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**IOM Medication Error Identification and Prevention Study**
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## Overview of QIO Programs

QIOs are private mostly non-profit entities that have a variety of public and private customers, including the Medicare program. Most also perform quality and access monitoring for Medicaid programs, and many adjudicate appeals under about a score of state managed care "patients' rights" laws. Medicare and a handful of Medicaid programs (e.g., Arkansas, Massachusetts, New York) comprise the customer base for clinical quality improvement work of the QIOs.

The Medicare work of the QIOs is authorized under the Utilization Review and Quality Control Peer Review Organization program (today known as the Quality Improvement Organization or "QIO" Program). The QIO program was created by Congress in 1982 in title 11 of the Social Security Act, with specifications for organizations qualified to receive Medicare QIO contracts primarily located in sections 1152 and a variety of tasks described in sections 1154 and 1862(g) of the Social Security Act. The main three purposes of the QIO program are:

- Improve quality of care for beneficiaries;
- Protect the integrity of the Medicare Trust Funds 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-issued notices of non-coverage [Hospital-Issued Notice of Non-Coverage (HINN), Notice of Discharge and Medicare Appeal Rights (NODMAR), and Medicare Advantage appeal]; Emergency Medical Treatment and Labor Act (EMTALA) violations; and other related statutory QIO responsibilities.

The statutory scope of the QIO work is very broad, authorizing the HHS Secretary to utilize the QIOs to review and improve the quality and effectiveness of any items or services for which Medicare pays in whole or in part. The breadth of the work the QIOs actually perform for the Medicare program may be limited by the content of contracts the Secretary enters into with the QIOs, and is subject to the availability of funding. The Secretary is authorized under these provisions to fund the QIOs (and only the QIOs) through a direct draw on the Medicare hospital

insurance and supplemental medical insurance Trust Funds. The HHS Secretary revises the QIO contract every three years (a statutory contract term) and must request trust fund "apportionment" from the Office of Management and Budget (OMB), located in the Executive Office of the President. In the "Seventh QIO Statement of Work" (SOW7, so-called because it is seventh in a series of multi-year contracts that began with implementation of the program in 1984), funding for the three-year period was $1.14 billion, of which the QIO contractors themselves were paid approximately $825 million over three years (about $275 million a year).

The next or 8th Statement of Work (SOW8) begins for the first third of QIOs in August 2005, the second third in November 2005, and the final set of QIOs in February 2006 and will run through the end of July 2008 (October 2008 or January 2009 for the second two "rounds" of QIO contracts. The new contract was distributed on the afternoon of Friday April 1, 2005, and set forth the new work assignments in the following areas:

- Nursing Homes;
- Home Health Agencies;
- Hospitals (including rural and critical access hospitals);
- Physician Offices;
- Protecting Medicare beneficiaries and the program through complaint investigations, adjudication of appeals of provider and Medicare Advantage plan coverage limitations and denials, and review of hospital admissions.
- Special studies on a variety of topics provide the Secretary a means of research and development for new program directions and approaches.

The QIO work in physician offices will focus on spurring more widespread adoption and use of health information technology, and on improving the quality and effectiveness of pharmacotherapy, and will include work to reduce disparities in care received by underserved populations.

In addition to oversight of the contracts by staff of the Centers for Medicare and Medicaid Services (CMS), the agency utilizes QIO program funding for about 17 additional (generally competitively awarded) contracts with QIOs to help administer the program and share successful strategies. These contractors are known as Quality Improvement Organization Support Centers (or QIOSCs, pronounced "kiosks"). CMS may fund a QIOSC to support the new work of QIOs in improving the quality of pharmacotherapy.

**Previous Work of the QIOs in Improving the Safety and Quality of Use of Pharmacotherapy**

In 1993, responding to the 1990 Institute of Medicine (IOM) report, *Medicare: A Strategy for Quality Assurance*, CMS began to transition the QIO program (then known as the"PRO" program) away from the emphasis of its first ten years. The PRO program up until that time had consisted mostly of retrospective implicit case review of individual patient medical records, with the primary intervention being a letter to the provider or practitioner about quality shortcomings identified by the reviewer. Beginning about ten years ago in the Fourth Statement of Work, the QIOs began to retool their staff and training to a more proactive mode, based on analysis of the health of the population of Medicare beneficiaries and providing data and support to practitioners and providers to improve the quality of clinical processes.

The 6th Statement of Work period (roughly 1999-2002) was the first in which every QIO was working to improve safety and quality of care using the same nationally defined set of quality indicators. QIO work to improve pharmacotherapy was almost entirely based on inpatient care, with the exception of QIO efforts to promote use of influenza and pneumococcal polyvalent vaccine (PPV) immunizations. Most of the work addressed timely use of evidence-based therapy for heart attack, based on the success of the CMS-funded QIO Cooperative Cardiovascular Project in four states (see Marciniak et al, JAMA, May 1998). In the 6th Statement of Work the QIOs addressed the same set of errors of omission (e.g., failure to ensure the reliable prescription of evidence-based pharmacotherapy to all who would benefit, such as beta blockers and aspirin for heart attack), errors of commission (e.g., administration of short-acting nifedipine to stroke patients), and errors of misuse (e.g., poor selection and timing of antibiotic administration for community acquired pneumonia or for surgical infection prevention).

Below are two tables listing the SOW6 QIO indicators that CMS defined, and the reduction in relative failure rate achieved by QIOs and their partners (hospitals except for immunization campaigns, which relied greatly on social marketing with community-based partners).

| Pharmacotherapy Quality Indicator | Median State Improvement (failure rate reduction) |
|---|---|
| ▪ Early Aspirin use for AMI | 15% |
| ▪ Aspirin order at d/c for AMI | 14% |
| ▪ Early Beta Blocker admin for AMI | 17% |
| ▪ Beta Blocker at d/c for AMI | 28% |
| ▪ ACEI at d/c for low LVEF for AMI | 10% |
| ▪ Warfarin/ASA in Atrial Fibrillation @ d/c | 9% |
| ▪ Antithrombotic in Stroke @ d/c | 12% |
| ▪ Avoidance of short acting Nifedipine in stroke | 78% |
| ▪ ACEI for low LVEF at d/c in CHF | 6% |

| Pharmacotherapy Quality Indicator --Community Acquired Pneumonia | Median State Improvement (failure rate reduction) |
|---|---|
| ▪ Antibiotic for CAP w/in 8 hours of arrival | 10% |
| ▪ Antibiotic for CAP consistent w/ current recommendations | 32% |
| ▪ Blood culture before antibiotic administration | -9% |
| ▪ Inpatients screened for flu shot | 10% |
| ▪ Inpatients screened for PPV shot | 12% |
| ▪ Flu immunization rate – statewide Medicare population | 16% |
| ▪ PPV immunization rate– statewide Medicare population | 22% |

All of these data except the flu and PPV immunization rates are derived from figures abstracted from the inpatient medical record by trained clinical data abstractors at two centers financed through the QIO program. The figures represent pre-post comparison; there was no comparison group. It should be noted in this connection that the QIOs used strategies modeled by four QIOs to improve AMI care in the Cooperative Cardiovascular Project (CCP). The CCP was evaluated by comparing the change in processes and mortality in the four intervention states compared to the rest of the nation during the same period, finding about 1 percentage point reduction in mortality in the intervention states compared to the rest of the nation.

In these tables the relative failure rate reduction is defined by CMS as the percentage reduction in the percentage of appropriate patients who did not receive indicated therapy. Patients for whom therapy is not indicated (generally based on an annotation in the medical record that a drug was contraindicated for use in a particular patient, for example, the patient had an aspirin sensitivity) were excluded from the numerator and denominator. For an indicator that at baseline showed 60% of appropriate patients received needed care, the failure rate would be 40%. If improvement of 5 absolute percentage points was observed at remeasurement 22 months later (i.e., the indicator now stands at 65%), the relative improvement would be calculated as a relative improvement of 12.5% (reduction of the 40% failure rate by 5 percentage points). This approach was used to more clearly illustrate that QIOs were being assigned to improve safety and quality by reducing clinical failures.

Surgical Infection Prevention Medication Therapy Work.

In the Seventh Statement of Work period (roughly 2002-2005), the work described above continued but stroke was discontinued as a clinical topic priority and instead QIOs began to work to reduce surgical infections through timely use of appropriate antibiotics. This was the only national project addressing this issue during this time period and preliminary results suggest the effort has been successful. QIOs recruited 56 hospital teams from 50 states and territories to work on improving three aspects of drug therapy to prevent surgical infections: selection of appropriate antibiotics, timely pre-surgical administration (less than one hour before incision), and timely discontinuation to minimize the risk for developing resistant strains. In the pilot hospitals' population of surgical patients (35,543 patients), preliminary results show improvement in these quality indicators:

- Provision of prophylactic antibiotics with 1 hour before incision increased from 72.2% to 92.4% (p <0.0001);
- Use of guideline antibiotic increased from 89.9% to 95.5% (p=0.016);
- Antibiotic discontinuation increased from 67.4% to 85.1% (p<0.0001);
- Surgical site infection rate fell from 2.28% to 1.65% (NS).

Other QIO Hospital Medication Therapy Work .

The QIO in Washington State, Qualis Health, has initiated a project in which emergency department personnel conduct medication reconciliation to improve care for patients arriving through the ED. The project is led by the hospital pharmacists.

Home Health Agency Medication Therapy Work.

During the 7th Statement of Work, QIOs worked with Home Health Agencies to improve care in a number of areas (about 40). One of these clinical target areas is the percentage of home health patients who demonstrate improvement in their ability to take oral medications. As a result of QIOs working with home health agencies on this quality problem, over the period 2002 through 2004, agencies self assessed their performance and submitted 521 plans of action to QIOs indicating their specific intentions to improve care in this dimension. Relative to the baseline measurement period, the year between May 2001 and April 2002 the following results have been observed:

**Relative Improvement in Percentage of Patients Improving Ability to take Oral Medications May 2001-April 2002 Compared to May 2003-April 2004**

| Nationally-- All HHAs | HHAs NOT Submitting POAs to QIOs | HHAs Submitting POAs to QIO |
|---|---|---|
| 8.7% | 8.4% | 14.3% |

Nursing Home Medication Therapy Work of QIOs.

Although not required under the core Medicare contract, some QIOs are already working to improve the quality of pharmacotherapy in long term care facilities. For example, Medical Review of North Carolina has engaged over 40 nursing homes in a medication safety program focused on the risky therapy hand offs involved as patients enter and leave the nursing home. HSAG, the QIO for Arizona, and Medical Review of North Carolina are both involved in projects to improve osteoporosis therapy among nursing home residents. These osteoporosis projects are being conducted with the valuable assistance of two AHRQ-funded Centers for Education and Research in Therapeutics (CERTs) located at Duke University and the University of Alabama at Birmingham.

QIO Medication Therapy Work with Medicaid Enrollees.

Several QIOs have used Medicaid claims data to evaluate the care needs of the dually enrolled population (those enrolled in both Medicare and Medicaid) and to improve care for people with asthma and diabetes, including the Arkansas Foundation for Medical Care, Medical Review of North Carolina, Mountain-Pacific Quality Health Foundation (the QIO for Hawaii, Montana, and Wyoming), and QSource (the QIO in Tennessee).

**New QIO Opportunities to Contribute to Improving Pharmacotherapy**

In section 109(b) of the Medicare Modernization Act (MMA), Congress added to the Medicare QIO program a new task. This provision updates the 1986 amendments assigning QIOs to work with "HMOs and competitive medical plans" to clarify that QIOs are meant to work with the new Medicare Advantage plans and Prescription Drug Plans created by the MMA. In addition, it states –

> "(b) PRESCRIPTION DRUG THERAPY QUALITY IMPROVEMENT- Section 1154(a) (42 U.S.C. 1320c-3(a)) is amended by adding at the end the following new paragraph:
>
> "(17) The organization [QIO] shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug sponsors offering prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy."

CMS has decided to implement this new responsibility under the QIO program under the physician office tasks of the SOW8 contract. The primary emphasis in the SOW8 physician office work is to assist particularly small and medium sized physician office practices in purchasing and implementing health information technology, including e-prescribing either as a freestanding technology or as a part of a more sophisticated system incorporating clinical decision support, such as a full electronic

health record (EHR). CMS and the QIOs alike appreciate that success will depend on the ability of QIOs to assist physicians not only to assess their practice readiness for automation of clinical information systems, and not only to have the confidence to invest in such systems, but also to facilitate actual use of the new systems in clinical practice. Eccles and colleagues studied ambulatory primary care practices and found the presence of health information technology systems –even with good quality clinical data support software-- were not effective in improving the care of patients with asthma and angina. The main problem was that physicians did not use the CDSS software on their office systems (see Eccles et al, BMJ, February 18, 2005).

In the text of the contract describing the new drug therapy work in task 1d3, CMS states:

> "In addition to QIO efforts in the physician practice setting in this SOW, the QIO shall focus on improving safety in the delivery of prescription drugs. The widespread use of e-prescribing with comprehensive decision support tools is expected to improve the quality of prescription drug delivery. Until this broader use, the QIO shall implement quality improvement projects focusing on improved prescribing derived from evidence-based guidelines."

This passage highlights CMS' view that electronic systems will accomplish much of what is needed in the area of improving the safety and quality of pharmacotherapy, with the guidance and support of the QIOs to spur adoption and proper use of such systems. CMS has made two important decisions to move forward on the HIT agenda but also to simultaneously assign the QIOs to work through other means to improve the safety and quality of drug therapy for the disabled and older Americans.

The new drug therapy safety and quality work is more developmental in nature than most other provisions of the new Medicare QIO contract. This is in part due to the fact that CMS has had little involvement with ambulatory pharmacotherapy quality improvement previously. Implementation of the statutory provisions governing quality oversight and improvement under the Medicaid drug benefit (section 1927(g) of the Social Security Act) having been left entirely to the states under Medicaid). In addition, work to improve the safety and quality of ambulatory drug therapy will be new to most of the QIOs. CMS has set forth the assignment in the following text:

> "General Requirements for Task 1d3
>
> i. When the PDP or Medicare Advantage PDP, both at risk for prescription cost, agree that the activities are supportive of its contractual goals of quality improvement and cost containment, the QIO shall provide resources of staff and data, including Part D integrated with Part A and B data, when that enhances PDPs' activities.
>
> ii. [QIOs shall work closely with groups of "identified participants," who] are physician practices and/or pharmacies designated by the QIO to engage in quality improvement activities. The QIO shall work with identified participants on clinical performance measure improvement.
>
> iii. The QIO shall conduct the following activities:

- Report the required information on drug plans and physician practices/pharmacies with which it has worked and quality improvement projects that it has deployed;

- Develop and deploy an intervention strategy;

- Contribute to the Program knowledge base through inter-QIO sharing by providing information to other QIOs and conducting a project that contributes to Program learning;

- Other appropriate activity to include PDPs and providers in quality improvement activities as determined by the Project Officer and Task 1d3 [government task leader]; and

- Respond to and track beneficiary written complaints as of January 1, 2006, regarding quality of care with respect to covered prescription medications in accordance with Title XVIII of the Act.

iv. If one or more PDPs, pharmacies, or physician practices in a QIO's state/jurisdiction serve Medicare beneficiaries in other states/jurisdictions, the QIO shall coordinate outreach and improvement work with the other QIOs in the states/jurisdictions in which such multi-state/jurisdiction entities operate."

CMS is currently developing a set of drug therapy quality measures and will provide these to QIOs for their use in assessing the quality of care at baseline and again after implementation of QIO improvement projects with plans, pharmacies and physician office practices. The contract describes some likely measures and characteristics of measures, provided below *verbatim*.

Further elaborating the work expected of QIOs in the course of implementing the activities described above, CMS outlines in the new SOW8 QIO contract language a set of options for the QIOs to choose from in undertaking this new work. QIOs must choose one subtask from each of two pairs of task options. Each QIO must choose either Option 1 or Option 2, described below.

<u>Option 1: Improve prescribing using Part D data</u>. CMS states in the new contract,

"In this option, the QIO shall work with physician practices and PDPs to improve prescribing with a particular emphasis on assisting physician practices that use or are adopting e-prescribing. CMS may specify that a percentage of the participating physicians must be e-prescribing. Quality of care measures for this option are currently under development" but may include—

- Use of avoidable drugs in the elderly;
- Frequency of selected, clinically important drug interactions;
- Generic prescribing ratios within certain therapeutic categories;
- Use of selected medications within certain therapeutic categories;
- Duplication of drugs in a therapeutic class.

Option 2: Improving patient self-management through medication therapy management services (MTMS). CMS states in the SOW8 contract, "In this option, the QIO, partnering with the PDP, shall offer assistance to all pharmacies or the delivery locus of the MTMS that serve beneficiaries in the state/jurisdiction, as well as multi-state PDPs, to improve MTMS. If this assistance is accepted, the QIO shall select and assist an identified participant group (IPG) of pharmacies that is no smaller in number than 5% of the total pharmacies participating in the PDPs. Quality of care measures for this option are currently under development" but may include—

- Medication management services: process measures [e.g., percent patients using MTMS];
- Medication management services: outcome measures [e.g., CAHPS survey, or "comparisons of the utilization of emergency room visits or re-hospitalizations for the same condition for selected conditions (e.g., acute myocardial infarction, diabetes mellitus) between those who have used MTMS and those who have not."]

In addition to its choice of either Option 1 or Option 2 above, each QIO must choose to perform either Option 3 or Option 4.

Option 3: Improving disease-specific therapy using integrated Part A, B, and D data.
CMS states in the SOW8 contract: "In this option, the QIO, partnering with the PDP, shall work with physician practices to improve management of patients who have specific conditions or who are receiving specific medications, focusing on physician practices that are using EHR or e-prescribing. The QIO shall select and provide assistance to IPG physician practices from Task 1d1 that are using EHRs and e-prescribing in addition to working with those that already use these technologies outside of the scope of Task 1d1."

CMS notes that quality of care measures for this option are currently under development but may include—

- Avoidance of specific drugs in beneficiaries with certain conditions (drug-disease interaction);
- Therapeutic monitoring for patients receiving specific drugs [e.g., timely INRs for patients receiving warfarin];

Option 4: QIO-directed project. CMS states in the new SOW8 contract, "The QIO may develop proposals to address identified and potentially significant issues in drug therapy and submit them to its Project Officer and Task 1d3 GTL [government task leader] for approval. The development and implementation of any project must be well documented. Additionally, CMS may direct the QIO to conduct specific drug therapy quality improvement projects."

**Recommendations**

In the future, QIOs will have data and systems capacity to merge claims data for use of Medicare benefits under Part A (hospital), Part B (physician office services and lab testing), and Part D (outpatient drug therapy). However, the system needed to merge these data is not yet built and there is some question whether it will be ready in time for QIOs to use merged data to identify plans, practitioners, pharmacies and physician practices that would benefit from a concerted quality improvement program.

In addition, by the end of the upcoming 8th Statement of Work, QIOs will have helped about 5% of small and medium size physician office practices to adopt and use health information technology to

monitor and improve patient care. However, most physicians and practices will not be in a position to use this technology even if the QIOs succeed beyond anyone's expectations.

Meanwhile, according to the estimates of Gurwitz and his colleagues, in each of the three years of the 8th QIO Statement of Work another 90,000 preventable life-threatening or fatal adverse drug events will occur in the ambulatory Medicare patient population. What can be done with the resources of the Medicare program, including the national network of Quality Improvement Organizations (QIOs), to meaningfully reduce this unacceptable figure?

Here are several recommendations as to how to make good use of the national QIO resource. These points will be the focus of AHQA's oral testimony before the IOM panel on Medication Error Identification and Prevention.

**Encourage CMS to approve QIO proposals for 8th SOW projects that do not--**
- rely greatly on as yet rare physician office practice health information technology systems;
- depend on as yet unbuilt data systems for merging Part A, B and D Medicare claims data.

**Encourage CMS to approve QIO proposals for projects in the 8th SOW that do establish as a high priority the transition between care settings, particularly hospital discharge,** because—
- CMS and the QIOs already have a well established national system for identifying patients who are hospitalized for AMI and heart failure and are therefore at high risk for readmission and death in the absence of reliably initiated and well-monitored pharmacotherapy;
- the most powerful single predictor of adherence to ambulatory drug therapy is the initiation of that therapy at the time of or immediately after hospital discharge (see Aronow et al, in Archives of Internal Medicine, November 24, 2003; Butler, Jain, and Ray in JACC, November 6, 2002; Butler, Jain, Ray, in JACC, June 2, 2004);
- the most common cause of adverse events befalling patients after hospital discharge are adverse drug events -- 66% of all adverse events, according to Forster and colleagues (see Annals of Internal Medicine, February 4, 2003);
- the potential for partnership between QIOs and several other organizations (including the American College of Cardiology the American Heart Association, , the American Pharmacists Association, the American Society of Health-system Pharmacists, the Institute for Healthcare Improvement (IHI), the Joint Commission for the Accreditation of Health Care Organizations (JCAHO), and others) all of which are gearing up for a coordinated national push to improve the reliable provision of a bundle of services cardiovascular patients need at the time of hospital discharge, including medication reconciliation, discharge medication orders, and discharge instructions;
- the financial savings accruing to Medicare Advantage plans from better discharge and follow up of chronically ill patients at high risk of readmission, such as those with heart failure, can be invested under the plans' Medication Therapy Management System for payments to mobilize the underused but critical infrastructure of community pharmacy.

**Encourage CMS to use public reporting of the quality of pharmacotherapy provided to enrollees in every prescription drug plan, including—**
- public reporting of *health outcomes* for patients whose condition requires reliable delivery of high quality pharmacotherapy (e.g., readmissions for heart failure patients).
- public reporting of key *clinical processes* for patients whose condition requires reliable delivery of high quality pharmacotherapy (e.g., discharge medications for heart failure; percentage of such

patients receiving a one week post-discharge follow up visit with the patient's community pharmacist).

- to motivate providers and secure leadership engagement in the need for improvement, CMS should build on the lessons of the combined public reporting and quality improvement programs in the nursing home, home health, and ESRD settings (the latter facilitated by Medicare funded ESRD Networks, analogous to QIOs), by publicly reporting the same (or a subset of) quality indicators as those the QIOs are also working with plans, practitioners and providers to improve performance.
- comparative data using a set of identical quality indicators (or subset of indicators) for both integrated Medicare Advantage and the freestanding Prescription Drug Plans in each market, to permit beneficiaries to identify differences in the quality of clinical care in conditions sensitive to reliable initiation and monitoring of pharmacotherapy.

**Establish a formal relationship between the QIO program and the AHRQ-funded Centers for Education and Research in Therapeutics (CERTs).** The two entities are complementary in their strengths. CERTs are university-based entities with extensive expertise in pharmacotherapy that are focused on translation of pharmacotherapy research into practice, while the QIOs maintain a strong field presence with relationships in every state and territory explicitly for the purpose of facilitating adoption of evidence-based practices. The rich data and analytic capacity of the QIOs is well-suited to test on a large scale the research findings and recommendations of CERTs.

**Ask Congress to authorize a demonstration project in which hospitals share in a portion of Medicare program savings resulting from improved discharge care of patients with selected conditions** (e.g., patients with heart failure who are at high risk of readmission). At present, institutions such as the LDS Hospital in Salt Lake City have dramatically improved the care of cardiovascular patients and documented reduced readmissions and mortality, but see only increased economic burdens as a result. Medicare should pilot a gain-sharing program with such institutions in which documented improvements in processes proven to reduce costs and improve quality are rewarded with a share of the savings created.

**To better reflect the lessons of the Agricultural Extension Service, create a capacity in the QIO program for QIOs to assist in the solving of problems identified by providers and practitioners themselves**. The QIO program is already providing a service very similar to the valuable field presence of the agricultural extension service, which helps to bring scientific findings to farmers. But the QIO program goes into the field with an agenda developed by CMS, aiming to persuade others to adopt changed practices. The agricultural extension service also offers value in fielding a force of science-based organizations to hear the problems of farmers and help them address concerns they identify. This approach builds trust and a sense of shared commitment to progress that will benefit Medicare beneficiaries as much as the American consumers of agricultural products.