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 competed 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	▪ Restraints ▪ Pressure ulcers ▪ Pain ▪ Depressive Symptoms	▪ Staff Satisfaction ▪ Resident Satisfaction ▪ Staff turnover ▪ Target-setting on clinical measures ▪ Process changes on clinical measures
Home Health	ACH Choice of one other publicly reported measure ▪ 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	▪ Immunization assessment ▪ Telehealth use ▪ Organizational culture assessment
Hospital	ACM (composite of pneumonia and cardiac publicly reported measures) SCIP ▪ Infection ▪ VTE	▪ Hospital reporting ▪ Validation of the publicly reported measures ▪ CPOE/barcoding/telehealth assessment ▪ Organizational safety culture assessment
Physician	DOQ-IT measures ▪ Coronary artery disease ▪ Hypertension ▪ Heart failure ▪ Diabetes care ▪ Preventive care Part D measures ▪ Prescribing ▪ Use of avoidable drugs ▪ Frequency of selected drug interactions ▪ Therapeutic categories ▪ Medication management services ▪ Avoidance of specific drugs ▪ Therapeutic monitoring	▪ Adoption/use of HIT ▪ Care management process utilization ▪ Reporting of electronically generated clinical measures ▪ Adoption of CLAS standards

Beneficiary Protection	▪ 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.