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Dear Dr. McClellan:

Thank you for this opportunity to comment on the draft summary of the proposed "8th Statement of Work" (SOW8) contract. The summary defines tasks that Medicare proposes to hire private Quality Improvement Organizations (QIOs) to accomplish during the period August 2005 through July 2008. AHQA leaders and staff have discussed the proposal extensively with the QIO community and with other health care stakeholders before drafting these comments. We urge you to review each of the comments submitted by individual QIOs, for their unique perspectives cannot be fully reflected in this short document and we have not attempted to catalog them all here.

Overview

We appreciate your efforts and those of Secretary Thompson and Dr. Brailer to promote transformational change to improve the quality of services provided through the Nation's health care system. The proposed SOW8 summary sets forth an ambitious Statement of Work that would, like the 7th Statement of Work launched in 2002, ask QIOs to accomplish fundamental clinical and cultural process improvement, on an unprecedented breadth of topics, statewide, in every state across the nation. As a practical matter, the 8th Statement of Work will require QIOs who want this work to accomplish these objectives during a period of approximately two years, because of data lags built into the CMS quality measurement and contractor evaluation system. Despite the daunting challenge of the SOW8 summary, there is ample reason for CMS' confidence in its QIO contractors: QIOs are discharging faithfully and well the greatly expanded responsibilities assigned to them in the 7th Statement of Work.

Strikingly at odds with this ambitious mission, however, are a few parts of the proposed SOW8 that suggest uncertainty that the QIOs can succeed in their important work. These sections of the summary propose to direct funds that Congress set aside for community-based QIO activities to instead fund the work of others outside of those communities. We believe that an ambitious Statement of Work can be crafted and accomplished if the proposal is modified as we suggest below. Without these changes, however, the essential relationships upon which CMS' successful national health care quality improvement program has been built will be badly undermined in every community of the United States. We believe that the proposed contracting methods will limit the

effectiveness of QIOs, undermine the accountability that is the linchpin of performance based contracting, and significantly raise administrative costs – remaking this successful program into one that accomplishes less at greater cost. Ultimately, we believe the proposed approach will create barriers to Medicare's success in achieving transformational change by burdening and unsettling stakeholders in the program. These concerns and related suggestions for alternative approaches are presented in greater detail below.

QIOs: A National Resource

Congress created a special funding mechanism, a draw on the Medicare trust funds --and a very broad mandate, covering any item or service paid for by Medicare in whole or in part-- for organizations meeting the stringent statutory requirements to serve as a "Utilization and Quality Control Peer Review Organization" (today known as QIOs). As a result of these demanding requirements of law, and CMS' broad assignment of tasks (still not as broad as that authorized by Congress), a typical QIO's capacity is extensive and its access to additional technical and professional resources is far-reaching. The work of most QIOs extends beyond the Medicare contract to engagements with Medicaid, research institutions and academia, and in many cases the private employer market. QIOs employ individuals who, among others, include physicians, nurses, statisticians, analysts, epidemiologists, information technology and informatics experts, health educators and quality improvement experts. QIOs partner with research scientists at universities, evaluative and consulting firms, technology firms, survey vendors and public relations firms to conduct their work.

QIOs have consistently adapted and expanded their skill set and capacity to meet the changing needs of its customers. In the 7th Statement of Work, although most had not worked with nursing homes on any significant scale, in a very short time (and I might add despite the objections of skeptics) QIOs built capacity, forged and consulted new local relationships and successfully supported CMS' quality improvement and public reporting priorities in the nursing home setting. You can be assured that with respect to information technology, QIOs are building capacity, developing expertise and partnering with outside experts and firms to respond to HHS' technology priority. Several QIOs already have experience and engagements in the health technology arena to support their quality improvement work within and outside of Medicare and are ready to expand their work focus for the 8th Statement of Work. For an assignment that requires close collaboration and onsite work with physicians and their office staff, QIOs are uniquely qualified to serve as the local trusted resource for physicians and hospitals as they proceed with information technology adoption and application. Few others can claim this strength, and no others can claim it on a national scale.

QIOs are free from the conflicts that come with most contractors. Because of the nature of the program, Congress set high standards for conflicts of interest and QIOs have always been mindful of the conflicts that may arise from affiliations with providers and payors. As one form of accountability, QIOs annually submit statements to CMS that disclose ownership, control, and contractual relationships with a variety of organizations that may present potential conflicts. These disclosure statements are used by CMS to ensure that services provided by QIOs are free from any potential or actual conflicts. Few non-QIO contractors can (or are likely to be willing to) limit their business to comport with the rigorous conflict of interest restrictions imposed on QIOs. These designed-in attributes should be kept in mind when considering others to do the work assigned to QIOs.

Proof of Capability and Competitive Subcontracting

In the summary, CMS proposes a major change to its proposal evaluation and award process, based on two possible alternatives or "options." In the first model, for subtasks not related to the provision of assistance to physician offices, a QIO must demonstrate capability for "excellent performance" for each subtask based on its performance under the 7th SOW. If it cannot, it must subcontract that subtask "from among organizations that CMS would designate." In the second model, for subtasks related to the provision of assistance to physician offices and the subtask related to health information technology, the QIO would be required to subcontract the subtasks to multiple entities regardless of its capability.

The second contracting option proposed in the SOW8 draft would require QIOs to subcontract out all physician office work as well as hospital information technology work. It would also allow providers a choice of vendors to assist them with the work. The providers could, if the QIO is included by CMS on a proposed vendor list, potentially opt to work with the QIO. Option Two has all the defects of Option One, magnified by the fact that it would leave all QIOs with no choice as to whether and with whom to subcontract, yet it would still hold QIOs accountable for the subcontractor's performance.

Comments Pertaining to Options One and Two

Each of these alternatives is inconsistent, in many respects, with existing law and regulation. As important, these alternatives represent a sharp break with the judgment of policymakers who have recently examined the government's success in performance based contracting within the QIO program.

Congress Rejected Restructuring of QIO Program Contracts Pending Program Evaluation.
CMS operates the QIO program in accordance with the Government Performance and Results Act of 1993 (GPRA), based on the principles of performance based contracting. CMS assesses the performance of QIO contractors with an array of evidence-based measures of clinical quality, which are used to evaluate the success of QIO contractors in recruiting and supporting providers, practitioners and health plans in voluntary clinical quality improvement initiatives. QIOs that are unable to create the conditions necessary for providers to improve their own performance must compete to retain their contracts. Through this process, many QIOs have lost their contracts over the past 20 years so that now 38 organizations hold 53 QIO contracts.

When congressional officials last year wrote new law to reform Medicare contracting practices involving Part A fiscal intermediaries and Part B carriers, they consciously rejected including the QIO program in those reforms. Instead, they chose to apply to other contractors several key elements of the QIO performance based contracting model, such as multi-year contracts with non-competitive contract renewal based on good performance. In lieu of including the QIO program in contractor reform, Congress directed the Secretary to retain the Institute of Medicine of the National Academy of Sciences to undertake a thorough two year study of the QIO program to see whether and how the program could be strengthened through competition or other means. That study has just begun and its findings will be reported by June 2006.

In that same provision of the Medicare Modernization Act legislation, Congress explicitly recognized the value of QIO technical assistance to providers, practitioners and health plans in statutory

language, and also added significantly to the specific statutory responsibilities of the QIOs by assigning to them a new quality improvement program to operate under the new Medicare outpatient drug benefit.

With Congress demonstrating confidence in the QIOs' capabilities and in CMS' application of the performance based contracting model to the QIO program, we cannot understand the sudden enthusiasm for immediately and radically restructuring this program and its relationship to the clinical community. The Department of Health and Human Services is paying the Institute of Medicine (IOM) to analyze the need for contractor reform in the QIO program. On behalf of the contractors and the community of stakeholders that would be affected by the proposal, AHQA recommends the Department allow the IOM to do the job it was hired to do, and learn the findings of that study before taking action that may in retrospect appear uninformed and precipitous.

Confusion as to the Purpose of a National List of Subcontractors.
AHQA understands from discussions with Dr. Brailer that the intent of the central list of qualified subcontractors (a key aspect of both Options One and Two) may have been for the federal government to negotiate favorable consulting rates with firms that possess the rare and valuable experience of assisting physicians and hospitals with implementation of new IT systems, and to then provide QIOs with the budget and the option of drawing on these talents when physician practices run into problems the QIOs are not equipped to resolve. We understand and support the benefits of that vision of a central list of subcontractors, because it provides needed expertise to QIOs but leaves it to QIOs—in consultation with local stakeholders—to decide whether to rely on the entities appearing on the list, or someone else instead. But this vision that empowers QIOs to be of greater service to physicians and hospitals is very different than the compulsory use of a limited list of resources that is described in the SOW8 summary.

In addition to describing a system in which QIOs could be compelled to use subcontractors from a centrally determined list, there are signs suggesting that CMS may be planning to insist on nationally standard subcontract language to govern such relationships. The choice of subcontractors (if any), and the nature and extent of the work they actually perform, should be determined locally by the QIO with the advice of its partners in that state. This is wise because the needs of physicians and hospitals will naturally vary from state to state, as will the capacity of local entities to meet those needs. It is difficult to imagine a standardized contract that can anticipate these local variations.

Proof of Capability for New Work Must be Based on Objective Criteria, Applied Judiciously.
The summary proposes to require each QIO to satisfy CMS that it is capable of the work it must perform under the 8th Statement of Work. QIOs are adept at creating the capacity to do new work, as they have proven many times during twenty years of frequent changes in government objectives for the program. AHQA can accept the notion of a proof of capability to perform *new* work, if the criteria to be used in gauging that proof of capability is developed by those who are not conflicted and who possess the requisite expertise.

We are uncertain whether CMS intended to apply this "proof of capacity" test, as the draft summary does, to both the current work in physician offices and the proposed new health information technology and pharmacotherapy quality improvement work. Inasmuch as CMS hires the QIOs for their expertise at clinical quality improvement, and CMS itself may lack personnel with equivalent expertise in the specific new tasks to be performed by the QIOs, the job of crafting criteria should

fall to an objective body of experts familiar with the new work. These criteria are needed very soon for QIOs to begin to develop the capabilities and attributes needed for the new work.

The draft SOW8 summary proposes to use performance in the physician office setting, as measured by the SOW7 evaluation, as one criterion to determine if QIOs may avoid directed subcontracting and continue to do their own work in the physician offices during the 8th contract. This is reasonable with the very important exception of the retinopathy and mammography measures, each of which requires not only that the physician and office staff alter their practices, but also that a sizable proportion of beneficiaries then follow up and go to another appointment at another practitioner's office. SOW7 data suggest strongly that QIOs are having a beneficial effect on measures of quality in physician office practices that the physicians themselves control, but there has been little progress on measures that depend on patient action. CMS officials have recently stated that there is little evidence that QIOs can influence beneficiaries' actions; if this is so, CMS should not use measures of the ability of QIOs to influence beneficiaries to disqualify QIOs from doing work that depends entirely on the decisions of the physician and office staff (e.g., health information technology implementation and some potential measures of pharmacotherapy quality).

If under either Option One or Two CMS chooses to develop criteria to qualify entities <u>other than QIOs</u> to perform the work of the 8th QIO Statement of Work, then the eligibility criteria for non-QIOs performing the work of QIOs must provide that any such organization (a) meets the statutory and regulatory requirements expected of QIOs, (b) must have the approval of stakeholder organizations in that state, and (c) must have demonstrated competency in statewide quality improvement. Otherwise, the subcontracting approach will favor non-QIOs because they will be free to seek the work of QIOs without meeting the tests Congress established for QIOs to qualify for receipt of trust fund dollars.

<u>Proof of Capability for Continuing Work Would Violate the Statutory Scheme for Noncompetitive Renewal.</u>

Continuing work (that carried on from the current 7th Statement of Work contract) should not be subject to new "proof of capability" requirements. Longstanding performance based contracting law, regulation and practice calls for this purpose to be accomplished through an evaluation of the contractor's previous work. Accordingly, Section 1153(c)(2) of the Social Security Act authorizes the Secretary to evaluate the quality and effectiveness of organizations performing quality improvement functions. The statute permits the noncompetitive renewal of QIO contracts based on efficient and effective performance as measured by the evaluation criteria and standards established by CMS (see Section 1153, subsections (c) and (h)(2)). Attachment J-7 to the 7th SOW QIO contract sets forth the evaluation criteria and standards that merit a noncompetitive renewal. To the extent that the proof of capability for "excellent performance" is interpreted by CMS as a higher standard than that required by Attachment J-7 for noncompetitive renewal, the model would be inconsistent with the statute and the current contract.

<u>Directed Subcontracting is Contrary to the Intent of Congress in Establishing the QIO Program.</u>

There are over twenty pages in the Social Security Act pertaining to the QIO program, because Congress has repeatedly considered and refined the program over two decades (building on the previous decade of experience with the QIOs' predecessors, the Professional Standards Review Organizations or PSROs). The Social Security Act states in Section 1862(g)--

> "The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a), and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this title, enter into contracts with utilization and quality control peer review organizations pursuant to part B of title XI of this Act."

Detailed requirements for the Secretary's contracts with QIOs appear in Title XI of the Act. At Section 1153(c)(1) the law states,

> "(c) Each contract with an organization under this section shall provide that—
> (1) <u>the organization</u> shall perform the functions set forth in section 1154(a), <u>or may subcontract</u> for the performance of all or some of such functions (and for purposes of paragraphs (2) and (3) of subsection (b), a subcontract under this paragraph shall not constitute an affiliation with the subcontractor)" . [Emphasis supplied]

The statute also clearly contemplates that the QIOs will engage qualified professionals as they determine necessary to accomplish the performance of the contract functions (see Section 1154 (a)(7)). It is clear from these provisions that the Secretary is to contract with QIOs for these functions, which are to be performed by entities qualified to serve as QIOs, and no one else. The language stating the QIOs "may" subcontract grants this discretion to the QIOs, who otherwise "shall" perform the functions themselves. AHQA believes Options One and Two would force functions funded through the congressionally established QIO trust fund mechanism to be performed by entities other than QIOs—without the QIO's acquiescence—and would violate these provisions.

<u>Directed Subcontracting Conflicts with the Statutory Scheme for Nonrenewal and Termination</u>. The Secretary may terminate a QIO's contract if it determines that its performance is inconsistent with the effective and efficient administration of the QIO program, or it may decide not to renew its contract if the QIO has failed to meet the performance criteria established by Attachment J-7 (see Section 1153, subsections (c)(4) and (c)(6)). Unless CMS intends to hold QIOs harmless for the performance of the directed qualified subcontractors, QIOs would be at risk of contract termination or nonrenewal due to the poor performance of the subcontractor directed or qualified by CMS. Similarly, such inadequate performance by a subcontractor could detrimentally affect the determination as to whether a QIO has earned a performance related "award fee." Holding the QIOs responsible for the performance of subcontractors that CMS has directed or qualified, whose performance may well be beyond the QIO's control, unfairly prejudices the QIO's ability to perform sufficiently to avoid termination or nonrenewal. Such a result is particularly unjust given that the QIOs have no judicial recourse against CMS. Section 1153(f) states that "any determination by the Secretary to terminate or not to renew a contract under this section shall not be subject to judicial review."

<u>Directed Subcontracting is Inconsistent With Performance-Based Contracting.</u>
CMS' stated policy is to use performance-based contracting methods in the QIO contracts. Federal Acquisitions Regulation (FAR) Subpart 37.6 establishes the policies and procedures for performance-based contracting. The first of these is to "describe the requirements in terms of results required rather than the methods of performance of the work" (see FAR § 37.601 (a) (1)). Directing a contractor to subcontract tasks rather than permitting the contractor to determine how to meet the contract requirements is inconsistent with these FAR provisions.

The tenets of performance-based contracting already provide CMS with a more appropriate framework than directed subcontracting for addressing performance concerns. In addition to the first attribute described above, such contracts should: set measurable performance standards; describe how the contractor's performance will be evaluated in a quality assurance plan; and identify positive and negative incentives as appropriate (*e.g.*, award of or reduction in award fee) (see FAR § 37.601). If the standards for inadequate and superior performance for specific subtasks are clear and the consequences are equally clear, presumably QIOs will have sufficient incentive to make their own informed decisions about what portions of the contract they should consider subcontracting.

Under the statutory scheme, it is the QIOs who should have the responsibility for deciding whether to subcontract, selecting their subcontractor and managing their subcontractor. The evaluation of the QIO will determine whether it retains or loses its contract. Generally, the Government does not guarantee that sources it designates will perform adequately, and presumably, CMS does not intend to insulate the QIOs from liability for the performance of the subcontractors that CMS has designated. If it does not, the proposed models would set the QIOs up for failure by requiring them to use subcontractors they do not select, then holding them responsible for inadequate performance by the subcontractor in the evaluation and noncompetitive renewal determination and in the award fee determination.

<u>Limiting Subcontractors To Those Designated By CMS Violates Qualification and Competition Requirements.</u>

CMS' intention to limit acceptable subcontractors to those it designates is also inconsistent with the qualification and competition in subcontracting requirements of the Federal Acquisitions Regulations (FAR). The FAR provisions addressing qualified sources require that offerors must be considered even if they were not formally designated as qualified by the Government as long as they demonstrate, by the time of contract award, that they meet the standards established for qualification (see FAR § 9.202 (c)). Thus, CMS must approve any proposed subcontractor that meets the relevant qualifications, regardless of CMS' designation of other "approved" subcontractors. Competition in Subcontracting, FAR § 52.244-5, requires the subcontractor to select subcontractors on a competitive basis "to the maximum practical extent" consistent with the objectives and requirements of the contract. Although subcontracts are not subject to the "full and open competition" standard applicable to prime contracts, the policy of maintaining competition in subcontracting is more fully effectuated by permitting the QIOs to consider all capable and willing subcontractors than limiting their choices to a prequalified pool.

<u>Directed Subcontracting QIO Activities Undermine Compliance With Small Business Subcontracting Goals.</u>

The 7th Statement of Work contract, at clause H.17, states that HHS has determined that "all non-profit organizations are defined as large businesses for reporting purposes." All but a few QIOs are non-profit organizations. Because QIOs have been formally designated as large businesses, they are obligated to prepare and submit a Subcontracting Plan (see SOW7 attachment J-10, and FAR Part 19.7). A requirement of a subcontracting plan is a statement of percentage goals for using small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and women-owned small business concerns as subcontractors (see FAR 19.704(a)(2)).

A QIO's subcontracting goals are based on total dollars to be subcontracted. If a portion of a QIO's funding is directed by CMS to a particular non-small business subcontractor, then we are concerned that QIOs will find it more difficult to comply with their legal obligations to subcontract with small businesses.

Directed Subcontracting is Unlikely to Result in More Efficient and Effective Performance.
The objective of these QIO contracts is to achieve as much improvement in quality as possible at the lowest possible cost. The proposed directed subcontracting model subverts this objective. It is unclear which entities CMS envisions designating as qualified subcontractors, but presumably they would include large national consulting companies and information technology service providers. This approach would undercut the goal of creating local partnerships. It will also create issues of oversight and control. At a minimum, QIO contract costs would increase by the cost of managing the subcontracts, which would be considered an allowable contract cost. Negotiating and managing such subcontracts would be difficult for many QIOs, particularly the smaller ones, given that such national entities are in a superior bargaining position to many of the QIOs. This balance of power and the subcontractor's accountability to the QIO would be further eroded by CMS' designation of such subcontractors, given that the subcontractor's participation in the program is not due to nor is it controlled by the QIO. Under these circumstances, the assumption that directed subcontracting will improve the overall effectiveness of the QIO program is unwarranted.

In addition, we would ask you to appreciate that the integration of QIO tasks is increasingly important to effective performance. For example, QIOs have established procedures to integrate the activities of their staff by applying quality improvement precepts to their complaint investigation responsibilities. Another example is the explicit QIO contractual requirement that communications and public reporting (i.e., Task 2 in the current contract), and beneficiary protection (i.e., Task 3 in the current contract), must be coordinated with a QIO's work with providers to improve performance on quality measures (Task 1 in the current contract). If some of these tasks (all of which will be tasks in SOW8) are to be performed by one QIO and some tasks by another QIO (or other entity), it will necessitate close coordination in day to day work between contractors performing these tasks. This degree of coordination will be impeded by splitting the functions up. The work will then have to be reintegrated, but this will be done with greater difficulty and at greater expense than is now the case.

These lost efficiencies will affect more than QIO contractors. Currently, by performing multiple tasks, QIOs are able to coordinate improvement activities with physicians and stakeholder organizations (e.g., medical societies, chronic disease groups) and leverage stakeholder involvement across the care continuum. Dispersing these tasks to different entities will result in the loss of integration and create redundancy as each contractor must explain its role and ask for physicians and others to join them in working on each fragment of the Medicare quality improvement agenda. There is no indication from the provider and practitioner communities that they wish to deal with more entities to address quality concerns, and there is in fact considerable evidence to the contrary.

AHQA Recommendations Pertaining to Proof of Capability and Competitive Subcontracting

AHQA recommends the following changes in approach to accomplish CMS' objectives under this section.

1) Delete the directed subcontracting provisions of both Option One and Two.

2) To the extent that subcontracting is encouraged (for example, by Dr. Brailer's model for making the best talent available at reduced cost), CMS should drop plans to specify the content of subcontracts. The agency has the right to review proposed subcontracts to ensure their adequacy, and that review is sufficient to protect the government's interests while preserving the QIOs' statutory option to subcontract.
3) For ongoing work (a task that will continue from SOW7 to SOW8), the same level of performance that merits a noncompetitive renewal of the entire contract should be deemed proof of capability to perform this work.
4) When a QIO fails to demonstrate its capacity at an acceptable level to perform a task that will continue from SOW7 to SOW8, CMS should require the QIO to obtain assistance from another entity of proven capability in that task. Subcontracting the task should not be required, but should be encouraged.
5) CMS should avoid applying the proposed new "proof of capacity" policy to the physician office quality work that is ongoing from the 7th Scope of Work, instead reserving this approach for the new health informatics and pharmacotherapy improvement work.
6) To ensure QIOs are capable of excellence in performing new tasks, CMS should—

   (a) develop criteria for proof of capacity to perform new work, seeking outside expertise for this purpose from those who are acknowledged experts in performing the work (e.g., those having assisted numerous IT implementations in physician offices and hospitals, and those who have conducted successful interventions to improve the quality of pharmacotherapy);

   (b) ask each QIO to submit a detailed technical proposal in which it must describe how it will satisfy the criteria; and

   (c) if CMS is not satisfied with the QIO's plan, it should then ask for resubmission of the proposal with additional expertise from whatever sources the QIO can muster (e.g., more or more qualified staff, another QIO, a subcontractor). CMS would retain the option to not contract the task with a given QIO. The leverage in this relationship favors CMS greatly, and because the potential for CMS to intrude on management decisions at the QIO through this mechanism is commensurately great, this should explicitly be prohibited.

Assessment of QIO Impact

AHQA strongly supports progress in this area of documenting the extent of real vs. perceived progress resulting from the joint efforts of QIOs, providers, practitioners and plans. What is needed to document the effect of QIO interventions is a valid comparison group. But we would caution against pursuing this aim single-mindedly, because our best information about CMS intentions is that the agency intends to achieve "transformational" change in a small group of providers that will be well disposed to help "spread" their success after the project has achieved success. A randomly selected group of providers or practitioners is unlikely to include many influential champions.

There is are a couple of change models documented in the literature for achieving widespread adoption ("spread") of "best" or "better" practices based on the experience of a small number of peers. This approach works when opinion leaders (called "educational influentials" in some articles) are engaged in a new process, because others will follow their lead. Individuals lacking the status of opinion leaders can achieve dramatic and lasting change as well, but only with comparatively in depth sessions of 30 minutes or more with one or a few practitioners at a time (this is the "academic detailing" literature.) But we are unaware of evidence supporting widespread adoption of the

practices of randomly selected practitioners who have adopted a recommended practice. Does CMS have some solid evidence that this is a model that has succeeded, before we pursue it nationally, financed by trust fund dollars?

Random selection of an "identified participant" group will work to measure whether the activities of QIOs can be expected to work in a typical population of practitioners and providers, but the "spread" models we know of suggest it is unwise to attempt to promulgate a new practice relying on average or typical providers and practitioners. We know there are practitioners and providers that are ready to change today, those that might be ready tomorrow, and there are a significant number who are not close to being ready. It will be very expensive to ask QIOs to expend Medicare resources on a randomly selected group of providers, a third of which are uninterested in change. CMS appears to be in the position of choosing to document an effect (through random selection of participants) that will be predictably (and inefficiently) tiny because it was attempted in a population that includes many uninterested parties, and also mostly uninfluential ones (the latter being important when the project goes into phase two and seeks to "spread" its lessons to more practitioners by showing them the success of the initial group.)

AHQA has two suggestions that may help resolve this problem.

1) Fund the identified participant groups at a size large enough to have two subgroups, each of which is large enough in every state for analysis of their results as an independent subgroup. These subgroups would be (a) a group randomly selected and tracked as such, and (b) a group selected for its believed propensity to change and/or its likely ability to influence others at the conclusion of the project's first phase. The QIO would treat the whole group as an IP group, but the subparts could be tracked and the influentials could be recruited to help "spread" the findings of the project when it is ready for that stage.
2) Explore use of a crossover design, in which a group of practitioners or providers serves as a comparison group initially and then is exposed to the intervention. Dr. Bratzler of the Oklahoma Foundation for Medical Quality has used this approach successfully and very persuasively in the past. Given that many interventions play out over a period longer than half a contract cycle, and data acquisition and measurement delays may consume at least that much time, this approach may require two contract cycles to work, but we feel it is worth considering.

Task 1a: Nursing Home

AHQA fully supports CMS' direction for the QIO program to help produce transformative organizational culture change and build on successes of QIOs in the nursing home setting. AHQA, along with the QIOs' national and local partners, are embracing the potential for culture change techniques to generate breakthrough and lasting improvements in the quality of life of residents and effectiveness of long-term care staff. However, if the demand for QIO technical assistance in the SOW7 is any indication, we believe that CMS should provide resources for QIOs to work intensively with an identified participant group larger than 10% of nursing homes in the state. QIOs should continue to have the option of including up to 15% of facilities in their identified participant group. In addition, facilitating culture change will necessitate more one-on-one consultation between QIOs and nursing homes, and CMS must recognize that these activities are resource intensive and fund them appropriately.

Culture Change

AHQA is concerned whether appropriate measures of culture change exist and is skeptical of whether CMS can accurately evaluate QIO performance at instituting culture change in nursing homes, particularly within the time period allowed by the three-year QIO contract. Research in this area indicates organizational culture change requires a long and sustained effort that can take from 3 to 10 years, under ideal circumstances, to achieve the desired results.

A group of QIO and CMS representatives struggled to identify potential appropriate culture change measures during the CMS nursing home strategic planning deliberations. The reason for the difficulty is that many factors that contribute to staff and resident satisfaction, workforce turnover, and other potential culture change measures are outside of the control of the QIO, and to a large extent, the nursing home itself. For instance, it's likely that the local job market, economy, and other environmental factors have a far greater impact on nursing home staff turnover than anything a QIO could do.

CMS should provide QIOs with evidence supporting the use of these proposed culture change measures, the use of interventions to impact these measures, and literature backing the proposed thresholds as achievable benchmarks of improvement. At this point in time, AHQA and QIOs have not been presented with any evidence to demonstrate that QIOs can have an impact in this area, other than reasons that are theoretical and qualitative. The QIO program has a proud tradition of working only on topics and measures supported by the best available science and supported by the consensus of knowledgeable individuals in the field. Until such science is developed in the area of culture change and workforce retention, QIO efforts in this area should be appropriately recognized as research-in-action dedicated to developing and furthering the evidence base supporting the benefits of culture change in nursing homes.

Leading up to the start of the SOW8, CMS should work with culture change experts in the field and with QIOs to determine sensible, evidence-based measures, interventions and improvement goals for QIOs in the nursing home setting. AHQA also recommends that CMS recognize that measuring culture change and assessing QIO performance on promoting culture change is highly developmental and experimental, and therefore the agency should attribute little weight to these proposed measures in its evaluation of the subtask. Furthermore, CMS should utilize QIOs in the SOW8 to develop the evidence-base for culture change measures by collecting and monitoring data related to organizational culture and by beginning to spread effective interventions among QIOs and their partner organizations as quickly as possible. CMS should also work with QIOs and experts to develop and refine appropriate measures that assess QIO efforts to track and act on culture change data and information. For instance, in the SOW8, CMS could monitor a QIO's ability to help a nursing home identify and implement the initial fundamentals and principles needed for culture change to take root. As time progresses and expertise evolves, CMS could get more ambitious in its performance goals and move towards monitoring a nursing home's and a QIO's ability to bring about small, then larger, changes in clinical care processes and outcomes.

Following CMS' recent quality initiatives, QIOs are increasingly learning about the powerful effect of incentives in driving providers and practitioners to participate and succeed in quality improvement projects. CMS should consider ways to offer nursing homes incentives to participate in organizational culture change activities led by the QIOs. Without incentives, we are concerned that QIOs will struggle to spread these important change concepts widely after acceptance by early adopters.

Reducing Turnover
While AHQA is supportive of the potential QIOs and culture change concepts have for reducing turnover in nursing homes, we object to the use of arbitrary thresholds such as the 50% reduction for nursing home employees and 15% of certified nursing assistants leaving in less than one year proposed in the SOW8 summary. It should be noted that the evaluation of one of the Nation's leading culture change programs, Wellspring, revealed only about a 6 percentage point improvement in staff retention.

In addition, all turnover is not bad; some is a sign of positive changes. CMS should consider that there is some evidence (quantitative and qualitative) that organizational culture change can result in unintended consequences by causing turnover among nursing home staff that are not willing or able to embrace this revolutionary approach to long term care quality improvement. For example, while some significant reductions in turnover were found in an evaluation of the Project LEAP culture change initiative, it is important to note that an evaluation of the Eden Alternative (Coleman et al. 2002) found that an Eden site had more staff terminations and new hires than a control site.

Similarly, a proprietary regional nursing home chain owner who has implemented culture change in several of his facilities reported at the AHQA Annual Meeting this year that he had a number of staff leave his employ specifically because of his initiating culture change in his facilities. He was glad they left, because they would not support the changes. If this were to occur in other nursing homes, as we must assume it would, it would most likely occur some months into the SOW8 contract period, after the QIO and the nursing homes have prepared themselves to initiate these major changes. When nursing home staff leave in the middle of a QIO contract, it will negatively affect turnover rates and likely predispose the QIO to be judged a failure in its efforts at culture change. This problem with turnover rates as a measure can and should be anticipated, and better measures adopted that are not likely to lead CMS to misinterpret the data.

Because of the developmental nature of these workforce measures as a means of assessing culture change, AHQA recommends attributing comparatively less weight to these workforce measures and awaiting evidence-based staff turnover experience guided by the workforce retention pilot currently underway. Another option may be setting a reasonable performance threshold for nursing homes that implement a workforce retention plan, as proposed in the hospital Task 1c1.

If CMS is committed to these workforce measures, it might consider the following alternatives:

- Measure a time frame in which a QIO might be more likely to have an impact. For instance, measure turnover within 90 days of employment, which will allow QIOs to address organizational culture issues related to staff orientation and initial training.
- Exclude some nursing home staff departments in the turnover measure. It is our understanding that nursing homes are increasingly contracting with temporary employment agencies for custodial, dietary and other staff, making these employees subject to leaving the nursing home for factors completely unrelated to organizational culture and quality. We would recommend focusing only on nursing or direct care staff, which, if stabilized, may impact turnover among other nursing home staff.
- Doublecheck the math on the targets for turnover reduction. Nursing assistants are the most numerous employees in a long term care facility. A 15% reduction in turnover for them is likely to be inconsistent with a 50% reduction for the entire staff.

In sum, until there is more consensus in the literature the potential for culture change to reduce turnover — research that the QIOs can contribute greatly to — we would strongly urge CMS to scale back its current expectations and examine testing a variety of other potential proxy measures for culture change.

Resident/Staff Satisfaction
These provisions are more experimental than ripe for implementation nationally. AHQA is not confident that the Nursing Home Consumer Assessment of Health Plans survey is or will be ready and reliable for use in assessing culture change and QIO performance over time. Before relying on it as a guidepost, it is critical that as the NHCAHPS is rolled out, CMS examine whether this survey, when added to the numerous satisfaction surveys already used by many nursing homes, could create a situation where residents and their families are overburdened with multiple surveys, affecting response rates or results. As for the Eden Warmth Survey, CMS should provide evidence that this instrument is appropriate to assess readiness for culture change in a facility, capable of tracking performance over time, and whether there is evidence that interventions can directly impact survey results. For both surveys, it is unclear whether CMS intends to require QIOs to show increased satisfaction on the entire survey or for a portion of questions. If CMS is committed to using these instruments to assess QIO performance on culture change, it is critical that CMS analyze results from questions that QIOs can have a direct impact upon, and not include those that measure the effect of activities beyond QIO influence.

AHQA strongly encourages CMS to more carefully study the NHCAHPS and Eden Warmth Survey to determine if their use as culture change measures is supported by evidence as both valid and reliable. If that evidence exists, it should be presented to the QIOs. If it does not, CMS should consider whether QIOs could help develop that evidence before it is used in performance based contracting. In the meantime, these measures should be considered developmental and weighted appropriately (very slightly, if at all) in the QIO evaluation.

Publicly-reported Measures
AHQA supports the continued use of the NQF-endorsed, publicly-reported nursing home measures, and acknowledges the goal of focusing on a smaller set of measures closely related to residents' quality of life. However, AHQA is confused at how adult immunizations can be a "breakthrough priority" for the department, and thereby the QIOs, when QIOs are not asked to address immunizations in the nursing home setting. Nursing home immunizations are a critical component of effective care and have tremendous implications for the health of residents and health care costs. We strongly encourage CMS to identify a data collection tool and quality measure for nursing home immunizations, perhaps (as we have previously recommended) by adding this to the MDS, or perhaps by having QIOs work with nursing homes to submit immunization data under the SOW8 process change implementation performance measure.

One proposed nursing home measure that may be suitable for refinement, replacement, or removal is "prevalence of depression." It is our understanding that this measure has tremendous potential for errant MDS coding and false positives. In addition, a disease prevalence measure does little to indicate a nursing home's effectiveness at assessing, diagnosing and treating depression, particularly through the use of appropriate medications. We would suggest, instead, measuring and designing quality improvement projects focused on a nursing home's ability to assess and manage depression.

AHQA supports CMS' recognition that a distinction should be drawn between nursing homes with

very low levels of restraint-use and those facilities with higher rates. AHQA recommends that CMS expand the use of this methodology in nursing homes and other settings so that QIOs are not inappropriately penalized in their evaluation for helping nursing homes reach and then maintain high levels of performance.

AHQA is concerned, however, about the proposed threshold for the physical restraint measure, which is set at a level well below the HHS Government Performance and Results Act threshold of 5-6%. The medical literature (Cohen et al, 1996) suggests that due to issues of family opposition to not using restraints and medically-necessary restraints, as well as varying definitions of restraints among states, it is believed the practical limit of restraint reduction would be about 5-6%. In addition, setting a goal far below that of the GPRA goal used by surveyors would make it more difficult to coordinate with them on this topic. While AHQA supports efforts to eliminate restraint use, it is necessary that we recognize the realities of these complicated issues and set reasonable goals. CMS might consider a better option, such as "maintain rate if <6%; reduce rate by 8.5% relative improvement if >6%."

AHQA also has serious concerns about nursing homes' capacity to work on multiple measures at one time, particularly for the identified participants, who under this proposal would have to address culture change, improve on five clinical measures, set targets, and send data to the QIO warehouse. Meanwhile, QIOs must assist nursing homes that are working on other clinical measures than those the QIO is addressing. This list of activities seems like a recipe for creating excessive burden on nursing homes, which could alienate them from essential quality improvement partnerships. The QIOs' experience, echoed in other settings beyond nursing homes, is that facilities can only reasonably be expected to concentrate on a limited number of quality improvement projects at one time. Focusing on multiple measures (five are proposed in the SOW8) could slow progress. We encourage CMS to consider having QIOs focus on the two GPRA measures from this set, and give the QIO and its nursing home partners the option of choosing an additional publicly-reported measure. In general, if CMS is committed to working on multiple measures, we suggest setting up a formal manner and appropriate evaluation that allows QIOs and their nursing home partners to use a "phase-in" approach for working on multiple measures. Some QIOs reported having success using this method in the SOW7, but they said success was limited by the brevity of the contract cycle, which allows substantially less than three years to intervene and show an effect on care practices.

AHQA is discouraged that CMS has opted not to pursue any cross-setting quality improvement projects. We feel this is an area of great need and one in which QIOs can have a considerable impact because of their relationships with providers in multiple settings and their expertise in health care systems. We strongly encourage CMS to expand upon the early efforts of some QIOs that are addressing pressure ulcers in the hospital and nursing home settings, and examine other appropriate topics for cross-setting work.

AHQA also has concerns that CMS has proposed a potentially unrealistic goal by proposing "statistically significant" improvement as a gauge of QIO performance in the SOW8. AHQA would like to understand why CMS no longer intends to use relative improvement to track performance on this task. The SOW8 proposal sets up a situation where identified participant nursing homes are asked twice to achieve statistically significant improvement. This plan likely would disadvantage smaller facilities or states with fewer nursing homes (depending on whether the QIO evaluation targets improvement by resident or by facility). Should statistical significance be used, CMS should

set the confidence level at an appropriate target so that both large and small states have the opportunity to meet the goal in this task. In many cases, there will not be enough statistical power to demonstrate statistically significant improvement. It would also seem more appropriate to compare identified participant group performance against non-identified participants, as opposed to the statewide average.

Target Setting

The SOW8 draft is unclear about the purpose for asking 80% of nursing homes in each state to set targets for at least restraints and pressure ulcers and for additional measures for identified participants. As written, QIOs are given no guidance on how they should go about setting these targets, which raises questions about how intensive this target setting activity will be. It is unknown whether CMS intends for QIOs to sit down with each of the 80% of facilities to analyze their current performance on these measures and apply a careful process for setting a reasonable (or transformational) improvement target. Or, does CMS merely intend to have these facilities pick a target on their own and register that target with the QIO? Additionally, it is unclear what, if anything, CMS intends for QIOs to do to help these facilities achieve these targets. Considerable harm could be done to vital nursing home-QIO relationships if QIOs do not provide some form of technical assistance to achieve these goals. Also, nursing homes are likely to be skeptical of these goals and whether survey agencies might hold them responsible for meeting these goals. There are a number of unanswered questions for this performance measure and it is incumbent on CMS to provide clarification and seek comment.

Process Change Implementation

AHQA is concerned that many nursing homes do not have the capacity or the incentive to send quarterly data to the QIO warehouse. This task should be flexible enough to account for the varying readiness levels among nursing homes to collect and submit data. We are also concerned that the 80% target is too high, as the QIO experience and the National Nursing Home Improvement Collaborative has shown that getting facilities to submit data is very difficult. It is also unclear whether QIOs will be responsible for 80% of identified participants sending quarterly data to the QIO warehouse for 90% of residents for all four process measures, or just for depression assessment at admission. It is critical that CMS avoid problems that plagued the release of the hospital CMS Abstraction and Reporting Tool by giving QIOs the freedom to help nursing homes select from a range of tools that meet the requirements for submitting data to the QIO warehouse. One of the strengths of QIO work in nursing homes has been the partnerships they have built with nursing home providers, and it is essential that these strong relationships and gains in quality not be jeopardized by burdensome responsibilities such as forcing nursing homes to use an unreliable data submission tool.

Since releasing the SOW8 draft, CMS has communicated that it intends to develop software that can be added to the MDS in order to submit this data. It is very unfortunate that CMS did not include this important detail in the SOW8 summary, because the proposal as described in the SOW8 summary has caused significant consternation and confusion among QIOs and stakeholders.

The process change portion of the subtask seems to be generally devoid of interventions that would help nursing homes understand their processes of care and how to take steps to improve these processes. Simply reporting data won't achieve the purpose of helping nursing homes to make necessary process changes. CMS must provide more information on what it intends for QIOs to do in this area, and more generally, to help nursing homes understand, measure and improve upon their

processes of care.

Finally, CMS should investigate ways to begin working with nursing homes on effective health care IT adoption, as is planned in the physician office setting. AHQA suggests that CMS develop and operate pilot programs in the SOW8 that involve QIOs helping nursing homes adopt IT systems with the necessary standards and then providing assistance to ensure that those systems are used in a way that improves the quality of care.

Task 1b: Home Health

Although the evaluation for task 1b in the SOW7 doesn't indicate it, an analysis of home health quality data shows dramatic improvement across the country on a number of OASIS measures, particularly for home health agencies working more closely with their QIOs. This is a validation of CMS' program, and a tribute to the QIO work in this area and the tremendous commitment of their home health agency partners.

AHQA members are heartened to see that CMS is no longer requiring statistically significant improvement for task 1b, given all the problems that caused with small providers. But to avoid some of the problems faced in the SOW7 with agencies that have a limited number of cases, we suggest that eligible HHAs for inclusion in the national denominator should have at least 30 cases for a given outcome. CMS should also examine whether QIOs could conduct specific quality improvement projects targeted to smaller agencies with less cases.

AHQA is concerned that HHS and CMS have failed to identify a "breakthrough priority" in its strategic plan for QIOs to address in the home health setting, while there is at least one priority for every other setting in which QIOs work. There is an impression among the QIO community and their home health partners that quality improvement in this setting does not rise to the same level of importance in CMS as other tasks. Not including home health in the breakthrough priorities may serve to further this perception, and reduce resolve by agencies to do the hard work of quality improvement. We encourage HHS and CMS to work with QIOs, AHQA, the home health industry, consumer representatives, and other stakeholders to identify a "breakthrough priority" in this setting.

AHQA has a number of concerns related to the task 1b SOW8 proposal, including:

- Asking home health agencies, particularly small agencies with limited resources and low performing agencies, to work on multiple measures at once. We have detailed problems with this policy under task 1a, and we encourage CMS to consider the potential impact from asking too much of QIOs' provider partners.
- Shifting away from the aspect of the OBQI methodology that stresses comparing HHA performance to that agency's prior performance, which accounts for those agencies that may have special needs and circumstances (i.e. rural HHAs). AHQA recommends evaluating QIO performance in a manner that emphasizes individual agency performance over time, as opposed to solely tracking agency performance compared to national or state averages.
- The process CMS will use to develop "national target rates" for the identified participant group's selected OASIS measures. AHQA recommends that the agency use an open process that consults with QIOs, home care representatives, and measurement and research

experts to set achievable target rates for the OASIS measures.
- Unlike process measures where 100% performance is the goal, it is unrealistic to expect perfect performance on OBQI outcome measures, and it is not known what constitutes optimal performance on these measures. CMS also must take into account that QIO performance in helping home health agencies implement OBQI process improvements is not always perfectly reflected in OASIS outcome measures.

Particularly for the two priority measures, acute care hospitalization and emergent care utilization, it's important for CMS to account for aspects of these proxy measures that are outside a home health agency's control. For instance, physician behavior plays a large role in whether a patient is sent to an emergency room for care. Also, while a home health agency can impact whether a patient's condition is worsening, the agency has no control over whether a hospital chooses to admit a patient, yet this is the action that is measured. In addition, we understand that increasing numbers of scheduled admissions under managed care are confounding the accuracy of the hospitalization measure.

We have identified the following additional issues related to the selection of acute care hospitalization and emergent care use:

1. There is an element of redundancy between these two measures, as patients that require emergent care in a hospital also are likely to be admitted. Particularly if agencies are asked to work on both measures, we encourage CMS to investigate the correlation between them, which may be as high as 80%.
2. We understand that there are significant coding errors and difficulty in appropriately answering the OASIS question on emergent care utilization, which results in instability for this measure.
3. Improvement plans may exist to help agencies develop systems to prevent patients' complications from heart failure, diabetes, and other conditions that can lead to emergent care or hospitalization. However, there is no known system intervention package that would address all of the most common reasons for a patient to visit the emergency room or require hospitalization. Therefore, it would be very difficult for a QIO to be able to help agencies have an impact on this measure. Perhaps CMS should measure and then determine whether QIOs could address emergent care or hospitalization related to a specific clinical condition.

If CMS is committed to these measures, we would recommend that CMS allow QIOs, in consultation with their statewide partners, to choose one of these measures for their state. It should be noted that QIOs have had difficulty helping providers improve each of these measures during the SOW7, and those who have shown improvement report that it's taken considerable time and effort to do so. Considering this experience, CMS should carefully consider whether these measures are appropriate for focus in the SOW8 and certainly should factor this experience into setting appropriate state-specified levels of improvement for adequate QIO performance. It is unclear how CMS plans on calculating the specified levels of improvement, but regardless, to determine these levels CMS should consult with stakeholders and account for historical performance on these measures for each state.

AHQA also is concerned that QIOs, as in the SOW7, in effect will have to recruit nearly 100% of agencies in their state in order to reach the proposed standard of helping 20% of agencies to improve on two OASIS measures. As CMS encouraged in the SOW7, QIOs recruited as many

agencies as possible in their states to help ensure that they would meet the Task 1b evaluation criteria. Particularly in large states, the SOW8 proposal will again necessitate a substantial recruitment and assistance effort, and the SOW7 has shown that QIOs will need to work on a one-on-one, consultative basis with many agencies to improve care on these measures. It is also unclear whether a QIO would have to establish two separate identified participant groups of 20% (in effect, 40% of agencies), or whether there would be a single group of 20% working on both the two priority measures and the OASIS measures. As mentioned above, it's proven exceedingly difficult for agencies to work on any more than one quality measure at a time.

The lack of clarity in the SOW8 identified participant improvement section for the OASIS performance measures also brings about the following complications.

1. It is not clear whether each agency would be able to select their own two OASIS measures—a fundamental component of the OBQI process—or would CMS or the QIO select the additional two measures for the identified participant group (which, in reality, will be the whole state—see above) regardless of the particular need of an individual agency.
2. It is difficult to surmise the impact of working with low performing agencies without knowing what percentage QIOs would be required to work with (it will also be difficult to recruit many "low-performing" agencies without adding OBQI to the conditions of participation).
3. If the goal for the identified participant group is for 20% of agencies to exceed a national target rate for the two OASIS measures, what happens if a state's IP group exceeds the national rate at baseline? It is also unclear whether the national target rate for each measure will vary from state to state. States that begin the contract at a level far below the national average for their measure would be severely disadvantaged under this approach. This sets up a situation where QIO performance on this task will be directly related to agency performance at baseline in their state as compared to the national target.
4. Another issue relates to the national target rate and whether it would be tied to the national reference sample, which changes over time. If the target is tied to the reference sample, QIOs would be faced with helping their agencies hit a moving target that would presumably rise as agencies perform better during the contract period. It is also unclear whether the national target rate for each measure will vary from state to state to account for differences among states.
5. If during the SOW7, an agency is working on and has made improvements on one of the proposed SOW8 selected measures, that agency may be unwilling to pursue that measure again, which could eliminate them from wanting to participate in the SOW8. This could be avoided by allowing states or individual agencies to select their measures for focus in accordance with the OBQI methodology.

The factors proposed for selecting agencies for the identified participant group are overly complex, burdensome, and likely to detract from the important work of actually causing improvement. As proposed, QIOs would have to be very aggressive at both recruiting agencies and then requiring them to work on more measures than they are reasonably capable of addressing, which is a formula that has serious potential to sour agencies on partnering with QIOs on quality improvement. A related issue is whether QIOs would be able to provide support to those agencies selecting measures from outside of the priorities proposed here. Withdrawing this support from agencies could severely damage the tremendous partnerships and relationships that currently exist with their QIO.

We strongly suggest that CMS consider a simpler approach that involves working only with home health agencies that want to work with the QIO on whichever measure is appropriate for them to work on and regardless of whether they are high performing or low performing. AHQA also requests clarification on whether CMS intends for QIOs to continue training all agencies on OBQI, or does it intend for QIOs to adopt a more ongoing consultative approach related to the specific quality measures listed here?

Finally, AHQA suggests that CMS explore extending to the home health setting the successful model used in the Corporate Nursing Home Improvement Collaborative model. We believe that a number of home health agency companies would be interested in working with one or more lead QIOs in pursuing a similar collaborative addressing a high priority measure.

Task 1c1: Hospital

CMS has proposed a very ambitious task for the QIOs in working with hospitals to achieve a "transformational level of improvement" in the SOW8. AHQA appreciates and supports the goal of increasing the pace of improvement in hospitals and the QIOs are certainly committed to that effort. However, the QIO community is concerned there is little evidence that what CMS is proposing can be realistically accomplished, particularly within the timeframe of a single "three-year" contract cycle.

CMS should avoid difficulties experienced in past scopes of work and ensure that all details of the SOW are determined before the contract begins. AHQA urges CMS to move quickly in releasing more of the details about the hospital task (and other tasks) so that QIOs and other stakeholders will have a reasonable opportunity to ask questions, raise issues and work with CMS to develop agreeable solutions.

Some of these details include:

- Complete definitions of all measures
- Clarification of identified participant group requirements for the performance measures
- Clear definition of "hospital" – status of critical access, psychiatric, rehabilitation and other types of hospitals in this task
- Baseline and remeasurement periods

AHQA questions why CMS has decided not have the QIOs work with hospitals related to the Hospital CAHPS that is expected to be implemented nationally in mid-2005. It is our understanding that hospitals will also start publicly reporting on HCAHPS measures at some point during the SOW8. The HCAHPS instrument appears to be much further along in development than the Nursing Home CAHPS that CMS is intending to use in promoting culture change in those facilities. In addition, QIOs already have some experience working with the HCAHPS through the three-state hospital pilot.

The HCAHPS represents a significant opportunity to work toward the aim of patient-centered health care identified by the IOM. AHQA recommends that CMS consider including some

developmental work in this task to explore how the QIOs can utilize HCAHPS to work with facilities on culture change to improve the quality of the patient experience in hospitals.

Appropriate Care Measure

AHQA endorses the vision of providing the right care to every person every time. The Appropriate Care Measure (ACM) will clearly challenge the QIOs to focus on ensuring that patients receive all of the appropriate care. However, we are unaware of any science/data to demonstrate that the 50% reduction in the failure rate is attainable. The baseline rate for the ACM is likely to be very low compared to the average performance across the measures, and we are very concerned that the goal is unrealistic. The QIO community is not opposed to being accountable for challenging goals, but we are absolutely opposed to being held responsible for unattainable standards. The setting of such a target is an important task that should be transparent with respect to assumptions and evidence undergirding it. We would like to see the basis for this figure explained.

It is unclear if CMS intends to publicly report the ACMs in order to refocus the hospitals in the same way as the QIOs. Without that incentive, it may be difficult to get hospitals, even 10% of them, to engage in the transformational change efforts necessary to achieve a 50% reduction in the failure rate on the ACM.

AHQA is also concerned that the ACM will only include the ten publicly reported measures. If this is the case, it will force QIOs not to focus on important measures, like heart failure discharge instructions and smoking cessation counseling in all three topic areas, that are part of the full CMS/JCAHO measures, but not part of the subset of ten reported measures.

This doesn't seem to be in the best interest of Medicare beneficiaries or the QIO program, as it could damage QIO relationships with hospitals that are actively engaged in improvement efforts on the measures that will not be part of the ACM. We urge CMS to ensure that QIOs can continue to work with hospitals to improve on the measures that fall outside the ten measure subset. As well, if the Measures Reporting component of this task will require that 25% of hospitals report the full CMS/JCAHO set of measures, then the QIOs should at least have the ability to offer QI assistance on the full set as an incentive to those facilities that are reporting them.

Validation issues with the hospital data will persist until hospitals begin using the fully aligned JCAHO and CMS measures in January 2005. CMS should use data beginning in the first quarter of 2005 to establish the ACM baseline. In addition, we believe the current sample size available from one quarter of data is too small to calculate a valid level of performance. At a minimum, CMS should use at least two quarters of data for calculating the baseline and remeasurement. Preferably, CMS should consider evaluating QIO performance based on trend data as opposed to the two-point measurement design.

Surgical Complications Improvement Project

AHQA is very enthusiastic about the expansion of the current surgical infection prevention topic to the Surgical Complications Improvement Project (SCIP). The QIOs are looking forward to participating in this major national partnership effort. However, we are concerned that the details of the project and the infrastructure necessary to support it may not be fully available in time to start the SOW8 in August 2005.

While some hospitals will be willing to use CART to collect the SCIP measures, our experience from the SOW7 leads us to expect that incorporating the new measures is likely to be a difficult for many of these facilities. Some hospitals will not report on the SCIP measures if CART is the only tool available to collect the data. It will be critical for JCAHO Performance Management System vendors to incorporate the SCIP measures into their products, and we urge CMS to work closely with JCAHO to ensure that happens.

It's unclear what data CMS will use to calculate the baseline for SCIP. It's our understanding that the full set of SCIP measures hasn't even been finalized yet. Further, we don't understand why CMS has decided to hold the QIOs responsible for an 8% reduction in the statewide failure rate for these measures. We are unaware of any evidence to show that this is an attainable level of improvement. CMS should not continue its practice of setting performance targets that are not based on science, data or real experience. In the absence of evidence supporting this target, AHQA urges CMS to take a developmental approach to SCIP in the 8th SOW in order to gain the experience needed to set a legitimate and reasonable performance goal for the QIOs.

Flu/Pneumonia Immunizations Standing Orders

AHQA agrees that increasing the use of standing orders in hospitals could result in a dramatic increase in inpatient flu and pneumonia immunization rates. However, a 50% relative improvement in the statewide standing order rate will require intense effort and significant additional resources. Again, we are unaware of any evidence to show that this level of improvement is reasonable or even achievable within the timeframe of the scope of work.

In addition, CMS needs to take into account that legal barriers to standing orders exist in some states. A standardized definition of a standing order that will be legal in all states needs to be established at the beginning of the SOW.

Workforce Retention and Adoption of Bar Coding or CPOE

AHQA is very concerned that the new measures aimed at workforce retention and adoption of bar coding/CPOE have not been adequately developed or tested. CMS should acknowledge the developmental nature of this work and treat it as a pilot in the 8th Scope of Work.

Obviously, the definition of "full implementation of a plan" will be critically important to the QIOs and the hospitals. Staff retention is a well known problem and many, if not most, hospitals may already have plans in place. It may be difficult for the QIOs to get hospitals to revise their own plans just to help the QIO meet an overly rigid definition for the QIO performance measure. AHQA recommends that CMS work closely with the QIOs and the hospital community in the development of this measure and the criteria CMS will use to judge hospital and QIO performance.

The role of the QIOs in pursuing hospital adoption of bar coding/CPOE is totally undefined. The adoption of these technologies requires a significant capital investment on the part of hospitals -- a tremendous barrier to success on this measure over which the QIO has no control. It doesn't appear that the QIO could get credit for interim steps that a hospital could take in moving toward the adoption of information technology. We have not seen any evidence to show that the QIOs could achieve CMS' envisioned level of performance.

AHQA questions why CMS is requiring separate identified participant groups for the ACM and workforce retention and bar coding/CPOE. Separate IP groups will compartmentalize the work

under the task and lead to lost opportunities for the integration of effort to achieve the transformational improvement we are seeking. As well, it's unclear whether QIOs will work with 10% of hospitals on workforce retention or bar coding/CPOE, or if they will be required to work with 10% on each.

Task 1c2: Rural/Low Volume Hospital

AHQA commends CMS for recognizing the need for QIOs to increase their efforts to help rural health care providers improve their quality of care. By creating a separate subtask, CMS has taken a significant step in the right direction that will begin to meet the high demand and need for QIO technical assistance among rural providers.

AHQA also supports the use of the clinical measures under development that hold great potential for helping rural providers assess and then improve their performance based on evidence-based guidelines of effective care. However, we caution CMS that while these measures are expected to be finalized and tested in time for the start of the SOW8, they should still be considered new measures in need of the large-scale testing and possible refinement that QIOs could provide under proposed task 1c2. CMS must consider the developmental nature of these measures when designing the evaluation components for QIO performance under task 1c2, and we encourage the agency to work with QIOs and the measures' developers to ensure an appropriate evaluation.

AHQA is unclear as to how CMS intends to define "rural/low volume hospitals" under task 1c2, although communication with CMS indicates that it will be critical access hospitals and PPS hospitals in non-metropolitan statistical areas (MSAs) and hospitals with less than 50 beds in MSAs. Confirmation on this definition is needed, as it will have a significant impact on the number of facilities QIOs would need to work with statewide and in identified participant groups. Depending on the definition, CMS may need to take steps to account for states with no hospitals that meet the rural/low volume definition and those with many rural/low volume hospitals (perhaps by setting a cap on the number of facilities a QIO should work with for its identified participant group).

CMS also must clarify and define it's expectations related to: implementing a quality improvement plan, setting and exceeding performance targets, implementing plans for IT systems change, administering staff climate change, implementation of safety culture improvement changes, and systems redesign to address locally identified patient safety issues—these terms can have many different meanings, and this listing gives QIOs little information on which to make comments.

For both performance measures, it also is unclear whether, for their identified participant group, QIOs will be expected to satisfy both requirements listed or just one. It appears that for the first performance measure, QIOs would be asked to complete one of the two projects. But it is unclear whether QIOs would have to complete both items listed for the structural performance measure. Also on the second item under the structural performance measure, is it CMS' intention for QIOs to work on the staff climate survey, safety culture changes, and systems redesign to address patient safety issues?

Regarding implementing plans for IT systems change, it is very difficult for a great number of rural/low-volume hospitals to devote the resources to purchasing IT systems. Without being able to acquire those systems, QIO support on implementing a plan for IT systems change would seem to

have a little impact on the quality of care delivery. Does CMS intend to assist rural/low-volume hospitals, through grants or loans, to purchase these systems so that the QIO support in this area will be worthwhile?

Another significant issue is to what extent, if any, there can be overlap within a state between tasks 1c1 and 1c2. Considering that the understood definition of rural/low-volume hospitals is one that would include a great many facilities, not allowing QIOs to overlap hospitals for their 1c1 and 1c2 projects could make it very difficult for QIOs to engage enough hospitals on these projects. However, CMS should also consider that having hospitals work on both 1c1 and 1c2 projects simultaneously likely would burden these facilities. For instance, while AHQA is very supportive of efforts to help rural/low volume hospitals report meaningful (of a significant sample size) quality data to the QIO warehouse, we are concerned that holding QIOs responsible for helping them report on both the full set of quality measures beyond the 10 listed in MMA, as well as clinical measures under task 1c2, may be very difficult. CMS needs to provide clarification on whether this is their true intent, and if it is, CMS should seriously consider ways to incentivize these actions on the part of rural/low-volume hospitals, as there are those that would require more than the MMA's 0.4% payment incentive to find value in reporting.

It is also unclear how this proposal would allow rural/low-volume hospitals to report on enough cases to ensure that the data is meaningful for quality improvement (and perhaps public reporting) purposes. A solution could be to apply the composite measure approach used for the Appropriate Care Measure under task 1c1. CMS should consider supporting research to develop such a measure for use in both the quality improvement and reporting components of 1c2.

We strongly encourage CMS to work with AHQA and QIOs to resolve issues related to potential overlap between 1c1 and 1c2, particularly in determining an appropriate "specified increase" in the number of reporting hospitals.

AHQA also is concerned with the mechanism these hospitals would use for reporting data. If CART is to be used, would it be modified in a timely fashion to incorporate the additional measures, particularly since "treat and transfer" patients would not be admitted to the facility? If a different tool is to be used, what will be the process for identifying and implementing an appropriate tool?

Considering the above concerns, AHQA strongly suggests refining the proposed task 1c2 by using the framework and elements suggested by Stratis Health in its recommendations on this task, such as:

- Collecting the Appropriate Care Measure to involve facilities in the larger effort and so as not to increase reporting burden.
- Recognizing the developmental nature of rural measures.
- Giving alternative options for hospitals that don't have the resources to acquire IT systems.

AHQA believes that the Stratis Health proposals would go far toward addressing problems with this proposal related to these hospitals' IT capacity, ability to report meaningful data, and the developmental nature of the new rural measures. CMS should strongly consider revising their proposal based on the principles outlined by Stratis, and then opening up this plan for comments among stakeholders.

1d1: Physician Office

The work outlined in the physician office setting is ambitious, and we commend CMS for its efforts to focus on assistance to providers that will enable transformational change in health care. We look forward to learning more about the specific measures and their weights in an actual draft of the SOW8.

Health Information Technology

AHQA welcomes the addition of the Health Information Technology (HIT) work in the SOW8. When implemented effectively, HIT holds great promise for transforming our health care system and improving the quality of care.

AHQA has been working closely with the eHealth Initiative to create a National Collaboration for HIT in the small physician practice. This Collaboration aims to bring together key physician organizations—including the American College of Physicians, the American Medical Association and the American Academy of Family Physicians—health care stakeholders and government agencies to create a national repository of knowledge that QIOs and other organizations can utilize and disseminate to support physician practices as they adopt and implement HIT. The Collaboration would develop publicly available publications, guides, checklists, case studies and other tools in at least four areas: selection and procurement of HIT systems, privacy and security, implementation assistance and connectivity. We look forward to sharing more with CMS about this exciting opportunity as it develops.

QIOs have strong local relationships with the providers and practitioners in their states. It is these relationships, coupled with QIOs' unique mix of skill sets, expertise, adaptability and proven track record of success in new areas of work (such as nursing homes) that will enable them to help overcome some of the barriers inherent to the widespread use of information technology in health care – particularly in the area of implementation.

To be sure, however, several barriers play a key role in preventing health care providers and practitioners from adopting and using HIT. Lack of standards, upfront capital investment, perceived high physician time costs and difficulty integrating a new system into a physician's workflow and care processes are obvious sources of resistance. While QIOs can provide a support system to help physicians address workflow and care process issues, several strong barriers to HIT adoption remain outside QIO control – namely capital investment costs and lack of standards for interoperability, both of which create significant physician hesitance in HIT adoption. AHQA encourages CMS to design an evaluation scheme that reflects these important realities.

Specifically, we recommend that CMS evaluate QIOs according to their results in moving physicians along a continuum of progress toward HIT adoption and implementation. For any physician office – but particularly for small and medium sized physician offices – the process that begins with consideration of whether or not to adopt an HIT system and ends with the physician reporting data to the clinical data warehouse and then undertaking efforts to improve that data is a process that takes significant time. We suspect it will be extraordinarily difficult to fully complete such a process for a significant number of physician offices in each state within the timeframe QIOs typically have before evaluation – 24 - 28 months. The SOW8 Summary does indicate CMS openness to such an approach in the table on page 10: "Assessment of the amount of progress a physician office makes relative to each of the following performance parameters," and we support this.

AHQA recommends that CMS consider a longer period prior to re-measurement with regard to provider adoption of HIT (e.g., interim evaluation at 28 months with final evaluation at 56 months).

CMS must also be mindful not to create an evaluation scheme that inadvertently creates an incentive to simply "get systems in place" and move on. Simply buying an HIT system to integrate with an existing system that is inefficient and produces poor quality will only make for an inefficient and poor quality electronic system. The fundamental goal of HIT is to achieve better quality outcomes for patients; its promise lies not in simply automating current practices, but in transforming them. QIO evaluation criteria should reflect the importance of systems redesign work, not simply HIT adoption and implementation.

AHQA also encourages CMS to design the SOW such that QIOs are encouraged to address the issue of partial use of EHR systems as well. We know that many physicians do not use their EHR or EMR systems to their fullest capacity in improving the quality of care – underutilization of clinical decision support or reporting functions is common. QIOs should be able to receive evaluation credit for assisting providers with systems already in place to better utilize their systems and improve quality.

CMS should also take great care in designing the evaluation not to penalize physicians who begin their HIT experience by adopting e-prescribing or some other more basic HIT tool that does not have the capacity to report data to the QIO data warehouse. We believe that the evaluation in this new area must be a careful balance between ambition and recognition of the developmental nature of this work – both for QIOs and for physicians – as well as the fact that a QIO's success in increasing the adoption of clinical information systems depends in large measure on factors outside QIO control. However, we also believe that because of the unique relationships that QIOs have with local physicians, they will be able to effectively identify, target and work successfully with physicians who are most likely to succeed in adopting some form of HIT.

In order to begin preparations for the HIT work -- including convening stakeholders in the state and working with physicians to understand their HIT needs, abilities and status -- we urge CMS to provide QIOs with the resources they need to begin this work as soon as possible.

It is also unclear in the document whether CMS will ask QIOs to work on HIT with primarily small to medium sized physician offices, or with any size physician office. We recommend clarification, including a definition of small, medium or large practices.

AHQA encourages CMS to use caution and consult with experts in the HIT field when it comes to determining the size of the Identified Participant group. We recognize the shift from working with a percentage of physicians in the SOW7 to working with physician *offices* in the SOW8, and this change will require significant additional resources. We support conversations between CMS and HIT experts who can advise on feasibility of various IP group sizes based on resources and time available in the contract for QIO interventions. Further, we also recommend CMS consult with QIOs on methods for identifying the IP group.

Reporting DOQ-IT Measures

AHQA has concerns about the reporting of clinical quality measures to the QIO clinical data warehouse:

- Readiness: AHQA recommends that prior to any large scale reporting effort during the SOW8, CMS first asks QIOs to identify a small sample of providers willing to report data and test the functionality of the reporting process prior to widespread implementation.
- AHQA is also concerned about the fact that we are unaware of any software vendor to date offering a product that can report the DOQ-IT measures to the warehouse. This is a factor that is outside of QIO control that CMS should take into account in designing the QIO evaluation. Further, we encourage CMS to thoroughly test the reporting ability of vendor software in order to prevent burden stemming from technical glitches.
- Further, CMS should explore the implications of putting QIOs in the position of recommending particular EHR products simply because they have the capacity to report CMS data, for which the QIO receives additional credit in evaluation. This could set up a major conflict of interest and jeopardize one of the biggest assets of the QIOs – their independence and objectivity.
- We recommend CMS explore alternatives for reporting for both QI purposes and measurement purposes for physicians whose systems do not easily permit reporting to the data warehouse.
- Will a tool be made available for physicians who cannot report data through an EHR system? If a reporting tool for physician offices is created by CMS, we urge CMS to be acutely aware of the existing realities of small and medium sized physician offices whose resources – particularly staff time – are strapped and may be unable or unwilling to devote additional time to entering data into a reporting tool.
- Incentives: There should be a clear benefit for providers to report data to the warehouse. CMS should also assure providers that such data will not be used against them to identify instances of poor quality.
- AHQA understands VistA office EHR may be available for QIOs to promote in SOW8

Finally, because many factors outside QIO control will affect a physician's decision to adopt HIT, we strongly support the ongoing work of Dr. Stephen Jencks to coordinate quality initiatives across CMS. We think that improved coordination of payment and coverage policies with quality initiatives – including perhaps payment incentives – can greatly enhance QIOs' ability to succeed in demonstrating the business case for EHR adoption to physicians.

Lessons from the Seventh Scope of Work

AHQA recommends that CMS examine the challenges of the physician office setting in the SOW7 to identify lessons for incorporation into the SOW8. It appears that CMS is proposing to add on to QIO work in the physician office setting without considering whether the work merits change over the previous scope. Some lessons we recommend for consideration include the following:

1. QIOs have faced serious challenges, specifically in the areas of mammography and retinal eye exams — the two clinical indicators that are plagued by multiple confounding variables largely outside the physician's control. Unlike the inpatient setting, where the provider and their systems of care have significant control and impact over the care delivered to the beneficiary, care delivered in the outpatient environment is influenced by a number of external factors, including health beliefs, health literacy and lifelong health behaviors, public awareness, access to a care facility, patient refusal of care, vaccine shortages, Medicare co-pays, and more. In several instances, even when QIOs and providers work together to

establish a consistent system of care, beneficiaries exercise final control over whether they accept the physician's advice, find a radiology facility and make mammography appointment, go for an eye exam, or otherwise follow up on their physician's recommendations.

AHQA strongly recommends that CMS consider ways to weight these indicators appropriately in the evaluation or develop alternative methods that measure providers' systems of care and patient interactions in these areas.

2. The data available to QIOs to support their efforts in the SOW7 have been between 12 - 15 months old for physician offices. CMS has done an admirable job of reducing the lag in hospital performance data down from 9 – 12 months to within 6 months, and we encourage you to seek ways to make similar headway in the physician office setting.

   Generating physician interest in improvement efforts can be difficult with performance rates that are a year or more old. We understand that provider claims are stored in such a way that it is extremely difficult for CMS to provide data to QIOs in a timely fashion, but data requests for quality improvement purposes are not given any priority in the CMS system. Increased use of information technology in physician offices holds significant promise for the future, but until a substantial majority of physicians label EHRs in every state, an interim solution is needed.

   These data are also critical to the process of Continuous Quality Improvement for the QIOs – they desperately need interim data to evaluate and rapidly change intervention strategies that prove problematic, or rapidly spread those that prove successful.

3. Medicare regulations for Quality Improvement Organizations [42 CFR 480] do not allow QIOs to give physicians information derived from claims data about named patients if that physician did not generate the claim. CMS is well aware of the attendant problems stemming from this issue, and we will not rehash them here.

   Sharing this information with physicians not only presents an opportunity to prevent and reduce medical errors, but we also believe that sharing this information can help QIOs spur providers to consider adopting HIT systems when they see what is possible with the right information. QIOs could also help reduce provider burden by using this data to populate registries or EHRs.

   AHQA strongly urges CMS to take action and change this regulation when it issues the final MMA regulations later this year.

Statewide Improvement in the SOW8

During the Tri-Regional Conference in June of this year, CMS officials discussed their aims for the program – specifically the new focus on transformational change. To this end, program officials indicated that the SOW8 would be refocused and place a higher value on big improvements among a small group of providers rather than small improvements spread across a big group. AHQA agrees with this approach.

However, we find no evidence of this approach in the Summary document. Rather, we find the same 8% reduction in failure rate on the statewide measures, and for the IP group, progress toward HIT adoption, effective use, data reporting and subsequent performance improvement on the DOQ-IT measures (presumably a subset of the measures, since undertaking improvement projects on all the DOQ-IT measures would be incredibly burdensome and unrealistic for providers).

If temporary suspension of the statewide measures is not possible, AHQA recommends that CMS consider alternative options, including: 1) employing a weighting strategy that decreases even more significantly the weight of the statewide measures, or 2) decreasing the 8% reduction in failure rate target. We believe that as QIOs make progress toward more widespread HIT adoption and effective use, rates for statewide indicators that are impacted by physician systems of care will climb with increasing speed as the percentage of providers using HIT systems with transformational capacities grows.

Separately, it is unclear in the Summary what the source of immunization data will continue to be, as information in the 1d1 table on page 10 conflicts with the narrative on page 9. Any change to the sole use of claims data for the purposes of calculating immunization rates would be problematic– Medicare beneficiaries often receive flu shots from entities that do not bill Medicare, or alternatively, when receiving services from a non-Medicare provider, beneficiaries may pay out of pocket for the shot. In vaccine shortage or delay years, these effects can be even more pronounced as many seniors take advantage of any available opportunity to receive an immunization.

Task 1d2: Underserved Populations

AHQA is pleased that CMS plans on continuing to direct QIOs to use their skills and expertise to help improve the quality of care received by underserved populations. In recent years, QIOs have made important strides in researching and understanding existing disparities and at designing locally appropriate interventions to boost performance on quality indicators for which a disparity has been identified.

AHQA welcomes CMS' intention to add cultural competency to a QIO's menu of available interventions to improve care delivered to underserved populations. However, AHQA is concerned that, as written, QIOs would be providing cultural competency services to providers who are already serving a large number of underserved patients and more likely to be from the same cultural/racial background. It would stand that these providers might already have satisfactory levels of cultural competency and could be in need of other technical assistance that QIOs could provide. Conversely, we also understand that some providers treating underserved populations may actually be the ones in the greatest need for cultural competency assistance. These confounding issues and others, particularly whether providers treating underserved populations have the resources to acquire and implement health care IT, are likely to cause significant problems for QIOs in choosing their identified participants and then working with providers on these measures. CMS should carefully reexamine the cultural competency proposal and seek input from experts in this field and QIOs.

Additional questions needing clarification related to the DOQ-IT and Cultural Competency section include:

- How does CMS intend to define and determine "specified proportion of physician offices

that provide care to underserved populations?"

- What is meant by "demonstrate an improvement comparable to the Task 1d1 for DOQ-IT measures?" Does this mean reduction of disparities on these measures? Absolute improvement for underserved populations on these measures? Improvements at the same rate as the general Medicare population? Please explain.
- Does CMS intend to target resources for IT systems toward physicians serving high numbers of underserved populations? Without necessary resources, it is unclear what impact QIOs will be able to make on the DOQ-IT measures.
- What is CMS' definition for "cultural competency?"
- Does CMS intend to allow for overlap between identified participants in 1d1 and 1d2?

With regard to the cultural competency measures that the Underserved QIOSC will be developing, we strongly encourage CMS to recognize that these measures, and subsequent interventions to improve on these measures, will have not yet been thoroughly tested in time for the SOW8, and therefore should be considered test measures during the contract cycle. Similar to new measures in other subtasks, CMS should limit appropriately weight QIOs' performance on developmental measures and should instead use QIOs to assess the appropriateness of these measures for future work. AHQA also commends CMS for committing to train QIOs on cultural competency prior to rolling this out in the SOW8, and would like to express its willingness to partner with CMS on this training.

Among the important lessons QIOs have learned in the SOW7 is that performance on clinical measures for diabetes, breast cancer, and immunizations involve factors that reach beyond the immediate control of the physician. Please review our comments related to these outpatient measures for task 1d1 above.

Regarding the SOW8 proposal, QIOs require the flexibility to design locally-appropriate interventions and partner with community organizations to reach the significant percentage of beneficiaries that receive care outside of the physicians' office. Under this proposed subtask, QIOs will have to significantly increase their outreach activities to beneficiaries in order to cause improvement on the statewide measures, particularly immunizations and cancer screening where a great number of underserved beneficiaries receive these services outside of the physicians' office. It's important that CMS recognize that requiring QIOs to address disparities on multiple outpatient measures, as opposed to one selected measure in the SOW7, will necessitate a significant increase in resources to communicate with beneficiaries, through partnerships and other avenues such as direct mailings and the media, as well as increasing their quality improvement efforts directly with physicians.

Also related to the clinical measures for underserved populations:

- It is unclear whether CMS intends to work to improve care on these measures for ALL underserved populations in their state or will QIOs be allowed to select one or more underserved populations to target? Clearly, this answer has tremendous implications for the nature and amount of effort required to complete this task.
- Will rural populations again be considered an underserved population?
- Does cancer screening include both colorectal and breast cancer screening?
- Does CMS intend to switch from basing immunization rates on CAHPS survey information

to claims? There are serious issues associated with basing rates using either of these two data sources, especially for measurement of underserved populations, and we strongly suggest that CMS work with QIOs (particularly AHQA's Analytic network) and other experts in this area to develop consensus around the appropriate data source especially for measurement of underserved populations, and methodology for calculating immunization rates.

AHQA applauds CMS for incorporating the important IT work into QIO disparity reduction efforts. However, we fear CMS may be missing an opportunity to get an early start addressing disparities that likely could occur under the new prescription drug benefit, such as gaps between underserved populations and the general Medicare population in filling prescriptions. We refer you to an important study conducted by Mathematica's Jennifer Schore—published this winter in Health Care Financing Review and presented during AHQA's Conference in May 2004—that used claims data to demonstrate widespread disparities in the use of Medicaid pharmacy benefits. CMS should find a way for QIOs to begin measuring, understanding, and working to reduce similar disparities that could emerge once the Medicare pharmacy benefit begins, and CMS should develop pilot interventions among QIOs to reduce these disparities.

Task 1d3: Part D Benefit

CMS' proposed approach will ask QIOs to propose quality improvement projects in the ambulatory Medicare population, involving assistance to physicians, Medicare Advantage Plans and Prescription Drug Plans. This is a wise approach, given the lack of experience both within CMS and the QIO community in implementing projects in an ambulatory population. In this way, successful approaches can be expanded in the 9th Statement of Work and possibly implemented nationally.

There are some lessons learned by others that are not yet reflected in the draft SOW8 document. AHQA hosted a national meeting on quality improvement under the new Medicare prescription drug benefit in May of this year, in cooperation with CMS officials. The conference materials are available to CMS and others, including speaker presentations and the key articles published in the past twenty years on this topic. The authors of these articles made several suggestions that AHQA summarizes below, in the hope that CMS will embrace these principles as the agency revises the draft SOW8 summary:

- Most drug-related problems in the elderly probably involve medications that are not on anybody's "bad drug" list.
- A focus on simply reducing the total number of drugs that an older patient receives may be a misguided approach to quality improvement.
- Quality-improvement efforts should focus on specific classes of drugs or specific medical conditions.

- Physicians, with the help of QIOs, need to figure out better ways to work together with clinical pharmacists.
- CMS and the QIOs should use methods such as academic detailing, proven effective and cost-effective repeatedly in randomized controlled studies --
    - Soumerai & Avorn (1986): $2 saving for each $1 spent on program
    - Silagy, May & Avorn (1997): Academic detailing based services in some therapeutic topics within ongoing service-based programs, direct cash savings can exceed costs by a ratio of 6 to 1
    - Mason, Freemantle et al (2001): Even with small overall effect sizes academic

detailing can be cost effective.

CMS has used language in the summary that has appeared to some stakeholders as ominous and concerning, specifically where the agency states that "QIOs will report on drug plans and providers." What is CMS contemplating when it says QIOs will "report the required information on drug plans and providers"? Does CMS intend to make these entities accountable to QIOs, or is the model one in which the QIOs offer themselves as a resource to practitioners and plans, as we have recommended and as Congress has outlined in Section 109 of the Medicare Modernization Act?

AHQA will assist CMS in any way we can to make this new QIO work as creative and effective in measuring and improving the quality of pharmacotherapy as possible.

Task 2: Creating an Environment for Quality

AHQA applauds CMS for recognizing the importance of creating an environment in health care that recognizes, encourages, values and rewards quality improvement. Individual QIOs have sought out ways to create such an environment in their respective states, and we welcome the encouragement of such coordinated activities in the SOW8 Summary.

We strongly agree with the importance of this work and believe it to be a key centerpiece of quality improvement efforts in the states, as well as nationally. In addition to state efforts, AHQA looks forward to working with CMS and other stakeholder organizations to create a national environment for quality.

While we see references to consumers in several other areas of the Summary, we believe CMS should explicitly include consumers in its list of stakeholders who can help "stimulate widespread change in attitudes and behavior with regards to the importance of ongoing quality improvement in health care" (p. 13). Consumers can play a key role in stimulating and demanding change by valuing and rewarding quality care through their choice of provider, conversations with their doctor about recommended care, and other ways.

AHQA also strongly supports CMS endorsement of QIO efforts to integrate communications into other SOW8 tasks – especially clinical quality improvement tasks -- and to utilize communication tactics like integrated campaigns and coalition building activities to contribute to the overall execution of the SOW8.

Fundamentally, integrating communications--including social marketing approaches--into SOW8 clinical tasks can be a transformational strategy. QIO communication directly with the beneficiary, coordinated with collateral messages from providers, practitioners and stakeholders, plays a key role in ultimately connecting the patient with their physician/provider. This approach, coupled with QIO efforts to improve that provider's system of care, makes for a powerful combination with transformational potential.

However, we recognize that there are multiple approaches to effectively communicating with beneficiaries in a way that leads to improved health behavior and/or quality of care, and AHQA supports having CMS gather successful QIO communications strategies through either the

Communications QIOSC and other QIOSCs or communities of practice, and providing that information to the QIOs.

AHQA supports the continuation of public reporting activities in the SOW8. These activities, many held in conjunction with Task 1 clinical staff, were highly valued by CMS and other important partners. The American Hospital Association has indicated their support in a separate letter for the technical assistance provided by QIOs, and AHQA urges CMS to continue this important work.

AHQA also strongly supports the creation of an integrated awareness campaign regarding the QIO program. We urge CMS to work with us to undertake a strong campaign at the national level to increase awareness of the program. We believe a national effort will help spur provider interest in state-based improvement activities.

We also encourage CMS to be mindful of the fact that, while it is important for QIOs to undertake state-based awareness campaigns aimed at providers and practitioners to increase awareness and positive views of the QIO program, it is also important for QIOs to seek recognition not for themselves, but for their provider and practitioner partners. This recognition helps generate further interest in the QIO's improvement activities. We encourage CMS to think about how QIOs can create programs that innovatively recognize providers. We think this represents another area where quality coordination efforts across CMS would be welcome.

Task 3a: Beneficiary Protection

AHQA commends CMS for including language in the SOW8 summary that demonstrates an intention to integrate the functions of quality improvement and case review within QIOs. This addresses the next part of the evolution of QIOs from medical review entities to organizations that address the entire spectrum of quality, both from the individual and system levels.

While we are very excited about the direction of the SOW8 summary, we require greater clarification on exactly how CMS intends for these two functions to be integrated. For instance, it is unclear whether CMS intends to integrate all forms of case review or solely beneficiary complaints. CMS should investigate ways to integrate all case review functions. In addition, it is expected that complaints necessitating quality improvement activities will involve conditions and topics outside of those addressed by QIOs in Task 1, and therefore CMS should provide QIOs the flexibility of designing system-based improvements that address other topic areas.

CMS also must provide more information on what it plans regarding "new methods of review that involve the provider early in the process." How are these "new" methods of review being developed? Will there be evidence that these new methods will lead to increased beneficiary satisfaction with the process and the outcome of the review?

Clarification also is needed regarding the types of review that will be required. It is curious that the SOW7 task 3c is not included in the summary. Will QIOs still be responsible for reviews such as higher-weighted DRG, LTAC, CMS/FI referrals, etc. that were previously included in Task 3c?

AHQA has concerns with the manner in which CMS utilizes the beneficiary satisfaction survey for the complaint process. While there may be customer satisfaction with the process, there is still often

low or no satisfaction with the outcome (due to factors outside of the QIO's control). CMS has recently issued an RFP for the development of alternative dispute resolution methodologies. CMS should instead consider measuring outcome satisfaction when an alternative dispute resolution is used. Since there is little evidence to show that the QIO can actually change the beneficiary's feelings about an outcome, a more appropriate measure might be to test whether beneficiaries that have gone through an alternative review process, such as mediation, are more satisfied with the outcome of the review than those going through the traditional review process.

CMS also needs to provide more information on how the use of external IRR for all reviews will operate. For instance, what organization will perform the reviews (in-state or out-of-state)? Will there be identification and sharing of best practices to improve the review process based on the IRR findings? What is the evidence supporting the 70% IRR as the target measure? Also, what is the rationale for setting a higher threshold for IRR (80%) for internal reviews and how was that figure established? CMS must also give a better indication of the level of effort required for QIOs to conduct internal IRR reviews.

The performance measure pertaining to quality improvement activities related to complaint reviews needs clarification. What is an acceptable proportion of complaint reviews for which a quality improvement activity was suggested? How will CMS attempt to define and track data on a "suggestion?" What is CMS' expectation for utilizing case review information in conduct of quality improvement activities?

CMS should also closely examine the 90% timeliness requirement for beneficiary complaint reviews and determine if performance in the SOW7 merits this threshold. For instance, a high volume of cases and implementing quality improvement plans will likely have a significant impact on the timeliness requirement.

Task 3b: Hospital Payment Monitoring Program

The plan to evaluate the QIOs on net payment error will provide a disincentive for QIOs to work on underpayment topics. The QIOs have been able to engage the hospitals in payment error projects because they look at both underpayment and overpayment errors. Changing the QIO evaluation in the SOW8 to include the net and absolute error rate will force QIOs to avoid projects that are more likely to result in the identification of underpayment to hospitals.

This could spoil good relationships that QIOs have been able to establish with hospitals in order to get them to work on payment error reduction projects. CMS should not put incentives in place in the evaluation that could jeopardize these efforts.

The evaluation plan for Task 3b creates a problem for states with low baseline payment error rates as it serves to unfairly penalize them for their low rates. A small backward change from a low baseline could cause a QIO to fail, while a QIO in a state with a far worse baseline error rate could pass with a much larger increase at remeasurement. CMS should consider setting a threshold error rate (e.g. equal to or below 2.0) that a QIO could stay below and still pass rather than requiring states with low rates to not get worse by more than 1.5 standard errors above baseline. This would provide a more fair evaluation for those QIOs in states that have achieved and are maintaining low error rates, but that might experience relatively minor fluctuations above or below the baseline.

Another problem for some states is that the small sample may only have 20 or 30 error records in an evaluation time period. Because the error rate is calculated in terms of dollars, this could cause one or more extreme or mildly extreme error(s) to have a disproportionate impact in the error rate. CMS should increase the sample size or the standard errors that the rate may increase in order to help alleviate this problem. As well, CMS should consider whether it would be more appropriate to evaluate the QIOs on incidence of payment error, independent of dollar amount.

The SOW8 Summary is unclear about whether QIOs will undertake projects as part of Task 3b or if they will be proposed, funded and evaluated as special projects, as was done in the SOW7. CMS should consider allocating more resources to this task to allow the QIOs to have more ongoing interaction with the hospitals even when the payment error rate is acceptable. This interaction will give QIOs the opportunity to prevent increasing payment error rates rather than reacting to increases after they occur.

Dr. McClellan, while we have had many comments and suggestions regarding the proposed 8th Statement of Work, I hope that you will accept my appreciation on behalf of all AHQA members in every state and territory for your leadership on health care quality issues generally, and for your recognition of the great national resource you have at your disposal in the network of Quality Improvement Organizations.

Please feel free to contact me to follow up on any of our suggestions. We stand ready to assist you in the realization of your important objectives.

Sincerely,

David G. Schulke
Executive Vice President