



1155 21st Street, NW
Suite 202
Washington, DC 20036
T 202.331.5790 • F 202.331.9334
www.ahqa.org

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Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 314 G Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan,

The National Academy of Sciences Institute of Medicine (IOM) has completed its report on the Quality Improvement Organization (QIO) program, authorized by Section 109 of the Medicare Modernization Act (MMA). MMA Section 109(d) states, “not later than June 1, 2006, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.” On behalf of the national community of QIOs, I offer this letter recommending legislative changes to modernize and ensure the accountability of the QIO program. In addition, I encourage prompt implementation of a number of program changes that the American Health Quality Association (AHQA) believes the Secretary may undertake without waiting for congressional action.

Part 1. Recommendations for Immediate Executive Action.

AHQA believes several policy changes can be implemented under current law. Except as noted below, we believe the cost of implementing most of these reforms can be funded out of the approximately \$28 million CMS has withheld from QIO core work in the field described in the 8th Statement of Work (SOW8). If it is your judgment that these provisions cannot be implemented without changes to federal law, we ask for your active support for these provisions in QIO modernization legislation that may be introduced later this year.

Organizational Integrity. QIOs representing 49 states and territories have now adopted the AHQA Organizational Integrity Standards. The AHQA policy establishes demanding industry standards for compensation of board members and executives, avoidance and mitigation of potential conflict of interest, responsible travel expenditures, and greater diversity on QIO boards. These standards are consistent with IOM’s recommendation to ensure broader representation of stakeholders and stronger accountability functions of QIO boards. QIOs adopting the AHQA Standards have committed themselves to a schedule for implementing these changes in their board composition and organizational policy and practice.

We appreciate that CMS must verify that these commitments are fully implemented. With proper training of auditors to ensure consistency, the existing annual audits of QIO contractors can be used to verify compliance with these standards. Where these standards are faithfully implemented, there is no need for additional action by CMS.

As you know, there is a national movement underway to raise expectations for the organizational integrity of both investor-owned and nonprofit firms. We are proud to lead the QIOs into embracing these reforms, and we understand that CMS must insist on the same high standards for any organization seeking to fulfill this important role. We ask you to consider, as well, that there are other Medicare contractors with important fiduciary responsibilities to the program and to the public. AHQA recommends that CMS ask all Medicare contractors (e.g., MACs, and others) to hew to similar standards. We believe CMS should support legislation to this effect if voluntary action is not forthcoming.

Beneficiary Complaint Program. We believe current law permits CMS to move ahead with the following reforms to the Medicare beneficiary complaint program.

1. CMS should assign QIOs to actively educate beneficiaries of their right to bring quality concerns to QIOs. This important outreach responsibility is nowhere to be found in the 8th SOW contract, nor is funding available for this function. We ask that CMS authorize QIOs immediately to use Task 3 (medical case review) funds for the purpose of educating beneficiaries about quality problems they may encounter, to encourage patients to provide timely honest feedback to caregivers, and to contact the QIO with their concerns when needed. If the limitations previously imposed on 8th SOW case review work by the Office of Management and Budget (OMB) would preclude this use of case review funds to educate beneficiaries about case review, the effect of that policy must be openly acknowledged and CMS should pursue corrective legislation.
2. Current CMS rules prohibit QIO disclosure of complaint investigation findings regarding physicians without the consent of the physician. CMS should reverse current policy and instruct QIOs to report findings of investigations to complainants, whether the complaint findings involve physicians or institutional providers.
3. CMS should clearly prohibit use of QIO work product, reviewers, and complaint findings in any form in a malpractice case.

Program Administration: Priority Setting. AHQA has previously expressed its concern that the QIO program's priorities are developed in a "black box" process at CMS headquarters. As the federal government's largest commitment to clinical quality improvement, the QIO program priorities should be debated and thought through in active consultation with informed representatives of consumers, plans, providers, practitioners, and both public and private purchasers, as IOM has recommended.

Individuals with a sustained interest in and familiarity with the program should perform this important job, and their deliberations should commence immediately so they can be completed well before the beginning of the 9th SOW. These deliberations should take place at two levels:

1. Nationally, through an appointed independent strategic advisory committee, composed of national quality measurement and improvement experts, representatives of beneficiaries, health care providers, practitioners, other stakeholders, and organizations holding QIO contracts. The committee's job is to set national strategic priorities and objectives for improvement in the clinical quality of care, and other duties related to program and contractor evaluation (see below).

2. Locally, through a process required of each QIO, beginning now to prepare for the 9th SOW with new funding from amounts withheld by CMS from the core work of the 8th SOW. The process should continue as a discrete task in each subsequent SOW. QIOs should convene stakeholders to identify high priority quality problems that are relevant to Medicare beneficiaries in that jurisdiction (these could either be the same as national priorities, or specific to the jurisdiction). Each QIO would propose one or more projects to CMS taking into consideration these stakeholder recommendations, along with suggested performance measures to evaluate progress. We believe this proposal reflects IOM's recommendation, under program management, that CMS should promote improvement in one or more locally defined priority areas. At least twenty percent of the Medicare QIO core contract resources for SOW9 should be devoted to these priorities.

Program Administration: Sharing Data. With so many chronically ill beneficiaries seeing multiple physicians, there is potential for serious or fatal preventable therapeutic duplication or contraindicated drug therapy that QIOs could prevent. AHQA recommends that CMS amend the QIO program regulation (42 CFR 480.140) that currently prevents a QIO from sharing data pertaining to care provided by one physician with another physician treating that beneficiary. The regulation should be revised to permit limited sharing of such information when, in the judgment of the QIO, notification of the physicians is necessary to prevent or mitigate a potential medical error.

Program Funding: Leveraging Medicare's Investment in Quality. IOM stated that, "given the limits of federal funding, the QIOs should be allowed to seek funds" from "providers and other organizations" for quality improvement and other forms of technical assistance. Currently, Medicare funding constraints limit QIOs to working with just 5% of primary care physician offices, 15-30% of hospitals, and 10-15% of nursing homes. As a result, physicians, institutional providers, or their associations may wish to retain the QIO to work privately to expand Medicare's priority projects or to initiate new work on their own quality priorities. AHQA recommends that these business relationships be permitted if the QIO has made arrangements to avoid a potential conflict of interest resulting from conducting case review of facilities that are customers.

Part 2. Recommendations for Modernization of the QIO Statute.

Many thoughtful CMS initiatives in the QIO program have waxed and waned with the priorities of each administration. Even the best of these executive initiatives has occasionally encountered resistance in OMB's allocation of funding because of the lack of a firm basis in law. AHQA recommends the law be amended to include those suggested above for immediate executive action, to ensure that they are a continuous priority of the program. AHQA is also suggesting several other changes to modernize the program that cannot be launched without changes in the underlying law.

Codifying the Quality Improvement Function. The health care quality improvement program, created in 1994 through executive action by CMS' predecessor agency, the Health Care Financing Administration in the wake of a 1990 IOM report, must be written into federal law. Because it has lacked an explicit statutory foundation, the OMB has been unwilling to adequately fund the quality improvement program, resulting in a simultaneous expansion of work and contraction of funding in the current contract period.

In accordance with IOM's recommendation, the law should clearly state that "QIO [quality improvement assistance] services should be available to all providers, Medicare Advantage organizations, and prescription drug plans." The nature of this assistance should be defined as including:

1. Education on quality improvement initiatives, strategies and techniques aimed at building provider capacity;
2. Instruction on how to collect, submit, aggregate and interpret data on measures that may be used for quality improvement, public reporting and payment;
3. Instruction on how to conduct root-cause analyses;
4. Technical support for the direct role of providers and practitioners in beneficiary education to facilitate patient self-management;
5. Assistance with convening and brokering cooperation among various stakeholders;
6. Facilitating adoption of procedures that encourage timely candid feedback from patients and their families concerning perceived problems;
7. Guidance on redesigning clinical, administrative, and information systems to improve the coordination, effectiveness, and safety of care.

Medicare Quality Accountability Program. AHQA requests that CMS and the Secretary actively support legislation to create a more comprehensive and patient-centered Medicare Quality Accountability Program that would:

1. Utilize QIOs to actively educate beneficiaries of their right to bring quality concerns to QIOs;
2. Clearly authorize QIOs to report findings of investigations to complainants;
3. Prohibit use of QIO complaint inquiry findings in any form in a malpractice case;
4. Allow QIOs to assist providers in adopting best practices for soliciting and welcoming feedback about patient concerns, and assist providers in remedying patient-reported problems that are confirmed by QIOs;
5. Allow QIOs to respond supportively to quality problems caused by unsafe systems, and refer for enforcement providers who are unwilling or unable to improve;
6. Instruct QIOs to publish annual quality reports in each state, including aggregate complaint data, provider performance on standardized quality measures, and names of providers which have been referred by the QIO for enforcement action.

Program Administration: Performance Measure Reforms. AHQA believes the adoption of quality measures for evaluation of contractors in the QIO program has too often lacked an evidentiary basis and proceeded without qualified external input. To remedy this, we propose that the Secretary utilize the strategic advisory committee identified above to qualify the validity, reliability, and feasibility of measures that will be used in evaluating the performance of organizations holding a contract under this section. Before any performance measure may be used for contract evaluation or program evaluation, it must have been designated by the strategic advisory committee to be valid, reliable, and feasible for use under similar circumstances, as demonstrated in at least one adequately powered study.

Program Administration: Reforms to Performance-based Contracting. The QIO program is built on performance-based contracts. Contractors have faced competition throughout the existence of the program, with many contracts changing hands. Contractors may be renewed non-competitively only if they meet CMS performance objectives.

AHQA supports IOM's call for increased competition for these contracts. We believe the following changes to contractor evaluation and competitive awarding of contracts should be accomplished together.

1. The current 3 year duration of QIO contracts was set in the 1980s when the work was limited to retrospective review of medical records. Due to the changed nature of the work, the contract period should be extended to 5 years, as recommended by the IOM. There are several reasons why this change is necessary:
 - a. To permit sufficient time for health care quality improvement interventions to develop and for changes to be measured.
 - b. To give CMS time to create the infrastructure necessary to measure performance of providers and QIOs in a sensible and timely way. That is not the case today. For example, in the 8th SOW, QIOs will learn the baseline rates for hospital surgical complications during the period when remeasurement of results is to be done.
 - c. To permit use of sequential interventions with control groups that would strengthen the evaluation.

On this last point, please note that a “crossover” design for interventions was identified by IOM as a promising evaluation method. This approach would permit QIOs to assist large numbers of providers, assess secular trends, and largely eliminate the problem of QIOs recruiting volunteer providers, randomizing them into two groups, and then telling half of them they are the control group and will receive no assistance. For an example of a QIO project involving this technique, see Chu and Bratzler, *Improving the Quality of Care for Pneumonia Patients in Very Small Hospitals*, 2003 (available upon request).

2. Beginning with the 9th SOW, all QIO contracts should begin on the same date, as recommended by the IOM. Current 8th SOW contracts should be extended until September 30, 2009 with all 9th SOW contracts written to begin on October 1.
3. Beginning with the 9th SOW, each QIO would be subject to open competition at the conclusion of each contract period. Only QIOs demonstrating excellent performance in fulfilling the terms of the contract would be non-competitively renewed. Non-competitive

renewal would only be permitted once before the organization would face mandatory competition at the conclusion of the next contract cycle.

4. In an open competition, if the incumbent organization bidding for a contract under this section demonstrated excellent performance in fulfilling the terms of the QIO contract for that jurisdiction during the previous contract period, the Secretary shall award the bidder a bonus equivalent to ten percent of the total possible score for the proposal.
5. Prior to publishing a request for proposals for each contract period, the Secretary would be required to establish measurable goals for each task, in consultation with the expert advisory committee.
6. The Secretary would not be permitted to reduce a financial contract award below the amount proposed by the prevailing bidder in a competitive bidding process.

Program Administration: Funding. The IOM has now joined the QIO community in observing that funding for this program is too low—less than one-tenth of one percent of Medicare spending—and is shrinking in relation to Medicare expenditures. The IOM noted that this is occurring at a time when “the committee expects that provider demand for technical assistance with quality improvement will increase.”

The 8th SOW represents a substantial increase in quality improvement work, yet funding for quality improvement was cut back in absolute terms by OMB. Funding decisions within the Department and OMB were so egregiously delayed that contractors went to work knowing their contracts were incorrect and that both funding amounts and the description of work would be significantly revised months into the 8th SOW period. To remedy these problems, AHQA recommends legislation to accomplish the following, beginning with preparations for the 9th SOW:

1. The apportionment may be no less than 0.5% of Medicare spending, in cognizance of the magnitude of quality problems affecting the elderly and disabled.
2. No less than 80% of QIO program funding in any contract period must be expended in support of core contracts held by QIO contractors. Today one-third of the contract is diverted to “support” contracts that do not involve direct assistance to improve the performance of plans, providers and practitioners in the field.
3. The Secretary shall submit a proposed apportionment to the Office of Management and Budget no later than 12 months prior to the beginning of the contract period to which such funding would apply (by October 1).
4. The OMB shall either approve or deny a proposed apportionment no later than 9 months prior to the beginning a contract period to which such funding would apply (by January 1).
5. For tasks the Secretary proposes to continue substantially unchanged from the previous contract period, if the apportionment is not authorized by 90 days prior to commencement of the contract period, funding shall continue for the next contract period at a level no less than the amount of the previous contract period, increased by the amount of CPI-medical over the preceding 12 month period.

6. The RFP for each Statement of Work must be published no later than 4 months prior to the start of the contract (by June 1).
7. In a performance based contract, the QIO shall have maximum flexibility to utilize the funds to accomplish all functions required by such contract. No portion of the funding provided by a performance based contract may be restricted to the purpose of any specific function required under the contract.
8. IOM stated that, “given the limits of federal funding, the QIOs should be allowed to seek funds” from “providers and other organizations” for quality improvement and other forms of technical assistance. AHQA recommends that these business relationships be permitted if the QIO has made arrangements to avoid a potential conflict of interest resulting from conducting case review of facilities that are customers.

Qualifications of Organizations to Serve as a Medicare QIO Contractor. It is in the federal government’s interest to sign QIO contracts only with entities that can demonstrate past success in working with a large number of providers and practitioners to redesign clinical and administrative operations, improve the coordination, effectiveness, and safety of health care, and promote cooperation among diverse stakeholders.

Coordination with Medicaid. The Medicaid and Medicare programs should coordinate on quality measurement and improvement strategies, as IOM has previously recommended in a congressionally requested report (*Leadership by Example*, 2002). As a condition for receiving enhanced federal matching payments under SSA section 1158, Medicaid programs must establish quality improvement priorities, provide quality improvement assistance to plans, providers and practitioners consistent with those priorities, and annually report plan, provider and practitioner performance using nationally standardized quality measures.

Dr. McClellan, thank you very much for your consideration of these recommendations to modernize and strengthen the Medicare QIO program. We look forward to working closely with you to realize the full potential of the QIO program to support your initiatives to measure, reward, publish, and dramatically improve the quality of health care in America.

Sincerely,



David G. Schulke
Executive Vice President

cc: John Dyer
William Rollow, MD
Barry Straube, MD