaries;
- Assisting with targeting disadvantaged populations to ensure maximum utilization of QIO resources.

11. 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 Themes in Section C.6.

The QIO shall implement an IQC program as described in Sections 13000–13030 of the *QIO Manual*. CMS encourages each QIO to collaborate with other QIOs in developing and implementing IQC programs. The QIO shall share lessons learned regarding these IQC activities with other QIOs using the available mechanisms, including QIO conferences, newsletters, and databases. The QIO shall submit its IQC plan in accordance with Section F – QIO Schedule of Deliverables.

12. Information Collection Activities

A QIO that seeks to conduct information collection activities, including surveys, as part of its work on the Themes in Section C.6., shall do so in accordance with the Paperwork Reduction Act; Sections 12600–12670 of the *QIO Manual*; and other administrative directives.

13. Staffing

The QIO shall, to the extent necessary to carry out its contract activities, enter into arrangements with entities and individuals with expertise in the following areas:

a. Medicine, nursing, and related medical/clinical disciplines–including expertise in nursing home, home health, hospital and physician practice settings; managed care; pharmacy; and prescription drug plans;

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 and safety of care and performance improvement;

e. Epidemiology, statistics, survey research, data analysis, information systems (implementing electronic health record systems), computer science, and related empirical and analytic disciplines;

f. Social and behavioral sciences including human factors disciplines;

g. Administrative and clinical aspects of case review, including case management and the use of mediation to resolve complaints;

h. IT networking, file server, and workstation support expertise in Microsoft and Novell Technologies, Microsoft Certified Systems Administrator (MCSA) preferred;

i. Database support and administration expertise in Solaris and Oracle;

j. IT security and data management expertise with at least 3+ years IT security experience in the work of Section C.4.3.

14. Independent Evaluation

The QIO shall fully facilitate and provide requested data, subject to the QIO confidentiality provisions in section 1160 of the Act and 42 CFR Part 480, for

any evaluation of the QIO Program that the Secretary, or CMS on behalf of the Secretary, chooses to conduct using an external contractor.

15. Systems Development

The QIO shall develop software only with prior approval through their Project Officer from CMS and follow all current QualityNet Systems/Software Development Life Cycle (SDLC) procedures and rules.

C.5. OVERALL CONTRACT EVALUATION

Under this SOW, the QIO's performance in undertaking activities to carry out the requirements of each of the four Themes (Beneficiary Protection, Patient Pathways, Patient Safety and Prevention) and components within those Themes will be used to determine the QIO's success or failure in meeting the overall evaluation criteria as specified below. The QIO shall be evaluated on the Themes and components under the Theme required under the contract. If a QIO is not tasked to work on a Theme or a specific component under the Theme, the QIO will not be evaluated under that particular Theme or component. Any Special Project (SP) that the QIO may carry out will be evaluated separately and will not be considered in the overall evaluation criteria.

There will be two periods of evaluation under this SOW. The first evaluation will focus on the QIO's work in three Theme areas (Patient Pathways, Patient Safety, and Prevention) and will occur at the end of 18 months using the most recent data available to CMS. The second evaluation will examine the QIO's performance on Tasks within all four Theme areas (Beneficiary Protection, Patient Pathways, Patient Safety, and Prevention). The second evaluation will take place at the end of the 28th month of the contract term and will be based on the most recent data available to CMS. The performance results of the evaluation at both time periods (that is 18 months and 28 months) will be used to determine the performance on the overall contract.

The first contract evaluation will determine if the QIO has met the performance criteria in the Theme areas of Patient Pathways, Patient Safety, and Prevention and in the components within a Theme. The Themes or components within the Theme as appropriate will be evaluated on an individual basis with the determination relative to only that area.

The second contract evaluation will determine if the QIO has met the performance criteria in all four Theme areas of Beneficiary Protection, Patient Pathways, Patient Safety and Prevention, and in the components within the Themes. The performance on the Beneficiary Protection Theme will cover the 28-month contract period.

The results of the first and second evaluations at the end of the 18- and 28-month periods will be used to determine how the contractor performed on the overall contract in total.

18-Month Evaluation Criteria (By Theme or component of the Theme excluding Beneficiary Protection)

- Pass = Criteria met and CMS may elect the option to continue the work (and funding) of the Theme or component of the Theme where appropriate.

- Fail = Criteria not met and CMS may, among other remedies, elect NOT to continue the work (or the funding) for the Theme or component of the Theme where appropriate for the contract duration.

28-Month Evaluation Criteria (By Theme or component of the Theme including Beneficiary Protection for the 28-month contract period)

- Pass = Criteria met for Theme or component of the Theme where appropriate.

- Fail = Criteria not met for Theme or component of the Theme where appropriate.

Overall Contract Performance

- Pass = Pass on all Themes and components within the Theme at both evaluation periods

- Fail = Fail any Theme or component within the Theme in either evaluation period

If CMS chooses, CMS may notify the QIO of the intention not to renew the QIO contract, and inform the QIO of the QIO's rights under the then current statute.

The specific evaluation criteria are described below for each Theme or component within a Theme as appropriate. In general, for areas of work that have been performed under the 8th SOW or other recent QIO SOWs where historical data is available for analysis, the acceptable performance expectation is a specific target or tighter target range than for areas of work that have not been in previous SOWs and where the experience under a previous SOW demonstrated that there was a range for acceptable performance. For the purpose of determining scores for all Themes, components within a Theme, or measures within a Theme, all percentages will be rounded to two places (with the value at or above five in the thousands position [e.g., .005, .015, etc.] rounded up).

Beneficiary Protection:

- Pass = 90% of Target
- Fail = <90%

Patient Pathways

- Pass = 100%-80% of Target
- Fail = <80%

Patient Safety: Surgical Care Improvement Project (SCIP), Pressure Ulcers and Restraints

- Pass = 100% of Target
- Fail = <100%

Patient Safety: Antibiotic Resistant Infections, Medication Management

- Pass = 100%-80% of Target
- Fail = <80%

Patient Safety: Adverse Drug Events (ADEs)

- Pass = 100%-90% of Target
- Fail = <90%

Prevention: Cancer Screening, Mammograms, and Immunizations

- Pass = 100% of Target
- Fail = <100%

Prevention: Chronic Kidney Disease (CKD)

- Pass = 100%-80% of Target
- Fail = <80%

The list of measures and performance criteria for each QIO will be recorded on the CMS Dashboard, which will be available on QIOnet (http://qionet.sdps.org), the standard information system that supports the QIO Program. CMS will also post these measures on the publicly accessible CMS website (http://www.cms.gov).

CMS will monitor the QIO's performance on Themes, components within the Theme and measures within Themes against established criteria on a quarterly basis, and may take appropriate contract action (e.g., providing warning for the need for adjustment, instituting a formal correction plan, terminating an activity, or recommending early termination of a contract because of failure to meet contract timelines as specified in Section C.6.).

CMS reserves the right at any point prior to the notification of CMS' intention not to continue the option for a Theme and/or to renew the contract to adjust the expected minimum thresholds for satisfactory performance or remove criteria from a Theme or Theme component evaluation protocol for any reason, including, but not limited to, data gathered based on experience with the amount of improvement achieved during the contract cycle or in pilot projects currently in progress, information gathered through evaluation of the QIO Program overall, or any unforeseen circumstances. Further, in

accordance with standard contract procedures, CMS reserves the right at any time to discontinue a Theme or a component of a task Theme regardless of QIO performance on the Theme or component of the Theme.

C.6. THEME REQUIREMENTS

C.6.1. BENEFICIARY PROTECTION

Overview

Beneficiary Protection activities will emphasize statutory and regulatory mandated review activity and quality improvement. Primary case review categories include utilization review, quality of care review, review of beneficiary appeals of certain provider notices, and reviews of potential anti-dumping cases. Quality of care review includes the review of beneficiary complaints. In conducting reviews of beneficiary complaints, the QIO shall utilize a number of tools intended to address the beneficiary's concerns, including implementation of quality improvement activities (QIAs), surveying of beneficiary satisfaction with the complaint process and outcome, and, if appropriate, alternative dispute resolution mechanisms. The Tasks under this Theme will focus on conducting activities to meet, in an efficient and effective manner, regulatory and statutory requirements, to enhance QIO collaboration with the Beneficiary Complaint Survey Contractor, FIs, Carriers, MACs, State Survey Agencies (SSAs), and the Office of Inspector General (OIG), and to clearly establish the link between case review and quality improvement through data analysis and improvement assistance.

Task Description/Required Activities

a. Review Activities

A. Task 1. Case Reviews: The QIO shall conduct case review activities, in accordance with CMS Internet-Only Manual instructions, TOPS and SDPS Memos, and other CMS policy directives for:

1. Quality of Care Reviews

a. Sources
   i. Beneficiary complaints
   ii. Complaints other than from beneficiaries
   iii. Quality of care reviews referred by CMS or CMS-designated entities (e.g., FIs, Carriers, SSAs, OIG)

b. Other Instructions
   i. In addition to required review activities, each case is subject to utilization review if indicated
   ii. All cases involving an Ambulatory Surgical Center (ASC) shall include utilization review

2. Utilization Reviews

a. Sources

i. Hospital-requested Higher-Weighted Diagnosis-Related Groups (DRGs)
ii. Utilization reviews referred by CMS or CMS-designated entities (e.g., FI, SSA, OIG)

b. Other Instructions
i. In addition to required review activities, each case is subject to quality of care review if indicated

3. Appeals

a. Sources
i. Hospital-based notice appeals
ii. Fee-for-service (FFS) expedited appeals
iii. Medicare Advantage (MA) fast-track appeals

b. Other Instructions
i. In addition to required review activities, each case is subject to quality of care review if indicated
ii. In accordance with CMS' Internet-Only Manual instructions, TOPS Memos, and other CMS policy directives, make personnel available to receive and process appeals during applicable non-business hours.

4. EMTALA—potential anti-dumping cases

a. Sources
i. 5-day reviews
ii. 60-day reviews

B. Task 2. Quality Improvement Activities

1. A QIA is an activity initiated by the QIO that requires:

a. An identified provider or practitioner to articulate a plan or activity to improve an identified quality of care concern, and
b. The QIO to follow up to ensure that the plan is complete or the action has been taken.

2. The QIO shall :

a. For case reviews in which a quality of care concern is confirmed at the highest level of review, conduct quality improvement activities (QIAs). If it is suspected that care is being compromised or denied due to discrimination on the basis of race, color, national origin, disability, or age, the QIO shall refer the case to DHHS' Office for Civil Rights (OCR) for investigation.
b. As a result of case review data analysis, conduct at least one QIA that focuses on systems change.
c. Analyze data from all QIAs to identify trends and develop and recommend changes having wide-spread implications for quality improvement.
d. Maintain all QIA information as Quality Review Study information, as described in 42 CFR 480.101(b) and 42 CFR 480.140.

C. Task 3. Alternative Dispute Resolution

1. The QIO shall utilize alternative dispute resolution (ADR) techniques in appropriate beneficiary complaint cases in which there are determined to be no significant clinical quality of care concerns. ADR options include:

    a. Mediation (utilization of a mediator in a face-to-face meeting or telephone meeting to resolve concerns),
    b. Facilitated resolution (QIO facilitator interacts with parties to generate a resolution or agreement; does not typically involve a face-to-face meeting),
    c. External resolution (QIO facilitates direct provider-complainant communication to resolve the complaint and follows up to ensure that the direct communication occurred and no further review is needed).

D. Task 4. Sanction Activities: The QIO shall follow CMS instructions (per 42 CFR Part 1004) regarding required activities, including providing an opportunity for discussion, imposing a corrective action plan (CAP), and reporting to the OIG when the QIO identifies a case or cases meeting the criteria for either:

1. Grossly and flagrantly violating any obligation in Section 1156(a) of the Act in one or more instances, or
2. Failing in a substantial number of cases substantially to comply with any obligation imposed in Section 1156(a) of the Act.

E. Task 5. Physician Acknowledgement Monitoring: In accordance with CMS Internet-Only Manual instructions, TOPS Memos, and other

CMS policy directives, the QIO shall conduct physician acknowledgement monitoring to ensure that each hospital has on file a physician acknowledgement statement for physicians billing for services provided in that hospital.

F. **Task 6. Collaboration with CMS Contractors**. The QIO shall collaborate with the QIO Beneficiary Satisfaction Survey Contractor, SSAs, FIs, Carriers, MACs, RACs, Qualified Independent Contractors (QICs) and the OIG.

1. As directed by CMS, the QIO shall provide complete and timely information to a designated Beneficiary Satisfaction Survey Contractor and shall cooperate/coordinate with the contractor for the efficient and effective conduct of these surveys.
2. As directed by CMS, the QIO shall enter into memoranda of agreement or joint operating agreements (JOAs) with FIs, Carriers, MACs, RACs, and QICs.
3. As directed by CMS, the QIO shall collaborate with SSAs. At a minimum, the QIO shall meet with the SSA annually to discuss information exchange and areas relating to QIO contract performance in that state. The QIO shall document the discussion. If the meeting does not occur due to factor(s) outside of the QIO's control, the QIO shall document the reason(s).

G. **Task 7. Transparency through reporting.** The QIO shall:

1. On an annual basis, make available to the public the periodic medical services review report per the CMS reporting template.
2. Participate in other transparency activities as directed by CMS.
3. On an annual basis, submit a report of all QIAs completed during the year and efforts to promote quality improvement, which includes:
    a. findings related to all completed QIAs and an evaluation of the QIO's best practices resulting from completed QIAs;
    b. recommendations for future QIO initiatives, including, but not limited to, proposed QIO outreach efforts;
    c. recommendations for future CMS activities in support of findings;
    d. all QIO efforts to promote and track the adoption of system changes by other providers within the QIO's state, including the adoption of CMS identified best practices.

H. **Task 8. Quality Data Reporting.** The QIO shall:

1. Actively promote and support hospitals with the measurement and submission of quality data for reporting and Annual Payment Update (APU) purposes. The contractor must have a basic understanding of all measures, deadlines for submission, and impact on the APU.

   This includes:
   a. Clinical measures for acute myocardial infarction (AMI), heart failure (HF), pneumonia (PN), and SCIP;
   b. Hospital Consumer Assessment of Healthcare Providers and Systems;
   c. Mortality Measures data;
   d. Tools that are available to hospitals;
   e. Data submission reports;
   f. Identifying when data are successfully accepted into Warehouse;
   g. Analyzing completeness of hospital submitted data relative to claims data and hospital-reported aggregate population counts (APU)..

2. Provide technical assistance for the use of the CMS Abstraction and Reporting Tool (CART) to hospitals in the state that request support.
3. Hold statewide trainings (via Web conferencing, teleconferencing, etc.) on CMS-identified and approved topics, when new versions are released.
4. Attend all educational offerings from Hospital Reporting or SDPS on CART in order to be able to pass along shared knowledge to hospitals in its state/jurisdiction.
5. Manage the interface between the hospitals and QualityNet Exchange through the Program Resource System (PRS) by keeping the data on the status of hospitals up-to-date, including information on the CEO, hospital mailing address, hospital campus physical location, and an e-mail contact.
6. Work with all hospitals to improve the accuracy, timeliness, and completeness of data submitted to the QIO Clinical Warehouse.

I. Task 9. Communication (Education and Information):

Maintenance of beneficiary helpline: The purpose of the helpline is to provide callers with information concerning Medicare beneficiary rights and responsibilities, beneficiary protections and the various QIO programs and or initiatives. The helpline must be staffed during normal business hours with the capability to record calls received outside of those hours.

Evaluation

Minimum performance thresholds for Beneficiary Protection Tasks are displayed in Table 1. These performance measures will be assessed quarterly. As these are performance standards each threshold must be met each quarter.

Table 1 – Minimum Performance Thresholds

Performance Measure	Performance threshold
Timeliness of review	90% of all cases reviewed by the QIO will meet timeliness of review standards

In addition to minimum performance thresholds, each QIO is expected to improve its performance on specified activities on a quarterly basis.

Performance Measure		Performance Improvement	
		Quarter 1	Quarter 2-12
Beneficiary satisfaction with the complaint process	Percentage of beneficiaries completing the satisfaction survey who are satisfied or very satisfied with the complaint process	Establish baseline	Improvement over prior quarter
Beneficiary satisfaction	Percentage of complainants agreeing to complete satisfaction survey from completed complaint cases	Establish baseline	Improvement over prior quarter
Quality Improvement Activities (QIAs)	Percentage of QIAs among cases with confirmed quality of care concerns	Establish baseline	Improvement over prior quarter

Deliverables - See Section F – QIO Schedule of Deliverables

Changes in Quality of Care Measures

In accordance with the Federal Acquisition Regulation (FAR), CMS reserves the right to discontinue, change, and/or add measures. In the event that CMS alters any measure(s), CMS will, after discussions with the QIO and other interested parties, amend the contract and evaluation strategy as necessary.

THEME C.6.2. PATIENT SAFETY

Overview

QIO activities under the Patient Safety Theme will focus on five topics: improving inpatient surgical safety, reducing rates of nosocomial Methicillin-resistant *Staphylococcus aureus* (MRSA) infections, improving drug safety, reducing rates of pressure ulcers, reducing rates of use of physical restraints, and poorly performing nursing homes.

Background

The requirements of this Theme are designed to address areas of patient harm for which there is evidence of how to improve safety by improving health care processes and systems. For each topic within this Theme the goal will be to have providers working with the QIO to reach performance benchmarks on specific clinical measures as defined by the Achievable Benchmarks of Care™ method—the mean of the best care for at least 10% of the measured population (http://main.uab.edu/show.asp?durki=14527). For surgical patient safety in hospitals, the measured population will derive from the CMS Clinical Data Warehouse, and for pressure ulcer and restraint use in nursing homes, the measured populations will derive from the Minimum Data Set (MDS) data repository. The measured population for work related to MRSA infection will derive from the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). For pressure ulcer reduction in hospitals, CMS will create a suitable representative sample for the measured population.

Theme Description/Required Activities

The QIO shall conduct the following activities for each topic area of the Theme (with the exception of drug safety, for which the QIO shall conduct only #16), in accordance with Section F – QIO Schedule of Deliverables:

1. Recruit up to a specified maximum number of Medicare providers from a state pool defined by CMS

By the end of month 2 of the contract period, the QIO shall recruit providers to participate in the QIO-led project to improve quality. The potential provider recruitment pool for each state/jurisdiction is delineated in Table B. For each topic, the QIO shall recruit up to the maximum number of providers specified in Table B. There is no minimum number of provider recruits in any state/jurisdiction.

2. Analyze, rate, and catalog specific interventions and tools, as well as program and policy implementation

The QIO shall provide feedback on the effectiveness of the tool portfolio and suggest improvements.

3. **Administer and collect results of the Healthcare Leadership and Quality Assessment Tool (HLQAT) and other Patient Safety Survey Instruments.**

The patient safety survey instruments to be administered during the 9th SoW are: Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture, and AHRQ's Nursing Home Culture Survey, as directed by CMS. Utilize these tools for providing tailored and structured interventions to identified participant groups that will ultimately assist them in reaching the Achievable Benchmarks of Care™ for their specialty. The QIO shall re-administer, collect and utilize the results by the 18th month of the effective date of contract.

4. **Conduct training session(s)**

The QIO shall conduct training sessions for provider staff, survey the participants on training effectiveness, provide feedback on training effectiveness, potential improvements, and lessons learned.

5. **Persuade specific providers and their respective executives to accept and participate in a QIO-led project to improve quality**

The QIO shall obtain agreement from the executive leadership of specific providers to work on a project to improve quality.

6. **Review provider data**

The QIO shall obtain individual provider data on applicable measures. As necessary, the QIO shall obtain authorization to receive and review data where applicable.

7. For each topic, the QIO shall **convene a meeting of key members of provider staff**

8. **Coordinate a local quality improvement community for each topic**

9. **Customize tools to meet specific quality improvement goals**

10. **Distribute implementation tools**
11. **Identify improvements with implementation details**

12. **Instruct** provider staff **on measures and data collection**

13. **Review improvement cycle data** for each topic

14. **Review individual provider processes of care** for each topic

For the MRSA topic only, the QIO shall:

15. Document TeamStepps trainer course completion for a physician and nurse from their staff. The TeamStepps training will be government-furnished training.

Within a time frame specified by CMS, the QIO shall provide to CMS the names of the physician(s) and nurse(s) who successfully completed the TeamStepps Training. Information regarding the TeamStepps training may be found at http://www.ahrq.gov/qual/teamstepps/.

16. Quality Improvement Assistance – Prescription Drug Therapy

As authorized by Section 1154(a) (17), as added by Section 109(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, the QIO shall offer quality improvement assistance pertaining to Prescription
Drug Therapy to:

- All Medicare providers and practitioners
- Medicare Advantage organizations offering Medicare Advantage plans under Part C; and
- Prescription drug sponsors offering prescription drug plans (PDPs) under Part D.

This offer shall describe the QIO activities conducted under this scope of work and will invite the recipients to partner with the QIO in improving the rate of drug on drug interactions, and the rate of inappropriate drugs prescribed. When any of the above entities and the QIO agrees that they have quality goals in common, the QIO shall endeavor to work in partnership with them. This partnership may include the QIO's providing staff time and/or data provided that these efforts contribute to both organizations' quality goals. Additionally, QIOs should be willing and able to provide those seeking assistance with information and guidance on quality improvement methods. In pursuit of this effort, QIOs are encouraged to have identified readily available, public resources, such as websites, that can be ready sources of information.

Each QIO will record the number of requests for assistance under this part. For each episode of assistance provided, evaluation of this part of the QIO work shall be determined by the nature of the projects in which the QIO is engaged. The criteria shall be quantitative and shall be determined in consultation between the QIO and those seeking assistance, subject to approval of the Project Officer.

17. QIOs – Poorly Performing Nursing Homes

The QIO will provide special technical assistance to a small number of very poorly performing nursing homes.

This special technical assistance will be for the QIO to conduct a root cause analysis (RCA) with at least one nursing home in its state per year (three over three years) on the Special Focus Facilities (SFF) candidate list. CMS will review the SFF candidate list and

select the nursing homes the QIOs will work with. The survey and certification process will identify the problems and trends for each nursing home. The QIO will conduct an onsite assessment of the facility to identify the underlying causes of the performance problems that affect the facility's quality of care and prepare a RCA based on those core findings. The RCA may address--

- management capabilities, e.g., corporate, facility and the relationship between the two
- financial capabilities, e.g., fiscal structure and controls
- staffing, e.g., level of staffing, skills/education, recruitment and retention
- procedures and processes of care, e.g., adequacy, correlation between admission policy and staff capabilities
- communication, e.g., among management and staff, and staff to staff
- processes of care and outcomes for reducing pressure ulcers
- processes of care and outcomes for reducing use of physical restraints

Based on the findings presented in the RCA, an Action Plan will be developed for the facility and will include specific actions to be taken and related timelines and measurement strategies designed to bring about change in the facility to improve its compliance status.

To monitor performance, CMS will evaluate the QIO on both nursing home satisfaction with the process (survey data) and on relevant outcome data. CMS will administer a questionnaire to nursing homes to evaluate the nursing homes' perception of effectiveness of QIO technical assistance (Questionnaire to be developed by support contractor).

Measure	**description**	**TARGET 18-months**	**CRITERIA 28-months**
% improvement in quality measures	Relative improvement rate	10% relative improvement from baseline	20% mean relative improvement from baseline
% nursing home satisfaction with the QIO technical assistance	Satisfaction Score	75% or greater score on Satisfaction criteria	90% or greater score on Satisfaction criteria

To pass the first evaluation period, the QIO must meet the following criteria:

1. QIO receives a score of 75% or greater on nursing home satisfaction.
2. the first NH assisted has recorded a minimum 10% relative improvement over baseline on the outcome measures

Those QIOs not meeting the criteria to pass the first evaluation period will fail the first evaluation period.

Evaluation

See Section C.5.

First Contract Evaluation Criteria:

Successful completion of the first contract evaluation as described in Section C.5. will require completion of the following activities by the specified month in the surgery, restraints, MRSA, and pressure ulcer topics:

Months 1 – 6

Activity Detail	Month
Recruit the proposed number of providers up to a specified maximum number from a state pool defined by CMS	2
Obtain authorization to receive and review data where applicable	2
Obtain executive agreement to work on specific QI project	2
Obtain individual provider data on measures	3
Provide names of physician and nurse who successfully completed the TeamStepps Training	6
Provide QIO feedback on training effectiveness and possible improvements or lessons learned	6
Survey participants on training effectiveness	6
Collect and/or administer leadership assessment or safety cultural assessment	6

Successful completion of the first contract evaluation will require meeting the following measure results by the specified month in the surgery, restraints, MRSA, and pressure ulcer topics:

Months 7–12

		Month		
Measure	**Topic**	**7**	**9**	**12**
Hospitals with an Active Surveillance Program	MRSA	0%	10%	20%
Wound Treatment of Identified Pressure Ulcers	Pressure Ulcers	0%	20%	30%
Preventative Measures	Pressure Ulcers	0%	15%	25%
Improvement of Long-Stay Nursing Home Residents Who Were Physically Restrained	Restraints	0%	0%	5%
Hospitals with pre or postoperative venous thromboembolism (VTE) protocol	SCIP	0%	10%	15%
Hospitals with an established prophylactic antibiotic protocol or policy	SCIP	10%	25%	30%

Successful completion of the first contract evaluation will require meeting the following measure results by the specified month in the surgery, restraints, MRSA, and pressure ulcer topics:

Months 13 – 18		Month		
Measure	**Topic**	**13**	**15**	**18**
Hospitals with an Active Surveillance Program	MRSA	20%	30%	50%
Wound Treatment of Identified Pressure Ulcers	Pressure Ulcers	30%	40%	45%
Preventative Measures	Pressure Ulcers	25%	30%	40%
Improvement of Long-Stay Nursing Home Residents Who Were Physically Restrained	Restraints	5%	5%	10%
Hospitals with pre or postoperative VTE protocol	SCIP	15%	20%	20%
Hospitals with an established prophylactic antibiotic protocol or policy	SCIP	30%	35%	40%

Second Phase Evaluation (Months 19 – 36)

Successful completion of the second contract evaluation will require meeting the following deliverable in the surgery, restraints, MRSA, and pressure ulcers:

Activity Detail	Month
Re-administer or collect leadership or safety culture assessment between 18-35 months	35

Furthermore in this second contract evaluation, each topic (SCIP, MRSA, restraints, pressure ulcers) is equally weighted and the "grade" for each topic the cumulative average for each measure of each provider recruited. The grade for each provider will be based on the percentage of the re-measurement score relative to the baseline Achievable Benchmarks of Care™ for each measure with 70% as the minimum average passing score for each topic with recruited providers. The pool of providers for the Achievable Benchmarks of Care ™ standard will be:

SCIP	National: CMS Clinical Data Warehouse
MRSA	National: NHSN providers reporting MRSA rates
Restraints	National: MDS reporting Nursing Homes
Pressure Ulcer (NH)	National: MDS reporting Nursing Homes
Pressure Ulcer (Hosp)	National: CMS random sample

Final Evaluation Measures

Topic	Measure	Measure Description	Repository

Topic	Measure	Measure Description	Repository
MRSA	MRSA1	Infection Rate	NHSN
	MRSA2	Transmission Rate	NHSN
Pressure Ulcers	Pressure Ulcer 1	High-Risk Long-Stay Residents Who Have Pressure Sores	MDS
	Pressure Ulcer 3	Patients with hospital acquired pressure ulcers	TBD
Restraints	Restr1	Long Stay Residents Who Were Physically Restrained	MDS
SCIP	Card 2	Surgery Patients on a Beta Blocker Prior to Arrival Who Received a Beta Blocker During the Perioperative Period	CART/ORYX
	Inf 1	Prophylactic antibiotic received on time--within one hour prior to surgical incision (2 hours for vancomycin).	CART/ORYX
	Inf 2	Prophylactic antibiotic selection for surgical patients	CART/ORYX
	Inf 3	Prophylactic antibiotics discontinued within 24 Hours after surgery end time	CART/ORYX
	Inf 4	Cardiac Surgery Patients With Controlled 6 a.m. Postoperative Serum Glucose	CART/ORYX
	Inf 6	Surgery Patients with Appropriate Hair Removal	CART/ORYX
	Inf 7	Colorectal Surgery Patients with Immediate Postoperative Normothermia	CART/ORYX
	VTE 1	Surgery Patients with Recommended VTE Prophylaxis Ordered	CART/ORYX
	VTE 2	Surgery Patients Who Received Appropriate VTE Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	CART/ORYX
Prescription Drug Safety	DDI	Drug-Drug Interactions	Medicare Claims Data
	PIM	Potentially Inappropriate Medications	Medicare Claims Data

Changes in Quality of Care Measures

In accordance with the FAR, CMS reserves the right to discontinue, change, and/or add measures. In the event that CMS alters any measure, CMS will, after discussions with

the QIO and other interested parties, amend the contract and evaluation strategy as necessary.

Support

For the MRSA topic, CMS will make available instruction and resource material for AHRQ TeamStepps.

Table A: Patient Safety Template: Data Collection Methods
Data Collection Methods for non-measure specific deliverables

Activity	Activity Detail	Deliverable Vehicle	Vehicle Description
Analyze, rate, and catalog specific tool, program, and policy implementation	Provide feedback on topic specific tool portfolio completeness and effectiveness	QualityNet	
Assess provider leadership and cultural assets and liabilities	Re-administer or collect leadership or safety culture assessment between 18-36 months	Cultural leadership survey-AHRQ Patient Safety Survey, Hospital Quality & Leadership Culture Assessment Tool Survey or equivalent approved by PO	Electronic version of AHRQ cultural assessment tool as well as CMS leadership survey.
	Collect and/or administer leadership assessment or safety cultural assessment	Cultural leadership survey	Electronic version of AHRQ cultural assessment tool as well as CMS leadership survey.
Conduct topic specific training sessions	Survey participants on training effectiveness	Training feedback survey	Electronic standardized training feedback survey
Recruitment: persuade specific providers, and their respective executives, to accept and participate in a QIO led quality improvement project (QIP)	Obtain executive agreement to work on specific QIP	Provider Sign-up Page	Secure, password protected web page with passwords assigned to CEO and delivered to him/her via QIO. This sign-up page is dedicated to QIO/provider signup, provides for unenrollment, with time/date stamp logging of each entry.

Activity	Activity Detail	Deliverable Vehicle	Vehicle Description
Review individual provider's topic specific quality improvement data	Obtain authorization to receive and review data where applicable	NHSN Data use Agreement	See "Obtain executive agreement to work on specific QIP."
	Obtain individual provider data on measures	NHSN interface	All measures, except MRSA, have CMS sponsored or endorsed data collection tools and warehousing. MRSA data will be collected per standard NHSN protocol and the hospital will agree to share/provide the data to CMS/QIO.

Table B: State maximum provider pools by topic:

This table is a listing of the providers in each topic with whom the QIO will work. Each of these providers has specific quality deficiencies – In short, each provider has a realizable quality deficit relative to a well-accepted benchmark in our measures that the QIO is expected to improve. The table and associated label is included to convey the relative size of the individual state pools and, for the purposes of any one individual QIO contract, will be removed and replaced with a state specific tally of the number of potential providers for each topic. This list will be provided at a later date. Below are the criteria used to create Table B.

- SCIP: Hospitals that score 30 points or more below the Achievable Benchmarks of Care™ for SCIP Infection 1 and SCIP Infection 3—on time prophylactic antibiotics and prompt discontinuance of prophylactic antibiotics respectively.

- Restraints: Nursing homes 6 or more percentage points away from the restraints goal of 5%.

- Pressure Ulcer: Nursing homes 15 or more percentage points away from the pressure ulcer goal of 5%. The hospitals listed for this topic were selected because of their proximity (in the same county) as nursing homes that are 15 or more percentage points from the pressure ulcer goal of 5%.

- NHSN: Hospitals that are reporting data to CDC's NHSN. MRSA-related data is included in the NHSN.

State	Pressure Ulcer Hosp	Pressure Ulcer Nursing Home	Restraints	SCIP	NHSN
AL	37	19	6	19	5
AK	0	0	0	1	1
AZ	50	11	14	21	5
AR	40	28	114	13	1
CA	364	190	575	129	21
CO	29	15	31	14	50
CT	27	25	17	3	5
DE	3	2	1	1	7
DC	7	4	0	2	4
FL	144	88	189	37	16
GA	73	60	57	39	8
HI	8	1	2	3	0
ID	2	2	6	5	1
IL	158	171	79	40	15
IN	81	58	52	27	4
IA	24	18	10	7	4
KS	45	30	10	15	1
KY	33	32	36	22	7
LA	128	83	112	42	11
ME	8	5	4	1	2
MD	34	29	18	8	10
MA	79	33	43	4	5
MI	75	48	68	10	22

State	Pressure Ulcer Hosp	Pressure Ulcer Nursing Home	Restraints	SCIP	NHSN
MN	23	8	13	9	3
MS	34	25	55	13	7
MO	76	74	92	25	10
MT	15	10	1	4	1
NE	6	1	4	3	2
NV	20	6	14	14	1
NH	8	3	2	0	0
NJ	83	138	36	4	11
NM	22	8	21	11	0
NY	172	119	33	30	197
NC	40	32	102	19	23
ND	5	5	2	2	1
OH	135	97	135	25	14
OK	98	91	130	14	14
OR	32	14	19	14	7
PA	152	65	48	46	45
RI	9	11	4	0	0
SC	25	16	34	10	61
SD	12	11	4	3	0
TN	61	35	72	27	31
TX	250	100	142	111	8
UT	4	4	27	10	1
VT	1	1	0	2	13
VA	38	52	9	18	11
WA	54	21	10	10	11
WV	21	16	8	4	4
WI	41	24	13	5	12
WY	3	3	1	4	0

THEME C.6.3. PREVENTION

Background

The Prevention Theme contains two cancer screening Tasks (breast cancer and colorectal cancer (CRC) two immunization asks (influenza and pneumococcal), and Tasks on disparities related to diabetes self-management and chronic kidney disease (CKD) prevention.

Breast Cancer Screening (Mammography)

Breast cancer is the most common non-skin cancer in women and the second leading cause of cancer death in women in the U.S. Every woman is at risk, and this risk increases with age. The National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER) in its Cancer Statistics Review 1975-2003 estimates that, based on current rates, 12.7% of women born in the U.S. today will develop breast cancer at some time in their lives based on breast cancer statistics for the years 2001 through 2003.[1] In 2005, an estimated 40,000 women died from breast cancer. The overall incidence of breast cancer has declined from a rate of 140.8 per 100, 000 females in 1998 to 124.2 per 100,000 in 2003 according to NCI's SEER Cancer Statistics Review 1975-2003. From 1969–2003, the rate of women dying from breast cancer has varied, depending on women's race and ethnicity. In 2003, Black women were more likely to die of breast cancer than any other group. White women had the second highest rate of deaths from breast cancer, followed by women who are Hispanic, American Indian/Alaska Native, and Asian/Pacific Islander.

All women with Medicare age 40 and older are covered for a screening mammogram every 12 months. Medicare also pays for one baseline mammogram for women with Medicare between ages 35 and 39. There is a 20% co-payment for this (but no deductible). Medicare also pays for one baseline mammogram for women with Medicare between ages 35 and 39. In 2007, reimbursement for Medicare providers averages about $90 for plain film mammograms and $130 for digital mammograms. Medicare Part A & B paid for about 3.5 million mammograms in 2004. Estimated fee-for-service (FFS) costs were approximately $350 million. Inpatient hospital costs exceeded $200 million for women 65 and over with a principal diagnosis of breast cancer in 2004.[2]

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[1] Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov).

[2] Weighted national estimates from HCUP Nationwide Inpatient Sample (NIS), 2004, Agency for Healthcare Research and Quality (AHRQ), based on data

The United States Preventive Services Task Force (USPSTF) found fair evidence that mammography screening every 12-33 months significantly reduces mortality from breast cancer. Evidence is strongest for women aged 50-69, the age group generally included in screening trials. The USPSTF concluded that the evidence can be generalized to women aged 70 and older (who face a higher absolute risk for breast cancer) if their life expectancy is not compromised by co-morbid disease. The USPSTF recommends screening mammography, with or without clinical breast examination (CBE) every 1-2 years for women aged 40 and older.[3]

The percentage of women aged 52-69 that received at least one mammogram in 2 years was about 59% for Medicare beneficiaries enrolled in FFS payment plans in 2004. Screening rates were considerably higher in Medicare Advantage (MA) plans, overall. For example, the National Committee on Quality Assurance's (NCQA's) "State of Health Care Quality 2006 Report" lists the mammogram screening rate for Medicare Advantage as 71.6% for women aged 50-69, reported for 2005.[4] It should be noted, however, that FFS rates are based on all paid mammograms (screening and diagnostic), but unpaid claims are not counted.

QIO interventions that support Health Information Technology (HIT) have the potential to improve screening rates by timely notification of providers and patients when a mammogram should be scheduled. Since Medicare beneficiaries enrolled in Medicare Advantage plans have higher mammogram rates, the QIO might be able to improve screening rates for FFS beneficiaries by using approaches that have been relatively more successful under Medicare Advantage.

Colorectal Cancer Screening

CRC is the third most commonly diagnosed cancer and the second most common cause of cancer death in the U.S. About 145,290 new cases occurred in 2005 with 56,290 deaths.[5] Between 1997 and 2001, the incidence per 100,000 age-adjusted to the U.S.

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collected by individual States and provided to AHRQ by the States. (www.ahrq.gov)

[3] http://www.ahrq.gov/clinic/uspstf/uspsbrca.htm

[4] The State of Health Care Quality 2006, National Committee for Quality Assurance, Washington, D.C. (http://www.ncqa.org/Communications/SOHC2006/SOHC_2006.pdf)

[5] American Cancer Society, Colorectal Cancer Facts & Figures: Special Edition 2005,

Standard Population was 63.4 for males and 46.4 for females. Age-adjusted mortality was 25.3 and 17.7 per 100,000 for males and females, respectively, during this time period.[6] The lifetime risk of being diagnosed with CRC is about 5.9% in men and 5.5% in women. About 91% of new cases occur in individuals older than 50, and the incidence rate of CRC is more than 50 times greater in persons aged 60-79 than in those younger than 40. Overall, CRC incidence rates have been declining since 1998, possibly reflecting increased detection and removal of precancerous polyps. The prevalence of CRC is estimated to be about 770,000 for Americans 65 years of age and older. Among patients diagnosed with CRC between 1995 and 2000, the 5-year relative survival rate was about 90% for those diagnosed with localized stage, about 67% for those diagnosed for regional stage, and about 10% for those with distal stage disease.

Current Medicare coverage for people aged 50 and older includes[7]

- Fecal Occult Blood Test (FOBT) - Once every 12 months
- Flexible Sigmoidoscopy - Once every 48 months
- Screening Colonoscopy - Once every 24 months (if at high risk); once every 10 years, but not within 48 months of a screening sigmoidoscopy (if not at high risk)
- Barium Enema - covered every 24 months if at high risk for CRC and every 48 months if not at high risk.

The costs of CRC screening vary considerably depending on the screening tests. The most sensitive test is colonoscopy which is the costliest; the least sensitive test is FOBT, the least costly. The American Cancer Society reports the following cost ranges for the four predominant CRC screening tests:

- FOBT—less than $20
- Flexible sigmoidoscopy-$150-$200
- Double-contrast barium enema-$300-$400
- Colonoscopy-$400 or more

These costs do not include facility fees and ancillaries. Medicare may reimburse providers at a lower rate than listed above. For example, current Medicare reimbursement for colonoscopy (Current Procedural Terminology (CPT) code 45378) is around $318 in an ASC and about $150 in a physician's office.[8]

(http://www.cancer.org/downloads/STT/CAFF2005CR4PWSecured.pdf).

[6] Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov).

[7] Preventive Services: Colon Cancer Screening: http://www.medicare.gov/health/coloncancer.asp

[8] http://www.cms.hhs.gov/HealthCareConInit/01_Overview.asp#TopOfPage (accessed 01/09/2007).

Beneficiaries pay 20% of the Medicare-approved amount for colonoscopy, flexible sigmoidoscopy, and barium enema. They pay 25% of the Medicare-approved amount if the test (colonoscopy, flexible sigmoidoscopy) is done in a hospital outpatient department. There is no co-pay for FOBT.

The USPSTF strongly recommends that clinicians screen men and women 50 years of age or older for CRC.[9] The USPSTF found fair to good evidence that several screening methods are effective in reducing mortality from CRC. The USPSTF concluded that the benefits from screening substantially outweigh potential harms, but the quality of evidence, magnitude of benefit, and potential harms vary with each method.

Medicare claims from 1998 - 2002 suggest that only about 31% of beneficiaries have ever had a CRC screening test.[10] The National Committee for Quality Assurance (NCQA) in its The State of Health Care Quality 2006 reports the Medicare beneficiaries enrolled in managed care health plans had a 53.9% CRC screening rate for 2006 based on the Health Plan Employer Data and Information Set (HEDIS) measure for CRC screening. Rates for 2004 and 2005 were, 49.5% and 52.6%, respectively.

QIO interventions that support HIT have the potential to improve screening rates by timely notification of providers and patients when a CRC screening should be scheduled. Since Medicare beneficiaries enrolled in Medicare Advantage have higher CRC screening rates, the QIO might be able to improve screening rates for FFS beneficiaries by using approaches that have been relatively more successful under Medicare Advantage.

Influenza Immunization

Influenza (flu) is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. The best way to prevent the flu is by getting a flu vaccination each year. According to CDC, every year in the U.S., on average:

- 5% to 20% of the population get the flu;
- more than 200,000 people are hospitalized from flu complications; and

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[9] U.S. Preventive Services Task Force: Screening for Colorectal Cancer: http://www.ahrq.gov/clinic/uspstf/uspscolo.htm

[10] Overview: Colorectal Cancer Screening: (http://www.cms.hhs.gov/ColorectalCancerScreening/).

- 36,000 people die from flu.[11]

Vaccine can be effective in preventing secondary complications and reducing the risk for influenza-related hospitalization and death among adults ≥65 years with and without high-risk medical conditions (e.g., heart disease and diabetes). Among elderly persons not living in nursing homes or similar chronic-care facilities, influenza vaccine is 30%--70% effective in preventing hospitalization for pneumonia and influenza.[12] Among older persons who do reside in nursing homes, influenza vaccine is most effective in preventing severe illness, secondary complications, and deaths. Among this population, the vaccine can be 50% - 60% effective in preventing hospitalization or pneumonia and 80% effective in preventing death, although the effectiveness in preventing influenza illness often ranges from 30% to 40%.[13] In a study of inactivated vaccine that included all age groups, cost utility (i.e., cost per year of healthy life gained) improved with increasing age and among those with chronic medical conditions. Among persons aged ≥65 years, vaccination resulted in a net savings per quality-adjusted life year (QALY) gained.

Influenza vaccination levels among adults aged ≥65 years remain well below the Healthy People 2010 objective of 90% coverage nationwide. Immunization rates based on survey data are as much as twice those based on claims data. The mean flu vaccination rate for this surveyed population was 74%—73.5% for FFS and 76.9% for Medicare Advantage. There is a need for more effective strategies for delivering vaccine to high-risk persons, their healthcare providers, and household contacts.

Pneumococcal Pneumonia Immunization

CDC reports the annual incidence of invasive pneumococcal disease as greater than 50 per 100,000 in the 65 and older population. This translates to more than 21,000 cases of invasive pneumococcal disease in the 65 and over population on an annual basis. Medicare pays for one pneumococcal vaccination for all beneficiaries. One vaccine at age 65 generally provides coverage for a lifetime, but for some high risk individuals, a booster vaccine is needed. Medicare will pay for the booster vaccine for high risk

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[11] http://www.cdc.gov/flu/keyfacts.htm (accessed January 29, 2007)

[12] Mullooly JP, Bennett MD, Hornbrook MC, et al. Influenza vaccination programs for elderly persons: cost-effectiveness in a health maintenance organization. Ann Intern Med 1994;121:947-52.

[13] Patriarca PA, Weber JA, Parker RA, et al. Efficacy of influenza vaccine in nursing homes. Reduction in illness and complications during an influenza A (H3N2) epidemic. JAMA 1985;253:1136-9.

individuals if 5 years have passed since their last vaccination. Medicare pays separate rates for the administration and cost of the vaccine.

With approximately 13,800 discharges at an average payment of approximately $7,700 per discharge, Medicare inpatient hospital reimbursements for pneumococcal pneumonia are currently about $106.3 million annually. CMS reports approximately 1,000,000 initial vaccinations of Medicare beneficiaries in 2001. At a reimbursement of $27.08 for the vaccine and its administration, the payments for immunization are about $27.1 million annually. This is approximately one quarter of total inpatient hospital expenses for pneumococcal pneumonia, a favorable cost ratio if vaccination decreases hospitalization by 25%.

For persons aged ≥65 years, CDC recommends a one-time revaccination if they were vaccinated ≥5 years previously and were aged ≤65 years at the time of primary vaccination[14]. Based on data from the CAHPS survey conducted by CMS for 2004, the pneumococcal vaccination rate was about 67.7% for combined FFS and Medicare Advantage beneficiaries. This is far from the Healthy People 2010 goal of 90%.

Task Description

The QIO shall work with a selected group of participating practice (PPs) in its state/jurisdiction with already implemented electronic health records (EHRs) which have been certified by a certifying body recognized by the Secretary to improve breast cancer and CRC screening rates and to improve immunization rates for influenza and pneumococcal pneumonia. As a condition of enrollment, PPs shall agree to implement care management processes using their certified EHR that include breast cancer and CRC screening and influenza and pneumococcal vaccination for at least 75% of their patients or patient encounters. A further condition of enrollment is the agreement by a PP to report their practice results for these preventive measures.

As directed by CMS, the QIO shall provide complete and timely information to a designated Survey Contractor and shall cooperate/coordinate with the contractor for the efficient and effective conduct of these surveys. In addition, the QIO is expected to obtain consent from any quality improvement participant allowing the QIO to provide identifiable information to a CMS contractor for purposes of customer/program satisfaction survey/evaluation.

EHR Requirements of Participating Practices

To be enrolled as a PP, the practice site's EHR must have all of the following capabilities:

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[14] Recommended Adult Immunization Schedule * United States, October 2006 – September 2007, Centers for Disease Control, Atlanta Georgia. (http://www.cdc.gov/nip/recs/adult-schedule-11x17.pdf) accessed 1/1/07.

- Maintain problem and/or diagnosis list;
- Identify specific patients by age and disease or disease risk;
- Create printed patient-specific care plans,
- Be certified by a recognized certifying body.

Care management processes must have been implemented in at least one of the following clinical topics:

- Hypertension,
- Diabetes,
- Preventive Services,
- Heart Failure, or
- Coronary Artery Disease

Definition of a Physician Practice:

For the purposes of this Theme, a Physician Practice includes only those physicians engaged in Solo or Group Practice as follows.

Solo Practice: To be included as a PP, a solo practice must be a medical practice of one full-time physician (i.e., one who practices more than 34 hours per week) with a primary specialty designation of General Practice, Family Practice, Internal Medicine or Geriatrics (Geriatrics is usually a Certificate of Added Qualifications earned by either an internist or family physician).

Group Practice: To be included as a PP, at least 40% of the full-time physicians in the practice (i.e., one who practices more than 34 hours per week) must be primary care physicians (i.e., physicians who have a primary specialty designation of General Practice, Family Practice, Internal Medicine or Geriatrics). (A Certificate of Added Qualifications in Geriatric Medicine does not change the status of a physician whose primary specialty designation is other than General Practice, Family Practice, or Internal Medicine.)

Practice Site: Is defined as the single place (office or site) where 50% or more of the PP provides care. Urgent care centers are not included as PP sites. Primary specialty designations are self-attested by the physician(s). A participating practice site shall submit to the QIO a practice site readiness assessment form and a signed consent form that meet CMS requirements for these forms.

NOTE: Each PP shall sign a form to be kept on file by its QIO consenting that the practice authorizes the release of all practice-level or de-identified patient-level data that are relevant to completion of the Prevention Task of the 9th SOW to the education contractor and the support contractor.

Definition of Reporting Data: For the purposes of the 9th SOW practices shall utilize, where available, health information technology systems and products that meet recognized interoperability standards, as the practices implement, acquire, or upgrade

their health IT systems. "Recognized interoperability standards" are interoperability standards that have been recognized by the Secretary of Health and Human Services in accordance with guidance developed by the Secretary. (See Executive Order (E.O.) 13410, published on August 22, 2006). To help ensure compliance with this provision, the 9th SOW contract requires that practices use EHRs that have been certified by a recognized certifying body, such as CCHIT, provided the EHRs were implemented, acquired or upgraded at a time when such interoperable health IT systems and products were available. Further, after the Secretary has recognized additional interoperability standards, such as those presented by the Health Information Technology Standards Panel (HITSP), when a practice implements, acquires or upgrades its health IT systems, it must utilize, where available, health IT systems and products that meet the more recently recognized interoperability standards. If health IT products or systems that meet recognized interoperability standards are not reasonably available when the practice is implementing, acquiring or upgrading its health IT systems, the practice may electronically submit reports using software as directed by CMS. All patient level data regardless of whether it was collected with or without an EHR shall be transmitted to a QIO data repository using secure transmission mechanisms as outlined by CMS.

Tasks

Task 1: Recruitment of participating practices (PPs)

The QIO shall recruit PPs from its state/jurisdiction to participate in this Task according to the criteria for participation. In pre-contract negotiations, CMS and the QIO will agree to the targeted number of PPs. The QIO shall successfully recruit at least 80% of the target by the end of Quarter 2. Every month, through Quarter 2, the QIO will report the number of successfully-recruited practices, and will report any attrition of practices and the reason for loss, e.g., practices closed or moved out of state; or no longer provide preventive care services

Task 2: Identification of pool of non-participating practices (NPs)

Each QIO shall identify a pool of NPs from its state/jurisdiction to be used as a comparison group. The NPs must have EHR capability. The size of this pool shall not be less than 50% of the number of PPs nor more than 125% of the number of PPs. For each PP and NP, the characteristics in the below table (solo or group, size of practice, etc.) shall be listed to help CMS create a matched sample of PPs and NPs for each state/jurisdiction. The QIO shall submit this list to the support contractor by the end of quarter 2 of the contract.

Note: Matching PPs and NPs will be performed by CMS or the support contractor. The PPs and NPs shall be matched on practice characteristics such as those that follow to protect against selection bias. The final list of PPs and NPs will be provided to the QIO by the end of month one of the contract.

Level of Characteristic:	Characteristic:
1. Baseline rates	For all clinical measures

2. Practice Characteristics:	Solo or Group
	Number of Physicians (size of practice)
	Urban or rural location
	Utilization of electronic clinical information (ECI) or no such utilization
	"denominator size" of a solo practice
	Practice affiliation/network/ownership
3. Provider Characteristics:	Primary specialty designation

Task 3: Promote Care Management Processes for Preventive Services using EHR

The QIO shall provide assistance to each PP in use of their EHR to: redesign and/or implement care management and patient self-management for preventive service needs.

The QIO shall educate each PP on using its EHR capabilities to improve rates of breast cancer and CRC screening and immunizations, using Doctor's Office Quality Information Technology - University. Every month, the QIO shall submit to CMS the number of practices that have received at least 2 hours of this post-recruitment education (in-person or by telephone). All Intervention Group Practices (PPs) shall complete this initial education by the end of the 7th month.

At the 18th month, at least 80% of the responding PPs will report tracking of each preventive service for at least 75% of their patients or patient encounters. This will be assessed by the Office Systems Survey (OSS).

Task 4: Completion of Assessment of Care Processes

The QIO will administer a CMS-developed "Assessment of Care Processes" to each PP. This tool will serve as a baseline assessment of PP care processes and EHR capabilities. The results of this Assessment will be reported to CMS by the end of Quarter 3.

Task 5: PP Data Submission

Each PP will use its certified EHR to report breast cancer and CRC screening and influenza and pneumococcal immunization data directly to the CMS clinical data warehouse. Alternately, the PP may generate an electronic report of this information from its EHR and transmit using software as directed by CMS. Each PP shall report the number of ordered as well as the number of performed screens and immunizations for the defined populations for each quarter. PPs shall report screens and immunizations performed in both at their practice sites and in other venues such as in the community. While it is recognized that PPs may not be aware of the occurrence of all screens and immunizations that they do not perform or specifically order, the PPs shall collect this information from patients that make up the defined populations. Reporting will begin during Quarter 3 and continue quarterly thereafter. Every two weeks, beginning Quarter 3, the QIO will report to CMS the number of PPs that are reporting data via each of these methods, and the actual rates each PP reports. Data will be reported by either directly

extracting information from the practices' EHR or in the case of practices without this functionally, by a CMS-defined data abstraction tool. In either case a common report format will be generated that will contain information regarding what test were ordered and what results were available for the patient. HITSP standards will be used for this process provided they are available on a time line that will support the 9th SOW. CMS will reflect the HITSP standards in future regulation changes, manual provisions, or other issuances.

Task 6: QIO monitoring of statewide rates (mammograms, CRC screens, influenza immunizations, pneumococcal pneumonia immunizations) and disparities

The QIO shall monitor and track the statewide rates for all four measures for its state/jurisdiction on a quarterly basis and report those rates -- including the numerators and denominators -- to CMS at the end of each quarter. Recognizing that these data are not available on a real-time basis, the QIO shall submit the most recent quarterly data available at this time with the data time lag noted.

The QIO shall demonstrate an understanding of disparities in rates (mammograms, CRC screening, influenza and pneumococcal pneumonia immunizations) in its state/jurisdiction by including a "report on disparities" as part of this quarterly report.

Task 7: Completion of Office System Survey (OSS)

CMS-developed OSS shall be completed by all PPs and NPs by the end of Month 16. This will assess practices' EHR capabilities and current care processes related to breast and CRC screening and immunizations. Ninety-percent (90%) of PPs and 65% of NPs will complete the OSS. Agreement to complete the OSS shall be a Condition of Participation for PPs.

Task 8: An Annual Report showing the baseline and rates for PPs and the statewide trends on each measure: The Annual Report shall include a self-assessment, barriers to performance and CAPs and shall be submitted by the QIO to CMS.

Task 9: The QIO shall submit plans to optimize performance based on experience to date (18 months).

Core Prevention: Evaluation

Establishment of Baseline Rates

The baseline period for the cancer screening and immunization measures for the population cared for by physicians with EHR capabilities will be in the reporting quarter of April – June 2008.

Minimum performance improvement thresholds for "core" prevention Tasks (mammography, CRC, influenza vaccination and pneumococcal vaccination) are

displayed in Table 1. Data lag issues need to be taken into account in setting performance targets that are challenging but attainable. There is typically a six-month (two-quarter lag) between the time services are provided (e.g., mammograms) and the time those services are reported. Table 1: Minimum Performance Improvement accounts for the data lag. Note that the recruitment targets are not affected by data lag issues; only the clinical measures are affected by this factor.

The consequences of failing to meet deliverables and performance criteria are described in Section C.5.: Theme Requirements and Evaluation. Table 1 lists the minimum performance improvement thresholds for all four Tasks in core prevention.

Table 1: Minimum Performance Improvement for Core Prevention Tasks

Thresholds for Core Prevention Tasks

Period when Measure is Reported	**Minimum # PPs[1] (% Total of recruits)**	**Relative Improvement Rate (%)[2]**			
		BC Screen-ing	**CRC Screening**	**Flu Immuni-zation**	**Pneumococcal Pneumonia Immunization**
Baseline	0%	N/A	N/A	N/A	N/A
Quarter 1	40%	0%	0%	0%	0%
Quarter 2	80%	0%	0%	0%	0%
Quarter 3	80%	0%	0%	0%	0%
Quarter 4	80%	0%	0%	0%	0%
Quarter 5	80%	2%	3%	2%	2%
Quarter 6	80%	3%	5%	3%	3%
Quarter 7	80%	5%	7%	5%	5%
Quarter 8	80%	6%	9%	6%	6%
Quarter 9	80%	7%	10%	7%	7%
Quarter 10	80%	8%	12%	8%	8%
Quarter 11	80%	9%	14%	9%	9%
Quarter 12	80%	10%	15%	10%	10%

[1] Same for all Tasks.

[2] Relative Improvement Rate = ($Quarter_n$ –Baseline / Baseline)

Note: Actual reported rates will be rounded to two decimal places using the standard rules for rounding.

To pass the first evaluation period (see Section C.5.), the QIO must meet the following criteria:

1. 80% of targeted PPs actually recruited;

2. 90% of recruited practices having received initial post-recruitment education on the Task, and

3. 70% of recruited practices electronically reporting quality data to the QIO, CMS, or a support contractor.

Breast Cancer Screening

In developing the specifications for calculating mammogram rates, an attempt was made to be as consistent as possible with the technical specifications used by NCQA for its HEDIS® effectiveness of care measure for breast cancer screening. The QIO shall be evaluated on the mammogram rate improvement using the following numerators and denominators:

Baseline:

Numerator: Number in denominator who received one or more screening mammograms in the previous two-year period.

Denominator (Eligible or "At Risk" Population): Number of women patients appearing in the PP's patient registry at the beginning of the contract who were between the ages of 52 and 69 and continuously enrolled in FFS Medicare Part B for at least 22 months.

Quarterly and Final Remeasurement:

Numerator: Number in denominator who received one or more screening mammograms within 24 months of the last day of the quarterly or final remeasurement period.

Denominator (Eligible or "At Risk" Population): Number of females appearing on the PP's patient registry on the last day of the quarterly or final remeasurement period who were aged 52-69 at that time and who were continuously enrolled in FFS Medicare B for at least 22 months prior to that time.

The codes used to identify mammograms will be updated annually. For more information on the HEDIS measure upon which this measure is based, refer to: https://www.qualitynet.org/qmis/measureDetailView.htm?measureId=10122&viewType=1

CRC Screening

The QIO will be evaluated on the percentage of Medicare beneficiaries 50–80 years of age who had appropriate screening for CRC. In developing the specifications for calculating CRC screening rates, an attempt was made to be as consistent as possible with the technical specifications used by the NCQA for its HEDIS® effectiveness of care measure for CRC screening as well as the current coverage for CRC screening for Medicare beneficiaries. The administrative data sets to compile the CRC screening rates will be the Medicare claims history records, Medicare enrollment records, and CRC screening data that can be supplied electronically by providers receiving intensive assistance from the QIO. The QIO will be evaluated on the CRC screening rate improvement using the following numerators and denominators:

Baseline:

Numerator: Number in denominator who received any of the following:

- FOBT within one-year of the beginning date of the baseline period.
- flexible sigmoidoscopy within four years of the beginning date of the baseline period.
- double contrast barium enema within four years of the beginning date of the baseline period.
- colonoscopy within ten years of the beginning date of the baseline period.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on the PP's patient registry on the last day of the quarterly or final remeasurement period who were aged 50-80 at that time and who were continuously enrolled in FFS Medicare B for at least 22 months prior to that time.

Remeasurement:

Numerator: Number in denominator who received any of the following:

- FOBT within one-year of the beginning date of the remeasurement period.
- flexible sigmoidoscopy within four years of the beginning date of the remeasurement period.
- double contrast barium enema within four years of the beginning date of the remeasurement period.
- colonoscopy within ten years of the beginning date of the remeasurement period.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on the PP's patient registry on the last day of the quarterly or final remeasurement period who

were aged 50-80 at that time and who were continuously enrolled in FFS Medicare B for at least 22 months prior to that time.

The codes used to identify CRC screens are updated annually.

Influenza Immunization

The QIO shall be evaluated on its influenza immunization rate improvement using the following numerators and denominators:

Baseline:

Numerator: Number in denominator who received one or more influenza immunizations within 12 months of the end of the reporting quarter.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on the PP's patient registry at the beginning of the contract who were aged 65 or older and continuously enrolled in FFS Medicare Part B for at least 22 months

Quarterly and Final Remeasurement:

Numerator: Number in denominator who received one or more flu shots within 12 months of the last day of the quarterly or final remeasurement period.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on PP's patient registry on the last day of the quarterly or final remeasurement period who were aged 65 or older at that time and who were continuously enrolled in FFS Medicare B for at least 22 months prior to that time.

The codes used to identify flu vaccinations are contained in attachment Q and will be updated annually.

Pneumococcal Pneumonia Immunization

The QIO shall be evaluated on its pneumococcal pneumonia immunization rate improvement using the following numerators and denominators:

Baseline:

Numerator: Number in denominator who received at least one pneumococcal pneumonia immunization in their lifetime.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on the PPs' patient registry at the beginning of the contract who were aged 65 or older and continuously enrolled in FFS Medicare Part B for at least 22 months

Quarterly and Final Remeasurement:

Numerator: Number in denominator who received at least one pneumococcal immunization in their lifetime.

Denominator (Eligible or "At Risk" Population): Number of patients appearing on the PP's patient registry on the last day of the quarterly or final remeasurement period who were aged 65 or older at that time and who were continuously enrolled in FFS Medicare B for at least 22 months prior to that time.

The codes used to identify pneumoccocal pneumonia vaccinations are contained in attachment Q and will be updated annually.

Deliverables

See Section F – QIO Schedule of Deliverables

Support

This Section lists the support activities that will be provided by the support contractor(s) to the QIO. The QIO will receive Information technology (IT) support from contractors and from SDPS. Performance measure rates will be analyzed and reported quarterly and will be used to validate QIO statewide reported rates throughout the contract. These data will also be used to assess relative performance of the PPs with that of statewide performance. Statewide data on disparities (racial/ethnic) in rates will also be analyzed and reported. In addition, a support contractor will aggregate data, track progress, and compare measures for the PPs and the comparison groups.

THEME C.7. SUB-NATIONAL REQUIREMENTS

THEME C.7.1. PREVENTION DISPARITIES (DIRECTED)

Background and Overview

From 1980 through 2005 diabetes has plagued our society. The number of diabetics has more than tripled (5.8 million to 20.8 million) through those years. The diagnoses of diabetes for African American and Hispanic patients continue to grow and far exceed the diagnoses of diabetes for Caucasians across all age groups. Compared to Caucasians, African Americans are 1.6 times more likely to be diagnosed with diabetes and suffer from complications related to the disease, i.e., kidney failure, eye disease, and amputations.

The Institute of Medicine (IOM) acknowledges that racial and ethnic minorities tend to receive a lower quality of healthcare than non-minorities. It is also noted that published research reveals that racial and ethnic minorities are less likely to receive routine medical procedures than Caucasians. One study also supports the fact that African Americans patients with diabetes were less likely to have their hemoglobin A1C (HbA1C) measured, lipids tested and eyes examined than Caucasians. African Americans had fewer routine physician visits and more visits to the emergency room.

Diabetes Self Management Education (DSME) is a proven intervention for allowing patients to control their disease by working with their health care provider. Whether the health care provider is a community health worker and/or certified diabetes educator, education is the key and DSME supports this fact. Educating beneficiaries about their disease allows the beneficiary to better understand that it is crucial to control levels of blood glucose, blood pressure and blood lipids by receiving preventive care. Education also helps the beneficiary to understand the complications that can result from diabetes, i.e., amputations, eye disease, kidney failure, etc.

Task Description

This Task is directed and shall be limited to a sub-set of states with sufficient underserved Medicare diabetes populations, as determined by CMS. A QIO with a contract in one of the following 33 states is eligible for this Task: **AL, AR, AZ, CA,CT, DC*, DE, FL, GA, HI, IL, IN, KY, LA, MA, MD, MI, MO, MS, NC, NJ, NM, NY, OH, OK, PA, PR*, SC, TN, TX, VA, WA, WI.**

***Note**: DC and PR technically are not states, but both have large numbers of Medicare diabetic underserved populations. The 33 “states” were selected based on the number of Medicare diabetic underserved within the state (having at least 5,000). This threshold was chosen so that the intervention (outreach efforts to spread DSME) would have

sufficient measurable impact and that CMS would be cost-efficient in its deployment of intervention activities.

The QIO shall work with practice sites and other organizations in its state/jurisdiction to improve diabetes measures within underserved populations. The QIO will be categorized into four peer groups based on the number of Medicare-underserved diabetics in the state, according to the latest available CMS FFS claims data using the Diabetes Quality Improvement Project (DQIP) criteria for definition of the diabetes population. Those with fewer than 15,000 diabetics are in Peer 1; those with 15,000 to 24,999 are in Peer 2, those with 25,000 to 59,999 are in Peer 3, and those with 60,000 or more are in Peer 4. Each Peer group shall include underserved practice sites with at least the minimum percentage of the Medicare-underserved diabetes population provided in Table A. For all Peer Groups, Medicare-underserved diabetes patients must represent at least 25% of the practice site Medicare diabetes population. Each PP must also have an average of the diabetes measures within the lower 50th percentile for the state.

Table A. Peer Groups and assigned age
Underserved Medicare Diabetic population

Peer Group	Number of Medicare Diabetic Persons	Minimum Underserved Population
1	<15,000	15%
2	15,000 to 24,999	10%
3	25,000 to 59,999	5%
4	>60,000	At least 2,500 persons

The QIO will identify both the practice sites and the ancillary organizations (e.g., health centers, senior centers, churches, etc.) that they will work with as part of the DSME RFP process. The QIO will facilitate training of appropriate personnel (e.g., nurses, Certified Diabetes Educators [CDEs], Community Health Workers [CHWs], etc.) at the identified organizational sites using evidence-based CMS-approved DSME programs within the underserved population of the PPs. See Appendix A for CMS-approved DSME programs.

The QIO will establish a partnership with the primary care physician (PCP), CDE, and CHW to facilitate the accessibility of DSME services to patients. The PCP is required to refer the patient for DSME. The CDE under the CMS payment rules (42 CFR Subpart H, sections 410.140-410.146) provides DSME. The CHW, while not an identified team member under 410.144, is an outreach extension into the community to the underserved populations to provide non-clinical aspects of DSME within a culturally-sensitive manner. This approach fits within the CMS payment model; minimizes the need for physician involvement (which historically has been very difficult to obtain), and provides for great inclusion of the underserved population that DSME has not historically been able to reach within the community where these persons with diabetes reside.

The QIO will need to assess the diabetes population through a CMS-approved environment scan to determine if previous or current diabetes education efforts have

occurred in this population, including participation with Medication Therapy Management (MTM), or other diabetes-related management activities that targeted underserved populations. CMS will provide an approved-environmental scan assessment tool. This environmental scan will include active or recent MTM programs related to the target population to determine educational needs of patients and its relationship to diabetes self-management. The QIO will obtain an agreement with the entity authorized to provide training under 42 CFR 410.141(e) before its activities begin.

As directed by CMS, the QIO shall provide complete and timely information to a designated Survey Contractor and shall cooperate/coordinate with the contractor for the efficient and effective conduct of these surveys. In addition, the QIO is expected to obtain consent from any quality improvement participant allowing the QIO to provide identifiable information to a CMS contractor for purposes of customer/program satisfaction survey/evaluation.

Task Definitions:

Underserved Population: Those persons who are African-American, Hispanic/Latino, Asian/Pacific Islander, or American Indian/Alaska Native as defined by the data source utilized for evaluation measurement. These data sources will be either the CMS Enrollment Data Base or claims processed through Physician Quality Reporting Initiative (PQRI).

Practice Site: Is defined as the single place (office or site) where 50% or more of the PP provide their care. Urgent care centers are not included as PPs. Practice sites may include any specialty, so long as they include the appropriate Medicare diabetes population.

Tasks

Task 1: **Recruitment of PPs**

The QIO shall recruit PPs from its state/jurisdiction to participate in this Task according to the criteria for participation specified above. There is no specific number of PPs that the QIO is required to recruit, other than the thresholds provided. The QIO shall submit the number, if any, of PPs that have "disenrolled". See Section F – QIO Schedule of Deliverables.

Task 2: **Submission of list of intervention participants that the QIO attempted to recruit as a PP** - See Section F – QIO Schedule of Deliverables

The QIO shall submit to CMS the actual number of practices it has attempted to recruit to the Intervention Group (PP) as well as the number of practices that it successfully recruited (PP) weekly until the end of recruitment. Recruitment shall close at the end of week 25. The QIO shall submit a final recruitment report to CMS by the end of week 26 of the contract. See Section F – QIO Schedule of Deliverables.

Task 3: **Identification of Matched Control Groups**

Results will be compared to improvement within both a state-specific and national comparison group.

I. The QIO will provide an Excel spreadsheet containing the identification of all physician practice sites with underserved diabetes patients during the latest 4 quarters of data available prior to August 1, 2008. The spreadsheet will include name and address of the practice site, number of practitioners at the site, number that are primary care, total number of diabetes patients, number of underserved diabetes patients, and individual and summary diabetes measures for each practice site. See Section F – QIO Schedule of Deliverables.

II. Randomly selected non-participating (NP) practice sites, excluding the PPs identified by the QIO within the RFP process, will be matched to PPs by CMS. The selection will range from 12 to 25 based on the size of the PP.

III. A national randomly selected sub-set of practice sites will be selected out of the remaining NP sites, by CMS.

Task 4: **Submission of Monthly completion report**

The QIO shall submit to CMS the number of patients that have completed a CMS-approved DSME program using the CMS-provided template on a monthly basis. As part of the reporting, the QIO will include data for each patient on the Diabetes Knowledge and Patient Activation Survey results for each patient completed at the start and end of the educational program. This data will allow CMS a continuous monthly assessment of progress and outcome measures. The progress measures are 1) completion of the DSME training, and 2) assessment of diabetes knowledge/skills. The outcome measures are the diabetes clinical measures. See Section F – QIO Schedule of Deliverables.

Task 5: **Submission of list of PQRI-reporting PP**

The QIO shall submit to CMS weekly until the end of the contract the number of practices reporting data through the PQRI, the numerators and denominators for all the measures being used for each practice as well as the measure rates for each practice. The QIO shall aggregate rates for each measure for each reporting period and report the combined totals for the PP in a CMS specified format. The QIO shall also submit the number of PPs calculating their own rates with each weekly report. See Section F – QIO Schedule of Deliverables.

Task 6: **QIO monitoring of statewide diabetes rates**

The QIO shall monitor and track the statewide rate for all diabetes measures for its state/jurisdiction on a quarterly basis and report those rates, including the numerator and denominator to CMS at the end of each quarter. Reporting shall include non-underserved, underserved, and appropriate racial/ethnicity rates for the state. Recognizing that these data are not available on a real-time basis, the QIO shall submit the most recent quarterly data available at this time with the data time lag noted. See Section F – QIO Schedule of Deliverables.

Task 7: **QIO monitoring of other diabetes education activities in its state/jurisdiction**

The QIO shall report on a quarterly basis, all identified diabetes education activities occurring within the state with special attention to those directed at underserved populations. Identification of entity providing the education, details concerning the event, and the results of the activity (if available), will be included. This report will be included with the deliverable for Task 5 on a quarterly basis. See Section F – QIO Schedule of Deliverables.

Task 8: **An annual report showing the baseline and rates for PPs and the statewide trends on each measure**

The annual report shall include a self-assessment, barriers to performance, and CAPs shall be submitted by the QIO to CMS. See Section F – QIO Schedule of Deliverables.

Task 9: **All QIOs will submit plans to optimize performance based on experience of data (12th and 18th month)**. See Section F – QIO Schedule of Deliverables.

Task 10: **All QIOs will submit a report of their experience in the Task using a CMS-provided template (28th Month)**. See Section F – QIO Schedule of Deliverables.

Disparities Reduction Evaluation

To pass the first evaluation period (see Section C.5.), the QIO must meet the following criteria:

1. 80% of targeted participating practices actually recruited.
2. 25% of targeted patients enrolled in the project.

Minimum performance improvement thresholds for the disparity (prevention) Task are displayed in Table 2. Data lag issues need to be taken into account in setting performance targets that are challenging but attainable. In this Task, there is typically a six-month (two-quarter lag) between the time services are provided and the time those services are reported. The table accounts for this data lag. Note that the recruitment targets are not affected by data lag issues; only the clinical measures are affected by this factor.

Table 2 lists the minimum performance improvement thresholds for the entire Task.

Table 2: Minimum Performance Improvement Thresholds for Disparity Task

Period when Measure is Reported	Min # PPs (% Total recruited)	Min # of patients (% Total Completed)	Relative Improvement Rate (%)[1]			
			Hemo-globin (HbA1c)	Eye Exam	Lipids	Blood Pressure Control
Baseline	0%	0%	N/A	N/A	N/A	N/A
Quarter 1	40%	0%	0%	0%	0%	0%
Quarter 2	80%	5%	0%	0%	0%	0%
Quarter 3	80%	10%	2%	1%	2%	1%
Quarter 4	80%	15%	5%	2%	5%	2%
Quarter 5	80%	20%	8%	3%	8%	3%
Quarter 6	80%	25%	10%	5%	10%	5%
Quarter 7	80%	35%	12%	6%	12%	6%
Quarter 8	80%	45%	15%	8%	15%	8%
Quarter 9	80%	55%	17%	9%	17%	9%
Quarter 10	80%	65%	20%	10%	20%	10%
Quarter 11	80%	70%	22%	12%	22%	12%
Quarter 12	80%	70%	25%	15%	25%	15%

[1] Relative Improvement Rate = ($Quarter_n$ –Baseline/Baseline)

Note: Actual reported rates will be rounded to two decimal places using the standard rules for rounding.

Diabetes:

Both PQRI and CMS FFS claims data will be utilized for measurement. The PQRI measures will be the primary measure for evaluation.

I. The PQRI measures utilized are:

- Item #1: HbA1c Poor Control in Type 1 or 2 Diabetes Mellitus; percentage of patients aged 18-75 years with diabetes (Type 1 or Type 2) who had most recent HbA1c greater than 9.0%.

- Item #2: Low Density Lipoprotein (LDL) Control in Type 1 or 2 Diabetes Mellitus; percentage of patients aged 18-75 with diabetes (Type 1 or Type 2) who had most recent LDL-C level in control (less than 100% Mg/dl).

- Item #3: High Blood Pressure control in Type 1 or Type 2 Diabetes Mellitus; percentage of patients aged 18-75 with diabetes (Type 1 or Type 2) who had most recent blood pressure in control (less than140/80 mm Hg).

- Item #18: Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy; percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months.

- Item #19: Diabetic Retinopathy: Communication with the Physician Managing ongoing Diabetes Care; percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed, with documented communication to the physician who manages the ongoing care of the patient with diabetes, regarding the findings of the macular or fundus exam at least once within 12 months.

II. The CMS Part A/B claims data utilized are the following measures:

- **Denominator criteria**:

  i. Medicare patients who had Part B coverage for at least 11 months of the one-year measurement period AND FFS coverage for at least 11 of the past 12 months
  ii. Are 18-75 years of age,
  iii. Have a ICD-9-CM code of 250.XX, 357.2, 362.01, 362.02, 366.41, 648.0X;
  iv. Have at least one inpatient visit or emergency department claim representing a face-to-face encounter with a principal or secondary diagnosis of diabetes during the measurement year, OR
  v. Two or more hospital outpatient, physician office, home health agency or SNF claims representing face-to-face encounters with different dates of service with a diagnosis of diabetes during the measurement year.
  vi. Alive on the last day of the measurement year.

- HbA1c; Patient received HbA1c testing at least once within a 12 month period;
- Eye Exam; Patient has received a diabetic eye exam within the past 12 months;
- Lipids; Patient has received Lipid testing within the past 12 months.

These measures are based on the Diabetes QIP (DQIP). The DQIP is a coalition of public and private entities founded in 1997 which developed and approved these measures. CMS has been using the DQIP/NCQA-approved measures since 1999. The denominator of the DQIP measures is based on the assessment of the diabetic patient over

a one-year time frame. The DQIP acknowledges that the definition for the denominator is a conservative assessment of the diabetic population.

Baseline:

Numerator: Number in denominator who received one or more of each diabetic indicator between August 1, 2007 and July 31, 2008.

Denominator (Eligible or "At Risk" Population): Number of Medicare persons age 18-75 with a diabetes diagnosis

Quarterly and Final Remeasurement:

Numerator: Number in denominator who received one or more of each diabetic indicator within 12 months of the last day of the quarterly or final remeasurement period.

Denominator (Eligible or "At Risk" Population): Number of Medicare persons, aged 18 – 75 with a diabetes diagnosis.

Deliverables

See Section F – QIO Schedule of Deliverables

Support

1. IT Contractors and SDPS
2. Rates will be analyzed and reported quarterly and will be used to validate QIO statewide reported rates throughout the contract. These data will also be used to assess relative performance of the PPs with that of statewide performance.
3. Evaluation contractor will aggregate and track progress and compare measures for three groups of physician practices: (1) intervention group, (2) Comparison Group A, and 3) Comparison Group B.

Appendix A

CMS Approved Diabetes Self-Management Education Programs

Background

Diabetes Self-Management Education (DSME) is an approach that has been demonstrated to be effective in improving diabetes clinical outcomes and other related health dimensions. DSME is an intervention in itself for diabetes behavior and outcomes improvement. DSME can be administered via professionals (e.g., Registered Nurses, Pharmacists, Research Developers, etc.) other Certified Diabetes Educators and may also include peer-to-peer education via Community Health Workers (CHWs) or other lay heath workers.

The definition of quality diabetes education most frequently used by diabetes educators is found in the National Standards for DSME. These are published each January in a supplement to the journal Diabetes Care. In these standards, the term DSME is defined as "an interactive, collaborative, ongoing process involving the person with diabetes and the educator(s). This process includes 1) assessment of the individual's specific educational needs; 2) identification of the individual's specific diabetes self-management goals; 3) educational and behavioral intervention directed toward helping the individual achieve self-management goals; and 4) evaluation of the individual's attainment of identified self-management goals."

While there are few standardized curriculums available, CMS will require the QIO to work with CMS-approved programs based on either the Chronic Disease Model developed by Stanford University or the Empowerment model developed as part of CDC's Racial and Ethnic Approaches to Community Health (REACH) 2010 initiative.

The Chronic Disease Management Model was originally tested within the Stanford Arthritis Self-Management Education program. Since that time Stanford has built on its previous successful results and developed several other programs to provide disease education and life skills training within several different chronic diseases, including diabetes.

The REACH 2010 empowerment model is a national, multi-level initiative that is the cornerstone for CDC's efforts to eliminate racial and ethnic disparities in health. REACH 2010 is based on a cooperative agreement program currently involving at least 40 communities to close the health disparity gap in at least one of the racial/ethnic minority groups in the U.S., in one of six health priority areas, which includes diabetes mellitus. The CDC provides training, technical assistance and support to REACH communities in understanding the social determinants of health and their relation to health disparities, developing and implementing effective interventions, evaluating programs, disseminating findings, and writing for scientific publications. REACH

supports community coalitions in designing, implementing and evaluating community-driven strategies to eliminate health disparities. Each coalition comprises a community-based organization and three other organizations, of which at least one is either a local or state health department or a university or research organization. The activities of these community coalitions include continuing education on disease prevention for health care providers, health education and health promotion programs that use lay health workers to reach community members, and health communications campaigns. REACH programs are built around five stages to guide the collection of qualitative and quantitative data:

1. Capacity Building – Community coalition actions to reduce disparities.
2. Targeted Actions – Intervention activities believed to bring about a desired effect.
3. Community/Systems Change – Changes to the community environment and to the knowledge, attitudes, beliefs and behaviors of influential individuals or groups.
4. Widespread Risk/Protective Behavior Change –Changes in rates of risk-reduction behaviors among a significant percentage of community members
5. Health Disparity Re-education – Narrowing gaps in health status.

Disparity Task CMS-Approved DMSE Programs for QIO use

Currently, two CMS-approved DMSE programs exist which the QIO may utilize for conducting the Disparity Task. The programs are:

1) Project Dulce is produced by the Scripps Institute in La Jolla, California. The project has a focus on diabetes care and education focused on working community-based organizations. The project has been developed for African-American, Hispanic/Latino and Asian/Pacific Islander populations. The program uses the Chronic Disease model from Standard University as its foundation.
2) Diabetes Education Empowerment Program (DEEP) produced by the University of Illinois at Chicago. This is a REACH US-based program for Latinos and African Americans.

Stanford University Medical Center is currently working on a diabetes self-management program with English-speaking, Spanish, and on-line versions to be available by August 2008. Additionally, Dr. Robert Anderson at the University of Michigan Diabetes Research and Training Center has developed a set of teaching outlines but has not currently created a train-the-trainer program. Should a training program be developed, it will be considered as a potential CMS-approved DMSE program.

Rules for utilizing CMS-approved DMSE programs:

1. The QIO may utilize only one program within a specific patient population. That is, patients may be under only one DMSE program at a time.

2. The QIO may not alter or otherwise modify the content of the approved programs. Updates by the parent organization of the DMSE program may be utilized as they become available, but no other changes to the program itself are allowed.

3. The QIO will be able to utilize other CMS-approved programs as they are identified and evaluated.

Evaluation of additional approved programs will consist of evidence of scientifically-valid data of the DSME program with comparison data for comparable populations (either receiving another related intervention or as a control group); whether the program is recognized by the American Diabetes Association (although this is not essential if other factors are positive); and whether the program has no other significant restrictions based on cost, licensure, or other federal regulations which would prohibit adoption as deemed reasonable by the CMS GTL.

THEME C.7.2. PATIENT PATHWAYS (CARE TRANSITIONS)

NOTE: Measure specifications and additional details on measures for the Patient Pathways (Care Transitions) Theme can be found in Section J, Attachment 10 of this document. Additionally, Reference materials supporting the Patient Pathways (Care Transitions) Theme can be found in Section J, Attachment 10a of this document.

Overview

The QIO work under the Patient Pathways (Care Transitions) Theme aims to measurably improve the quality of care for Medicare beneficiaries who transition among care settings through a comprehensive community effort. These efforts aim to reduce readmissions following hospitalization[15] and to yield sustainable and replicable strategies to achieve high-value health care for sick and disabled Medicare beneficiaries.

Background

a. The process by which patients move from hospitals to other care settings is increasingly problematic, as hospitals shorten lengths of stay and as care becomes more fragmented. Medicare patients report greater dissatisfaction in discharge-related care than in any other aspect of care that CMS measures[16]. Within 30 days of discharge, 17.6 percent of Medicare beneficiaries are re-hospitalized, and the Medicare Payment Advisory Commission (MedPAC) estimated that up to 76 percent of these readmissions may be preventable[17]. Of Medicare beneficiaries who are readmitted within 30 days, 64% receive no post-acute care between discharge and readmission[18].

b. This situation can be changed. These rates of re-hospitalization, and healthcare utilization in general, vary substantially among geographic locations, suggesting opportunities for improvement in the areas with higher observed rates.[19,20] Recent studies by Coleman[21] and Naylor[22] suggest that interventions targeting comprehensive transitional care from the hospital to the community can reduce

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[15] In this contract, "hospitalization" refers to "acute care" hospitals reimbursed by Medicare in the PPS approach. This does not include critical access hospitalization that is not followed by hospitalization at a PPS hospital, nor does it include psychiatric hospitals, inpatient rehabilitation facilities, long-term acute care hospitals, or other special-purpose hospitals.
[16] Care Quality Information from the Consumer Perspective Hospital Survey (HCAHPS) Pilot
[17] MedPAC: June 2007 Report to the Congress: Promoting Greater Efficiency in Medicare.
[18] MedPAC: June 2007 Report to the Congress: Promoting Greater Efficiency in Medicare.
[19] Fisher E, Wennberg J, Stukel T, Sharp S: Hospital readmission rates for cohorts of Medicare beneficiaries in Boston and New Haven NEJM. 1994; 989-995.
[20] The Dartmouth Atlas of Healthcare, www.dartmouthatlas.org
[21] Coleman E, Parry C, Chambers S, Min S: The Care Transitions Intervention Arch Intern Med. 2006; 1822-1828
[22] Naylor M, McCauley K: The effects of a discharge planning and home follow-up intervention on elderly hospitalized with common medical and surgical cardiac conditions. J Cardiovasc Nurs. 1999; 14 (1): 44-54.

readmission rates by approximately one third. Quality improvement work, including by the QIOs with selected home health agencies, has reduced re-hospitalizations. The Veterans Health Administration has reduced re-hospitalization significantly through use of a care coordination program utilizing the conceptual framework of programming and feedback.[23] Improved healthcare processes at and after discharge correlate with substantial reductions in early re-hospitalization for particular conditions, such as heart failure.[24] In addition, prior and ongoing QIO work has assisted providers to analyze data, and to identify and address gaps in care, such as transitions and end-of-life planning and care.

c. The primary purpose of this initiative is to improve care for Medicare beneficiaries through interventions that reduce re-hospitalization. Since local areas vary substantially in healthcare utilization, the most effective interventions may depend on changes in the processes of care at a community level that engage more than one provider (including hospitals, home health agencies, dialysis facilities, nursing homes, and physician offices), as well as patients, families, and community healthcare stakeholders. The unit of intervention for this initiative is the community, and the QIO will be judged on whether it has improved results for the population of Medicare beneficiaries in the community.

d. The most effective systems changes will often affect Medicare and non-Medicare patients alike; thus, a program that reduces re-hospitalization for Medicare beneficiaries is likely also to benefit other patients. The QIO's use of contract funds, however, must produce maximum benefit for Medicare beneficiaries. The QIO must maintain relationships with many community organizations and play a coordinating and catalyzing role to ensure community-wide adoption of improved practices. Additionally, messaging among providers and the community will have the greatest impact when it is consistent among purchasers (such as health plans and employers), payers (such as insurers), providers, and public health authorities.

Task Description/Required Activities

Task 1: Community/Provider Recruitment/Selection:

A. Initial Report Characterizing the Selected Community:

The QIOs shall provide a written, site-selection report for CMS approval within 1 month of contract award. The report shall characterize the proposed geographic area and its health care delivery system and shall describe the potential origins and drivers (root causes) of observed patterns and the opportunities that current leadership and recent

[23] Gittel JH. Fairfield K, Bierbaum B, Head W, Jackson R, Kelly M, Laskin R, Lipson S, Siliski J, Thornhill T, Zuckerman J: Impact of relational coordination on quality of care, post operative pain and functioning, and the length of stay: a nine hospital study of surgical patients. Med Care 38: 807-819, 2000

[24] Philips CO. Comprehensive discharge planning with postdischarge support for older patients with congestive heart failure: a meta-analysis. JAMA. 2004; 291: 1358-67.

history provide for collaboration and vigorous improvement activities. This report shall also present the initial intervention plan (Task 2). This report shall attend to at least the following elements:

1. The presence of (and likelihood of sustaining) the will to pursue improvements in care across settings. This might arise from, for example, personal commitments of area leaders, demographic changes, and local plans to reduce hospital bed supply, or other considerations. The evidence may include, among other considerations:
    a. The presence of cooperative interventions across settings such as Certified Value Exchanges (CVEs), shared protocols, quality review, standards, or cooperative investment in needed services.
    b. The status of readiness for cooperation among providers on information technology, including RHIOs (Regional Health Information Organizations) and commitment to use the Continuity Assessment Record and Evaluation (CARE) instrument.

2. The presence of various drivers of unreliable, inappropriate, or wasteful services affecting re-hospitalization rates, and the degree to which they offer opportunities for improvement in quality.
    a. Specific medical conditions which have a substantial prevalence and cost to Medicare, and for which coordination of care has been shown to improve outcomes.
    b. Relative rates of re-hospitalization for Medicare beneficiaries;
    c. Relative rates of Intensive Care Unit (ICU) services or specialist physician services for Medicare beneficiaries; and
    d. Relative rates of utilization of other services for Medicare beneficiaries selected by the QIO.

3. A population that is defined with precision and that is expected to be reasonably stable for at least three years, and also that is appropriate for evaluation of a statistically significant impact of no less than 2% in the 30-day all-cause re-hospitalization after all-cause discharge measure (Measure 0-4a) at the end of the contract (1% over the duration of the contract). The proposal may target a more substantial impact. The report must show the calculation which confirms that the population is large enough to detect the targeted reduction in re-hospitalization (at least an 80% threshold for the likelihood of detecting the change at a $p<0.05$ level). CMS expects sites to use a ZIP code list; if a site has a more complex method to identify the population, the site must present a very specific and stable way to identify the population over the three years and must expect to provide the finder file for working with Medicare claims reliably and on-time. Once defined and approved, any change in the target population during the course of the project requires permission from CMS. May use:
    a. Geopolitical boundaries of the residence of the beneficiaries,

b. Hospital Referral Regions (HRRs) and/or Hospital Service Areas (HSAs)[25]
c. Multiple hospital-associated extended hospital medical staffs[26]
d. Other methods by which to determine a reliable and stable denominator population that matches the provider community.

4. A characterization of the target Medicare population, including, as possible, estimate of the following elements:
   a. Age
   b. Socio-economic status
   c. Ethnicity and language
   d. Mortality
   e. Rates of illnesses, causes of hospitalization or re-hospitalization
   f. Utilization of Medicare-covered services (e.g., from the Dartmouth Atlas)
   g. Potentially avoidable hospitalizations (e.g., using Healthcare Cost and Utilization Project (HCUP) and the Agency for Healthcare Research and Quality (AHRQ) definitions)
   h. Hospital-specific and regional rates of ICU use and re-hospitalization
   i. Evidence as to the presence and severity of identifiable groups of beneficiaries that experience more substantial shortcomings in care at the time of transitions, or more substantial risk of re-hospitalization.

5. A description of any particular opportunities to address disparities or any particular risks of exacerbating disparities.

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[25] From www.dartmouthatlas.org
Hospital Service Area: local health care markets for hospital care. An HSA is a collection of ZIP codes whose residents receive most of their hospitalizations from the hospitals in that area. HSAs were defined by assigning ZIP codes to the hospital area where the greatest proportion of their Medicare residents were hospitalized. Minor adjustments were made to ensure geographic contiguity. Most hospital service areas contain only one hospital. The process resulted in 3,436 HSAs, ranging in total 1996 population from 604 to 3,067,356.
Hospital Referral Region: represent regional health care markets for tertiary medical care. Each HRR contained at least one hospital that performed major cardiovascular procedures and neurosurgery. In a similar fashion, HRRs were defined by assigning HSAs to the region where the greatest proportion of major cardiovascular procedures were performed, with minor modifications to achieve geographic contiguity, a minimum population size of 120,000, and a high localization index. The process resulted in 306 hospital referral regions which ranged in total 1996 population from 126,329 to 9,288,694.

[26] From www.dartmouthatlas.org
Extended Hospital Medical Staff: identifies patients with the "virtual" medical staff that serves a particular hospital – rather than using ZIP codes as in HSAs, this process uses patterns of inter-referral among physicians and utilization of the hospital to figure out what hospital network the patient is effectively using. The extended hospital medical staff patients overlap geographically and there are more of them than HSAs.

6. A characterization of the health services delivery arrangements in the target population, including explanation of the leverage points for improvement.

7. An estimate of the expected size of the contribution of each institutional or organizational provider (with the provider name and Medicare provider number) to the overall number of transitions involving Medicare patients. The population defined by geography (#3 above) and the population served by the providers given here should overlap as extensively as possible, since some measures and interventions align with providers (e.g., hospitals) and some with geography. The analyses for the Initial Report shall estimate the alignment of the provider-based approach and the geographic approach. If the definitions given in the project proposal do not match well, the QIO and community may propose definitions that provide better alignment before the definitions are locked in for the project (no later than at the end of the first month of the contract).

8. An initial strategic plan for organization, intervention, monitoring, and decision-making that articulates how the QIO proposes to achieve the aims of this project, based upon the insights that are anchored in this evidence.

9. That strategic plan will include plans for including a broad range of community leaders and providers within the selected region, including whether each of the following potential participants will be recruited and how these decisions align with the proposed strategic plan.

    I. Regional health initiatives, community campaigns, and similar activities.

    II. State and local government: e.g., mayoral offices, legislators, state or local health departments, state or local licensing agencies

    III. Major purchasers and payers: e.g., Medicaid programs, commercial insurers, large employers, state governments

    IV. Advocacy and service organizations: e.g., Medicare beneficiary and patient advocacy organizations

    V. Healthcare providers:

        i. Hospitals

        ii. Home health agencies

        iii. Dialysis facilities

        iv. Nursing homes and rehabilitation facilities

        v. Physician practices providing follow-up care

        vi. Hospices.

    VI. The QIO shall identify all existing collaborations in the target community, such as CVEs.

VII. The QIO shall describe how it plans to facilitate relationships with these existing groups with the goal of working together to create a cohesive working and collaborative environment among health care providers in the target community.

B. Updated Reports Characterizing the Selected Community:

1. The QIO shall provide CMS at 18-, 28-, and 36-months following contract award, a report that describes and analyzes the impact that QIO efforts have had on the origins and drivers (root causes) of the observed patterns of unreliable, inappropriate, or wasteful services affecting re-hospitalization rates within the target community. Each report shall use the "Initial Report Characterizing the Selected Community" (see Task 1A) as a baseline and describe substantial changes, growing insight, and altered strategic plans. The report shall estimate the effects on the baseline quality of care at and after hospital discharge and on the rates of re-hospitalization. The report shall evaluate and include evidence as to the degree that changes, or lack of changes, are attributable to the efforts of the QIO or to other forces.
2. In addition to what is specified in Task 1.A, the 28- and 36-month reports shall analyze, evaluate and describe the rates of re-hospitalization (Outcome Measures O-4, O-5a, b, & c). This report shall fully describe the factors (both controllable and uncontrollable) that contribute to the rates seen at 28- and 36-months and provide an assessment as to the attributable impact that QIO efforts have had on these re-hospitalization rates.

Task 2: Interventions

1. **QIO Functions**: The QIO functions include, within the limits of enabling legislation and regulation, any or all of the following activities:
    a. Recruiting providers into the work.
    b. Helping parties negotiate ways to make shared decisions.
    c. Recruiting citizens, advocacy groups, and non-provider civic leaders into the work.
    d. Providing ongoing data collection and analysis services to guide the work
    e. Shaping public awareness and understanding of the project
    f. Providing assistance in prioritizing projects and selecting interventions
    g. Providing technical support for quality improvement activities
    h. Providing technical assistance for proper uses of personal health information
    i. Providing technical support for implementation of CARE instrument
    j. Supporting meetings and documentation of the process

k. Supporting processes designed to achieve accord on treatment protocols and standards of care.

l. Securing support for sustained work after the QIO contract ends

m. Assisting in providing monitoring for adverse effects.

n. Addressing patient or provider concerns for adverse effects

o. Contributing to a growing body of insight concerning how care transitions and after-hospital care can improve, and how this affects re-hospitalization

p. Assisting other QIOs and collaborating partners in solving problems in this work.

q. Reporting activities and insights to CMS

r. Making plans for sustaining the local gains and spreading successful strategies

2. **Areas of Activity**: The QIO shall catalyze cooperative quality improvement throughout the target community concerning quality care for Medicare beneficiaries at or after discharge from hospitalization. The QIO and its partners shall consider intervention efforts in three categories and will undertake improvement activities in all three, as outlined in Table 1 (Provider Processes (Interventions) for Improving Care Transitions**)**. When the QIO and its community intend to implement an intervention that is not yet listed in Table 1, the QIO must document the plan, why it is reasonable, how it will be monitored, and the risk (if any) of adverse effects and how they will be monitored. Upon approval of the GTL, the proposed intervention will be added as a supplement to Table 1:

   a. **Hospital/community system-wide interventions**: these interventions are designed to address system-level weaknesses. The QIO and its partners shall select at least one intervention listed on Table 1.

   b. **Interventions that target specific diseases or conditions**: evidence-based practices and process that are designed to have an impact on rates of re-hospitalization for that particular condition (e.g., Acute Myocardial Infarction (AMI), Congestive Heart Failure (CHF), Pneumonia (PNE)). The QIO and its partners shall select at least one intervention listed on Table 1.

   c. **Interventions that target specific reasons for readmission**: interventions tailored to the address the reasons/causes that drive local readmission rates. The QIO and its partners shall select at least one intervention listed on Table 1.

3. **Intervention Plan:** Based on the findings from Task 1, and addressing each of the three focus areas, the QIO shall partner with appropriate

community health care providers to develop and implement an evolving Intervention Plan. The initial intervention plan will form part of The Initial Report Characterizing the Selected Community, due within the first month of the contract under Task 1.A. Updated reports will be due for the 18 month and 28 month revisions (see Task 1.B). To do so, the QIO shall:

a. Collaborate with existing organizations to set priorities and to generate the commitment to test and adapt interventions aimed to improve patient transitions from hospitals and between other health care providers. This will yield an evolving intervention plan with community collaborators which will be tailored to the local community and achieve improvements in quality and value as measured in Task 4.

    i. At a minimum, the QIO shall lead the target community through interventions found on Table 1 in the following categories, and shall report as described in Outcome Measure O-3 (see appendix A):

        1. Medication Management
        2. Plan of Care
        3. Post-Discharge Follow-up

    ii. Additionally, the QIOs shall work with the target communities to implement and use the CARE instrument (an internet-based instrument to support high quality clinical care, and more equitable payment policies) by March 1, 2009. Implementation of CARE shall be reported as Outcome Measure O-6 (see Appendix A).

        1. CMS shall provide Train-the-Trainer style instruction to QIO personnel (scheduling to begin within 2 months of contract award).

b. Assist the providers (and, as appropriate other parties) to implement selected interventions and monitor the effects.

c. Generate analyses and interpret findings to providers and practitioners as well as patients, families, payers, purchasers, local government entities, and other stakeholders.

d. Implement ways to monitor for intended and unintended consequences of the effort (such as creation of barriers to timely appropriate hospitalizations);

e. Promote shared payer-purchaser strategies to encourage implementation of interventions;

f. Participate in a collaborative learning community convened by the theme support QIO, including conference calls, meetings, on-line communications, shared problem-solving, and development of expertise in the QIOs and in their communities.

4. Data and Analysis Methods Supplied

a. Databases:

i. By November 1, 2008 and annually thereafter, CMS will supply a database to the QIO with the following characteristics.

1. Selected by the intersection of beneficiaries living in the ZIP codes specified by the QIO (at the time of hospital discharge) (Task 1.3) and beneficiaries using the hospitals specified by the QIO (Task 1.7) in the third quarter of the prior year (initially, 2007).

2. The utilization of services and diagnoses for one year prior and six months after the third quarter of the prior year (initially 2007).

ii. By November 1, 2008 and semi-annually thereafter, CMS will supply a database to the QIO with the following characteristics:

1. Selected by the intersection of beneficiaries living in the ZIP codes specified by the QIO (Task 1.3) and beneficiaries using the hospitals specified by the QIO (Task 1.7) in the quarter that begins nine months earlier (initially, the first quarter of 2008).

2. The utilization of services and diagnoses for one year prior and one month after that quarter (initially the third quarter of 2007).

iii. The databases will include variables as listed in Appendix C.

iv. Databases may be received and analyzed by the QIO or by the theme support QIO. At all times, the data use must comply with the provisions governing privacy and use that apply to QIOs.

b. Analytic methods:

i. By November 1, 2008, CMS will supply statistical analysis system (SAS) code necessary to calculate the rates given in the sample table in Appendix C. These rates may be shared as appropriate with the participating providers.

ii. By November 1, 2008, CMS will supply SAS code necessary to generate the sequential record of claims on a particular patient as given in the samples in Appendix C. At this time, these records cannot be shared with the participating providers, though insights arising from the QIO scrutiny of them can be shared.

iii. All QIOs that do new analyses in these databases will contribute to a shared and documented library of SAS code that will be maintained by the theme support QIO and at CMS.

Task 3: Monitoring and Reports

1. **Plans and Reports**.

   a. **The Initial Report Characterizing the Selected Community, including the Initial Intervention Plan**. Within one month of the contract execution date (CED), the QIO shall submit an Initial Report Characterizing the Selected Community, including the Initial Intervention Plan (As specified in Task 1.A and 2.3). This report shall be an update of the plan submitted in response to the Request for Proposal (RFP) and shall be submitted in accordance with Section F – QIO Schedule of Deliverables. The initial report must include:

      i. A plan to engage with and recruit on a time schedule consistent with the initial strategic plan:

         1. Health care providers

         2. Regulators and public health programs (the involvement of regulators is important because many issues in re-hospitalization are also the subject of local regulation and many public health programs directly address issues in re-hospitalization).

         3. Payers and purchasers in the target community (other payers and purchasers are important because conveying consistent messages to providers will enhance the likelihood of successfully promoting change) (see definition of target community).

      ii. The report must include an updated list of provider organizations as required by Task 1, #7 above, an updated list of ZIP codes to define the community geographically, and an estimate of the degree to which the two definitions do and do not overlap. The report must explain any adjustments needed to the earlier proposed plan in order to align these two definitions.

      iii. Political, business, and union leaders; other opinion leaders; advocates for the aging (including Area Agencies On Aging), disabled, and persons with End Stage Renal Disease (ESRD); women's issues advocates; chronic disease organizations (e.g., Alzheimer's, Amyotrophic Lateral Sclerosis); family caregivers; media reporters and editors; representatives of the liability industry, and other groups with the potential to be helpful or create obstacles. The plan must also include a strategic list of these individuals and the status of engagement with each.

iv. A plan for development and execution of the Intervention Plan on a time schedule consistent with the 18-month evaluation criteria. This shall include quarterly targets for recruitment and change implementation that are consistent with the 18-month criteria.

v. A plan for provision of technical assistance to groups of providers and individual providers for each of the groups of providers identified in Task 1.9.

vi. A plan to make patients and families active partners in the care transition process, including giving them the information and skills they need to play such a role.

vii. Specific details and target processes for the QIO's activities.

viii. A communications plan for the Patient Pathways (Care Transitions) Theme to address the information needs of all of the groups identified in Task 1.9, as well as patients and the public generally.

ix. An updated list of systems changes on which the QIO expect efforts to focus and the strategy for bringing about those changes.

b. Nothing in this language is intended to limit the QIO's ability to assist providers or the community in either creating resources (such as palliative care) for more effective transitions or in implementing improvement activities beyond the period of transition at hospital discharge.

c. This report will be updated in full for the 18-month evaluation and for the 28-month evaluation, as directed in Task 1.B and below in Task 3.2.a.vi. In addition, the QIO will report on its progress and revisions to the intervention plan as directed by the GTL, which will be no less than monthly (see Task 3.3 below).

2. **Narrative report on project progress**

a. To measure the qualitative aspects of the QIO's progress at 18-months and at 28 months toward full implementation of various selected interventions, the QIO shall provide CMS with a narrative response to the following questions. This will be part of the updated Report Characterizing the Selected Community as described in Task 1, 2, and 3.1.a.

i. **QIO role**: What roles do provider and public participants want the QIO to play, or to avoid playing? Is there growing accord on this, or are important schisms arising or persisting? Are these roles consistent with eventual success?

ii. **Governance**: How are the participants making decisions? Have they formalized any organization or decision-making? Is the

current pattern working reasonably well? What are the threats or dysfunctions?

iii. **Patient/family representation**: How are the voices of beneficiaries being heard? Are there representatives on working groups, or an advisory council? Are there plans to change current practices?

iv. **Public perception**: How is the project being perceived by important elements of the community (a question which will require some definition and justification of that category)? Have there been positive or negative statements by leaders, or in the press? What are the plans now for shaping public perception and addressing any challenges? What partnerships with community voices are in place or being pursued?

v. **Sustainability:** Have any plans been made to ensure that the project continues past the QIO contract period? What are they and are other steps needed?

vi. **Update on status and strategy:** Revision of the initial report in Task 1.A and Task 2.3.

3. **Reports**. In the monthly reports that the QIO submits to the Government in accordance with Section F – QIO Schedule of Deliverables, the QIO shall describe its progress in carrying out the Intervention Plan, report progress on activities that relate to the Patient Pathways (Care Transitions) Theme, and identify any areas in which adjustments to the Work Plan and IQC measures are needed. In addition, the QIO shall discuss progress on the interim and outcome measures listed below and, if that progress falls below the quarterly milestones laid out in the work plan, the QIO shall describe the correction actions that it has or will take along with the timeframe for those actions and expected results.

4. **Conference Calls/Meeting Minutes**. As directed by CMS, the QIO shall participate in regular conference calls with CMS and/or other QIOs that are engaged in the Patient Pathways (Care Transitions) Theme and contribute findings, tools, and other information that are of potential use to other QIOs. Meeting minutes shall be sent from the QIO to CMS and other parties no later than 2 working days following each meeting.

Task 4: Evaluation of Task Performance

Each project must show evidence of improved quality of care and of implementation of strategies that should reduce re-hospitalization. The overall evaluation of this theme requires that multiple local projects succeed at reducing re-hospitalization, through improved quality of care. The first set of measures below will serve as evidence that the projects implemented appropriate strategies early in the project and thus could be authorized to continue through the entire project. The second set serve to summarize the achievements with regard to the outcome goals and these will anchor the major evaluation of this theme. As appropriate, the measures incorporate flexibility so that the QIOs can propose strategies that will make measurement as

intrinsic to improvement and as helpful to the local situation as possible, while still ensuring rigorous evaluation of the overall effort.

Each project will work with CMS or its designee to name one or more (as determined by CMS) specific comparison communities that are not affected by this project and which are expected to have only the background secular trend in the society. Those communities will have roughly the same size and performance characteristics as the target communities and may be in other states. The measures noted as having comparisons available in Table 2 below will have the same measures calculated for those comparison communities, as well as for the states and the nation.

In accordance with the FAR, CMS reserves the right to discontinue, change, and/or add measures. In the event that CMS alters any measure(s), CMS will, after discussions with the QIO and other interested parties, amend the contract and evaluation strategy as necessary.

All Measures are specified more fully in Appendix A. The data bases, analyses, and timing of reporting of measures is given in Appendix C.

The summary of measure timing and use is in Table 2 and the targets for all measures are in Table 3.

1. **First Evaluation Period**:

This Task is awarded for 18 months. CMS may exercise its option to continue this work for an additional 18 months if the Minimum Acceptable Performance Thresholds interim measures for I-1, I-2, I-3, I-4, I-5 and I-6 are achieved. If the Minimum Acceptable Performance Thresholds are not achieved then CMS may, among other remedies, elect not to exercise its option to continue the work.

Minimum Acceptable Performance Thresholds					
I-1	I-2	I-3	I-4	I-5	I-6
30% of transitions	15% of transitions affected by combining I-2, I-3 and I-4			25% of transitions	10% of transitions

2. **Interim Measures Defined:**

    a. The interim measures are designed to provide part of the evaluation of the work being done in the project, at a time when it is not reasonable to expect a measurable impact upon the outcome measures above. These are all mandatory measures and will be combined with the narrative report to enable a qualitative assessment by CMS in order to make a decision as to whether to continue a project at the 18-month point.

3. **Interim Measures:**

a. **I-1 Description**: Percentage of patient care transitions (Fee for Service (FFS) Medicare) in the specified geographic area that is attributable to providers who agree to participate.

   i. **Numerator**: Transitions in the specified geographic area attributable to the providers who agrees to participate.

   ii. **Denominator**: Total transitions by Medicare FFS beneficiaries in specified geographic area.

   iii. **Data Sources –** Numerator and Denominator:

      1. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

      2. Quarterly report by the QIO as to the providers who have agreed to participate.

   iv. **Exclusions**: None

b. **I-2 Description**: Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses hospital/community system-wide processes.

   i. **Numerator**: Number of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses hospital/community system wide processes.

   ii. **Denominator**: Number of patient care transitions (FFS Medicare) in the specified geographic area.

   iii. **Data Sources**:

      1. Quarterly report by QIO of proportion of transitions attributable to each provider that are potentially affected by an implemented intervention that addresses hospital/community system wide processes.

      2. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

   iv. **Exclusions**: None

c. **I-3 Description**: Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses AMI, CHF, PNE.

i. **Numerator**: Number of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses AMI, CHF, PNE.

ii. **Denominator**: Number of patient care transitions (FFS Medicare) in the specified geographic area that involve the patients with the targeted condition (AMI, CHF, PNE).

iii. **Data Sources**:

1. Quarterly report by QIO of proportion of transitions attributable to each provider that are potentially affected by an implemented intervention that addresses AMI, CHF, PNE.

2. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

iv. **Exclusions**: None

d. **I-4 Description**: Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses specific reasons for readmission.

i. **Numerator**: Number of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses specific reasons for readmissions.

ii. **Denominator**: Number of patient care transitions (FFS Medicare) in the specified geographic area.

iii. **Data Sources**:

1. Quarterly report by QIO of proportion of transitions attributable to each provider that are potentially affected by an implemented intervention that addresses specific reasons for readmissions.

2. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

iv. **Exclusions**: None

e. **I-5 Description**: Percentage of implemented interventions in the specific geographic area that are measured.

i. **Numerator**: Number of implemented interventions in the specific geographic area that are measured.

ii. **Denominator**: Number of implemented interventions in the specific geographic area.

iii. **Data Sources** – Numerator and Denominator:

1. Quarterly report by QIO of numerator and denominator.

iv. **Exclusions**: None

f. **I-6 Description**: Percentage of patient care transitions (FFS Medicare) in the specified geographic area to which implemented and measured interventions apply.

i. **Numerator**: Number of patient care transitions (FFS Medicare) in the specified geographic area to which implemented and measured interventions apply.

ii. **Denominator**: Number of patient care transitions (FFS Medicare) in the specified geographic area.

iii. **Data Sources**:

1. Quarterly report by QIO of proportion of transitions attributable to each provider in their list to which the implemented and measured interventions apply.

2. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

iv. **Exclusions**: None

4. **Outcome Measures** (specifications in Appendix A)**:**

a. **O-1a Description:** Percentage of patients over 65 years who rate hospital performance meeting Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) performance standard for medication management.

i. **Numerator**: Number of patients over 65 years who rate hospital performance as meeting HCAHPS performance standard for medication management.

ii. **Denominator**: Number of patients over 65 years who completed an HCAHPS.

iii. **Data Source**:

1. HCAHPS survey data questions 16 and 17 and age.

iv. **Exclusions**: None

b. **O-1b Description**: Percentage of patients over 65 years who rate hospital performance meeting HCAHPS performance standard for discharge planning.

i. **Numerator**: Number of patients over 65 years who rate hospital performance meeting HCAHPS performance standard for discharge planning.

ii. **Denominator**: Number of patients over 65 years who completed an HCAHPS.

iii. **Data Source**:

1. HCAHPS survey data, questions 19 and 20 and age.

iv. **Exclusions**: None

c. **O-2 Description**: Percentage of patients discharged and readmitted within 30 days who are seen by a physician between discharge and readmission.

i. **Numerator**: Medicare FFS beneficiaries discharged alive from acute care hospital who are readmitted within 30 days and for whom a physician (including nurse practitioner or physician assistant) claim was submitted for services in the time between discharge and readmission.

ii. **Denominator**: Medicare FFS beneficiaries discharged alive from acute care hospital who are readmitted within 30 days.

iii. **Data Source**:

1. Medicare claims for the specified geographic areas for codes listed below:

a. New patient, office – 99201- 99205

b. Established patient, office – 99211- 99215

c. Consultations, office or outpatient – 99241 – 99245

d. Nursing facility, new or established – 99304 – 99310, 99315-99316, 99318

e. Domiciliary and assisted living – new – 99324 – 99328

f. Domiciliary and assisted living – established – 99334- 99337 and 99339-40

g. Home care – new – 99341- 99345

h. Home care – established – 99347 – 99350

iv. **Exclusions**:

1. Claim for dates of service for institutional post acute care in the time between discharge and readmission.

2. Claim for hospice or home care in the time between discharge and readmission.

d. **O-3 Description**: Percentage of patient care transitions (FFS Medicare), in the specified geographic area, for which implemented and measured interventions show improvement.

   i. **Numerator**: Number of patient care transitions (FFS Medicare) in the specified geographic area for which implemented and measured interventions show improvement.

   ii. **Denominator**: Number of patient care transitions (FFS Medicare) in the specified geographic area.

   iii. **Data Source**:

      1. Quarterly report by QIO of proportion of transitions attributable to each provider in their list to which the implemented and measured interventions show improvement.

      2. Proportions of transitions table. This provides the proportion of transitions in a specified geographic area attributable to each provider specified by the QIO as a potentially participating provider.

      3. Report of interventions with time series.

e. **O-4 Description**: Percentage of patients from the specified geographic area re-hospitalized within 30 days of discharge from an acute care hospital.

   i. **Numerator**: Number of hospital live discharges of patients from the specified geographic area that were re-admitted within 30 days.

   ii. **Denominator**: Number of hospital live discharges of patients from the specified geographic area.

   iii. **Data Source**:

      1. Medicare Part A claims

   iv. **Exclusions**:

      1. Transfers to another acute care hospital

e. **O-5a, O-5b, O-5c Description:** Specific Diagnosis Discharge/All-Condition 30 – day Readmission Rates (3 measures)

   v. **Measure**: 30-day all-cause risk standardized readmission rates following HF, AMI and PNE hospitalizations

   vi. **Population/Index Hospitalizations**: Discharges for Medicare fee-for-service beneficiaries age 65 or over admitted to the hospital with a principal ICD-9-CM discharge diagnosis of HF, AMI or Pneumonia and discharged alive.

iii. **Risk Standardized Readmission Rates (RSRRs):**

$$\text{RSRR} = \frac{\text{P (predicted)}}{\text{E (expected)}} * \text{National Rate}$$

Numerator of the RSRR: The number of readmissions predicted by the hierarchical model among a hospital's patients, given the patients' risk factors and the hospital-specific effect

Denominator of the RSRR: The expected readmissions among that hospital's patients given the patients' risk factors and the average of all hospital-specific effects in the nation

National Rate:

$$\frac{\text{Number of readmissions in the nation}}{\text{Number of discharges in the nation}}$$

iv. **Data Source**: Medicare administrative data including hospital inpatient and outpatient claims, physician practice claims and Medicare Enrollment Data Base file.

f. **O-6 Description**: Percentage of patient transitions within the specified geographic area for which a CARE instrument was used.

i. **Numerator**: Number of patient transitions within the specified geographic area for which a CARE instrument was used.

ii. **Denominator**: Number of patient transitions within the specified geographic area.

iii. **Data Source**:

1. CARE instrument data from CMS' Office of Information Systems.
2. Proportions of transitions table.

Care Coordination			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Medication Management • Strong evidence that medication errors and lack of medication reconciliation leads to adverse events manifested in re-hospitalizations.	Coleman, et al, 2005[27]	Good – Excellent med reconciliation correlated with reductions in readmissions for six months	65 yrs+ with 1 of 11 Dx-CHF, COPD, CAD, DM, stroke, spinal stenosis, hip frax, PVD, cardiac arrythmias, deep venous thrombosis, PE – use of Advanced Practice Nurse, English-speaking only pts.
	Schnipper et al., 2006[28]	Excellent - RCT	Hospital discharge and post-discharge at 3 to 5 days pharmacist outreach to general medicine population (not elderly), English-speaking pts only
	Lappe, et al., 2004[29]	Good – non-randomized, design pre-post, n = 57,465	D/C of any pt with primary Dx of MI, CHD, CHF or atrial fibrillation
	MedPAC, June 2007[30]		
	Kind et al, 2007[31]		
	Bernard & Encinosa, 2004[32]		
Plan of Care (POC): *Complete, accurate POC including history, situation, likely progression, patient/family preferences with end of life issues* • Complete, accurate post-discharge POC care yields more successful outcomes resulting in fewer re-hospitalizations, than	AHRQ, 2007[33]	Rating Incorporated into AHRQ's Evidence Report	

[27] Coleman et al., 2005, Post hospital medication discrepancies: prevalence and contributing factors
[28] Schnipper et al., 2006, Role of pharmacist counseling in preventing adverse drug events after hospitalization
[29] Lappe et al., 2004, Improvements in 1-year cardiovascular clinical outcomes associated with a hospital-based discharge medication program.
[30] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.
[31] Kind et al., 2007, Bouncing back: patterns and predictors of complicated transitions 30 days after hospitalization for acute ischemic stroke
[32] Bernard and Encinosa, 2004, Adverse patient safety and patient outcomes following discharge

Care Coordination			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
solely doing a "needs assessment" as a discharge planning activity.			
Post Discharge Follow-Up *Established* with *Identified* Healthcare Provider. • Facilitates adherence to medication regime, post-d/c instructions, understanding of sign/symptoms & responses needed to reduce likelihood of re-hospitalization.	Kripalani et al., 2007	Excellent-Cochrane database, 73 studies	
	Van Walraven et al., 2002	Good-888 pts	
	Jack, 2007[34]		
	Koelling et al., 2005[35]	Excellent – RCT	Chronic Heart Failure (CHF) – average age 65 yrs, 38% participation
	Forester et al, 2005[36]		
	Naylor et al., 1999[37]		
	Naylor et al., 2004[38]		
	IHI, 2007[39]		
Accountability/Responsibility/Capability: Sending and Receiving providers • Holding providers accountable for an entire episode of care, and compensating them based on the outcome of the episode, encourages collaboration across providers to improve care coordination and reduce re-hospitalization rates.	MedPAC, June 2007[40]		
Care Transitions	Coleman, et al,	Excellent- 2006 study	65 yrs+ with 1 of 11 Dx-CHF,

[33] AHRQ, 2007, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies" Volume 7: Care Coordination
[34] Jack, 2007 "Project RED: Re-engineered Discharge," Boston University. http://www.bu.edu/fammed/projectred/
[35] Koelling et al., 2005, Discharge education improves clinical outcomes in patients with chronic heart failure
[36] Forester et al., 2005, Adverse drug events occurring following hospital discharge
[37] Naylor et al., 1999, Comprehensive discharge planning and home follow-up of hospitalized elders, a randomized clinic trial
[38] Naylor et al., 2004, Transitional care of older adults hospitalized with heart failure: a randomized controlled trial
[39] Institute for Healthcare Improvement, 2007. "Transforming Care at the Bedside How-To Guide: Creating an Ideal Transition Home for Patients with Heart Failure."
[40] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.

Care Coordination			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
www.caretransitions.org-Strong evidence that use of "transition coach" contributes to reduced rate of re-hospitalization.	2004[41]; Coleman et al., 2006[42]	RCT	COPD, CAD, DM, stroke, spinal stenosis, hip frax, PVD, cardiac arrhythmias, deep venous thrombosis, PE – use of Advanced Practice Nurse, English-speaking only pts
Bridging Nurse Support– Strong evidence that use of Advanced Practice Nurse, home visit within 24-48 hours of D/C contributes to reduced rate of re-hospitalization.	Naylor et al., 1999[43]	Excellent- RCT	65 yrs+ with one of top ten Medicare Dx in 1992, 45% African American
	Naylor et al., 2004[44]	Excellent- RCT	Chronic Heart Failure (CHF) – use of Advanced Practice Nurse, English-speaking only pts, 36% African American
Clinical Protocols, Best Practices, and Regional Guidelines • Evidence that congruence of practice standards increases continuity of care among settings, supports successful transitions resulting in fewer re-hospitalizations.	MedPAC, June 2007[45]		
	AHRQ, 2007[46]		
	Trisolini et al., 2006[47]		
	IHI, 2007[48]		
Electronic Health/Medical Record • EHRs/EMRs facilitate rapid transfer of	MedPAC, June 2007[49]		

[41] Coleman et al., 2004, Preparing patients and caregivers to participate in care delivered across settings: the care transitions intervention
[42] Coleman et al., 2006, The care transitions intervention, results of a randomized controlled trial
[43] Naylor et al., 1999, Comprehensive discharge planning and home follow-up of hospitalized elders, a randomized clinic trial
[44] Naylor et al., 2004, Transitional care of older adults hospitalized with heart failure: a randomized controlled trial
[45] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.
[46] AHRQ, 2007, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies" Volume 7: Care Coordination
[47] Trisolini, et al., 2006. *Medicare physician group practices, innovations in quality and efficiency.* New York: The Commonwealth Fund. December.
[48] Institute for Healthcare Improvement, 2007. "Transforming Care at the Bedside How-To Guide: Creating an Ideal Transition Home for Patients with Heart Failure."
[49] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.

Care Coordination			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
critical information among providers to enable informed decision making, appropriate care coordination & follow through on POC to reduce likelihood of re-hospitalizations.	Rosewell, 2003[50]		
Personal Health Record (PHR) • Empowering patients and caregivers to transmit information (PHR) among care-settings contributes to improved transitions, potentially fewer re-hospitalizations.	Coleman, et al, 2004[51]; Coleman et al., 2006[52]	Good – unable to say the PHR is responsible for reductions in readmissions	65 yrs+ with 1 of 11 Dx-CHF, COPD, CAD, DM, stroke, spinal stenosis, hip frax, PVD, cardiac arrhythmias, deep venous thrombosis, PE – use of Advanced Practice Nurse, English-speaking only pts
Telemedicine • Telemedicine enhances post-discharge access to care providers, especially in rural areas and for populations with mobility challenges.	Jerant et al., 2001[53]	Expert opinion, more study is needed very small RCT (n =37 pts with 3 distinct groups)	Chronic Heart Failure (CHF) – 40 yrs+, English-speaking only

[50] Rosewell, 2003, "Transforming VA Healthcare," U.S. Medicine Information Central
[51] Coleman et al., 2004, Preparing patients and caregivers to participate in care delivered across settings: the care transitions intervention
[52] Coleman et al., 2006, The care transitions intervention, results of a randomized controlled trial
[53] Jerant et al., 2001, Reducing the cost of frequent hospital admissions for congestive heart failure: a randomized trial of a home telecare intervention

Patient, Family, Care Giver Support			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Patient/Caregiver Education • Education prepares patients and caregivers to meet post-discharge needs, facilitates access to timely/appropriate follow up care, and reduces likelihood of re-hospitalizations.	Reigel et al., 2005[54]	Good - RCT but based upon physician assignment	CHF
	Phillips et al., 2004[55]	Excellent – meta-analysis of 18 studies in 8 countries, all RCTs	Chronic Heart Failure (CHF) – 55yrs+,
	Cline, et al., 1998[8]	Good – RCT however 16 pts randomized to tx refused consent	Chronic Heart Failure (CHF), NY class III (62%), 65 -84 yrs.
	Krumholz et al, 2002[56]	Good – Prospective RCT (n = 88)	CHF- $\geq$ 50 yrs.
	Kimmelstiel et al, 2004[57]	Excellent - RCT (n = 200)	CHF, regardless of ejection fraction or NY class
	Coleman, et al, 2004[58]; Coleman et al., 2006[59]	Good – Excellent unable to say that education and coaching account for reductions in readmissions	65 yrs+ with 1 of 11 Dx-CHF, COPD, CAD, DM, stroke, spinal stenosis, hip frax, PVD, cardiac arrhythmias, deep venous thrombosis, PE – use of Advanced Practice Nurse, English-speaking only pts

[54] Reigel et al., 2005, Effect of standardized nurse case-management telephone intervention in resource use in patients with chronic heart failure
[55] Phillips et al., 2004, Comprehensive discharge planning with post discharge support for older patients with congestive heart failure
[56] Krumholz et al., 2002, Randomized trial of an education and support intervention to prevent readmission of patients with heart failure
[57] Kimmelstiel et al., 2004, Randomized, controlled evaluation of short- and long-term benefits of heart failure disease management within a diverse provider network
[58] Coleman et al., 2004, Preparing patients and caregivers to participate in care delivered across settings: the care transitions intervention
[59] Coleman et al., 2006, The care transitions intervention, results of a randomized controlled trial

Patient, Family, Care Giver Support			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Education of patients/families on advocating for interests during transfers • Patients and caregivers are consistent throughout each encounter with the healthcare system. Empowering them to transmit information among settings of care can improve transitions.	Coleman, et al, 2004[60]; Coleman et al., 2006[61]	Good – unable to say if "coaching" is responsible for reductions in readmissions	65 yrs+ with 1 of 11 Dx-CHF, COPD, CAD, DM, stroke, spinal stenosis, hip frax, PVD, cardiac arrhythmias, deep venous thrombosis, PE – use of Advanced Practice Nurse, English-speaking only pts
Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies	AHRQ, 2007[62]		

[60] Coleman et al., 2004, Preparing patients and caregivers to participate in care delivered across settings: the care transitions intervention
[61] Coleman et al., 2006, The care transitions intervention, results of a randomized controlled trial
[62] AHRQ, 2007, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies" Volume 7: Care Coordination

Provider Environment			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Feedback to sending provider as to adequacy • Provides valuable information for needed modifications in provider practice patterns to better coordinate care and reduce re-hospitalization rates.	Payne et al., 2002	Excellent - Systematic review of 53 studies on information transfer	
Multidisciplinary team with multifaceted interventions • Multidisciplinary teams facilitate community treatment, collaborative care, and shared primary-specialty care, all of which contribute to well coordinated care, lower re-hospitalization rates.	Kasper et al., 2002[63]	Good – Prospective RCT	CHF, NY Class III/IV – at risk for readmission, English-speaking,
	Rich et al, 1995[64]	Excellent – RCT-blinded	CHF – 70 yrs+, at risk for readmission, 52% treatment group was nonwhite
	Holland et al., 2005	Excellent - meta analysis, 30 RCTs	CHF – heterogeneity across studies
Rebalancing Incentives & Services Used: hospitals, SNFs, specialty services, home • Questions current policy and payment incentives with regard to delivery of appropriate post-discharge care.	MedPAC, June 2007[65]		
Community Supports (ex: transportation, Meals on Wheels, etc) • Facilitate access to needed follow-up care and services.	AHRQ, 2007[66]		
Expectations (ex: back-up phone support, response time, advanced care plan documentation)			

[63] Kasper et al., 2002, Randomized trial of the efficacy of multidisciplinary care in heart failure outpatients at high risk of hospital readmission
[64] Rich et al., 1995, A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure
[65] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.
[66] AHRQ, 2007, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies" Volume 7: Care Coordination

Provider Environment			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies	AHRQ, 2007[67]		

Multi-dimensional Approaches			
Intervention Strategies	**Supporting Evidence**	**Evidence Rating**	**Intervention Target**
Palliative Care Consultation/Support • Palliative care emphasizes care coordination, multidisciplinary teams, care planning, case management, and integrated care.	www.capc.org		
IHI "Moving the Dot" – Hospital Mortality Review Tool, ventilator bundling, multidisciplinary rounds, implement Plan-Do-Study-Act improvement cycles	Institute for Healthcare Improvement, 2003		
"Promoting Greater Efficiency in Medicare," Report to Congress	MedPAC[68]		

[67] AHRQ, 2007, "Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies" Volume 7: Care Coordination
[68] MedPAC, June 2007. "Promoting Greater Efficiency in Medicare," Report to the Congress.

Table 2. Measures: Title, Frequency, Use and Comparison Group:

Meas Num	Measure	Frequency and Use				Comparison Group
		Quality Improvement	Evaluation			
		Quarterly	18-Month	28-Month	36-Month Report	
Interim Measures						
I-1	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are attributable to providers who agree to participate.	Yes	Yes	Yes	Yes	No
I-2	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses hospital/community system wide processes.	Yes	Yes	Yes	Yes	No
I-3	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses AMI, CHF or pneumonia.	Yes	Yes	Yes	Yes	No
I-4	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses specific reasons for readmission.	Yes	Yes	Yes	Yes	No
I-5	Percentage of implemented interventions in the specific geographic area that are measured.	Yes	Yes	Yes	Yes	No
I-6	Percentage of patient care transitions (FFS Medicare) in the specified geographic area to which implemented and measured interventions apply.	Yes	Yes	Yes	Yes	No
Outcome Measures						
O-1	**Patient Assessment of Hospital Quality (HCAHPS)**					
O-1a.	Percentage of patients over 65 years who rate hospital performance as meeting HCAHPS performance standard for medication management.	Yes	No	Yes	Yes	Yes
O-1b.	Percentage of patients over 65 years who rate hospital performance as meeting HCAHPS performance standard for discharge planning.	Yes	No	Yes	Yes	Yes
O-2	Percentage of patients discharged to community and readmitted within 30 days who are seen by a physician between discharge and readmission.	Yes	No	Yes	Yes	Yes
Meas Num	Measure	Frequency and Use				Comparison Group
		Quality Improvement	Evaluation			
		Quarterly	18-Month	28-Month	36-Month Report	
O-3	Percentage of patient care transitions (FFS Medicare), in the specified geographic area, for which implemented and measured interventions show	Yes	No	Yes	Yes	No

	improvement.					
O-4	Percentage of patients from the specified geographic area re-hospitalized within 30 days of discharge from an acute care hospital.	Yes	No	Yes	Yes	Yes
O-5	**Diagnosis related 30-Day Readmission Rates**					
O-5a.	AMI Discharge and All-Cause Readmission Rates	Yes	No	Yes	Yes	Yes
O-5b.	CHF Discharge and All-Cause Readmission Rates	Yes	No	Yes	Yes	Yes
O-5c.	Pneumonia Discharge and All-Cause Readmission Rates	Yes	No	Yes	Yes	Yes
O-6	Percentage of patient transitions within the specified geographic area for which a CARE instrument was used.	Yes	No	Yes	Yes	No

Table 3: Targets for Care Transitions Measures

Measure Number	Brief Measure Name	18-Month Minimum Performance Improvement Thresholds	28-Month Performance Targets
Interim Measures			
I-1	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are attributable to providers who agree to participate.	30% of transitions	N/A
I-2	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses hospital/community system wide processes.	15% of transitions affected by combining I-2, I-3 and I-4	N/A
I-3	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses AMI, CHF or pneumonia.		N/A
I-4	Percentage of patient care transitions (FFS Medicare) in the specified geographic area that are the potential subject of an implemented intervention that addresses specific reasons for readmission.		N/A
I-5	Percentage of implemented interventions in the specific geographic area that are measured.	25% of implemented interventions	N/A
I-6	Percentage of patient care transitions (FFS Medicare) in the specified geographic area to which implemented and measured interventions apply.	10% of transitions affected	N/A
Outcome Measures			
O-1a	Percentage of patients over 65 years who rate hospital performance as meeting HCAHPS performance standard for medication management.	N/A	8% reduction in failure rate
O-1b	Percentage of patients over 65 years who rate hospital performance as meeting HCAHPS performance standard for discharge planning.	N/A	8% reduction in failure rate
O-2	Percentage of patients discharged to community and readmitted within 30 days who are seen by a physician between discharge and readmission.	N/A	8% reduction in failure rate
O-3	Percentage of patient care transitions (FFS Medicare), in the specified geographic area, for which implemented	N/A	Documenting at least 2% improvement 1 or

Measure Number	Brief Measure Name	18-Month Minimum Performance Improvement Thresholds	28-Month Performance Targets
	and measured interventions show improvement.		more interventions, affecting at least 10% of the transitions
O-4	Percentage of patients from the specified geographic area re-hospitalized within 30 days of discharge from an acute care hospital.	N/A	Reduce rate of readmission by at least 2%.
O-5a	AMI Discharge and All-Cause Readmission Rates	N/A	Reduce rate of readmission by at least 2%.
O-5b	CHF Discharge and All-Cause Readmission Rates	N/A	Reduce rate of readmission by at least 2%.
O-5c	Pneumonia Discharge and All-Cause Readmission Rates	N/A	Reduce rate of readmission by at least 2%.
O-6	Percentage of patient transitions within the specified geographic area for which a CARE instrument was used.	N/A	10% of transitions

Deliverables

See Section F – QIO Schedule of Deliverables.

THEME C.7.3. PREVENTION: CHRONIC KIDNEY DISEASE (OPTIONAL)

Overview

The goal of the Task is to detect the incidence and decrease the progression of chronic kidney disease (CKD) among Medicare beneficiaries through provider adoption of timely and effective quality of care interventions; participation in quality incentive initiatives; beneficiary education; and key linkages and collaborations for system change at the state and local level. While this Task is for the purpose of fulfilling the requirements of the QIO statute, it will benefit the goals of Healthy People 2010 in the area of diabetes, access to health services, disparities, and CKD; the CMS arteriovenous fistula, "FistulaFirst" Government Performance Results Act (GPRA) measure; PQRI; and the Value-Driven Health Care Initiative. In addition to improving the quality of care for the elderly and frail-elderly, this Task aims to reduce the rate of Medicare entitlement by disability through the delay and prevention of ESRD; thus, resulting in higher quality care and significant savings to the Medicare Trust Fund.

Opportunity for Quality Improvement

Kidney disease is the ninth leading cause of death in the U.S. CKD affects 11% of the US population over the age of 65, and those affected are at increased risk of cardiovascular disease (CVD) and kidney failure. The cardiovascular mortality risk rate is 32 deaths/1000 person-years among those with CKD vs. 16/1000 person-years among those without it. In more than 90% of Medicare patients with CKD (1,336,320), the disease is accompanied by diabetes (4.1%), hypertension (42.9%), or both diagnoses (43.9%), with 9.1% diagnosed with CKD only. In comparison, while still high, 70-71% of CKD patients aged 50 and older covered by group health plans carry a diagnosis of diabetes, hypertension, or both[69]. The leading cause of renal failure is diabetes with a primary diagnosis of diabetes representing 41.5% of the dialysis patients in 2005. Additionally, ethnic minority populations are more likely to develop kidney failure, particularly African-Americans (four times more likely than Whites), Hispanics (two times more likely than Whites), and American Indians (three times more likely than Whites).

Cost Impact of CKD to Medicare

The cost to Medicare for managing CKD is high. Medicare beneficiaries with CKD (non- ESRD) account for 16.5% of Medicare costs in the year the disease is identified, and 11.1% in the next year. In 2004, CKD costs per person per year (PPPY) reached $20,668, 5.3% more than in 2003, and a 41% increase over 1993. Individuals with CKD or ESRD together consume 24% of Medicare expenditures. According to the United States Renal Data System (USRDS), the savings to Medicare for each patient who does not progress to dialysis is estimated to be $250,000 per patient ($65,000 annual cost of Medicare services times' four-year life expectancy). Patients who carry a diagnosis of CKD, diabetes, and hypertension represent the greatest disease burden to the Medicare program. Patients with any of these conditions, alone or in combination with one another, account for 61.2% of the Medicare population, but they use 80.8% of total expenditures[70]. While the costs are high, the potential for

[69] USRDS 2006 Annual Data Report.
[70] U.S. Renal Data System (2005). National Institutes of Health. National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD

savings through effective medical interventions are significant. For example, in persons with diabetes, when all patients were treated with angiotensin converting enzyme (ACE) inhibitors which have been shown to slow the progression of disease by 50%, the cost effectiveness ratio is $7,500 per QALY (Quality-adjusted Life Years) gained.

Quality Intervention Focus for CKD

The focus areas for quality improvement in CKD include:

1. Timely testing to detect the rate of kidney failure due to diabetes;
2. Slowing the progression of disease in individuals with diabetes through the use of ACE inhibitor and/or an angiotensin receptor blocking (ARB) agent; and
3. Arteriovenous fistula (AV fistula) placement and maturation (as a first choice for arteriovenous access where medically appropriate) for individuals who elect, as a part of timely renal replacement counseling, hemodialysis as their treatment option for kidney failure.

QIO Activities

In accomplishing this goal, the QIO shall:

1 Focus on provider implementation of clinical practices that have been tested and proven to be successful in the prevention and management of CKD;
2 Target beneficiaries that are most likely to benefit from education on risk factors, early identification, and treatment choices for CKD;
3 Disseminate tools and resources to providers and beneficiaries that are in existence and available through Federal partners in the collaborative model;
4 Work through a collaborative model to affect system change that will have a lasting impact on the prevention and management of CKD.

Impact on Disparities

As a requirement of all contract awarded funds for Tasks related to CKD, in all measures, the QIO shall anticipate and monitor the impact the quality interventions have on disparities in care (e.g., ethnic, racial, socio-economic, and geographic). If the disparity in care is increasing, it is expected that the QIO will take rapid corrective action and implement activities to correct, and reverse, the undesired trend. Further, additional funds are available to the QIO that includes, as a component of its plan, activities aimed at the reduction of a disparity in care, such as ethnic, racial, socio-economic, geographic, and other forms of inequity that may exist within a particular state. To receive additional funding, the QIO must include specific target(s) that reduce the disparity to a greater degree than would otherwise be realized without additional emphasis.

Task Description

CKD Required Task 1: Clinical Quality Improvement

[vi]USRDS 2006 Annual Data Report.

The QIO shall work in a collaborative manner with such partners as ESRD Networks, provider affiliations and associations, beneficiary representative groups, state and local agencies, community health centers (CHCs), and others, to develop quality improvement projects (QIPs) which advance the achievement of the following clinical measures.

Task 1.a. Timely testing to detect the rate of kidney failure due to diabetes:

Guidelines have been developed by the National Diabetes Association and the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) to improve the detection and management of CKD in high risk groups such as individuals with diabetes. Early manifestation of CKD in individuals with diabetes is often under-diagnosed due to the absence of an annual urinary microalbumin measurement to identify kidney damage.

The overall goal of this clinical focus area is to increase the adoption of evidence-based standards to identify CKD in Medicare patients through an annual urinary microalbumin measurement for individuals with diabetes. The primary target group for intervention is the primary care physicians (PCPs) as well as other practitioners (such as endocrinologist) who care for individuals with diabetes.

There is an opportunity to further the goals of PQRI through Medicare providers' participation and performance in this clinical quality improvement area as there are companion measures in the PQRI measurement set covering the same clinical area (e.g., testing for CKD). There are opportunities for system change, working in collaboration with partners, such as incorporation of clinical standards in health information systems (HIS); by diabetes counselors and CHCs; and local and state health programs.

Task 1.b. Slowing the progression of disease in individuals with diabetes through the use of ACE inhibitor and/or an ARB agent

The overall goal of this clinical focus area is to increase the frequency with which individuals with diabetes and earlier stage CKD (stage 1-4) are treated with an ACE inhibitor and/or an ARB agent for the treatment of hypertension. The primary target group for intervention is the PCPs as well as other practitioners (such as endocrinologists) who care for individuals with diabetes. There is an opportunity to further the goals of PQRI through Medicare providers' participation and performance in this clinical quality improvement area as there are companion measures in the PQRI measurement set covering the same clinical area (e.g., use of ACE and/or ARB for the treatment of CKD).

There are opportunities for system change, working in collaboration with partners, such as incorporation of clinical standards in Health Information Systems (HIS); by diabetes counselors and CHCs; and local and state health programs.

Task 1.c. AV fistula placement and maturation (as a first choice for arteriovenous access where medically appropriate) for individuals who elect, as a part of timely renal replacement therapy counseling, hemodialysis as their treatment option for kidney failure

The overall goal of this clinical focus area is to ensure that Medicare patients receive comprehensive renal replacement therapy (RRT) (including discussion of all available treatment options) timely enough to allow sufficient time for AV fistula evaluation, placement where appropriate, and maturation to occur if hemodialysis is the treatment choice for kidney failure. An AV fistula is the "gold-standard" for obtaining arteriovenous access for hemodialysis and should be considered as a first option, although not necessarily the right (or final) choice, for all medically appropriate individuals who elect hemodialysis for the treatment of kidney failure.

Consistent with this standard, the goal for the QIO is to increase the rate of individuals (where medically appropriate) who start their first dialysis treatment with a mature AV fistula. While this is the goal, it may not always be possible to achieve because there is not sufficient time between the recognition of need for dialysis, and time of need, for a fistula to mature. Where there is not sufficient time for an AV fistula to mature in time for use at the first dialysis treatment, the QIO goal is to increase the rate of individuals who have fistulas in place and maturing (at the time of their first dialysis treatment).

The target provider groups for this clinical focus area are PCPs, nephrologists, other practitioners who care for individuals with CKD, and surgeons and other practitioners who perform vascular access procedures. There is an opportunity to further the goals of the PQRI through Medicare providers' participation and outcomes in this clinical quality improvement (CQI) area as there are companion measures in the PQRI measurement set.

There are opportunities to achieve system level change by working in hospital settings, nursing homes, and through incorporation of clinical standards by CHCs and local and state health programs.

Additionally, there are opportunities to build on quality improvement and system level change efforts that are occurring to improve the AV fistula rate through participation in the FistulaFirst Breakthrough Initiative Coalition. The Coalition has already been established through the leadership of CMS and the ESRD Networks whereby, ESRD Networks, consistent with their statutory authority, are charged to improve AV fistula rates for individuals with ESRD. As a required element of the QIO plan, the QIO shall actively participate in the FistulaFirst Breakthrough Initiative Coalition to improve the AV fistula rate for Medicare beneficiaries preparing for dialysis (e.g., pre-ESRD), consistent with the QIO statutory authority. Active engagement in activities shall include participation in Coalition meetings AND:

1 Leading, implementing and measuring results of an activity that supports the goal of the QIO Task;
2 Providing supporting data for an activity that is in keeping with the goal of the QIO Task; and/or
3 Working collaboratively with another participant in the Coalition, such as an ESRD Network, on a joint Coalition project that is in keeping with the QIO Task.

CKD Required Task 2: Community Collaboration

As part of the QIO plan, the QIO is required to conduct a portion of work through existing collaborative efforts and/or develop new mechanisms (as needed) to support a community effort to effect quality improvement at the system level. Specifically, as a required element, the QIO must include in its plan, a component whereby the QIO shall be responsible for assembling and/or

sustaining an active coalition at the state/local level that conducts activities that support achievement of one or more of the clinical focus areas in the area of CKD. In fulfilling this requirement, it is expected that the QIO shall create or actively participate in a coalition that goes beyond just promoting information exchange, but also promotes collaboration among members. Whereby a coalition or other collaborative already exists, the QIO is responsible for clearly documenting the QIO's specific attribution in the success of the coalition including all activities, responsibilities, staffing, etc., performed by the QIO. It is expected that the QIO work beyond administrative lead of the coalition as key partner, contributor, and leader.

In meeting this requirement, it is expected that the QIO shall:

1. Build partnerships with new entities;
2. Expand and enhance existing partnerships;
3. Create greater ownership by partners in the coalition;
4. Utilize other available resources by having coalition partners bring resources to the table or identify others with resources (in accordance with conflict of interest and other requirements of the SOW);
5. Engage in innovative problem solving by collaborating with coalition partners.
   In forming, refining, and expanding the collaborative, the QIO shall consider including the following entities:

   - ESRD Networks;
   - State/local health department diabetes grantees;
   - CHCs;
   - Local chapters of kidney organizations;
   - State and county government representatives (e.g., survey and certification and Medicaid);
   - Provider groups as appropriate (e.g., nephrologists, surgeons, dialysis centers);
   - Community representatives reflecting the diversity of the community served; and
   - Patient representatives (attempts should be made to have more than one patient representative).

If the above entities are not going to be included in the collaborative effort, the QIO shall document why it is not feasible, desirable, possible, etc. to do so.

OPTIONAL TASK DESCRIPTION

In addition to required elements of the QIO plan, below are optional Tasks that a QIO can elect to include in its QIO plan. If the requirements outlined below are met, a QIO will be eligible to receive additional points during the selection process to ensure the most qualified QIOs are chosen. The number of points awarded will be in accordance to the criteria outlined in the QIO Selection Process for CKD.

CKD Optional Task 1: Support for Companion CMS Quality Initiatives

In developing its plan, the QIO shall consider as an optional component the Task of providing technical assistance to providers in Medicare quality incentive programs that are directly aligned, and support achievement of the CKD clinical focus areas defined in this SOW. Such quality incentive

programs can include Medicare providers' increased participation and quality of care outcomes in PQRI measures that are similar to the QIO clinical focus areas for CKD, and other targeted CMS-sponsored quality initiatives that support the achievement of the CKD clinical focus areas and are consistent with QIO statutory authority for quality improvement. This is not to be confused with typical technical assistance in the focus areas that will likely be part of all proposed QIO plans. To receive extra points, the QIO plan must clearly document the Task that will be undertaken, and set specific targets for achievement. Further, the QIO must establish quarterly benchmarks for monitoring the progress and meeting targets (e.g., recruit 50% of providers by the second quarter), and report data that can be used to clearly attribute the QIO activities to changes in outcomes.

As an example of activities that may receive additional consideration, the QIO can consider a component that would increase the number of Medicare providers reporting the companion measures to the clinical focus areas of this CKD Task under the PQRI reporting set. The QIO would have to set a target for the number of Medicare providers, establish a timeframe for meeting this target, and clearly report and link QIO activities that fostered the reporting. Additionally, the QIO can consider including components that would assist providers that are, or will be, reporting and improving their clinical outcome rates in the CKD focus areas. The QIO would have to set a target for assistance and the level of improvement, designate a timeframe for achievement of target, and clearly report and link QIO activities that led to improvement (e.g., rate of increase higher with providers that the QIO worked with in contrast to like providers in which the QIO did not provide assistance).

CKD Optional Task 2: HIT

Similar in nature to the work in the Prevention Theme in the area of cancer screening and immunization, the QIO can elect to include a component that supports HIT adoption and the implementation of clinical components that align with the clinical focus areas of the CKD Task. If such a component is included, the QIO should follow, to the degree possible, the requirements as defined in the Prevention Theme. For example, the QIO must work with practice sites in its own state/jurisdiction that have already implemented electronic clinical information systems and/or those that formed the "Identified Participant Group" (IPG) in the 8th SOW. Further, the QIO must incorporate a method to compare the results of this approach (HIT adoption/use) to other activities undertaken, and where no activity is undertaken by the QIO. The QIO must establish specific targets, and include quarterly benchmarks and deliverables that ensure achievement of targets. Extra points will be awarded during the selection process to the QIO that includes an HIT component in its plan that sufficiently meets these requirements.

CKD Optional Task 3: Reduction in Disparities

All QIO plans shall have mechanisms in place to monitor the impact of quality interventions on disparities in care and shall include provision for rapid cycle adjustments to reverse and correct any negative trends that occur. In addition to these required elements for all QIO plans, opportunities exist to actively target and reduce the disparity in care provided to Medicare beneficiaries. These instances will vary by state, within a state, by population, region, etc. Therefore, if the QIO determines that a specific disparity exists that the QIO has the capacity and ability to affect, there is an opportunity to receive extra points in the selection process. Since there will be wide variation among QIO contractors, it is the QIO that must identify in its proposal the disparity that exists, the strategy for

reducing the disparity, and the target that will be achieved. The QIO is required to have capacity in-house through subcontract, partnerships, etc., with representative groups that have expertise and experience in the targeted area. Baseline information must be provided; quarterly benchmarks and deliverables must be established; and a system for tracking, at a minimum, quarterly progress must be in place.

Task Guidelines

The QIO can propose to include in its plan a vast array of activities aimed at achievement of Task goals. However, there are general guidelines that must be followed in the area of CKD, in addition to those specified throughout the SOW, if a QIO includes components of technical assistance and beneficiary and/or practitioner outreach in the area of CKD.

Guidelines for Beneficiary/Practitioner Outreach and Technical Assistance

The QIO is in a unique position to use available data to target individuals and practitioners that would benefit from direct information related to clinical focus areas. However, in consideration of inclusion of this activity in its plan, the QIO must conduct activities through the most effective and efficient approaches possible (e.g., through meetings/trainings, such as those sponsored by renal partners; through patient membership organizations and in conjunction with other renal partners, such as ESRD Networks; and at private and employee health fair events sponsored by large group health plans, State, county, and local governments where caregivers of Medicare beneficiaries, who are also future Medicare beneficiaries, attend. Activities should be closely monitored to ensure they are having desired impact and modified/discontinued rapidly if they are not.

The QIO shall utilize, to the extent possible and practical, information and resources that are already available through CMS, CMS contractors (other QIOs, ESRD Networks, the ESRD National Coordinating Center, etc.), other federal agencies (e.g., National Institute of Diabetes and Digestive and Kidney Diseases and the CDC, and renal partners (e.g., beneficiary representative groups, provider organizations, and corporations), and other sources as appropriate. Only by exception and approval by the PO should the QIO develop new outreach, educational materials, or other resources. Further, for this component to be acceptable, the QIO plan must include a systematic plan with focused intent/action items that are likely to result in adoption and/or use. Interventions without targeted intent/action are not acceptable as they are not likely to result in meaningful quality improvement. Further, the plan must include provisions for reporting, as part of the quarterly report and/or other CMS required data reporting elements, changes in policies, practices, procedures, behavior, or other areas as a direct result of activity.

Evaluation

See Section C.5.

In the area of CKD, a QIO is required to successfully pass the established targets in all clinical outcome measures (e.g., testing, ACE/ARB, and AV fistula), to successfully pass the CKD Task. For the purpose of determining QIO success (pass), or failure, at reaching established targets, because CKD is a relatively new CMS program focus area for quality improvement, and since measures are

still evolving through PQRI and other sources, a "pass" in the area of CKD will be considered achievement of the established target at a rate of 80% or greater.

Clinical Outcome Measures

(See attached "CKD Code Description" for definitions and details on specific ICD-9 codes, medications, etc. that will be used to calculate measure. Codes, medications, definitions, etc., are based on current industry standards and will be updated to reflect changes to standards. QIO will be notified in writing when changes occur. It is not anticipated that changes will impact actual measure, or measurement rate.)

Task 1.a. Timely testing to reduce the rate of kidney failure due to diabetes.

Definition: Increase in the percentage of elderly and disabled Medicare beneficiaries 18-75 years of age with diabetes (type 1 or type 2) who had nephropathy screening test and/or medical attention for nephropathy. (HEDIS, NQF, and Healthy People 2010 measure.)

Denominator: Elderly and disabled Medicare beneficiaries between 18-75 years of age with a diagnosis and/or indication of diabetes with continuous enrollment in the measurement period (defined by no more than one gap in enrollment of up to 30 days during the measurement period).

Exclusions: Individuals with a diagnosis of polycystic ovaries, gestational diabetes, or steroid induced diabetes who did not have any face-to-face encounters with the diagnosis of diabetes.

Numerator: Individuals in the denominator with at least one of the following;

- A Nephropathy Screening Test (NST) (urine microalbumin);
- Evidence of nephropathy (diagnosis or a nephrologists visit);
- A urine macroalbumin test; or
- Evidence of ACE inhibitor and/or ARB therapy.

NST: For the purpose of measurement: urine microalbumin tests include 24 hour urine for microalbumin; timed urine for microalbumin; spot urine for microalbumin; urine for micro-albumin/creatine ratio; 24-hour urine for total protein; random urine for protein/creatine ratio. "Trace" urine macroalbumin test results are not considered numerator compliant.

Evidence of Nephropathy: any of the following meet criteria for evidence of nephropathy.

- A claim with a code to indicate evidence of nephropathy (see table for codes) during the measurement period;
- A Nephrologist visit during the measurement year (no restriction on the diagnosis or procedure code submitted);
- A urine macroalbumin test in the measurement period;
- Evidence of ACE inhibitor/ARB therapy during the measurement period (claim indicating therapy or who received an ambulatory prescription).

Guideline for Care (Based on Medical Evidence): 100% testing of eligible individuals with diabetes.

Data Source: Administrative data.

QIO Performance Target Methodology: improvement over baseline, factoring historical trend for improvement.

Second Evaluation Performance Target: 10% improvement at the end of the evaluation period (statewide rate).

First Evaluation Period (18-month) QIO Performance Target: 40% of second evaluation performance target.

Task 1.b. Slowing the progress ion disease in individuals with diabetes through the use of ACE inhibitor and/or an ARB agent

Definition: Percentage of elderly and disabled Medicare beneficiaries with CKD (stages 1-4) and with diabetes and hypertension and indication of ACE inhibitor and/or ARB agent use.

Denominator: Elderly and disabled Medicare beneficiaries 18-75 years of age with CKD (stage 1-4) and diagnosis of diabetes and hypertension.

Numerator: Individuals in denominator who have a claim for ACE inhibitor and/or ARB in the reporting period.

Data Source: Part D claims data supplemented by other Medicare administrative data.

Guideline for Care (Based on Medical Evidence): Use of ACE inhibitor and/or ARB by 100% of individuals whereby use is not contraindicated and/or side effects have been experienced. (Note: QIO measure utilizes administrative data alone due to cost and feasibility and does not factor in percentage of patients where ACE and/or ARB use is contraindicated and/or side effects have been experienced (since this data would need to be obtained from medical records).) Therefore, there is an expected difference in percentages in companion measures that are self-reported or use other than administrative data to factor in such considerations. The difference should be noted when used for comparison purposes, since 100% used is not appropriate under the QIO measure, but is not a factor in QIO activities as the goal remains the same – increase use of ACE and/or ARB where medically appropriate.

Performance Target Methodology: Percent improvement over baseline.
Second Evaluation Performance Target: 10% improvement over baseline (statewide-rate).

First Evaluation Period (18-month) QIO Performance Target: 40% of second evaluation performance target.

Task 1.c. AV fistula placement and maturation (as a first choice for arteriovenous access where medically appropriate) for individuals who elect, as a part of timely renal replacement counseling, hemodialysis as their treatment option for kidney failure

Definition: The rate increase in new (incident) elderly and disabled Medicare beneficiaries 18 years of age or older using an AV fistula at their first dialysis treatment or with an arteriovenous fistula maturing at the first dialysis treatment.

Denominator: Incident Medicare beneficiaries that are an adult (≥18 years of age) HD patient with a Medicare Entitlement Form (2728).

Numerator: Individuals in denominator dialyzed using an AV fistula at their first dialysis treatment or with an AV fistula maturing at the first dialysis treatment as reported on the Medicare Entitlement Form (2728).

Exclusions: Incident patients that do not have a diagnosis of CKD, or evidence of CKD, at least six months prior to first dialysis treatment.

Guideline for Care: 50% AV fistula rate for new patients (Healthy People 2010 target, and KDOQI Guidelines).

Data Source: Medicare Entitlement Form (2728).

Performance Target Methodology: Reduction in failure rate, as established utilizing 50% AV fistula rate for incident patients.

Performance Target: Reduce the quality deficit between the statewide baseline rate and the 50% goal by 10% at the end of the second evaluation period. (This methodology results in approximately 2.4% improvement each year.)

First Evaluation Period (18-month) QIO Performance Target: 40% of second evaluation performance target.

MONITORING OF TASK PERFORMANCE

Required Deliverables

In developing the QIO plan, the QIO shall include deliverables that demonstrate, on a quarterly basis, that progress is being made at realizing the desired outcomes. In addition to proposed deliverables that are specific to the QIO plan, and approved by CMS as part of the QIO contract, in planning deliverables, the QIO shall incorporate the following requirements:

Practitioner/Provider Recruitment

- For all targeted practitioner/provider activities, in all areas, by the end of quarter 2, 50% of practitioners/providers recruited.

- For all targeted practitioner/provider activities, in all areas, by the end of quarter 3, 75% of practitioners/providers recruited.

- For all targeted practitioner/provider activities, in all areas, by the end of quarter 4, 100% of practitioners/providers recruited.

Collaborations

By the end of Quarter 1, the QIO shall have secured the participation of partners in the collaborative. In cases where the collaborative is already in existence, the QIO shall review membership and secure any additional members that would benefit the collaborative.

The QIO shall be able to demonstrate, minimally, one change at a system level that is in place as a result of collaborative activities. Change at the system level is considered a change in practice, policy, and/or procedure that is likely to result in sustained improvement. The change can be that of a partner, or organization, agency, payer, etc., influenced by activities of the collaborative.

Provider Experience with Service

As a component of the QIO plan, the QIO shall plan for a survey administered to target providers and partners to determine the effect the QIO interactions had on driving change. The survey will be developed by an independent source. The survey is not an evaluation of satisfaction with the services provided by the QIO; rather, the survey will be aimed at gathering information to determine the impact the QIO activities had on driving quality improvement. The QIO will be responsible for administering the survey to a random selection of providers and partners, at initiation of the contract for use in mid-course review and the end of the contract for use in the final evaluation. The number of providers/partners will be determined when the plan is approved and submitted. The QIO is responsible for reporting the results of the survey to CMS, in an aggregate manner, and to the CMS contractor tasked with conducting an independent evaluation of the QIO Program in the manner specified by CMS. The results of the survey shall be used for IQI by the QIO and for verification by CMS of system change reported by the QIO. Additionally, results will be used in an aggregate manner in the QIO Program level evaluation.

Monthly System-Level Reporting

The long delay between targeted actions and the resulting widespread behavior change and improvement in population-level outcomes makes it difficult to assess whether the effort is bringing about change. Accordingly, in dynamic systems, it is important to document those new programs and procedures that form the comprehensive intervention that unfolds over time. Therefore, the QIO is responsible for monthly documenting system level changes in programs, policies, procedures, and the action(s) that caused system change so that they can be analyzed with intermediate clinical outcomes and longer-term outcomes to strengthen correlation of change with activities.

Including this level of evaluation can systematically document the unfolding of the intervention in the dynamic and diverse contexts of collaborative efforts. Real time, minimal data entry makes analysis

of the contribution of community/system changes, as well as specific partner activities, on population-level outcomes possible. Additionally, the community/system changes documented by collaborating partners will suggest promising approaches for intervention in other communities and contexts.

To conduct such analysis requires a real time data entry system that is simple to use with the ability to give instant feedback reports to a varied level of user. The QIO is required to have an internal system in-place that is capable of reporting such data to CMS, as specified by CMS.

Quarterly Report

In keeping with the IOM's model for continuous evaluation, the QIO is expected to monitor and report, quarterly, on four continuous evaluation questions in all clinical focus areas, for the mandatory Task on collaboration, and for all optional Tasks elected (under contract) by the QIO. These areas shall be addressed in each quarterly status report:

1. Is the effort serving as a catalyst for change in order to improve health care?

2. What factors or processes are associated with the rate of change for improving health care?

3. How are community/system changes contributing to the efforts to improve health care?

4. Are community/system changes associated with improvements in population-level outcomes?

Deliverables

See Section F – "QIO Schedule of Deliverables" for a listing of required deliverables in the area of CKD.

ATTACHMENT

CODES FOR USE IN Chronic Kidney Disease (CKD) MEASURES

CKD Valid Codes
DX 016.0, 095.4, 189.0, 189.9, 223.0, 236.91, 250.40, 250.41, 250.42, 250.43, 271.4, 274.1, 283.11, 403.01, 403.11, 403.91, 404.02, 404.03, 404.12, 404.13, 404.92, 404.93, 440.1, 442.1, 572.4, 580.0, 580.4, 580.81, 580.89, 580.9, 581.0, 581.1, 581.2, 581.3, 581.81, 581.89, 581.9, 582.0, 582.1, 582.2, 582.4, 582.81, 582.89, 582.9, 583.0, 583.1, 583.2, 583.4, 583.6, 583.7, 583.81, 583.89, 583.9, 585.1-5, 585.9, 586, 587, 588.0, 588.1, 588.81, 588.89, 588.9, 591, 753.12, 753.13, 753.14, 753.15, 753.16, 753.17, 753.19, 753.20, 753.21, 753.22, 753.23, 753.29, 794.4 (any DX on the claim)

Diabetes Valid Codes
DX 250.00, 250.01, 250.02, 250.03, 250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33, 250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.70, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93, 357.2, 362.01, 362.02, 366.41 (any DX on the claim)

Prescriptions to Identify Diabetics

(Where feasible, codes will be updated at quarterly increments to reflect changes/new products)

Description	Prescriptions			
Insulin	Mix 50/50 Mix 70/30 Mix 75/25 Apidra (glulisine) Continuous subcutaneous infusion of insulin Exubera	Humalog Humulin Iletin Insulin pen Insulin pump Regular insulin NPH Lente	Levemir (detemir) Lantus (glargine) Lispro Multiple daily injections Novolin	Novolog Penfill Semilente Ultralente Velosulin

Oral hypoglycemic/ antihyperglycemic	Acetohexamide Actos ActosPlus Met Amaryl Avandamet (Metformin-Rosiglitazone) Avandaryl (Glimepiride-Rosiglitazone) Avandia Byetta (Exenatide)—Oral Chlorpropamide	Diabeta Diabinese Dymelor Glimepiride Glipizide Glipizide XL Glucamide Glucotrol Glucotrol XL Glucovance (Glyburide-Metformin) Glyburide	Glynase Glyset Metaglip (Glipzide-Metformin) Micronase Miglitol Nateglinide Orinase Orimide Pioglitazone Prandin (Repaglinide)	Precose (Acarbose) Rezulin Rosiglitazone Starlix Tolazamide Tolamide Tolbutamide Tolinase Troglitazone

Codes to Identify Visit Type

Description	CPT	UB-92 Revenue
Outpatient	92002-92014, 99201-99205, 99211-99215, 99217-99220, 99241-99245, 99324-99328, 99334-99337, 99341-99345, 99347-99350, 99384-99387, 99394-99397, 99401-99404, 99411, 99412, 99420, 99429, 99455, 99456, 99499	051x, 052x, 057x-059x, 077x, 082x-085x, 088x, 0982, 0983
Non-acute inpatient	99301-99313, 99404-99310, 99315, 99316, 99318, 99321-99328, 99331-99337	0118, 0128, 0138, 0148, 0158, 019x, 055x, 066x
Acute inpatient	99221-99223, 99231-99233, 99238, 99239, 99251-99255, 99261-99263, 99291	010x, 0110-0114, 0119, 0120-0124, 0129, 0130-0134, 0139, 0140-0144, 0149, 0150-0154, 0159, 016x, 020x-022x, 072x, 080x, 0987
Emergency department	99281-99285	045x, 0981

Codes to Identify Nephropathy Screening Tests

Description	CPT	CPT Category II	LOINC
Nephropathy screening test	82042, 82043, 82044, 84156	3060F, 3061F	11218-5, 14956-7, 14957-5, 14958-3, 14959-1, 30000-4, 30001-2, 30003-8, 1753-3, 1754-1, 1755-8, 9318-7, 13705-9, 14585-4, 20621-9, 21059-1, 32294-1, 2887-8, 2888-6, 2889-4, 2890-2, 12842-1, 13801-6, 18373-1, 21482-5, 26801-1, 27298-9, 32209-9, 32551-4, 34366-5, 35663-4

ACE Inhibitors/ARBs

Description	Drugs			
ACE inhibitors	Benazepril (Lotensin) Captopril (Capoten) Enalapril (Vasotec)	Fosinopril (Monopril) Lisinopril (Prinivil Zestril) Moexipril (Univasc)	Perindopril (Aceon) Quinapril (Accupril)	Ramipril (Altace) Trandolopril (Mavik)
ACE inhibitors—	Benazepril + HCTZ (Lotensin HCT)		Lisinopril + HCTZ (Prinzide, Zestoreti, Hydrochlorothiazide +	

Combination products	Captopril + HCTZ (Capozide, Hydrochlorothiazide + Capropril) Enalapril + HCTZ (Vaseretic) Fosinopril + HCTZ (Monopril HCT)	Lisinopril) Moexipril + HCTZ (Uniretic) Quinapril + HCTZ (Accuretic)	
ARBs	Candesartan (Atacand) Eprosartan (Teveten) Irbesartan (Avapro)	Losartan (Cozaar) Olmesartan (Benicar)	Telmisartan (Micardis) Valsartan (Diovan)
ARB—Combination products	Candesartan (Atacand HCT) Irbesartan (Avalide)	Losartan (Hyzaar) Telmisartan (Micardis HCT)	Valsartan (Diovan HCT)

Codes to Identify Exclusions for Screening Measure

Description	ICD-9-CM Diagnosis
Polycystic ovaries	256.4
Steroid induced	251.8, 962.0
Gestational diabetes	648.8
Renal auto transplantation	55.61
Other kidney transplantation	55.69

C.8. SPECIAL PROJECTS

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

A special project is defined as work that CMS directs a QIO to perform or work that CMS approves the QIO to perform that is not defined under this SOW. The special project work shall fall within the scope of Section 1154 of the Act. The special project shall be conducted in accordance with Sections B.4., G.18. and H.12.

All special projects awarded under this contract will be evaluated individually. The QIO's performance on a special project will not be factored into the evaluation of the QIO's work under the Themes in this SOW.

The performance assessment for each special project will be conducted jointly by the QIO's PO and the special project GTL.

The QIO's PO and each project's GTL will conduct periodic monitoring of the contractor's progress towards completion of the special project. The frequency and nature of this monitoring is to be determined by the PO and GTL, but is anticipated to occur on a quarterly basis by teleconference or videoconference. The contractor shall participate in these monitoring activities, including the provision of a brief summary of activities, internal quality improvement, barriers and efforts to address those barriers, and other pertinent information as directed by the PO.

C.9. TRANSITION FROM INCUMBENT QIO TO SUCCESSOR QIO

A. General Guidelines:

At the end of this contract, if a determination is made to terminate or not renew the incumbent QIO's contract, the QIO shall provide similar transition/phase-in/phase-out support to the successor QIO selected by CMS (refer to FAR 52.237-3 Continuity of Services).

In no case will this transition begin more than 120 days before the end of the contract and the aim will be for it to end at the contract's end date. During this period, the incumbent QIO shall work with the successor QIO, CMS Staff, and other identified CMS contractors to assure continued operation of the QIO Program.

Prior to commencement of transition, the incumbent QIO shall provide a transition plan in accordance with Section F – QIO Schedule of Deliverables. The transition plan shall provide adequate coverage to assure uninterrupted service to the QIO Program, be effectively and efficiently administered, and be completed within 30 days of CMS' review and revision of the QIOs' proposed termination plan.

Within 60 days the incumbent QIO will follow all actions identified within the current QualityNet Startup and Shutdown Procedures.

The QIO shall cooperate fully with the successor QIO, as directed by the PO, to assure that all services continue without interruption.

The QIO shall transition quality improvement and information systems activities as directed by CMS.

B. Transition Plan

At a minimum, the Transition Plan shall provide detailed methods that will be used to ensure a smooth transition from the incumbent QIO's operation to sole operation by the successor QIO. At a minimum, the Transition Plan shall provide for the following:

1. A plan to complete or transition to the new contractor all case reviews within 30 calendar days;
2. A plan to transition (without any lag time), receipt and processing of all expedited and fast-track appeals;
3. A milestone chart detailing the timelines and stages of transition from the effective date of contract performance until the QIO assumes sole responsibility for the QIO Program work;
4. An organizational chart that displays internal and external organizational relationships. The organizational chart shall identify the individuals (at all levels) who will be responsible for the transition and their respective roles; detail the lines of communication and how the QIO will interface with CMS during this phase of contract performance;
5. Plans to communicate and cooperate with the current incumbent QIO.

Transition services will include transfer of Government-Furnished Property (GFP) (e.g., hardware, software, records/data) from the incumbent QIO to the successor QIO, or to CMS or another CMS contractor. CMS may elect to require the transition of GFP as follows:

1. Prior to procurement of an asset, the QIO shall propose a transition charge to be evaluated and negotiated by CMS;
2. A successor QIO to this contract, or CMS, will be afforded the opportunity to acquire QIO assets at a reasonable transition charge;
3. All existing assets shall remain installed and usable by CMS through the transition of assets for their replacement by the successor QIO;
4. In the event a decision is made not to procure the assets, the QIO has the responsibility to dispose of the assets as instructed by CMS.

C. Transition of QIA Materials

1. At a minimum, the incumbent QIO shall include all materials necessary for the successful transition of the QIAs to the successor QIO. These materials shall include the following items so that the successor QIO can build upon the work of the incumbent QIO with regard to its SOW QIAs:
2. Materials associated with SOW communications activities and information collection activities;

3. Materials and relevant information regarding coordination with stakeholders and other activities focused on provider satisfaction and provider/stakeholder knowledge/perception of the QIO Program;
4. Materials and relevant information regarding identified participant and statewide efforts, including recruitment, measures, and background information and materials for Task 1;
5. Other materials and information that the incumbent QIO determines necessary for the successful transition of its QIAs to the successor QIO.

D. Transition of Information Systems Activities

Within 60 days, the incumbent QIO shall:

1. Contact SDPS Help Desk and provide locations;
2. Designate a Point of Contact's (POC's) of QIO to initiate process;
3. Coordinate actions with CMS Management Team (CMS OCSQ's Quality Improvement Group and the Information Systems Group, and the Division of Quality Improvement in the Boston, Dallas, Kansas City and Seattle Regional Offices, etc.);
4. Coordinate actions with QIO Primary POC;
5. Coordinate with the SDPS contractor to determine what application access rights need to be changed for any systems access and perform a master backup of the QIO applications data;
6. Coordinate and work with CMS Network GTL in ISG to shutdown the T1/Network lines;
7. Coordinate with CMS, SDPS contractor, and BCSSI to ensure that all the workstations/file servers are functioning properly and have been properly repaired in accordance with the warranty/service agreement per the terms of the lease;
8. Coordinate Secondary Domain shut down procedures with QIO/SDPS contractor/BCSSI/CMS prior to performing any "Wipe Clean" applications on the Dell File Servers and Dell System Administration desktop work stations;
9. Coordinate "Wipe Clean" shut down procedures with CMS on the Dell desktop work stations prior to site visit to perform the shutdown;
10. Coordinate w/ SDPS contractor to obtain all necessary packing materials from Austin Foam to ship to QIO to be utilized by contractor staff to box up the systems for shipment (transfer to successor QIO or return to Dell);
11. Coordinate File Server backup procedures with CMS on the Dell File Servers prior to site visit to perform the shutdown and move;
12. Coordinate any Data Server backup procedures with SDPS contractor on the RS-6000 Database Servers prior to site visit to perform the shutdown and move;
13. Coordinate with SDPS contractor to determine if transfer or return of the systems is being executed prior to site visit to perform the shutdown and move;
14. Coordinate with SDPS contractor/QIO/CMS Property Disposal Office to obtain up to date inventory prior to site visit;
15. Coordinate with SDPS contractor to obtain moving contractors/supplies prior to site visit to perform the packing & shipment of IT assets;
16. Coordinate Site Visit with PO: perform inventory and reconcile any discrepancies;
17. Coordinate Secondary Domain shut down to close out Microsoft Outlook e-mail accounts on the Dell File Servers with BCSSI/CMS;

18. Coordinate with SDPS contractor /CMS all backups and prepare for delivery to successor QIO;
19. Perform “Wipe Clean” on Dell File Server and System Administrator desktop work station;
20. Coordinate with shipping contractor to prepare, box, and ship all inventory to new location;
21. Complete the DHHS Property Action Forms and return to CMS Property Disposal Office.

SECTION D - PACKAGING AND MARKING

All deliverables shall be marked clearly using the contract number and shall follow any directions provided in Section F.2, Deliverable Schedule.

SECTION E - INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address:

www.arnet.gov/far/fac.html

52.246-5 Inspection of Services - Cost Reimbursement (APR 1984)

E.2. PERFORMANCE IMPROVEMENT PLAN (PIP)

In the event a QIO fails to meet its contract requirements for acceptability, a PIP may be required in accordance with QIO Manual Section 15400-15420.
(See http://www.cms.gov/manuals/110)

Section F – Schedule of Deliverables is included as a separate file due to formatting issues. Please download and insert here. Section F begins on page 127 and ends on page 165

Section G – Administration is included as a separate file due to formatting issues. Please download and insert here. Section G begins on page 166 and ends on page 190.

Section H – Special Contract is included as a separate file due to formatting issues. Please download and insert here. Section H begins on page 191 and ends on page 214.

Section I – Contract Clauses is included as a separate file due to formatting issues. Please download and insert here. Section I begins on page 215 and ends on page 218.

Section J – List of Attachments is included as a separate file due to formatting issues. Please download and insert here. Section J is page 219.

Section K – Representations, Certifications, and Other Statements of Offerors or Quoters begins on page 220 and ends on page 229. Please download and insert here.

Section L Instructions, Conditions and Notices to Offerors and Section M Evaluation Factors for Award begin on page 230 and end on page 281. Please download and insert here.

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