

Report to Congress

**Improving the Medicare Quality Improvement Organization
Program – Response to the Institute of Medicine Study**

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Executive Summary

The Medicare Quality Improvement Organization (QIO) Program (formerly referred to as the Medicare Utilization and Quality Control Peer Review Program) was created by statute in 1982 to improve quality and efficiency of services delivered to Medicare beneficiaries. In its first phase, which concluded in the early nineties, the Program sought to accomplish its mission through peer review of cases to identify instances in which professional standards were not met for purposes of initiating corrective actions. In the second phase, quality measurement and improvement became the predominant mode of Program operation. As a result of significant changes that have occurred in our understanding of how to improve quality, as well as changes in the environment to promote public reporting of provider performance and the development of performance-based payment programs, the QIO Program launched the QIO 8th Scope of Work (SOW) with a revised approach to supporting high levels of provider performance.

Section 109(d)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) mandated that the Institute of Medicine (IOM) conduct a review of the Program and how its impact could be enhanced. The IOM issued a report based on its study on March 9, 2006. The Centers for Medicare & Medicaid Services (CMS) also undertook its own intensive internal review of the Program beginning the fall of 2005. As a result of the IOM study and the internal Agency review, CMS has determined that there is a need for improvement of the Program to enable it to effectively promote high quality, efficient, and person-centered care for Medicare beneficiaries. This report responds to Section 109(d)(2) of the MMA, which requires the Secretary to report on the results of the IOM Study, including any recommendations for legislation, and provides a discussion of how CMS is taking action to address the issues raised in the Study.

CMS views the QIO Program as a cornerstone in its efforts to improve quality and efficiency of care for Medicare beneficiaries. The Program has been instrumental in advancing national efforts to measure and improve quality, and it presents unique opportunities to support improvements in care in the future. Consequently, CMS is undertaking these activities to ensure that the Program is focused, structured, and managed so as to maximize its ability for creating value. These improvements support broader initiatives to provide transparency for beneficiaries and create performance-based payment programs for providers. Most health care providers deliver care to Medicare beneficiaries as well as patients insured by commercial insurers. Recent efforts to improve quality reflect the idea that shared quality improvement goals and consistent quality measures for all patients will result in less burden to providers, as well as the opportunity to identify and achieve meaningful performance improvements. Thus, to achieve demonstrable and significant improvement in care for Medicare beneficiaries, the Program is supporting partnerships that engage a broad group of stakeholders for the purpose of improving quality of care for all patients based on common goals and measures. This approach facilitates leveraging private sector resources and expertise at the local and national level, with a potentially more significant impact on the quality and efficiency of the health care system.

CMS' response to the IOM study includes the following important Program improvement actions:

- Strengthening evaluation design to better assess the impact of the Program
- Strengthening financial oversight and establishing requirements for QIO board governance to assure appropriate use of contractor funds and the representation of key constituencies
- Increasing competition for QIO contracts
- Enabling QIOs to release information to beneficiaries about QIO findings related to their complaints
- Directing QIOs to focus on the local achievement of national quality and efficiency goals, to improve care for beneficiaries with significant medical needs
- Directing QIOs to support local initiatives to develop and use information on quality and cost to help beneficiaries, their caregivers, and their health professionals make better choices about their treatment options, and self-care

The paper has three sections. The first provides a brief history of the Program, with an emphasis on recent activities relevant to Program improvement activities. The second describes IOM's mandate under the MMA as well as the IOM recommendations to the QIO Program to enhance its impact. The third summarizes CMS' response to the IOM recommendations. Generally, the IOM recommendations for restructuring and improving the QIO Program are consistent with the improvements that have been undertaken in the QIO Program. As part of CMS' ongoing internal review of the QIO Program, CMS will continue to consider the IOM recommendations and make changes as appropriate to the Program.

Also included are two appendices – QIO 8th SOW Performance Measures and Proposed QIO Contractor Governance Guidelines.

Section One: Background

In 1982, Congress established the Medicare Utilization and Quality Control Peer Review Program, which was incorporated into Title XI of the Social Security Act. The purpose of the Program, as stated in Section 1862(g), is to improve the efficiency, effectiveness, economy, and quality of services delivered to Medicare beneficiaries.

Initially, during the Program's first phase, case review by physician peers was the primary method of accomplishing its purpose. Peer Review Organizations (PROs) reviewed cases referred by beneficiaries and providers and selected via sampling to identify instances in which professional standards were not met, and required providers to implement corrective action plans or referred them for sanction proceedings where appropriate. Although case review may have resulted in improvement by individual providers, the improvement was not systematic or measurable, and the reliability of case review determinations was questionable.

In the early nineties, in part in response to the recommendations of a report by the Institute of Medicine (IOM), the Program made a major change in its method. Case review was supplemented by the collection of data for quality measures, and where there was opportunity for improvement, PROs (renamed Quality Improvement Organizations or QIOs several years ago) offered technical assistance to providers. During this second phase of the Program, improvement on quality measures occurred. However, the impact of QIO activities on these improvements was not clear, and in 2003, the MMA mandated a review by the IOM of the Program's effectiveness.

Also over the past decade, the quality improvement landscape in health care has changed dramatically in several respects:

- Gaps in healthcare quality are more widely recognized by policymakers, consumers, and provider organizations. The landmark IOM publication "To Err is Human," that documented safety issues in hospital care, stimulated such recognition.
- The need for more fundamental changes in health care processes and systems to deliver consistent high-quality care is also recognized, again in part as a result of another IOM report, "Crossing the Quality Chasm."
- Movement has begun and momentum has now developed toward consumer choice in healthcare, through public reporting of provider performance and, more recently, performance-based provider payment.

Cognizant of these trends, the Program launched a strategic planning process in preparation for the current contract period (the QIO 8th Scope of Work or 8th SOW—effective in August 2005). Through this process, the Program determined that although improvement had occurred on clinical quality measures during the recent contract periods, there was a need for improvement of the Program if it was to succeed in promoting broader, more rapid improvement that resulted in high levels of quality for Medicare beneficiaries and efficient use of Medicare resources. To accomplish this, CMS planned improvements of QIO quality improvement work in the 8th SOW around

the provision of assistance related to four strategies that if adopted by providers can lead to high performance: measurement and reporting of quality, adoption and use of health information technology, redesign of care processes, and change in organizational culture and management.

During the spring of 2005, the Program convened a series of four two-day meetings with providers, accreditors, provider organizations and medical specialty societies, and other government agencies. The meetings were organized by setting: nursing home, home health, hospital, and physician office. Participants made recommendations on setting-specific future quality measurement development, use of the four strategies in improving care, and how the QIO Program should operate to support quality improvement. Participants strongly endorsed the need for the Program to support quality measurement and to improve through the dissemination of information and provision of assistance directly to providers who need it for quality reporting and quality improvement.

Concurrently, CMS expanded its emphasis on demonstrable, systematic quality improvement. The Agency issued, in July 2005, a Quality Improvement Roadmap that included as its aim the provision of “the right care for every person every time.” The Roadmap described five activities that CMS will use to achieve this aim:

- Work through partnerships, including within HHS, with other Federal and State agencies, and with nongovernmental partners including health professionals.
- Publish quality measurements and information, including measures directed toward both the beneficiary audience and the professional/provider/purchaser audience.
- Pay in a way that expresses our commitment to supporting providers and practitioners for doing the right thing – improving quality and avoiding unnecessary costs, and promoting competition to improve quality and lower costs – rather than directing more resources to less effective care.
- Assist practitioners and providers in taking the necessary steps to make care more effective and less costly, in particular greater use of effective electronic health systems.
- Become an active partner in driving the creation and use of evidence about the effectiveness of healthcare technologies, to bring effective innovations to patients more rapidly, and to help doctors and patients use the treatments we pay for more effectively.

The Roadmap ensures that the QIOs will play a crucial role in these activities.

The QIO 8th SOW was launched in August of 2005. The 8th SOW incorporated several features of Program improvement:

- National goals were set, with QIO contracts setting related targets at the state level, based on a focused set of largely publicly-reported measures, and aiming at high levels of performance (see Appendix 1 for 8th SOW contract measures)
- QIOs were assessed with respect to their ability to succeed on each contract task, primarily based on 7th SOW performance, and those determined to be at risk were required to implement acceptable capability improvement plans
- The award fee structure was enhanced such that most of the award is based on individual QIO performance and the achievement of national goals by the Program
- Program evaluation was strengthened by concentrating most QIO resources on working with identified subsets of providers in each state, with the collection of data on the type and intensity of QIO assistance, and survey information on whether the provider believes that improvement could have been achieved without the assistance
- National contracts for support of QIO work at the state level were restructured and made performance-based, with a new structure for coordination of management and activities

While measurable quality improvements have been occurring in Medicare, concerns have been raised about whether the QIOs are having the greatest impact possible on achieving these improvements. For example, a month prior to the 8th SOW launch, an article in the Journal of the American Medical Association raised questions about whether the improvement that had been observed in hospital quality measures in the 6th SOW was attributable to the Program. Members of Congress and others have also raised questions about Program management, impact, and the low volume of beneficiary complaint reviews and policies restricting the release of information on the review to the complainant.

Over the past six months, CMS undertook an intensive internal Agency review of the Program and its future. Through this ongoing review, the Agency took a fresh look at what needs to be done to improve the quality and efficiency of care for Medicare beneficiaries. We considered the role that the QIO Program should play in supporting Agency efforts as described in the Quality Improvement Roadmap, particularly related to the Agency's initiatives to modernize Medicare through pay-for-performance and competitive bidding programs. We assessed what changes need to be made to Program management. We have also considered how the Program can support the Presidential initiative to provide better information on quality and cost for health care consumers and providers. Recent efforts to improve quality reflect the idea that shared quality improvement goals and consistent quality measures for all patients will result in less

burden to providers, as well as the opportunity to identify and achieve meaningful performance improvements. Thus, to achieve demonstrable and significant improvement in care for Medicare beneficiaries, the Program is supporting partnerships that engage a broad group of stakeholders for the purpose of improving quality of care for all patients based on common goals and measures. This approach facilitates leveraging private sector resources and expertise at the local and national level, with a potentially more significant impact on the quality and efficiency of the health care system.

The IOM recommendations for restructuring and improving the QIO Program are generally consistent with the improvements that have been undertaken in the QIO Program. In the next section, we describe the IOM recommendations on different aspects of the QIO Program, and indicate CMS' improvement efforts in these areas. Our ongoing review of the program is expected to produce results that CMS will use to consider possible further improvements to the Program.

Section Two: IOM Study and Recommendations

Section 109 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Institute of Medicine (IOM) of the National Academy of Sciences to conduct an evaluation of the program under Part B of Title XI of the SSA, and submit a report on the results of the study, including any recommendations for legislation. The IOM is directed to include in the study a review of the following:

- An overview of the program under such part.
- The duties of organizations with contracts with the Secretary of HHS under such part.
- The extent to which quality improvement organizations improve the quality of care for Medicare beneficiaries.
- The extent to which other entities could perform such quality improvement functions as well as, or better than, QIOs.
- The effectiveness of reviews and other actions conducted by such organizations in carrying out those duties.
- The source and amount of funding for such organizations.
- The conduct of oversight of such organizations.

Section 109 of the MMA also provides that if, based on the IOM study, the Secretary of HHS finds that other entities could improve quality in the Medicare program as well as, or better than, the current quality improvement organizations, the Secretary shall provide for increased competition through the addition of new types of entities which may perform quality improvement functions.

The IOM made recommendations in five areas: focus on quality improvement and performance management; data processing; program management; program evaluation; and, program funding. The recommendations follow:

1. Focus on Quality Improvement and Performance Measurement

Recommendation: The Quality Improvement Organization (QIO) Program must become an integral part of strategies for future performance measurement and improvement in the health care system. The U.S. Congress, the Secretary of HHS, and the Centers for Medicare & Medicaid Services (CMS) should strengthen and reform key dimensions of the QIO program, emphasizing the provision of technical assistance for performance measurement and quality improvement. These changes will enable the program to contribute to improve quality of care for Medicare beneficiaries as they move through multiple health care settings over time.

- Quality improvement should embrace all six aims for health care established by the IOM (safety, effectiveness, patient centeredness, timeliness, efficiency, and equity).
- QIO services should be available to all providers, Medicare Advantage organizations, and prescription drug plans.

- QIO services should emphasize hands-on and other technical assistance aimed at building provider capacity as needed by each provider setting, such as:
 - Instruction in how to collect, aggregate, and interpret data on the measures to be used for internal quality improvement, public reporting, and payment.
 - Instruction in how to conduct root-cause analyses and deep case studies of sentinel events or other problems.
 - Advice and guidance on how to bring about, sustain, and diffuse internal system redesign and process changes, particularly those related to the use of information technology for quality improvement and those that promote care coordination and efficiency through an episode of care.
 - Improvement of and technical support for the direct role of providers in beneficiary education as an integral component of improved care, better patient experiences, and patient self-management.
 - Assistance with convening and brokering cooperation among various stakeholders.

Recommendation: Quality Improvement Organizations (QIOs) should actively encourage all providers to pursue quality improvement and should assist those providers requesting technical assistance. If demand exceeds resources, priority should be given to those providers who demonstrate the most need for improvement or who face significant challenges in their efforts to improve quality. CMS should encourage and expect all providers to continuously improve the quality of care for Medicare beneficiaries.

Recommendation: Congress and CMS should strengthen the organizational structure and governance of QIOs to reflect the new, narrower focus on technical assistance for performance measurement and quality improvement. The Congress should eliminate the requirement that QIO governing boards be physician-access or physician-sponsored, while also enhancing the boards' ability to provide oversight and direction. Congress and CMS should improve QIO governance by requiring: (1) broader representation of all stakeholders on QIO boards, including more beneficiaries and consumers with the requisite training and executive-level representatives of providers; (2) expansion of the areas of expertise represented on QIO boards through the inclusion of individuals from various health professional disciplines, group purchasers, and professionals in information management; and (3) greater diversity of quality improvement professionals on QIO boards through the inclusion of experts from outside the health care field and beyond the local community.

- QIO boards should strengthen their committee structures and consider development plans for individual members, implementation of annual performance evaluations, and annual assessments of the board as a whole as well as plans for its improvement.
- Organizations holding QIO contracts should include on their websites a listing of members of their boards of directors, along with information on the compensation provided to those members and the chief executive officer.

Recommendation: Congress and CMS should develop mechanisms other than those already in place to better manage complaints and appeals of Medicare beneficiaries, as well as other case reviews. The QIO in each state should no longer have responsibility for handling beneficiary complaints, appeals, and other case reviews for payment or other purposes.

- Reviews of beneficiary complaints regarding the quality of care received are critical and should be a top priority for contractors that treat the beneficiary as their primary client. CMS should consolidate the review functions into a few regional or national competitive contracts or determine the most appropriate agencies with which to contract for the purpose in each state.
- To handle beneficiaries' appeals concerning coverage and other case reviews more efficiently, CMS could contract at the national or regional level with a limited number of appropriate organizations, such as fiscal intermediaries or individual QIOs.
- This devolution of responsibilities would allow QIOs to concentrate their resources on quality improvement efforts with providers.

2. Data Processing

Recommendation: The Secretary of DHHS and CMS should revise the QIO program's data-handling practices so that data will be available to providers and the QIOs in a timely manner for use in improving services and measuring performance.

- CMS should initiate a comprehensive review of its data-sharing systems, processes, and regulations to identify and correct practices and procedures, including abstraction of medical chart data, that restrict the sharing of data by the QIOs for quality improvement purposes or that inhibit prompt feedback to the QIOs and providers on provider performance.
- The QIO program should support the processes of national reporting of performance measures, data aggregation, data analysis, and feedback.
- The Secretary of DHHS should allow and encourage the sharing of medical claims data when the sharing of such data is not precluded by the privacy protections of the Health Insurance Portability and Accountability Act, as well as the sharing of more detailed complaint-resolution data with complainants.
- CMS should work toward the ultimate goal of integrating more care data from all providers and public and private payers to create both records of patient care over time and population-level data.
- Independently of the core QIO contract, CMS should be responsible for ensuring and auditing the accuracy of data submitted by providers that participate in the Medicare program. Providers should be accountable for the validity and accuracy of the quality measurement data they submit. The QIOs should supply providers with technical assistance to improve the validity and accuracy of the data collected.

3. QIO Program Management

Recommendation: CMS should establish clear goals and strategic priorities for the QIO program. Congress, the Secretary of DHHS, and CMS should improve their management of the QIO program as necessary to support those goals, especially by enhancing contracting processes for the QIO core contract and QIO Support Center (QIOSC) contracts; integrating core, support, and special study contracts within the program; and improving coordination and communication within the program.

- CMS should provide the QIOs with a coherent and feasible scope of work that sets forth clear priorities for quality improvement and performance measurement.
 - CMS' priorities and planning efforts should focus on integrating QIO collaboration with various types of providers to improve the coordination of patient care across multiple settings.
 - To prepare for the 9th scope of work, CMS should consider conducting a national survey of the main provider settings (nursing homes, home health agencies, hospitals, outpatient physician practices, end-stage renal disease facilities, prescription drug plans, and pharmacies) to determine specific unmet needs for technical assistance. Such information might be complemented by information from focus groups conducted with a mix of representatives from the various settings.
 - The QIO core contracts and the QIOSC contracts should include incentives aimed at promoting a broader transfer of knowledge concerning successful quality improvement interventions and more rapid improvement.
 - The QIOs should have the resources they need to conduct at least one locally initiated quality improvement project on the basis of demonstrated need and the design and evaluation criteria established by CMS.
- Congress and CMS should change the contract structure for core QIO services for the 9th Scope of Work:
 - Strong incentives and penalties that reward high performance and penalize poor performance should be included. CMS should encourage sufficient competition for the core contracts to permit the selection of a QIO contractor on the basis of contractor-proposed interim and final performance measures and goals. During the contract period, there should be less process management of internal QIO operations by CMS.
 - Congress should permit extension of the core contract from 3 to 5 years to allow for the measurement, refinement, and evaluation of technical assistance efforts and the achievement of transformational goals.
 - There should be greater competition for each new contract. CMS should consider previous experience and performance as a QIO among the selection criteria; demonstrated capacity to support quality improvement on the part of any eligible organization should predominate.
 - Performance periods should be consistent. All QIOs should begin and end the contract cycle on the same date so the planning, implementation, and evaluation of each scope of work can be applied nationally.

- A timetable should be established for goal setting, program planning, and funding processes for the core QIO contracts. The schedule should ensure that new scopes of work are issued in a timely fashion and that contract and funding levels are developed and finalized so as to allow sufficient time for QIOs and competing organizations to prepare in advance for the new contract without major program and staff disruptions.
- CMS should award QIOSC contracts several months in advance of a new QIO contract cycle to allow for the preparation of tools and materials for QIO use, definition of the required tasks and deliverables that will serve the QIOs and the Government Task Leaders, and inclusion of explicit methods for assessment of the contractor's performance. Congress and CMS should allow entities other than QIOs with expertise in quality improvement to bid on QIOSC contracts; familiarity with QIO work, the capability to carry out the work, and experience in carrying out the required functions should be appropriately weighted when the bids are assessed.
- The QIO core contract and contracts for special studies, support services, and QIOSCs should all reflect the explicit goals and priorities of the program.
- CMS and the Agency for Healthcare Research and Quality should establish ongoing mechanisms for sharing quality improvement knowledge and research results especially through QIOSCs.
- CMS should take steps to improve coordination and communications within the QIO program and with QIOs. In particular, the roles and responsibilities of, and communications among Project Officers, Contract Officers, Government Task Leaders, Scientific Officers, and QIO executives and their staff should be clarified.
 - CMS should build self-assessment, transparency, clearer communications, and continuous quality improvement into the daily workings of the team overseeing the QIO program, just as the QIOs expect providers to do.
 - The contracting function should be subordinate to and support the program management and business functions.
 - Ongoing program evaluations should provide guidance for the continuous improvement of program management, coordination, and communications.

4. QIO Program Evaluations

Recommendation: CMS should develop four types of evaluation to assess the QIO program. CMS should conduct three of these four types of evaluation internally to assess QIO performance against predetermined goals and priorities at the following levels: (1) the program as a whole, (2) individual QIOs with respect to the core contract, and (3) selected quality improvement interventions implemented by QIOs. DHHS should periodically commission the fourth type of evaluation—independent, external evaluations of the QIO program's overall contributions.

- The QIOs should be learning organizations, continually improving the assistance they offer to health care providers. CMS should develop explicit benchmarks for

use in ongoing measurement of progress on the effectiveness and the costs of the program.

- CMS should form a technical expert panel to offer ongoing guidance on the design of the three types of internal CMS evaluations, including options for identifying optimally performing QIOs, as well as methodologies for attributing quality improvements to the QIO program's interventions.
- CMS should ensure that evaluation of the effectiveness of quality improvement interventions is conducted. The committee suggests that CMS should use the most rigorous evaluation designs practicable, including randomized controlled trials. This approach should also contribute to CMS' overall program evaluation.
 - Evaluations should include concurrent, qualitative descriptions and assessments of the nuanced nature of the QIOs' role in quality improvement interventions and the roles of other players.
 - As appropriate, evaluations should be stratified among provider settings and across states and regions.
 - CMS should assess the cost-effectiveness of each type of intervention to assist with the allocation of resources.
 - The Secretary of DHHS should allocate adequate funds from the QIO apportionment to carry out, on an ongoing basis, both internal and external evaluations.

5. QIO Program Funding

Recommendation: Congress and the Secretary of DHHS should focus all QIO resources on supporting health care providers' performance measurement and quality improvement efforts. The Secretary should remove from QIO core contracts funds sufficient to support case reviews, appeals, and beneficiary complaints when those functions are devolved to other organizations. The Secretary should increase the remaining funds to allow for inflation, the incorporation of evaluations into all QIO work, the increased numbers of providers and beneficiaries being served, and the labor-intensive nature of technical assistance and quality improvement activities.

- The multiple evaluations undertaken during the 8th and 9th SOWs should guide future funding decisions, with budget increases or decreases being provided according to the evaluation findings. If the evaluations demonstrate that no positive impact is attributable to the QIO program's efforts, CMS will need to rethink its quality improvement approach and the possible benefit of transitioning funds to an alternative structure and strategy for Medicare.
- Once a national performance measurement and reporting system has been established, its priorities should help guide the funding levels and policy direction of the QIO program, recognizing that adequate funding is necessary to reach the goals set for the QIO program.
- The Secretary of DHHS should ease the conflict-of-interest restriction with regard to supplementing the QIO quality improvement budgets with external funds. Given the limits of federal funding, the QIOs should be allowed to seek funds for quality improvement activities from providers and other organizations as appropriate.

Section Three: Response to IOM Recommendations

Following the release of the IOM study, CMS refined its approach to program improvement that resulted from the internal review that the Agency initiated last fall. CMS views the IOM recommendations as generally consistent with the conclusions that arose from this ongoing internal review of the Program. In some areas, there are differences. A summary of CMS' response to the IOM recommendations and a discussion of ongoing CMS activities in each of the five IOM recommendation areas are as follows:

1. Focus on Quality Improvement and Performance Measurement

- CMS agrees that the Program should support performance measurement and improvement. We see the Program as an essential component of Agency and Departmental initiatives in transparency and performance-based payment of providers.
- CMS agrees that all providers should be encouraged to measure and improve quality, and that QIOs should provide technical assistance to support such improvement.
- CMS views the change in the requirements for QIO contractors as requiring statutory change, and will explore the inclusion of that in a proposal for statutory change through the established mechanisms for such a proposal.
- CMS agrees that QIO governance requirements should be changed, and will modify current contracts to incorporate such changes.
- CMS views case review, particularly related to beneficiary complaints, as an important part of the Program, and believes that changes to the current structural and confidentiality requirements would necessitate statutory change. CMS will explore the inclusion of that in a proposal for statutory change through the established mechanisms for such a proposal, and will propose regulatory changes as appropriate.

Performance Measurement and Improvement

Over the past several years, improving quality of care for Medicare beneficiaries has become an increasingly important part of CMS' agenda. Since 2002, CMS has supported collaborative quality initiatives in nursing home, home health and hospital settings, with a focus on making publicly available measures of provider performance on quality measures on its Compare website. More recently, the Agency has begun to link these measures to provider reimbursement, with payment related to reporting of quality data by providers, and ultimately to performance on these measures. These efforts are consistent with provisions in section 501(b) of the MMA, and as revised under section 5001(a) of the Deficit Reduction Act of 2006 (DRA). The efforts are also providing further steps toward greater transparency of information on quality and cost for consumers of health care services. They reflect a growing understanding of the importance of quality measurement and improvement to the safety, effectiveness, and patient-centeredness of care for beneficiaries, and to the efficiency of resource use and its impact on the Medicare Trust Fund.

In the Quality Roadmap the CMS issued in July 2005, the Agency committed itself to the vision of achieving “the right care for every person every time,” where the right care corresponds to the six IOM aims of safety, effectiveness, efficiency, patient-centeredness, timeliness, and equity. The Roadmap identified five activities that it would use in pursuit of this vision:

- Partnerships with governmental agencies and with nongovernmental partners
- Collection and public reporting of quality measurements and information
- Payment policies for providers that are consistent with improving quality and avoiding unnecessary costs
- Assistance to practitioners in improving quality and efficiency, particularly through greater use of effective health information technology.
- Developing and using information about the effectiveness of health care technologies

As CMS pursues these strategies, the need for leadership and support for their implementation will increase. Performance measures, and a reporting infrastructure, will be as increasingly important as public reporting, pay-for-performance, competitive bidding for Medicare services, and other aspects of value-based purchasing expand. These strategies will increase the motivation of providers to improve quality, but help is needed in order for improvement to occur and to reach high levels of performance. This will stimulate need and demand by providers for technical assistance.

The QIO Program is a primary source of leadership and support for implementation of the Quality Improvement Roadmap as it evolves to meet future needs and developments, and particularly for Agency activities related to public reporting and pay-for-performance. The Program is doing this by providing CMS with an infrastructure and field support to lead its efforts to achieve high levels of quality and efficiency in its programs through private-public collaboration on performance measurement and improvement. The Program is accomplishing this through:

- Quality measure development
- An infrastructure that measures data collection, reporting, analysis, and validation
- The development and provision of information on how to improve performance, and the provision of direct technical assistance to providers that seek to improve performance
- The setting of national goals and leadership and support for partnerships and campaigns that seek to achieve them at the national and state levels
- Local and regional quality initiatives that seek to improve quality and efficiency in identified areas of high opportunity and impact
- The provision of information to beneficiaries and the public that supports person-centered care
- The review of beneficiary complaints with an emphasis on promoting transparency of response and improvement activities by providers
- Other case review activities

- Evaluation of its methods so as to promote learning about how to achieve excellence in care delivery
- Evaluation of its impact on quality and efficiency of care

Measure Development and Reporting Infrastructure

Many stakeholders have an interest in the development of quality measures and reporting of performance on them by providers. CMS is committed to working in partnership with provider organizations, consumer groups, accreditation organizations, payers, purchasers, other federal agencies, and other stakeholders to increase the availability of measures and performance reporting.

As part of the current quality measurement and reporting activities, the QIO Program is a key source of support for measure development activities. The Program will continue to identify areas in which measure development is needed in order to improve quality and efficiency, and through expert panels and field testing, it will support development and specification of measures in these areas. Other stakeholders are also contributing to such measure development, and the Program contributes to the measures consensus work of the National Quality Forum.

The Program is playing an expanded role in the collection of performance information on an increasing array of quality measures. A substantial part of the data reported in the National Healthcare Quality Report published by the Agency for Healthcare Research and Quality (AHRQ) is supported by Program activities. The Program currently provides the national infrastructure for hospital reporting on quality measures. This infrastructure includes a data collection tool, a channel for data submission, a data repository, data validation, and results reporting to providers and the public. Hospital reporting is linked to payment in the Medicare program, and will form the basis for performance-based payment under Medicare. The Program also supports maintenance of data collection tools, and data warehousing used in nursing home and home health agency public reporting.

On August 22, the President issued an Executive Order directing federal agencies that administer or support health insurance programs to take steps that will result in more complete and open information for consumers. The order requires agencies to take steps to share information about the quality of care delivered by doctors and hospitals, as well as the prices paid to these providers. The order also requires agencies and their health care contractors to promote the use of interoperable health information technology products, so that data can be easily shared. In addition, it requires agencies to offer insurance options that reward consumers who exercise choice among health providers based on value and quality of care.

The QIOs are supporting expanded efforts for quality data reporting, building on private-sector efforts, which are more effective in helping consumers make decisions about their care and in supporting provider efforts to improve care. These new activities include a Medicare pilot project, which will be conducted initially in six regions of the country that

will incorporate data from private insurers and Medicaid, as well as Medicare, in providing information on the quality of physician services in those areas to Medicare beneficiaries, and the public generally. Providers, employers, unions, insurers, and consumer alliances have been cooperating in this Medicare project, which will evaluate effective approaches to measuring quality and costs of care, including innovative approaches to collecting data electronically. The project will also include development, implementation, and expansion of the use of measures that reflect Medicare and non-Medicare patient data, and that as a result are more precise and comprehensive, and less burdensome to providers. In collaboration with AHRQ, and in cooperation with the private sector, the Department expects to promote the expansion of this project to other areas of the country as rapidly as possible.

Technical Assistance

Achievement of the vision of the right care for every person every time requires a high level of performance by providers. Public reporting and performance-based payment programs also drive and support high performance levels. However, the impact of programs to support and reward better performance is limited by the fact that many providers do not know how to effectively implement needed changes to achieve maximum performance improvement. Innovators and change agents in health care need access to the best ideas, the most useful measures, the most inspiring case studies, and the support of peers.

Over the past decade, the QIO Program has been an important national resource in identifying and spreading best practice information, and in developing the capacity of organizations and providers to use it in improving care. In 2005, the Program brought together providers, provider organizations, accreditors, and other stakeholders in a series of meetings to assess the type of assistance that the Program should provide in the nursing home, home health, hospital, and physician office settings. Two types of assistance were identified: information that providers and other organizations can access and use without QIO involvement, and technical assistance that QIOs offer directly to providers.

The QIO Program has already begun to offer these two types of assistance to providers seeking improvement. Through its website, www.medqic.org, the Program offers comprehensive information and tools related to best practices and ideas for change on a variety of topics in nursing home, home health hospital, and physician office settings. The Program is beginning to make some of this content available through online interactive support. This enables providers to directly access information that helps them improve care, and is also available to other organizations that work with providers on improvement, such as provider trade organizations, medical specialty societies, and private sources of assistance and consulting.

The bulk of Program resources in the 8th SOW are committed to offering providers direct assistance in the form of learning collaboratives and consultative assistance. QIOs in each state are helping providers make changes needed to achieve high levels of

performance in nursing homes, home health care, hospitals, and physician offices on measures of performance that are specified in the QIO contract (see Appendix 1).

In order for providers to achieve high levels of performance, fundamental changes in how they provide care are often needed. The QIO Program is using its resources to help providers implement four strategies that can yield high performance: measurement and reporting, adoption and use of health information technology, redesign of care processes, and changes to organizational culture and management. These transformational strategies differ from the incremental changes that QIOs promoted in the past, and are needed if providers are to achieve high performance.

In offering assistance, the QIO Program must make choices about where to commit resources. Support for the Quality Improvement Roadmap vision means helping providers offer care that is safe, effective, efficient, patient-centered, timely, and equitable. During its second phase, the Program focused largely on effectiveness of care, with a more recent emphasis on safety in hospitals. Increasingly, the Program will add support for patient-centeredness, equity, and efficiency.

With rising costs, efficiency of resource use is critical to the future of the Medicare program. Quality improvement has the potential for improving resource use by promoting evidence-based care and reducing overuse of services, preventing complications and adverse events, and improving the ability of patients to manage their conditions. This especially includes improvements in the coordination of care for patients with multiple illnesses or end-stage renal disease. The QIO Program has the potential to make a substantial contribution to efficiency of resource use in Medicare, and investments in the QIO Program will increasingly focus in areas where their costs can be substantially offset by quality improvements that increase efficiency.

The Program is currently in the process of contracting for special projects that will develop the evidence base for improving quality and efficiency for the Medicare population. Projects include:

- Preventing hospital admission for patients in nursing homes;
- Improving transitions of care for patients moving across settings;
- Measuring and improving palliative and hospice care; and
- Improving the quality and efficiency of care for patients with multiple chronic illnesses.

The Program must also make choices about which providers to assist. In the first phase of the Program, case review was used to identify providers with deficiencies, who were expected to undertake corrective action plans. In the second phase, QIOs made a decision about which providers to work with based on an assessment of those who could make the most improvement. The Program will continue to seek to support all providers who request help in measuring and improving performance, using either or both of the two types of assistance. In prioritizing resources, the Program will continue to use capability for improvement as a criterion for receipt of assistance, but this will be considered in the context of need for assistance (whether the provider could improve

using internal or other non-QIO resources), opportunity for improvement (gap between current and ideal performance), and design considerations related to Program evaluation.

Support for National Goals and Partnerships

The Quality Improvement Roadmap highlights partnerships between CMS and other stakeholders as a critical component of Agency efforts to improve quality and efficiency. CMS works closely with provider organizations, medical societies, accreditors, purchasers, payers, business coalitions, consumer groups, and other federal agencies in developing its quality initiatives. The QIO Program has played a significant role in such partnerships. The Program has led and supported nursing home, home health, hospital, and ambulatory care initiatives at the national and state level, and will continue to do so.

Since 1999, CMS has set goals for quality of care for Medicare beneficiaries in compliance with the Government Performance Results Act (GPRA). Current goals relate to such measures as nursing home pressure ulcers, nursing home restraints, influenza immunization, mammography, diabetic care, surgical infection prevention, and use of fistulas for dialysis access.

CMS is committed to expanding its role in setting of goals for the Medicare Program in conjunction with other federal agencies and stakeholders. Such goals are a critical component of the Agency's efforts to move from volume- and intensity-based payments to financial support that is based on patient need and quality of care. Some goals will be embedded in national campaigns that set specific targets for achieving measurable results within defined periods of a year or two. CMS is planning a Nursing Home Campaign the goal of which is to monitor key indicators of nursing home care quality, promote excellence in care giving for nursing home residents, and acknowledge the critical role of nursing home staff in providing that care. Specifically, the Nursing Home Campaign will assess progress toward achieving the following measurable goals:

1. Reducing high risk pressure ulcers;
2. Reducing the use of daily physical restraints;
3. Improving pain management for longer term nursing home residents;
4. Improving pain management for short stay, post-acute nursing home residents;
5. Establishing individual targets for improving quality;
6. Assessing resident and family satisfaction with the quality of care;
7. Increasing staff retention; and
8. Improving consistent assignment of nursing home staff, so that residents regularly receive care from the same caregivers.

Most health care providers deliver care to Medicare beneficiaries as well as patients insured by commercial insurers. Recent efforts to improve quality reflect the idea that shared quality improvement goals and consistent quality measures for all patients will result in less burden on providers, as well as the opportunity to identify and achieve meaningful performance improvements. Thus, to achieve demonstrable and significant improvement in care for Medicare beneficiaries, the Program is supporting partnerships that engage a broad group of stakeholders for the purpose of improving quality of care for

all patients based on common goals and measures. This approach facilitates leveraging private sector resources and expertise at the local and national level, with a potentially more significant impact on the quality and efficiency of the health care system. The QIO Program sets targets for improvement at the state level for each QIO during each contract period. In the 8th SOW, these goals were formulated so as to achieve Program-level performance targets. In some cases, these goals were also formulated on the basis of recommendations from technical expert panels convened under special QIO contract.

Future QIO Program goals will be based on the Agency's expanded goal-setting process, on expert input. Some QIO Program goals will also be derived from national campaigns. The QIO will be responsible for developing state-specific plans for achieving targets, and for tracking provider-specific performance and progress in implementing changes that are needed to achieve high levels of performance, as well as for providing technical assistance to providers. Program goals at the state level will be specified in QIO contracts.

Support for Local/Regional Initiatives

Over the past several scopes of work, QIOs have had the ability to propose projects that they believe address local opportunities in specified areas, such as nursing home and home care in the 6th SOW, healthcare disparities focused on underserved populations in the 6th and 7th SOWs, hospital payment error in the 7th and 8th SOWs, and Part D services in the 8th SOW. Additionally, there has been opportunity for QIOs to propose projects for special funding outside of the "core" QIO contract. Most of the resources in the Program, however, have been devoted to funding the work of the core contract, and the tasks in the contract have generally been required in all states. This has the advantage of creating consistency across states in the content of QIO work. It has the disadvantage, however, of reducing the opportunity for applying funds to areas of specific opportunity for impact.

The QIO program is expanding its role in producing comprehensive quality measures. CMS will identify topics and measures on which improvement is a priority, to achieve national goals, to reduce regional variation, or to impact efficiency of resource use. The Program will invite contractors to submit proposals for projects to achieve improvement in these areas, and will award these contracts based on projected impact and contractor ability. CMS will assure those who submit proposals will be evaluated in a systematic manner, consistent with other proposals submitted to the Department, and submitters will be notified in a timely manner of the results of the review or the status of the project. Additionally, QIOs and other entities may submit proposals for local/regional projects that impact quality and efficiency of care for Medicare beneficiaries. The local/regional initiatives will be expected to promote person-centered care.

Person-Centered Care

Person-centered care is one of the six IOM aims. It can also be seen as a defining aspect of the vision in the Quality Improvement Roadmap—the right care for every person every time calls for care that reliably meets the patient’s needs. To achieve this vision, care must be organized around the person’s, not the provider’s, needs. Person-centered care can also result in better self-care, which is particularly important in chronic conditions, which are a substantial part of the burden of illness, and cost, in the Medicare population. As such, person-centered care is an important element in the improvement of quality and efficiency.

The IOM Quality Chasm report articulated the goal of person-centered care in this way: “to customize care to the specific needs and circumstances of each individual, that is, to modify the care to respond to the person, not the person to the care.” Person-centered care changes the person’s role to becoming an active consumer and participant in care. It enables patients and families to make choices based on good information about diagnostic/treatment decisions and selection of providers, to be full partners in care planning and management, to have service delivery design match their likely priorities, and to receive responsive review of and information about complaints and appeals about the shortcomings of their care.

Achieving person-centered care requires fundamental changes in the way care is delivered: information that supports patient and family choice and self-care, care process design and customization to the patient’s preferences and values, continuity/reliability/advance planning, assessment of patient experience, responsive complaints and appeals processes.

In the 8th SOW, the QIO Program has provided leadership and support for initiatives to move health care toward patient-centered practices. QIOs are assisting nursing homes in measuring and improving resident experience, in managing pain, in reducing pressure sores, and in reducing use of restraints. QIOs have taken the lead in helping physicians’ offices to adopt electronic health records systems and in putting into place care management processes that enable patients and families to manage their chronic conditions and that help to ensure continuity and reliability across time. The QIO Program supports the availability of information about the comparative performance of provider organizations through the Compare websites. The QIOs also address beneficiary complaints, with use of mediation among the parties in appropriate situations.

The QIO Program is expanding its support for person/patient-centered care through these mechanisms. Additionally, the Program continues to:

- Support development and reporting of patient-centered measures, including measures of patient experience;
- Promote public understanding of provider/local/regional performance results on quality and efficiency, and the use of this information to improve care and self-care;

- Promote public sector and market-based availability of information and tools, including Personal Health Record Systems, that patients can use in selecting providers, in making informed diagnostic and treatment decisions, and in self-care, by supporting reporting of provider performance data and information on the functionality and usability of personal health systems and tools;
- Offer assistance to providers in redesign of care processes so that they improve patient experience and better meet the needs and preferences of patients and care-givers, through development of information regarding best practices, help in implementing them, and participation of patients and families in quality improvement teams;
- Responsively address beneficiary complaints and appeals;
- Promote the expansion of the Medicare pilot project under which Medicare data will be combined with data of other insurers and Medicaid in order to provide comprehensive measures of the quality of services;
- Support improvements in the coordination and management of care across settings and transitions from one setting to another (e.g., the hospital to nursing home or home care); and
- Lead and support national and local collaborations between patient, care-giver, and consumer groups, provider groups and other federal agencies to promote person-centered healthcare.

Beneficiary Complaints

The QIO program is required by law to provide an appropriate review of all written beneficiary complaints about the quality of healthcare services they receive. The process established to provide that review was the subject of two critical reviews by the Office of the Inspector General in 1994 and 2000. As a consequence, for the QIO 7th SOW, significant changes were made to the process. The QIO contract was revised to create accountability for performance on several key metrics: timeliness of response, beneficiary satisfaction, and the initiation of quality improvement activities where appropriate to an identified quality concern. Additionally, mediation was offered to beneficiaries and providers to facilitate resolution of issues. As a result, 93% of complainants are now satisfied with the review process, and one quarter of cases with identified quality concerns result in systematic quality improvement plans implemented by providers.

Despite these gains, CMS believes that there is opportunity for substantial further improvements in the handling of beneficiary complaints, some of which can be accomplished by regulation. Most complainants want a process that helps them understand what happened, and if there is something that should not have occurred, they want to know that action has been taken to prevent future occurrences. In addition to the current beneficiary complaint work, CMS is determining how it can permit the disclosure of information from complaint review to beneficiaries and restrict redisclosure of this information and its use in liability actions.

To support needed changes in the QIO's very important complaint review activities, CMS will engage QIOs to expand outreach to beneficiaries through media, print publications, direct communications, and work with the CMS Ombudsman on developing a link on the CMS web page.

Other Case Review

The QIO program has an existing statutory requirement to review some or all of the professional services in the QIO review area. Sections 1154(a)(1) and 1869 provide for state-based physician peer review of such services. Currently, in addition to review of beneficiary complaints as required by sections 1154(a)(1) and (a)(14), the QIO program satisfies this requirement by conducting the Hospital Payment Monitoring Program (HPMP), reviewing certain referrals, and reviewing all hospital requests for higher-weighted diagnosis related group payments (HWDRG). Additionally, such requirements are met through QIO review of certain beneficiary appeals resulting from the issuance of a notice of non-coverage, and reviews of alleged dumping cases they receive from the CMS regional offices in order to assist the regional office or the Office of the Inspector General. QIOs are also currently required by statute to review requests for assistants at cataract surgery and they monitor hospital compliance with obtaining physician acknowledgements.

These reviews are important to the Medicare program and its beneficiaries, and support for them by the QIO Program is appropriate. CMS is evaluating the need for developing other mechanisms to fulfill these review obligations as efficiently and effectively as possible. Some of the changes can be accomplished by regulation.

2. Data Processing

- CMS agrees that the provision of timely and accurate data to QIOs and providers is important, and will seek to further improve the timeliness of such data.
- CMS agrees that the Program can be an important source of data for other quality improvement, public reporting, performance-based payment, and other programs and will continue to engage in policy discussions concerning the infrastructure to provide such data.
- CMS believes that changes to requirements that govern QIO sharing of data would necessitate regulatory change, and will propose such change.

Data Management

CMS is committed to promoting the dialogue that is currently occurring regarding the appropriate structure for oversight and operation of quality data reporting, the roles for the public and private sectors, and the policies and procedure that should govern these activities. Through such dialogue, the most effective role of the QIO Program in this regard can be explored. As this occurs, the Program will examine and work to improve the current performance of the data infrastructure that it operates with respect to the timeliness of data availability, the ease of data submission and validation processes for providers, and the quality of the data itself.

These quality data are available through QIOs for their work with providers on improving quality. The timeliness of data is largely constrained by lag time in its submission, but the Program will assess and seek to improve timeliness. To achieve a substantial improvement in the breadth, timeliness and cost of producing performance data, it must be produced by electronic systems at the point of care. CMS is committed to promoting the use of health information technology by providers and the specification of quality measures such that they can be reported from electronic systems, and to harmonizing such activities with the developing National Health Information Network. In the QIO 8th SOW, the Program is supporting one of the largest national efforts to provide help to physician offices in adoption of health information technology, and its use in improving care and reporting clinical quality measures. The Agency is also encouraging hospitals and other providers to adopt health information technology that will allow for reporting of clinical quality data.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) embodies policy objectives that include protecting the privacy and security of certain individually identifiable health information, while ensuring under specified conditions that patients have access to their own protected health information. The Program currently has confidentiality rules that make it difficult for the reporting infrastructure to share information with a provider that is based on the care given by another provider. CMS promulgated these rules in order to prevent disclosure of the data the QIOs obtain during the course of case review, but they preceded more recent laws and regulations that provide updated protection for health information.

3. QIO Program Management

- CMS agrees that the QIO Program should set clear goals that are consistent with Agency and national goals.
- CMS agrees that the content of QIO contracts should be developed with input from stakeholder organizations, national and local.
- CMS agrees that the QIO contract should be clearly written, issued in a timely fashion, with support infrastructure developed so that it is available at the beginning of the contract period.
- Current statute requires a three-year contracting period.
- CMS agrees that there should be greater competition for QIO contracts and greater rewards and penalties built into the contract structure.
- CMS agrees that continued efforts to improve communication with and oversight of contractors should occur and such efforts are underway.

Performance-Focused Contract Structure

The current contract structure for the QIO Program as specified in section 1153(c)(3) of the statute states that CMS must contract with state-based organizations to do the work of improving quality and efficiency of care for Medicare beneficiaries. The majority of Program resources are devoted to funding this “core” contract. For each state, under the statute there can be only one QIO contractor, which is required to do all of the work required by the contract in that state, and the core contract is required to be three years in

duration. As the contract has become more complex, the requirement to assign all the work to a single contractor in each state, and to limit it to a three year contract period, has created significant challenges for Program management and effectiveness.

Alongside of the core contract are contracts for task-specific lead QIOs (“QIOSCs”) that provide support to QIOs related to the core contract and special project contracts that are also only available to QIOs. A minority of funds are committed to non-QIO contractors for various functions that also support the core contract.

The QIO Program will allocate funds to work that can best support the Agency’s agenda for improving quality and efficiency of care. The core contract will provide for state-based activities that support national goals and priorities, and although it will be similar it may not be identical for each state, depending on state-specific needs. The contractor holding the core contract in each state is the Medicare QIO. The use of project-based contracts will increase, to address specific opportunities for improvement or reduction in variation or project work that supports implementation of Quality Improvement Roadmap strategies. National contracts will have greater responsibility for results at the state and project level, and for national partnership and infrastructure activities that support the Roadmap strategies and national campaigns.

Competitive Contracting

The current contract requirements of the Program do not allow for adequate competition among potential contractors. The effectiveness of two specific contract requirements has been questioned: the requirement that all of the work for the full range of QIO activities in the state go to one contractor, and the requirement that QIOs meet physician sponsorship or physician access criteria.

In the 8th SOW, CMS sought to increase the competitiveness of the Program by assessing the ability of the QIO to perform successfully on each task, requiring a Capability Improvement Plan for QIOs that did not sufficiently demonstrate the ability to succeed. Additionally, CMS restructured the award fee such that only one percent of it is non-performance-based, with the other four percent depending on individual performance and performance of the Program overall. Building on these recent reforms, CMS agrees with the need to achieve further performance enhancements in particular QIO activities through further improvements in competition, and is considering other steps to create greater competition in contracting within the QIO Program.

Contractor Expenditure Oversight

CMS monitors QIO expenditures through an oversight process that includes four steps:

- QIO consultation with CMS over questionable expenditures
- Project, desk, and contracting officer review of invoices submitted
- Annual variance analysis by project and desk officers
- Audit by the Defense Contractor Audit Agency (DCAA) of a sample of invoices, both direct and indirect costs, annually.

Through its intensive internal review of the Program, CMS has determined that the second step was inconsistently implemented, and has therefore taken the following actions:

- Review of all invoices by project officer prior to payment;
- Assured access to financial reporting system (FIVS) by all project officers;
- Training of all project officers on invoice review; and
- Detailed review by CMS staff of a sample of QIOs, with modification of internal controls and development of guidelines for review of invoices to focus on areas of potentially inappropriate expenditure such as travel, conferences, and personal, government, provider use of property, etc.

The results of these actions will be reviewed by management on a monthly basis. CMS has also modified the QIO contract (May 2006) to require the creation of a Board committee to set policy for travel and senior staff and Board compensation. QIOs without an acceptable policy implemented by January 2007 will be placed on a performance improvement plan that will include limits on such compensation.

Contractor Governance

Under the current requirements for contractor eligibility, many QIOs have heavily physician-dominated boards, which are not ideally suited to the need for broad relationships with stakeholders related to their current quality improvement responsibilities. Additionally, IOM was concerned that there is the potential for conflicts of interest in setting standards and making determinations as part of their case review activities. Finally, given that QIOs determine which providers they will work with under their QIO contract, there is the potential for conflicts of interest if they offer similar services for purchase by providers.

Given that any requirements related to contractor governance boards can create barriers to competition, such requirements should be carefully considered. At the same time, it is important that CMS assure that contractors have appropriate board diversity, relationships with providers and stakeholders within the state (for state-based contracts), transparency, and structures for mitigating conflict of interest situations.

In a modification to the 8th scope of work contract, the QIO Program will require that state-based contractors (QIOs) have boards with an independent committee charged with review of compliance, conflict of interest, ethics, and program integrity.

In a modification to the 8th Scope of Work contract, the QIO Program will require that state-based contractors (QIOs) disclose information regarding their boards, including board size, length of appointment, cap on service, when appointments are made, what portion of the board is typically appointed each year, and names, affiliation and compensation of board members.

The QIO Program will evaluate, during the procurement process, the governance and structure of each state-based QIO contractor and its relationships with providers and stakeholders within the state. In the meantime, CMS will modify the QIO 8th SOW contract to incorporate a set of proposed guidelines as set forth in the Appendix. These guidelines will help ensure that QIO boards are representative and well suited to transparent, unbiased governance.

Program Operations

Over the past five years, the QIO Program has made many changes in operations that are aimed at improving effectiveness and efficiency. For the past two years, the Program has had an explicit structure for internal quality improvement that is driven by Program goals and is organized around improvement teams that report on progress at quarterly meetings. However, there continues to be opportunity for substantial improvement, particularly in four areas.

The first relates to overall Program management. Although much improvement has occurred as a result of the work of the past two years, there is need for further improvement in management processes. This is particularly important given the increased contracting and program evaluation requirements that are detailed in other sections of this paper. The Program will continue to specify program management goals, and will examine how to restructure program operations and resources to better accomplish them. For example, CMS has appointed a new leadership team to manage the QIO program and has formulated a business operations staff to manage the funding and contractual aspects of the program. Additionally, CMS has implemented management reviews of the QIO contractors to strengthen oversight.

The second relates to timely contract preparation and implementation, which will help achieve Program goals. CMS has already initiated the preparation process for the 9th SOW. Contracting for special projects to develop the evidence base for contract tasks has begun. A second round of contracting will begin in summer 2007 to develop the support infrastructure for the 9th SOW contract period, which will begin in August 2008.

A third area of opportunity for improvement is the evaluation component of the core contract. The 8th SOW contract evaluation methodology has been criticized as too complex. CMS will convene a workgroup that will propose a simplified framework for contract evaluation. Furthermore, movement toward a consistent and potentially longer contract period with all QIOs completed at the end of the contract will contribute to the ability to simplify the contract.

The fourth area of opportunity involves the structure and processes of contractor management. The current structure is complex, with Project and Science officers in four Regional Offices, and Government Task Leaders and other Program support staff primarily in the Central Office. Over the past year, CMS has made significant changes to the communications infrastructure that supports Program management, and to the contractor monitoring process. Increasingly, we are relying on quarterly data related to

measures that are in the contract, and we are implementing measures of provider progress in making changes that are likely to lead to subsequent improvement in contract measures. These data will be evaluated as part of the Agency's internal quarterly monitoring meetings that we have initiated.

4. QIO Program Evaluation

- CMS agrees that there is need for strengthened methods of evaluating the Program, its methods, and the contractors, and will convene a technical expert panel that will include in its deliberations the recommendations of a contractor that the Department currently has in place to develop recommendations for an evaluation design to achieve this.

Program Evaluation

Careful evaluation of the QIO Program is an essential component of effective program management. Evaluation and continual learning about how best to measure and improve quality of care is essential to successful achievement of the vision of the Quality Improvement Roadmap, and is important to providers seeking to participate in public reporting and pay-for-performance programs, to beneficiaries seeking excellent person-centered care, and to the Agency's responsibility for efficient stewardship of the Medicare Trust Fund.

In the QIO Program, evaluation is challenging for several reasons. There are time lags in availability of clinical quality measures. The Program aims at creating broad improvement, and helping all providers who need assistance, so that identifying appropriate control groups can be challenging. The Program also works with other stakeholders and partners, so the specific effect of the Program is difficult to isolate. These challenges are also applicable to other programs that promote improvement in healthcare quality.

Despite these challenges, for the past several scopes of work, the Program has operated performance-based contracts that collect data on clinical measures at the national, state, and provider level, and has conducted and published formal evaluation of program results.

In the 6th SOW, CMS found that there was improvement in 20 of 22 ambulatory and hospital measures nationally, with most states showing improvement. Because the extent to which such improvement was specifically attributable to the efforts of QIOs could not be assessed, CMS designed the 7th SOW contract to permit better assessment of Program impact.

In the 7th SOW, CMS widened the scope of QIO activities to include two additional settings beyond hospitals and physician offices: nursing homes and home health agencies. In addition to promoting improvement at the statewide level in the 7th SOW, CMS required QIOs to offer more intensive assistance to a subset of nursing homes (NHs), home health agencies, (HHAs), and physician offices. This subgroup is termed an

identified participant group (IPG). CMS has published an article in the *Annals of Internal Medicine*, *Assessment of the Medicare Quality Improvement Organization Program* (Rollow, Lied, McGann et. al.), that summarizes the national results related to measures for which QIOs have been providing assistance in each of four settings. This article demonstrates improvement in most measures for each of the four settings and shows that the IPG improved more than the Non-IPG. However, selection bias cannot be ruled out as contributing to the differential in performance, although providers in the IPG improved more on the measures that they worked on with QIOs.

In the 8th SOW contract, similar to the 7th SOW contract, providers are grouped according to participation or non-participation with the QIO Program (IPG vs. Non-IPG). In addition, however, for the 8th SOW evaluation, CMS will collect information that will give us the ability to control for provider motivation for improvement, and to better explore the relationship between improvement and the intensity of assistance that the provider receives from the QIO. Additionally, a survey will be used to directly assess whether providers believe that they could have achieved similar results without QIO assistance.

CMS is beginning its planning process for the 9th SOW, and design of the contract will be based in part on the need for evaluation of impact of each activity. The QIO Program will convene an evaluation expert advisory panel that will make recommendations on the framework for the next contract. Designs with case controls, crossover and randomization will be considered. Performance benchmarks will be sought. The framework will permit evaluation of contractors, methods, and Program impact on quality and efficiency. The office of Assistant Secretary for Planning and Evaluation (ASPE) in the Department of Health and Human Services has a contractor currently working to develop recommendations for an evaluation design, and this information will also be used to formulate the 9th SOW evaluation framework. The framework will then be used to formulate plans for the 9th SOW contract, evaluation of contractors and methods, and for internal and independent external evaluation of the Program.

5. QIO Program Funding

- CMS generally agrees with IOM's recommendations. However, because the planning process for the 9th SOW and the program evaluations that accompany it are currently in process, it is not clear at this time whether an increase in funding will be appropriate.

Program Funding

Our primary emphasis has been on assuring that currently allocated funds for QIO activities are spent as effectively as possible. In many cases, this goal has required reallocation of resources across the different QIO priorities. CMS will continue to evaluate Program funding levels in the context of Program changes and as planning for the 9th SOW progresses.

Conclusion

The QIO Program has been an important contributor to the national effort to measure and improve quality and efficiency. The Program also plays an essential role to the Agency's ability to provide quality care for the beneficiaries of its programs and to its stewardship of the Medicare Trust Fund. While the QIO program has had some notable achievements, we believe that QIOs can and should aim to achieve even more. The IOM report as well other evaluations, including our own, make clear that the QIO Program holds more potential for achieving improvements in health care and health. The eight IOM recommendations for restructuring the QIO Program are consistent with a comprehensive set of improvement activities that CMS is implementing now, and other initiatives that are under consideration as we approach the 9th SOW to assure that the resources directed to QIO activities are achieving their intended purpose: higher quality care, and more efficient and person-centered care. We expect to work closely with the Congress to assure that these improvements to the QIO program are implemented effectively.

Appendices

- Appendix 1: QIO 8th SOW Performance Measures
- Appendix 2: Appendix 3: Proposed QIO Contractor Governance Guidelines

Appendix 1: 8TH SOW Measures

| Subtask | Clinical Measures | Non-clinical Measures |
|--------------|--|--|
| Nursing Home | <ul style="list-style-type: none"> ▪ Restraints ▪ Pressure ulcers ▪ Pain ▪ Depressive Symptoms | <ul style="list-style-type: none"> ▪ Staff Satisfaction ▪ Resident Satisfaction ▪ Staff turnover ▪ Target-setting on clinical measures ▪ Process changes on clinical measures |
| Home Health | <p>ACH</p> <p>Choice of one other publicly reported measure</p> <ul style="list-style-type: none"> ▪ Improvement in Bathing ▪ Improvement in Transferring ▪ Improvement in Ambulation/Locomotion ▪ Improvement in Management of Oral Medications ▪ Improvement in Pain Interfering with Activity ▪ Improvement in Status of Surgical Wounds ▪ Improvement in Dyspnea ▪ Improvement in Urinary Incontinence ▪ Discharge to Community | <ul style="list-style-type: none"> ▪ Immunization assessment ▪ Telehealth use ▪ Organizational culture assessment |
| Hospital | <p>ACM (composite of pneumonia and cardiac publicly reported measures)</p> <p>SCIP</p> <ul style="list-style-type: none"> ▪ Infection ▪ VTE | <ul style="list-style-type: none"> ▪ Hospital reporting ▪ Validation of the publicly reported measures ▪ CPOE/barcoding/telehealth assessment ▪ Organizational safety culture assessment |
| Physician | <p>DOQ-IT measures</p> <ul style="list-style-type: none"> ▪ Coronary artery disease ▪ Hypertension ▪ Heart failure ▪ Diabetes care ▪ Preventive care <p>Part D measures</p> <ul style="list-style-type: none"> ▪ Prescribing ▪ Use of avoidable drugs ▪ Frequency of selected drug interactions ▪ Therapeutic categories ▪ Medication management services ▪ Avoidance of specific drugs ▪ Therapeutic monitoring | <ul style="list-style-type: none"> ▪ Adoption/use of HIT ▪ Care management process utilization ▪ Reporting of electronically generated clinical measures ▪ Adoption of CLAS standards |

| | | |
|------------------------|--|--|
| Beneficiary Protection | <ul style="list-style-type: none">▪ Timeliness▪ Satisfaction with the complaint process and outcome▪ Quality improvement activities resulting from case review activities▪ Absolute and net payment error rates | |
|------------------------|--|--|

Appendix 2: Proposed Guidelines for Contractor Governance and Senior Staff and Board Compensation

The QIO contract will be modified to reflect the following requirements. Failure to meet these guidelines by January 1, 2007 will result in the issuance of a Performance Improvement Plan (PIP). Failure to successfully execute the PIP by August 1, 2007, will result in the QIO contract being terminated or its being competed for the 9th SOW.

1. The contractor board must have a committee, composed of independent (defined in 11. below) board members, that is charged with review of issues regarding compliance, conflict of interest, ethics, program integrity, senior staff and Board compensation and travel costs. The committee shall use information regarding compensation levels for similar organizations in its geographic area and other appropriate information to establish compensation policies. The full Board shall not have veto or override authority over the committee in these areas. The committee shall operate a compliance program that, at a minimum, consists of the following:
 - a. Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards
 - b. The designation of a compliance officer that is accountable to senior management and the Board
 - c. Effective training and education between the compliance officer and organization employees
 - d. Effective lines of communication between the compliance officer and the organization's employees
 - e. Enforcement of standards through well-publicized disciplinary guidelines.
 - f. Procedures for internal and external monitoring and auditing
 - g. Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the QIO contract
2. The contractor must disclose semi-annually information regarding its board, including size, length of appointment, cap on service, when appointments are made, what portion of the board is typically appointed each year, and names, affiliation and compensation (where permitted) of board members and senior executives.
3. The QIO may not own or operate, or be owned by or affiliated with, a health care facility or an association of health care facilities in the area, as stated in sections 1152 and 1153 (b) of the Social Security Act (the Act), and in 42 CFR 475.100-106.
4. Each contractor must specify a size limit for its board, generally not to exceed 15 members.

5. Each contractor must adopt policies ensuring that Board membership is representative of appropriate constituencies within the state to advance QIO efforts to improve quality and efficiency of health care, including representatives of a variety of healthcare settings and organizations, as well as business, consumer, and other relevant stakeholder groups, such that the Board is not comprised of a majority of physicians or any other provider type.
6. Section 1152 (3) of the Act requires a minimum of at least one consumer representative on the QIO board. The QIO Manual, Section 2220, specifies minimum qualification criteria for this representative, including that the individual must be a Medicare beneficiary. CMS encourages greater diversity in consumer representation, which would help the QIOs to maintain a focus on the consumer as a customer, such that no less than twenty percent of the board would be comprised of consumer representatives.
7. Each contractor board shall adopt a policy ensuring that at least two-thirds of the members are independent (defined in 11. below). The CEO, CFO, CMO and COO shall not receive additional compensation for board membership if they are members of the board. Officers of the QIO and its parent entity shall not comprise more than 20% of the Board.
8. In order to ensure that the contractor boards remain vital, consecutive board service time is capped at six years in order to ensure new and different perspectives. There is no restriction on reappointments after a break of at least one year in board service. The contractor may allow up to 20% of its board membership to exceed the six year term limit for one term, or for more than one term where such members are owners of the organization.
9. The Board must establish a quorum rule that states that no business of the Board can be conducted unless a majority of the present and available membership consists of independent (defined in 11. below) Board members.
10. The Board must establish and implement policies for review of performance of Board members, relating to such aspects of performance as attendance at meetings, participation in Board subcommittees, contribution to Board policy-making and other activities, contribution to contractor outreach and partnership efforts, and other indications of value to the contractor's efforts to improve quality.

Independent board members are defined as individuals (1) who have not been compensated by the organization in the past twelve months, including full-time and part-time compensation as an employee or as a contractor, except for reasonable compensation for board service; (2) whose own compensation, except for board service, is not determined by individuals who are compensated by the organization; (3) who do not receive, directly or indirectly, material financial benefits (i.e., service contracts, grants or other payments) from the organization except as a member of the charitable class served by the organization; and (4) who are not related to (as a spouse, sibling, parent or child) any individual described above.