Statement of Dale Bratzler, D.O.
President, American Health Quality Association

Submitted August 3, 2004, to the Institute of Medicine's Committee on Redesigning Health Insurance Benefits, Payment and Performance Improvement Processes

The American Health Quality Association (AHQA), representing the national network of Quality Improvement Organizations (QIOs), thanks you for the opportunity to submit testimony for the initial meeting of Institute of Medicine's (IOM) committee conducting the assessment of the QIO program authorized in Sec. 109 of the Medicare Modernization Act (MMA). QIOs hold contracts with the Centers for Medicare & Medicaid Services (CMS) to improve the quality of health care for Medicare beneficiaries in all 50 states and the U.S. territories. These organizations work with hospitals, medical practices, health plans, long-term care facilities, home health agencies, and employers to encourage the spread of best clinical practices and improve systems of care delivery.

Recent reports published by the Agency for Healthcare Research and Quality (AHRQ) and the Medicare Payment Advisory Commission (MedPAC) have shown that the quality of care provided to Medicare beneficiaries is improving according to a number of important quality measures. However, these and other studies continue to show a clear gap in quality between the care beneficiaries need and what they actually receive. To close this pernicious quality chasm, we recommend that IOM encourage the federal government to expand the QIO program's efforts to develop, test, and implement initiatives that will accelerate the pace of quality improvement.

The Medicare QIO program represents the largest coordinated federal effort dedicated to measuring and improving the quality of health care for America's seniors and the disabled. Since CMS implemented the IOM-designed road map for improving the quality of care for Medicare beneficiaries in the 1990 report, *Medicare: A Strategy for Quality Assurance*, QIOs have been at the

forefront of the movement to promote wider adoption of proven quality improvement approaches into health care. Nearly 15 years later, it is appropriate that IOM again has been called upon to examine the QIO program and make recommendations to HHS to improve its effectiveness. In our view, the 1990 report was a turning point for the QIO program that revolutionized and dramatically improved the program by transforming it from a sole focus on retrospective individual case-based quality review to population-based quality improvement. We are grateful that this Committee will again look for ways to further improve the QIO program today.

As directed by CMS, the program has built an extraordinary national quality measurement and improvement infrastructure that has contributed materially to the early gains in the crusade to close the quality gap. Today, QIOs and CMS are challenged to translate the program's existing measurement infrastructure, productive relationships with providers and practitioners, and menu of intervention strategies into a transformational change in the country's health care delivery system.

CATALYSTS FOR CHANGE

QIOs are private-sector local organizations, employing local professionals, with a national mandate to improve systems of care. QIOs work to accelerate diffusion of evidence-based medicine to all providers—small, large, urban and rural—in many health care settings.

Medical professionals work voluntarily and often enthusiastically with QIOs because they benefit from the free expert assistance they receive to help them improve their care. In addition, QIO projects often reduce duplication of effort for doctors participating in multiple hospitals and health plans. QIOs' ability to coordinate and support local and national quality activities significantly helps providers that are increasingly faced with mounting quality requirements and expectations, including conditions of participation, accreditation, and public reporting of quality information. QIO projects also reduce the burden on hospitals that participate in multiple health plans by bringing the parties together to work on the same urgent clinical priorities, using the same

measures, the same abstraction tools, and the same key messages for practitioners. Even the best consultants working for individual hospitals and physician offices cannot have this effect—and many providers cannot afford costly consultants.

Another factor making QIOs an attractive entity for partnerships on quality improvement projects is the strict confidentiality requirements conveyed upon QIOs under the Social Security Act (SEC. 1160. [42 U.S.C. 1320c-9]. These requirements, which limit disclosure of quality and review information, serve as another distinctive characteristic that contributes to QIOs' capability to measure and improve quality. The ability to work with QIOs without fear that sensitive quality information could be used in legal proceedings is a critical benefit to providers participating in quality improvement projects.

Confidentiality also is an essential factor as QIOs expand their existing activities related to patient safety. For example, under proposed patient safety legislation, Congress may allow providers to report medical error information to state-based patient safety organizations, making that information protected from unauthorized disclosure. The Missouri QIO and a dozen other QIOs are engaged in state-level patient safety commissions—many in leadership roles—and are beginning to collect medical error data, analyze that data for trends, and then work with providers to address the underlying causes of those errors. There is little or no funding for this, however. If Medicare made patient safety reporting a priority for the QIO program, the purposes of the new legislation could be met on a larger scale, even if the bill were not enacted.

IMPLEMENTING IOM'S VISION

QIOs are helping to close the quality chasm by continuing to work on the improvement goals set forth by IOM in its 1990 report as well as the aims outlined in the landmark 2001 report *Crossing the Quality Chasm*—that care is safe, timely, effective, efficient, equitable, and patient-centered. Today, QIOs are working to:

- Improve patient safety by reducing pervasive, harmful errors of omission and comission.
- Ensure that appropriate care is delivered in a timely manner and quickly respond to beneficiary complaints about clinical quality of care issues.
- Make certain care regularly is provided in accordance with accepted best practices and professional standards of care.
- Make sure preventive care is delivered to improve health and avoid unnecessary costs to the health care system.
- Eliminate health care disparities that disadvantage racial and ethnic minority populations.
- Help consumers use available quality information to make health care decisions.

Last month, AHQA submitted to IOM staff a document highlighting specific ways CMS and the QIO program have responded to recommendations IOM made in its 1990 and Chasm reports. Starting with the IOM's work in 1990, the subsequent seminal articles published by Drs. Gail Wilensky and Stephen Jencks in the *Journal of the American Medical Association*, and then initially implemented through the Cooperative Cardiovascular Project (see below for more details), the program indeed has transformed and continues to move closer and closer to realizing the vision laid out by IOM—and largely ahead of the 10-year phase-in proposed in 1990. Motivated by the 1990 report, CMS and the QIO program have responded by implementing many of IOM's recommendations including:

- Hastened the pace at which evidence-based medicine is adopted into routine clinical practice.
- Published national data on Medicare quality in *JAMA*.

- Renamed the program to reflect its changed mission to work with providers to carry out quality interventions to address clinical shortcomings and to subsequently obtain and analyze quality data.
- Provided quality data back to providers and the public for selected health care settings as a tool for quality improvement.
- Selected priority topic areas based on reaching the maximum possible number of beneficiaries, the opportunity for improving performance based on reliable measures, and having the greatest potential for lowering Medicare costs (as recognized by IOM in its *Priority Areas for National Action* report).
- Worked actively to interpret clinical practice guidelines as well as field test and reconcile competing and conflicting clinical quality measures.
- Devised a complex evaluation using quality indicators and other factors to measure performance of the program and individual contractors.
- Served as test sites for new innovative strategies for improving health care.

And while there has been much progress on these items, there remain recommendations made by IOM in 1990 that have not yet taken form either in spirit or action. For instance, in the executive summary of the 1990 report, IOM's Committee said, "We conclude that an increase in the MPAQ [Medicare Program to Assure Quality] budget over present Peer Review Organization (PRO) levels is necessary… A reasonable estimate of the costs of this program might be that it would eventually double the investment in the present PRO program." The IOM report did not specify an amount and noted that this was an "order of magnitude estimate, not a detailed point estimate."

Since the report, the Office of Management and Budget, which is largely responsible for funding the program, has been reluctant to increase QIO apportionment funding commensurate with new quality improvement and review work that has been added to QIO contracts by Congress

and CMS. There also is the potential for funds directed to the QIO program to be diverted within HHS and CMS to other initiatives and projects not directly related to the functions of the Medicare QIO program (such as the National Medicare Education Program and the Pittsburgh Regional Healthcare Initiative). We encourage IOM to examine the support contracts funded by the QIO program to ensure that trust fund dollars are being spent on activities in an appropriate manner and as directed by federal statute.

QIOs AT WORK TODAY

Given the transformational changes in the QIO program that have come about since IOM's 1990 report, we would like to highlight some areas where the community is particularly proud of its accomplishments and point out emerging areas of concern:

Nursing Homes: As part of the CMS National Nursing Home Quality Initiative (NHQI), QIOs have been assisting long-term care facilities on a national basis since 2002. The effort has involved helping consumers understand and use publicly reported quality data for making better health care choices, providing informational material and workshops for facilities, and offering intensive technical assistance to a smaller group of nursing homes in each state to improve their care—with a specific focus on nursing home quality measures (addressing pain, pressure sores, delirium, and others) endorsed by the National Quality Forum.

Historically, most nursing homes have focused on compliance with regulations and quality assurance. But public reporting of quality data and the availability of QIOs for technical assistance have resulted in more and more nursing homes developing a quality improvement approach to improving resident outcomes and quality of life. Across the country, nursing homes are voluntarily connecting with QIOs that are training nursing home managers to implement quality improvement systems in a culture where front line staff not only participate in quality improvement projects, but also are empowered to continually identify and solve problems.

We are confident that as nursing homes continue embracing QIO quality improvement support and QIOs gain more experience and incorporate additional cutting-edge quality improvement techniques, such as resident-centered culture change, progress in this area will hasten further.

Home Health: QIOs also are playing a pivotal role in a federal initiative to help home health agencies improve the quality of their care and assist consumers in understanding how publicly-reported quality data can be used to select a home health agency provider. QIOs are training agency caregivers to evaluate their own performance using standardized Medicare quality measures; select treatment processes for improvement; create and implement step-by-step plans to improve care; and integrate continuous quality improvement into ongoing staff training.

QIOs are training home health agencies in an evidence-based process called Outcomes-Based Quality Improvement (OBQI). OBQI involves collection, analysis, and feedback of data on quality of care and patient progress that is of practical value to clinicians. The data documents how well agencies are helping patients improve grooming, bathing, dressing, meal preparation, and other activities. OBQI provides home health agencies with methods for interpreting patient data, targeting care processes for improvement, restructuring care, and monitoring how change in care impacts patient recovery and quality of life.

The Delmarva Foundation, the QIO for Maryland and the District of Columbia, trained all QIOs in the OBQI method prior to the launch of the initiative, and those QIOs in turn trained home health agencies in their states that volunteered to participate. These agencies continue to demonstrate a persistent dedication to working with QIOs on improving their residents' clinical outcomes and quality of life.

Hospitals: QIOs work with hospitals and physician offices to reduce errors of omission and comission by improving clinical care for heart attack, congestive heart failure, pneumonia and post-

surgical infections. QIOs work in this setting strives to assess the use of accepted best practices, analyze systems for providing care, and assist with implementation of quality improvement interventions to ensure that care meets IOM's six aims of quality improvement.

In the 7th Scope of Work, QIOs have expanded their efforts in the inpatient setting, particularly by using the collaborative method of quality improvement—developed by the Institute for Healthcare Improvement and being spread throughout the country by QIOs—to prevent the destructive and costly effects of surgical infections. Qualis Health, the Washington QIO, led a nationwide Surgical Infection Prevention Collaborative that both trained QIOs on how to conduct collaboratives and helped participating hospitals from every state prevent surgical infections by improving on several evidence-based measures of effective surgical care. In the next contract cycle, it is expected that QIOs will engage in a joint effort with numerous medical professional organizations, CMS and the Centers for Disease Control and Prevention to build on the surgical infection prevention effort by improving care on other measures of surgical care.

Physician Offices: QIOs are bringing a number of intervention strategies to physician offices in the 7th Scope of Work to improve care on diabetes, breast cancer and influenza and pneumonia. QIOs conduct regular education programs for physicians and their staffs, including on-site education opportunities. QIOs help physicians implement reminder systems and patient flow charts to help doctors ensure that patients regularly get recommended care, particularly for preventive services such as standing orders for influenza and pneumococcal immunizations. Using the audit and feedback approach, QIOs often mail physicians their quarterly performance reports on targeted clinical indicators. QIOs in a number of states also have assisted physician offices with implementing electronic disease registry systems, which are particularly effective at helping doctors' monitor care delivered to their patients with chronic conditions.

Reducing Disparities/Improving Rural Care: Each QIO conducts quality improvement projects in their state to improve care for rural beneficiaries or address racial and ethnic disparities in care between minority populations and the general Medicare population. QIOs frequently use a two-pronged approach that has been effective reducing statewide disparity rates. They work with health care providers and practitioners on ways to recognize and eliminate racial and ethnic disparities that may exist in their treatment of patients. The establishment of systematic, reliable methods of routinely delivering evidence-based care to every patient can eliminate much of the under treatment that otherwise afflicts vulnerable populations. Also, QIOs have partnered effectively with local coalitions addressing disparities, particularly faith-based organizations, to reach out to African Americans, Hispanics, and other medically underserved beneficiaries to assist them in getting evidence-based health care.

About 20 QIOs are currently working with critical access hospitals, health centers, and clinics to improve care delivered to rural beneficiaries. However, the demand for QIO assistance in rural areas far exceeds available funding. AHQA supports recommendations by MedPAC and others that the HHS Secretary increase dedicated funding for QIO work in rural areas, so the rural population can receive more attention without undermining indispensable QIO work that focuses on higher-volume. In general, IOM should identify ways QIOs can expand and improve QIO rural improvement and health disparity reduction efforts and support allotting additional funds for QIO rural and disparity projects above the approximately $13 million being spent annually during the 7th Scope of Work for these vulnerable populations.

EMERGING STRATEGIES FOR IMPROVEMENT

While providers and practitioners working with QIOs have made significant progress on the quality problem facing Americans, it's clear that one of the keys to the next round of needed transformational changes that will radically improve care is financial and non-financial incentives for

providers to engage in quality improvement. CMS and QIOs are actively working to integrate federal and local incentive programs, such as public reporting and pay for performance, into the program's ongoing efforts to improve quality.

Public Reporting: Well-organized public reporting of health care quality data can help consumers make more informed health care choices. Equally important is the effect of public reporting on providers—making readily apparent clinical areas where the quality of their care can be improved, and motivating them to seek out assistance to do so. While participation in QIO quality improvement activities is voluntary, the volume of providers seeking assistance has been tremendous, and appears to have been augmented directly by the impetus of public reporting.

As mentioned above, CMS launched in 2002 national public reporting and quality initiatives in nursing homes, home health agencies, and hospitals. Consumers can now turn to their local QIOs for help in understanding the publicly-reported quality measures and how they can be used to make better health care decisions. QIOs also are assisting hospitals, nursing homes, and home health agencies to ensure the accuracy of the information they collect and report.

In the 7th Scope of Work, QIOs have provided their data collection and measurement expertise to hospitals to assist them in self-collection and reporting of hospital data, which is being publicly reported through a public-private partnership led by the national hospital association groups. Hospital self-reporting is increasingly looked upon as a critical function to get facilities to take ownership of their clinical care processes and look to improve on identified gaps in quality care. With the reporting of this data being tied to payment under the MMA legislation, this activity has taken on increased urgency as QIOs provide support and technical assistance to ensure that all willing hospitals are able to receive their full payment update by reporting quality information to the QIO clinical data warehouse.

Public reporting of hospital quality data depends on capturing large amounts of comparable data, requiring a set of uniform quality measures and data collection tools that permit easy reporting of a standard set of quality data. The QIO program funded the creation of a sophisticated set of evidence-based clinical quality process measures, now widely used in both public and private sectors, which provides an ongoing assessment of the quality of fee for service health care under Medicare.

Payment for Quality: The concept of payment-for-performance also holds real potential for spurring improvement, and we look forward to working with the Committee as it examines this issue as well. IOM should continue encouraging CMS, as health care's largest payer, to test ways to provide differential payments to providers and practitioners that provide high quality care.

QIOs are available to assist hospitals in the Premier Hospital Quality Incentive Demonstration with data submission and quality improvement, and some QIOs also are working with private sector innovators to examine options for differential payment. One key challenge of such programs is that no payer, public or private, should offer additional payments for performance that has not been verified by an independent organization such as a QIO. The Virginia Health Quality Center (VHQC), which serves as the Medicare QIO for Virginia, is participating in a private pay-for-performance initiative sponsored by Anthem Blue Cross and Blue Shield of Virginia (Anthem). The QIO receives quality and safety measures submitted by hospitals, and checks them so Anthem can be assured of paying only for verified quality. IOM should consider the Anthem-VHQC partnership as a model for a national payment incentives program under Medicare.

CMS also is considering using QIOs currently involved in the Doctors Office Quality—Information Technology project (DOQ-IT) to implement the care management performance demonstration in Section 649 of the MMA. In this capacity, QIOs would work with physicians to implement information technology to improve care for chronically ill beneficiaries, provide technical

assistance with quality improvement interventions and care process redesign, and measure provider performance on quality measures that could lead to increased payment.

In general, AHQA supports the explicit inclusion of QIOs and their quality improvement technical assistance whenever the federal government undertakes a health care improvement initiative—whether it be pay-for-performance, public reporting, or revised conditions of participation. Also, IOM should encourage use of QIOs' technical assistance capacity to help providers reap the benefits of these incentive programs, especially among small and rural providers that otherwise might struggle to qualify for participation or achieve incentive thresholds.

Health Care Information Technology: More than a decade ago, IOM presciently recommended that Electronic Health Records (EHRs) become the standard for patient care. The widespread adoption of EHRs and other technologies holds great promise for transforming the health care system by helping providers and practitioners provide the right care, every time.

Many experts agree that one of the most challenging barriers to the widespread adoption of EHRs and other IT tools is a lack of affordable, high quality and long term support when it comes to preparing for and implementing IT into the practice setting. As mentioned above, QIOs in several states have experience successfully promoting use and assisting with implementation of electronic registries for chronic disease management in physician offices.

Under the DOQ-IT project, also mentioned earlier, QIOs in pilot states of California, Utah, Massachusetts and Arkansas, are working together to develop a model for improving office efficiency and patient outcomes by assisting small- to medium-sized physician offices in their implementation of EHR systems. These QIOs also are working to ensure that practices use their EHR systems to the fullest capacity so that ultimately, physicians can use clinical data reports to monitor and improve their performance in several key areas of health care. In keeping with IOM's Chasm report, one primary aim of this project is to develop a model for QIOs nationally to provide

no-cost support and assistance to providers so their IT systems will help them improve patient safety and quality of care through the practice of evidence-based medicine.

QIOs have found overwhelming support and teamwork on this endeavor from key national organizations such as the American Medical Association, the American Academy of Family Physicians, the American College of Physicians, the eHealth Initiative, and the National Committee on Quality Assurance.

Prescription Drug Quality Improvement: The MMA has created major new opportunities for quality improvement, expanding the work of the QIOs to Medicare Advantage (MA) plans under Part C and outpatient prescription drugs under Part D. QIOs will offer quality improvement assistance to providers, practitioners, MA plans and prescription drug plans with regard to medication therapy.

The QIOs are in a unique position to integrate inpatient and outpatient claims and medical record data with prescription drug data to provide a more complete view of patient care that can be used as a powerful tool for quality improvement. QIOs will be able to develop and test new measures of effective medication therapy and new interventions designed to help providers improve their prescribing practices and prevent medication errors of either omission or commission. For this potential to be realized, it is essential that CMS insist that new prescription drug plans provide frequent data transfers of drug utilization data, not just claims, so QIOs can work with providers on nearly real-time data.

Utilizing QIOs as a resource for collecting and analyzing Medicare prescription drug data will be a powerful tool to support the safe and effective use of prescription drugs in the health care of Medicare beneficiaries. However, QIOs can provide an even more valuable service to providers, beneficiaries and the Medicare program if they were able to share with providers beneficiary-specific information that indicates a gap in care or patient safety issue. We encourage IOM to recommend

that CMS remove regulatory barriers to QIOs' sharing beneficiary-specific data for the purpose of documenting clinical system failures and triggering appropriate interventions.

Partnerships: To coordinate and enhance local and national quality improvement efforts QIOs have taken steps to formalize and strengthen relationships with state and national organizations to encourage their memberships to seek out QIO assistance in the wake of increasing pressure to improve quality. For instance, in 2003, AHQA's then-President Dr. David Thomas, on behalf of QIOs, cosigned a letter with American Academy of Family Physicians' (AAFP) President Dr. James Martin encouraging AAFP members and state chapters to engage their local QIO and cooperate to achieve the aims stated in the IOM Crossing the Quality Chasm report. "We believe that by working together in a collaborative fashion at the national and state level, our organizations and members can promote a more organized and effective approach to physician participation for quality improvement," the joint letter said.

AHQA and QIOs are pursuing similar joint activities with other organizations, including the American Osteopathic Association, the American College of Physicians, and the eHealth Initiative. Such organizations at the national and joint level are increasingly recognizing and relying on QIOs, which they perceive as objective organizations with a sole interest in improving health care quality, to play the critical role of conveners. This convening role perhaps has been most evident in the CMS public reporting initiatives as QIOs in every state, and AHQA on the national level, brought together typically disparate stakeholders such as provider organizations, consumer representatives, survey and certification agencies, and other groups to help support and guide the federal effort. This model is spreading quickly to other settings QIOs are involved in such as patient safety, reducing disparities, and cross-setting topics.

Cross-Setting Projects: QIOs' presence in both inpatient and ambulatory clinical settings make them a superior vehicle for quality improvement work helping providers avoid the harmful

discontinuities that occur when patients transition between clinical settings (e.g., pressure ulcer prevention in hospitals and nursing homes and adherence to evidence-based drug regimens for heart attack and heart failure among hospitals and physician offices). A number of QIOs already are piloting some cross-setting projects in their states. IOM should recommend that CMS make better use of the QIOs' potential on this emerging quality of care issue by launching a new program to improve the continuity of care in high priority clinical problem areas in which work already has begun in one setting.

Collaboratives: QIOs continue to improve upon and expand the use of national and state-level collaboratives to improve care on measures for inpatient topics beyond surgical infection prevention to include topics such as AMI, heart failure, and pneumonia. QIOs also are using collaboratives to improve care in outpatient settings, such as diabetes for physician offices as well as pain and pressure ulcers in nursing homes. The Washington Diabetes Collaborative, run by Qualis Health, was recognized during the IOM Crossing the Quality Chasm Summit in January 2003 and is considered a model of QIO efforts to improve care in the outpatient setting.

Collaboratives represent an excellent example of QIOs' ability to replicate promising quality improvement interventions nationwide, while tailoring these projects appropriately for the local community involved. IOM should encourage CMS to work with QIOs to standardize a core set of quality interventions, and also provide QIOs with significant resources and significant discretion to design, test, and use additional interventions to address local quality improvement gaps.

Case-Based Quality Improvement: In its 1990 report on Medicare quality assurance, the IOM recommended that the then-PRO program should retain only those review activities that have a clear clinical peer review component and serve an unequivocal quality of care purpose, rather than the then-routine preadmission reviews of hospital stays for various procedures. In response, CMS

pared down QIO case review activities to those required by federal statute and regulation. These now include the following:

- Reviews of beneficiary complaints
- Emergency Medical Treatment and Active Labor Act reviews
- Hospital Issued Notices of Non-coverage and Notice of Discharge and Medicare Appeal Rights reviews
- Hospital Payment Monitoring Program reviews
- Hospital-requested higher-weighted DRG reviews
- Long-term care hospital reviews
- Medicare+Choice (Medicare Advantage) fast-track appeals
- Hospital outlier reviews
- Reconsiderations (also termed appeals or re-reviews)
- Reviews of Requests for Assistant at Cataract Surgery

There are a number of other case-review related activities required by law or regulation that are not regarded by CMS as "types" of review and so are not listed above. These include: sanction activities, handling of referrals from CMS, physician acknowledgment monitoring, and establishing Memorandum of Understandings with hospitals, HMOs, nursing homes, home health agencies, long-term care hospitals, and fiscal intermediaries.

Beneficiary observations of quality issues can be a source of valuable insight into quality problems involving many providers in addition to the subject of the complaint. Slightly more than half of QIO respondents in a recent AHQA survey reported identifying quality deficiencies in one office or setting that was subsequently found to be common to a large number of providers and practitioners. This suggests that individual beneficiaries can be a source of valuable information

concerning quality problems affecting large numbers of beneficiaries, which can then be addressed through quality improvement interventions.

As QIOs have become increasingly focused on quality improvement theory and practice, a number of QIOs have begun looking differently at their case review activities. This examination has resulted in part from recognition of some flaws that exist in current QIO practices for reviewing individual cases, such as variability in the reliability of reviewer decisions. But more and more, particularly during the current scope of work, some QIOs have started applying organizational quality improvement analysis and techniques to these previously distinct review actions. This introspection has led to a new perspective on case review, modeled on the notion of "population-based quality improvement," which is being called "case-based quality improvement."

Case-based quality improvement is helping some QIOs improve patient safety, protect beneficiaries, and identify opportunities to improve systemic quality of care by integrating the QIOs' typically discrete case review and quality improvement activities. This patient-centered approach to individual- and population-based quality improvement allows QIOs to address shortcomings in quality at both the system and individual levels. The QIOs' experience, also reflected in previous IOM reports and the literature on patient safety and quality, is that most individual-based quality problems are the result of poorly designed or damaged systems of care. Under these circumstances, punishing the individual practitioner associated with a quality problem—often an individual whose workplace lacks appropriate support and safeguards—may do little or nothing to ensure that problem won't reoccur, and can contribute to embitterment and cynicism about quality oversight.

An example of case-based quality improvement is an actual case in which a QIO received a beneficiary complaint in which the patient had an adverse reaction to amoxicillin despite notifying their emergency room physician of a preexisting allergy. The physician had noted the allergy, but in the bustle of a busy ER forgot the information and prescribed a related antibiotic to the patient at

discharge. When the QIO received the complaint from the patient, their staff approached the hospital and found the institution was already aware of the serious situation. Hospital personnel informed the QIO of actions it had taken with the specific doctor to ensure that the error would never happen again. As a result of internal reforms that spread quality improvement knowledge from the QIO's quality improvement staff to its case review staff, the QIO personnel responsible for the case took a deeper look at the system flaw that caused the problem. They subsequently worked with the hospital on a quality improvement project to minimize the likelihood of a recurring error – not only by the erring physician, but also all other members of the emergency department care team. Previously, QIOs would have noted that a corrective action plan was in place, and would simply have monitored adherence to the plan.

Integration vs Separation of Case Review and Quality Improvement: Many have come to believe it is a conflict for QIOs to perform both medical case review and quality improvement. This has come to be a matter of belief and opinion, seldom backed up by evidence. Usually, when evidence is offered, it consists of anecdotes reflecting the work of QIOs in the 1980s and early 1990s, prior to the program's shift in emphasis to population based quality improvement, and the maturation of the QIOs in this new role. In practice, over the past five years, QIOs have found that this concern to be more theoretical than actual. Nonetheless, AHQA takes this view seriously, as unchecked perceptions can and do sometimes generate dysfunctional realities.

As a first step in considering whether QIOs should continue to perform both medical case review based quality improvement and population-based quality improvement, we recommend the Committee carefully distinguish between the different forms of medical case review performed by the QIOs.

As identified above, there are numerous categories of medical case review QIOs perform for Medicare alone. Of all the categories of Medicare case review, investigation of beneficiary

complaints poses the most direct theoretical challenge to the relationships and trust essential to the quality improvement process. The job of investigating beneficiary complaints was added to the work of PROs by Congress in 1986 (Sec. 9353 of the Omnibus Budget Reconciliation Act of 1986) in response to the bipartisan Heinz-Stark proposal to ensure that beneficiaries could inject their quality concerns into the priorities of the Medicare quality organizations, and could seek redress of their grievances.

For several of the other categories of case review, there is little or no even theoretical conflict between the nature of the review and the quality improvement mission of the QIOs. For example, activities involving hearing beneficiary appeals are clear examples of high-value case review activities that pose no meaningful risk to the clinical quality improvement work. Other case review activities related to program integrity (assuring appropriate hospital billing) involve different staff in both the QIO and the provider, and QIOs find that even when there are disputes in the course of this kind of work for Medicare, Medicaid and other purchasers, it doesn't carry over to relationships with clinical personnel and leaders.

QIOs seldom find conflicts between their complaint investigation and quality improvement work, whether for Medicare, Medicaid, or for other purchasers. There are several reasons why this conflict, though it seems intuitive that it would be a problem, is in fact quite manageable in practice.

1. There are few beneficiary complaints, so there are few opportunities for conflicts.
2. There is a relatively much larger volume of QIO quality improvement activity in communities across the country, so the QIOs' reputation has become one of facilitator and technical assistance provider;
3. Few complaints involve substantiated clinical quality problems (fewer than 15% of complaints filed during the last Scope of Work; AHQA has requested more recent data);

4. Many providers and practitioners associated with confirmed quality complaints accept the diplomatic feedback they receive from QIOs about complaint allegations;
5. QIOs now offer a voluntary mediation option to providers/practitioners and complainants to help resolve the complaints that do not involve clinical quality problems, but which nonetheless can bloom into malpractice litigation if left unaddressed;
6. QIOs are competent at addressing the anger of the few providers and practitioners that resent the QIO approaching them about quality problems. QIOs report that the challenge of managing these problems is akin to the challenge of working past the disbelief, denial and resentment which sometimes attends population-based, data-driven efforts to highlight quality shortcomings and then recruit providers for quality improvement initiatives.

In short, the diplomatic skills that QIOs need to draw attention to the quality chasm and then recruit provider and practitioner support for clinical improvement efforts also qualify them to managing the emotional reaction to quality problems found as a result of case review.

<u>Medical Case Review in the Marketplace:</u> Many purchasers in the marketplace other than Medicare utilize the experience and expertise of the QIOs to investigate individual cases of care. Medicare and these other public and private payers rely on QIOs for medical case review to ensure appropriate payment of claims, review patient safety incident reports, adjudicate health plan enrollee appeals, and validate managed care organization HEDIS reports and providers' claims that they qualify for private "pay for performance" incentives. In fact, most of the quality assessment and oversight being purchased today by public and private health care organizations other than Medicare is based on medical case review, rather than population-based quality assessment and improvement. For the few that purchase both types of services (e.g., the New York and Massachusetts Medicaid programs) there is little evidence supporting the belief that they are incompatible.

Policy Options: Greater Integration or Thicker Firewall? There have been suggestions, including from CMS officials, that medical case review work should be more isolated or "firewalled" from quality improvement operations of the QIOs. A different set of options involves consciously knitting these two services more closely together. It is AHQA's contention that the policy options for separating the two kinds of work create more difficult problems than they solve, and that thoughtful integration of the two functions is the better course.

As the Committee considers its policy options, AHQA offers the following observations and recommendations.

1. The Committee could recommend to Congress that the beneficiary complaint provisions of the QIO portion of the Social Security Act be deleted. This option is not optimal because complaints are valuable sources of data for those interested in quality improvement.
2. The Committee could recommend to Congress that Medicare seek out companies qualified to do case review which do not work with providers to measure and improve quality. But to do so would mean finding case review entities that lack the quality improvement expertise of the QIOs. This would mean recreating HCFA's old unpopular PRO program of the 1980s, in which case review was performed by entities unschooled in the principles of quality improvement and unaware of the causal role of flawed systems in producing poor quality patient outcomes. This option will maximize the number of providers and practitioners that are named and blamed for quality problems.
3. The Committee could recommend to CMS that it restructure the complaint process, which is centrally controlled in virtually every detail by CMS, to ensure QIOs use quality improvement precepts in conducting and following up on the findings of medical case review. CMS should instruct all QIOs to utilize an integrated approach in which systems problems are assessed as part of the complaint investigation process, providers are engaged

early in efforts to address quality problems that led to the complaint. To improve the validity of findings, CMS should modify the complaint process, in accordance with the consensus approach utilized by the Harvard Medical Practice and COPIC research teams, to include a panel of physicians who must agree on findings regarding the responsibility of any provider or practitioner. Finally, in acknowledgement that a small number of providers and practitioners will simply not respond to data and offers for assistance to improve, the QIOs should be instructed to initiate formal proceedings against those providers that refuse to improve when approached in a collegial manner.

There are several benefits of close integration of complaint investigation and quality improvement within one organization, including:

Optimize the Validity of findings: IOM, the Institute for Healthcare Improvement and others have concluded that most clinical quality problems result from failed systems that promote errors and/or fail to prevent them from reaching the patient. As a matter of public policy, the entity that investigates quality problems that reach the patient should be well-schooled in clinical quality improvement precepts, including current knowledge of the system flaws that can lead to quality problems and the patient safety processes that can prevent their recurrence. As a practical matter, this means assigning the investigative duties to organizations whose primary work is cooperative quality improvement. The validity and reliability of QIO case review can and should be improved by use of a panel of medical reviewers who must discuss and come to agreement regarding a case.

Utilize Expertise in Recommending Quality Improvement Plans. When clinical process problems are verified by medical case review staff as a result of a complaint investigation, most cases will best be addressed through a quality improvement plan aimed at the source of the problem, often a process that has not been thought through and needs to be reexamined. In identifying the root causes of such problems and recommending an improvement strategy, the medical case review staff

at a QIO have available for consultation the QIO's quality improvement staff, who are adept in such analysis and the crafting of improvement solutions.

Avoid Inappropriate Assignment of Blame. To avoid a perceived conflict, federal officials could assign complaint investigations to entities without quality improvement duties, but the result is likely to be missed opportunities for improved systems, as well as larger numbers of practitioners being blamed for failures for which they should not bear unique responsibility. Medicare implemented the pure case review approach nationwide from 1984-1994 and then rejected it in favor of clinical quality improvement.

Since then, case review was treated as a vestigial function by CMS until the current Scope of Work, when, in response to a report by the HHS OIG, reforms were made to improve the responsiveness of the process to complainants and to offer a mediation option to help resolve the many non-clinical problems identified by patients and their families.

Maintaining the Option to Compel Improvement. Some providers and practitioners are unresponsive to voluntary clinical improvement methods, and persist in providing care that demonstrably conflicts with evidence-based care, harming patients. It isn't possible to know which providers and practitioners the laggards are until considerable efforts to encourage internal improvement or participation in externally facilitated improvement have failed.

One option is referral to state licensure authorities, but most of those entities are poorly funded, lack a staff of physician investigators, have limited data systems and record abstraction capability. As a result many state licensure boards tend to develop for legal action cases involving only the most egregious violations of professional norms (substance abuse, sexual relations with patients). Clinical quality issues are seldom litigated in the absence of one of these other problems. In this context it should be noted that some state licensure boards have begun to develop innovative programs to recognize practitioners with substance abuse problems and then provide an opportunity

for remediation (with the alternative being legal action against the practitioner's license). In these states, QIOs might refer practitioners with these problems for remediation.

Another option is to build on the knowledge, clinical assessment capacity, local awareness, and existing sanction authority of the QIOs. As a result of its efforts to recruit providers and practitioners and respond to beneficiary complaints, as well as its work for other purchasers in the jurisdiction, the QIO in each state is in a good position to identify recalcitrant providers and practitioners, and, when appropriate, to transfer responsibility for the matter to the medical case review team within the organization with the authority to insist on improved clinical quality. We recommend that CMS encourage QIOs to pursue sanction recommendations in cases in which clinical quality problems are well documented but providers or practitioners refuse to address them meaningfully.

<u>Recommendations:</u> AHQA has several recommendations to the IOM BPPI Committee that would improve the value of medical case review for beneficiaries as well as providers and practitioners.

1. Support the integration of case-based and population-based quality improvement activities of QIOs.
2. We further recommend that the next QIO contract be written and funded to permit QIOs to propose local or statewide quality improvement projects to address problems initially found as a result of one or more complaint investigations.
3. Another important reform we recommend is for CMS to ask QIOs to increase the reliability of clinical reviews through the use of a consensus panel of practitioners with the appropriate training to review and discuss complaints in a manner consistent with that employed by RAND and quality researchers in the Harvard Medical Practice and COPIC studies.

EVALUATING EFFECTIVENESS OF QIOs AND THE QIO PROGRAM

Facilitation of health care quality improvement is more akin to clinical practice than research. It takes place in the field, and the topics, interventions, and pace of change are largely determined by factors beyond the quality improvement professional's control. It is similar in another way, in that much of clinical practice lacks a basis in scientific evidence, yet the trained professional practitioner is permitted to exercise judgment in the interest of improving the health and quality of life of patients.

For example, physicians often lack scientific evidence indicating when patients should be admitted to a hospital, but it would be unconscionable to restrict access to hospital care until such research becomes available. Quality improvement practitioners, both inside QIOs and in general practice, also do their work guided by professional judgment and experience without proof of the effectiveness of their interventions. Because of the way CMS identifies its clinical priorities, those in the Medicare QIO program do have the benefit of knowing that they seek to promote evidence-based care, but they must do so using techniques that are themselves unproven.

When researchers have studied quality improvement interventions they have generally found that these activities are conducted in an uncontrolled fashion, and involve partnership with health care professionals who are likely to be what Rogers called "early adopters" rather than average providers. Though these may well be atypical providers and practitioners, there is wisdom in this approach. It makes a great deal of sense to recruit "early adopters" to try new and improved ways of organizing their clinical processes, because they are likely to be opinion leaders in the health care community that can spread these practices more widely with help from the QIO.

Another distinction between sound scientific study design and quality improvement work was revealed by a joint CMS-CDC project a few years ago to investigate the value of standing orders for immunizations in nursing homes. The CDC participants insisted on a rigorous design in which

the participating QIOs were prohibited from communicating interim results back to nursing home staff during the two year course of the study. This robbed the project of one of the most important tools of improvement technique, the ability to engage health care workers in ongoing assessment and adjustment of their intervention approach. Without the ability to make mid-course adjustments to the intervention, the project was impoverished by its rigid commitment to the originally agreed-upon intervention, staff were not repeatedly energized and challenged to improve, and the effort showed little or no benefit. In this case, good study design was revealed to be poor quality improvement technique.

The reality that most clinical improvement activities take place outside of a strong research design complicates the work of the Committee in trying to assess the effectiveness of the QIOs and of the QIO program. In the absence of a large number of studies of QIO performance utilizing a strong research design, what is the Committee to compare the QIOs' work to? What is a reasonable expectation for these entities?

In an article in the June 1, 2004 *American Journal of Medicine* on quality improvement evaluations that doesn't even mention the QIOs, Drs. Shojania and Grimshaw observed:

> "Research in quality improvement consumes less than half of a percent of federal biomedical research funding but is expected to produce dramatic results – the computer order system that will eradicate medication errors, the decision support system that will ensure delivery of evidence-based prevention strategies to all eligible patients… Considering the intrinsic complexity of most quality improvement interventions, it is striking how poorly described they are in research reports of their evaluation….In addition to improving rigor, however, we must also adjust our expectations. After decades of relative neglect of quality improvement research, there is indeed an 'urgent need to improve quality'. But there is no reason to expect miracles. We routinely embrace clinical interventions that achieve relative improvements in important outcomes on the order of 10% to 20%. When it comes to quality improvement, however, we throw up our hands in despair when interventions fail to deliver quantum leaps in provider's performances or patient's outcomes. The unrealistic quest for quality improvement wonder drugs (or, increasingly, wonder information systems) may ultimately prove harmful if we repeatedly discard interventions that consistently deliver more modest improvements."

QIO projects have overcome many of the methodological shortcomings identified in the article by Shojania and Grimshaw, but the lack of controlled design alone makes it difficult to evaluate results with the confidence researchers have come to expect in other fields. Even the gold standard for quality improvement interventions, the breakthrough collaboratives pioneered by the Institute for Healthcare Improvement—and replicated nationally by QIOs—have been simultaneously praised and subjected to fundamental questions concerning evidence of effectiveness and sustained impact. After a review of the international literature on collaboratives, Ovretvreit, Cleary and colleagues concluded in the journal *Quality and Safety in Health Care* (vol. 11, 2002) that:

> "[a]t this stage there is no evidence about the long term results or about the cost effectiveness of collaboratives compared to other methods."

Confounding the Committee's assignment further is the fact that CMS has pushed the QIOs hard to partner with other entities sharing their commitment to quality improvement in every clinical area in which such partnerships are feasible. Under these circumstances, it makes no sense to uniquely attribute resulting improvements to one of those partners. Sometimes, the role of the QIO is to broker a combined strategy between partners with approaches that compete for loyalties and resources at the local level, as in the Virginia Health Quality Center's work with the state chapters of the American Heart Association (sponsor of the Get With the Guidelines initiative) and the American College of Cardiology (originator of the Guidelines Applied in Practice or "GAP" program). This approach is wise when one is seeking to maximize the involvement of others with resources and the ability to generate commitment by physicians and other caregivers to improved care. But this approach is a poor way to design a project for evaluation of cause and effect. Which is more important? Does it matter that the quality improvement interventions are promoting evidence-based care?

Available Evidence of QIO Effectiveness: QIOs have recognized their obligation to contribute to the knowledge base of quality improvement, by authoring over 500 articles published

in the peer reviewed literature since 1990 (see attachment #2). Today, AHQA is providing the Committee with an electronic and hard copy of a bibliography of this body of research, organized by clinical topic area.

Following the 6th Scope of Work evaluation, CMS Quality Improvement Group Director Dr. Stephen Jencks co-authored a pre-post observational study (*JAMA*, January 15, 2003) explaining that providers and practitioners working with QIOs improved care on 20 out of 22 standardized Medicare quality indicators between 1998 and 2001. These data are suggestive of an effect attributable to the QIOs, but the article appropriately conceded that it is difficult to determine how much of this impact was definitively the result of QIO actions. An accompanying editorial by Dr. David Hsia of AHRQ concluded that the QIOs significantly contributed to the gains in quality.

The article shows that the health care community reduced the quality gap in care received by Medicare fee for service patients by about 13% between 1998-2001. For example, in the median state, prescription of the correct antibiotic for pneumonia patients went from 79% (a quality gap of 21%) in 1998-1999 to 85% (a quality gap of 15%) in 2000-2001. This is a 6-point absolute improvement and a 32% reduction of the quality gap, expressed in the study as "relative improvement." Other clinical quality indicators reflecting significant gains nationally included administration of aspirin for heart attack within 24 hours (15% relative improvement) and prescribing of beta-blockers at discharge for heart attack patients (28% relative improvement).

Most of the published articles and unpublished government statistics regarding the effectiveness of the QIO program and the QIOs themselves pertain to inpatient care, because this has been the earliest and longest-lived focus of the quality improvement program.

The improvement observed in hospital measures of surgical infection prevention is relevant to the Committee's charge to examine the effectiveness of the QIO program and the QIOs. During the period in which these improvements have been noted, there were no other significant initiatives

focused on improving these rates either nationally or in the facilities participating in this project. It is therefore likely that the gains are a direct result of the added QIO program support for hospital efforts. A similar conclusion can be drawn from the QIOs' attention to improvement on inpatient immunization rates, a clinical problem area no other entity is working to improve on a significant scale, where the joint efforts of QIOs and hospitals is associated with significant reduction in the failure rate.

Surgical Infection Prevention National Collaborative

- Beginning in March 2002, 56 hospital teams from 50 states and territories came together for a 13 month collaborative to improve processes of care related to surgical site infection prevention. Hospitals focused on timely administration of pre-incision antibiotics, appropriate antibiotic choice, and discontinuation of antibiotics within 24 hours of surgery end.
- Forty-four hospitals reported regularly on a pilot population of 35,543 patients. Provision of prophylactic antibiotics with 1 hour before incision improved from a quarterly median of 72.2% at baseline to 92.4% ($p < 0.0001$), appropriate antimicrobial selection from 89.9% to 95.5% ($p=0.016$), and discontinuation of antimicrobial within 24 hours of surgery end time from 67.4% to 85.1% ($p<0.0001$).
- Reported surgical site infection rates fell from 2.28% in the first three months of the collaborative to 1.65% in the last three months of the collaborative (a 26% reduction).

Cooperative Cardiovascular Project

- A pre-, post-intervention study was conducted of acute myocardial infarction care in four states (Alabama, Connecticut, Iowa, and Wisconsin) as compared to a random sample of acute myocardial infarction Medicare discharges from the rest of the nation. The intervention included measurement and feedback of process measures reflecting

acute myocardial infarction care, along with educational interventions by QIOs (then PROs) in the four states.

- Performance on all quality indicators improved significantly in the four intervention states.
- Performance improvement on all quality indicators except reperfusion was better in the intervention states that in the rest of the nation and was significant for aspirin use at discharge ($p<0.001$), beta-blocker use ($p<0.001$), and smoking cessation counseling ($p=0.02$).
- The project was evaluated in an article published in *JAMA* (May 6, 1998). The authors concluded from the degree of improvement in evidence based clinical practices documented in the four state intervention group compared with the rest of the nation that the QIO project had achieved a 1 percentage point reduction in AMI mortality. AHQA projected that this reduction in mortality translates to about 3,000 lives a year in the United States. Based on this project, CMS retained QIOs in every state to replicate the CCP in the 6th Scope of Work.

Fifth Scope of Work

- A rural health quality improvement project involving pneumonia care in 36 hospitals utilized a crossover design to demonstrate the effectiveness of a QIO intervention. Pneumonia care quality as measured by four clinical quality indicators was improved by 20% to 300%, with changes in all indicators being highly statistically significant. When the data were evaluated by hospitals to address the effect of clustering of care within a single hospital, patients receiving care in an intervention hospital were ten times as likely to receive antibiotics within the recommended four hour window as patients receiving care in a control hospital.

6th Scope of Work

- In a pre-, post-intervention analysis of performance on 18 hospital quality indicators, there was improvement on 15, and the average relative improvement for the inpatient quality indicators was 11.9%.

7th Scope of Work

- There have been notable improvements in a variety of hospital quality indicators related to care of cardiac patients. In particular, utilization of aspirin at arrival and at discharge has increased significantly and there has been a 15% absolute increase in use of beta-blockers both at the time of admission and at discharge. Smoking cessation counseling has increased significantly for patients hospitalized with acute myocardial infarction and heart failure.
- Improvements in pneumonia care have included a 16% absolute increase in the proportion of patients who receive guideline-recommended antibiotic therapy. In addition, provision of both influenza and pneumococcal polysaccharide vaccines has more than doubled.
- Although limited intervention efforts have been completed, provision of an antimicrobial dose in the hour before surgical incision has increased significantly.

Evidence of the effectiveness of QIOs as facilitators of quality improvement can also be seen in interim data in several other settings in which QIOs are engaged under the current 7th Scope of Work.

Nursing Homes: While the initiative has only been in place for less than two years, nursing homes and their QIO partners can show significant nationwide improvement as measured by several indicators. The improvements seen in two of the three nursing home quality measures that the QIOs have focused on comprise another example of quality improvement work being facilitated by

QIOs that is unique in its scale, timing and focus. It would be difficult to attribute these improvements to secular trends. Public reporting was implemented on these measures, but publication of performance also applied to a larger number of measures that have not shown significant improvement. By contrast, two of the three indicators focused on by the QIOs have improved significantly, and the one that has not improved (pressure ulcers) is the result of multiple causes that may be expected to take more time to control. Our interpretation at AHQA is that public reporting helps to motivate providers to improve, but they still need assistance to know how to start, how to continue, and how to sustain improvements in care. Since the NHQI began in November 2002:

- Nearly all of the nation's 17,000 nursing homes have been contacted by their local QIO to participate in quality improvement efforts. Approximately 2,500 nursing homes, out of a much larger number of facilities expressing interest (more than the QIOs were originally budgeted to assist), have been recruited by their QIO to actively pursue quality improvement.
- Residents reporting chronic pain dropped by about 36% (from 10.7% to 6.9%) and improvement has been achieved in every state.
- Residents who were physically restrained declined by 20% (from 9.7% to 7.8%) nationally and improvement has been achieved in 92% of states.
- The percentage of short stay residents who reported experiencing pain decreased nationally by 10% in one year (from 25.4% to 22.7%).
- QIOs are receiving high customer satisfaction ratings from nursing homes surveyed as part of the QIO evaluation.

Another widely targeted clinical problem (pressure ulcers) has not improved very much, so QIOs are reengaging local stakeholders to find better ways to influence performance. At this point, every QIO is surpassing its required quality improvement targets for the nursing home setting.

Home Health Agencies: Staff in more than 5,275 agencies, or three-quarters (76%) of all Medicare-certified Home Health Agencies, have been trained by QIOs. Nearly two-thirds (63%) of all Medicare-certified HHAs have submitted quality improvement plans of action based on the training they received from their QIO in Outcomes Based Quality Improvement (OBQI) and self-assessment, and more than half (55%) of all HHAs have signed up to share quality improvement information with other agencies via the website www.obqi.org, where they can also receive refresher trainings from QIOs.

Provider/Practitioner Satisfaction: QIOs consider health care providers and practitioners to be partners in improving care for Americans, and every QIO strives to satisfy its partners by providing services they value. In the 7th Scope of Work, CMS recognized the importance of the QIO relationship with its partners and created an additional customer satisfaction component of the QIO evaluation to both incentivize and assess that relationship.

Outcomes from CMS' survey are generally very good for nearly all QIOs. Data reflecting all QIOs' work with nursing homes is very positive—CMS reported that 93% of identified-participant nursing homes (about 15% of the homes in each state) rated the QIO highly. About 79% of the rest of the homes in each state – those that QIOs worked with on a less intensive basis (e.g., through regional workshops, web-based resources, and mailings) reported satisfaction with their QIO. Interestingly, despite difficulties in improving rates on outpatient quality indicators reflecting patient behavior, rates for indicators directly reflective of physician actions are significantly improved and QIOs are receiving very high marks from the first third of physician offices surveyed around the U.S.

Intangible Impact: Some of the positive impacts QIOs have on health care quality in America may be incalculable. For instance, QIOs play a large role in their communities and states, and increasingly on the national scene, promoting high quality health care practices and greater awareness of the quality chasm that exists nationwide and in local communities. As community-based and primarily nonprofit organizations, QIOs are trusted local resources on the Medicare program and health care issues that affect those beyond the Medicare population. QIOs also actively engage the media on important health care issues and provide scientifically-based health care quality information to providers, consumers, and policymakers.

CMS EVALUATION OF QIOs

The QIO program was one of the first within CMS to adopt the concepts of performance-based contracting. This move has been largely positive, leading to a more robust program that generates better performance through contractor accountability. However, there are a number of issues that serve to complicate or severely inhibit the fair and effective evaluation of QIO contractors. We fully support recent efforts by CMS to pursue reasonable solutions to these problems and acknowledge there are no simple answers. We hope that the Committee will closely examine these important issues in its evaluation and lend its expertise to devising solutions.

Incomplete and changing performance evaluation: The contract evaluation is the most significant driver for managing a QIO contract. In order to be successful with the limited resources available in their contracts, QIO efforts must be effectively focused to meet challenging evaluation requirements across the broad variety of task areas. In the 7th Scope of Work, the QIOs were asked to sign and start contracts without a complete and finalized evaluation plan. Additionally, CMS has chosen to change elements of the evaluation criteria well into the contract period, causing significant confusion and distraction within the QIO community and possibly hindering performance.

Delays in performance data: Provider/practitioner performance data is a critical resource for targeting QIO efforts to recruit participants for quality improvement projects. However, in order for this information to be maximally useful, it must be accurate and timely.

The data available to QIOs to support their efforts in the 7th Scope of Work is, at best, about six months old for nursing homes and home health agencies, and, at worst, 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. Unfortunately, this improvement didn't occur until well into the current contract performance period for most QIOs.

Generating physician interest in improvement efforts can be difficult with performance rates that are 6 months old, let alone 12 months or more. The problem with physician quality indicators is that they are based on provider claims that are stored in such a way that it is extremely difficult for CMS to provide data to QIOs in a timely fashion. Further, data requests for quality improvement are not given any priority in the system. Increased use of information technology in physician offices holds significant promise for the future, but an interim solution is sorely needed.

Limited evidence for QIOs to use in identifying what works: QIO intervention activities with providers are implemented using a quality improvement design. Because they can't utilize a controlled research design, it is very difficult for QIOs to ascertain which interventions have the potential to create the greatest impact and under what conditions. QIOs are then forced to make qualitative judgments about the effectiveness of interventions with limited evidence and ability to account for the positive or negative impact of external factors. In rare instances, they can benefit from some quasi-experimental analysis of interventions.

CMS needs to put more emphasis into identifying what works and what doesn't to improve quality. Developing a more substantial science basis for quality improvement would assist the QIOs and providers/practitioners in selecting interventions. As well, it could provide a real basis for CMS

to establish justifiable improvement criteria for the QIO evaluation, as opposed to the current practice of setting arbitrary performance targets (e.g. 8% reduction in failure rate on the quality indicators).

Dependence on deliverables: QIO performance is often dependent on deliverables from CMS or other CMS contractors that are completely out of their control. Some examples of deliverables include quality indicator performance data, software programs, communication resources and support contractors. In many cases, QIOs are restricted to only using these deliverables and are left with no options for dealing with delays or problems. When these deliverables are late or are not provided in useful form, this can significantly hinder the ability of QIOs to meet the evaluation requirements within the short window of contract performance actually used for evaluation. Additionally, problems with deliverables create dissatisfaction among providers and practitioners.

Use of prescriptive task requirements: The major idea behind performance-based contracting is to set performance outcomes for a contractor without being overly prescriptive in how the contractor should meet those goals. Contrary to this idea, CMS is increasingly dictating how the QIOs must perform their work. For instance, in the 7th Scope of Work, the QIOs have been required to use a very structured process for improving the quality of care provided by home health agencies. The Outcomes Based Quality Improvement (OBQI) method leaves little room for QIOs to pursue alternative improvement strategies that could result in better performance. However, the QIOs are still being evaluated on home health agency improvement on the quality indicators.

Holding the QIOs responsible for performance-based outcomes, while severely limiting the strategies they can use to meet those outcomes, is unfair to the contractors and potentially harmful to the entire program. Prescriptive tasks can lead to major failure, especially when QIOs are forced

to use relatively unproven methodology. Even worse, they stifle the innovation and learning that can result in even more effective interventions.

Unsupported improvement thresholds: While there may be some explanation for how CMS arrived at the improvement targets for evaluating QIO performance in the 7th Scope of Work, a cursory examination of their reasoning reveals that the targets are arbitrary and without any legitimate basis. One only need to note that CMS set the same target, 8% relative reduction in failure rate, for the QIOs in the nursing home, hospital and physician offices tasks. These settings are very different—the quality indicators, patient populations, interventions, providers, QIO experience—and realizing those differences, it is unclear why the same improvement criteria would be uniformly applied to all the settings. In many cases, CMS has failed to recognize the significant challenges a QIO faces moving into a new provider setting.

Limitations of improvement measurement methodology: The current pre/post improvement methodology is subject to the impact of special cause variation (e.g. random variations associated with only two data points or state level variations in achievable improvement that reflect demographics, size, and population) on the determination of whether QIOs have successfully carried out their work. As well, in some settings the samples sizes or number of available cases are too small to permit meaningful distinctions to be drawn between providers or contractors.

A transition should be made from pre-post measurement towards an evaluation strategy more philosophically and statistically consistent with that of continuous quality improvement (e.g trend analysis—a pattern analysis of control charts with multiple measures over time to indicate direction of change).

Additionally, in the outpatient setting, QIOs continue facing a significant challenge that complicates efforts to improve compliance with best practice guidelines, such as regular diabetes testing, mammograms, and vaccinations. 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 copays, 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 come to the physician office, accept his/her advice and follow up on their physician's recommendations. It is critical that IOM consider these confounding issues when assessing QIO performance in the outpatient setting, and help explore effective ways to improve measurement of performance in this context.

Changing science: The evolution of performance measures may not keep pace with the evolution of science. An example is the issue of whether appropriate treatment for heart failure patients includes ACE inhibitors or Angiotensin Receptor Blocker (ARB) drugs. QIOs risk losing significant credibility in the eyes of their provider partners if they lack the ability to quickly adapt to changing science.

Variability in application of evaluation: Significant variability in QIO performance assessment, particularly on the part of CMS Regional office staff, has resulted in an unacceptable level of subjectivity being inserted into the evaluation process. This uneven application of performance criteria has led to some inexplicable decisions, like when the highest performing QIO in the 6th Scope of Work was put out for competition and ultimately lost its contract.

Competition: AHQA encourages IOM to analyze cases in which QIO contractors were forced to re-compete for a state's Medicare contract and generally assess the amount and opportunity for turnover among contractors. We have found that in recent cases where a contract was lost, virtually no organizations that are not already QIOs compete for the contract.

It is difficult to know why more organizations don't compete for QIO contracts when they are available, but it is likely due primarily to the limited opportunity to earn a significant contract award fee (current QIO contracts are cost-based contracts with only a few additional percentage points available as a surplus) and the rigorous eligibility requirements for serving as a QIO. These stringent qualification requirements, which necessitate substantial access to licensed physicians to conduct statutorily-mandated reviews, are essential to fulfilling the duties of the QIOs and AHQA strongly supports the maintenance of these requirements.

In addition, IOM should advise CMS to take steps to avoid competing QIO contractors merely for the sake of competition. As mentioned earlier, CMS has defined a rigorous contract evaluation that contractors must pass every three years. In addition, when combined with the relatively short contract performance period, turnover of effective contractors can disrupt and slow quality improvement progress for Medicare beneficiaries in a state. In sum, AHQA supports CMS' model approach to performance-based contracting used for the QIO program and urges refinement of the QIO evaluation methodology to ensure a fair assessment that retains effective contractors.

Three-year Contract: Both CMS and the QIOs are becoming increasingly frustrated by limitations imposed by the statutory three-year contract period. Because CMS needs time to evaluate all 53 contractors at the end of a contract period and then give ample opportunity for competition on new contracts, the actual remeasurement period available for QIOs to bring about improvements is less than 28 months. QIOs effectively have two years or less to impact the quality indicators because it takes at least a few months and in some cases much longer to hire staff and develop or implement interventions for new tasks in each new scope of work. As QIOs look more and more toward implementing transformative quality improvement strategies that are new to the contract—such as organizational culture change and health care information technology—it is critical that Congress extend the three-year contract period to allow more time for QIOs and their

provider partners to properly implement these beneficial strategies and allow adequate time for them to show their tremendous promise.

In sum, AHQA strongly supports the use of the performance-based contracting method for the QIO program and considers it a model for federal contracting. In fact, the MMA contractor reform provisions were largely based on the QIO program. However, for performance-based contracting to work effectively, contractors must have access to the information they need and be able to trust that the evaluation structure reliably and fairly accounts for performance. IOM may be able to help CMS and QIOs achieve these reforms to improve the program's evaluation.

PROGRAM FUNDING

Another important task for IOM to assess is the source and amount of funding for QIOs. As stated earlier, AHQA has serious concerns that QIO program funding has not increased commensurate with all new work, particularly for additional review responsibilities. Nor does AHQA believe that program funding has increased sufficiently to meet the need and demand for QIO services to help achieve transformational change and rectify the dramatic quality problems facing Medicare beneficiaries. By our calculations, Medicare spends less than 0.2% of its annual budget to fund the quality improvement activities of the QIOs—an extremely low figure in relation to the scope and size of the quality chasm. This means that QIOs have the resources to devote relatively few full-time employees to individual contract tasks. IOM should obtain from CMS figures to assess the program's budget since 1998—when Congress set a new baseline funding level and required increases for inflation and new work—and determine whether funding should be increased to account for additional work.

Nonetheless, AHQA supports the QIO program's existing funding mechanism, which involves an apportionment from the Medicare Trust Fund. This mechanism is essential to ensuring the consistency and stability required for effective quality improvement efforts to occur. AHQA

also would support IOM recommendations on ways to further insulate QIO program funding from shifting political priorities.

In the 7th Scope of Work, CMS implemented a new national quality improvement strategy focusing on QIOs working intensively with "identified participant" groups of motivated providers that volunteered for additional QIO services. AHQA generally supports the notion of providing more intensive technical assistance to willing providers, but is concerned that this limited approach will not achieve the necessary transformational health care quality improvement needed by nearly every provider across the country. IOM should encourage the federal government to provide funding that is adequate to provide intensive local support for all providers, not just an identified few.

For instance, preliminary 7th Scope of Work data shows that QIOs and their nursing home partners have improved care on several long-term care quality measures at higher rates among the 15% of nursing homes targeted as identified participants than the nationwide cohort of all Medicare-certified facilities. In the 8th Scope of Work, CMS should build on this impressive improvement by significantly expanding resources dedicated to this effort to allow QIOs to intensively engage nursing homes far beyond the current 15% figure. However, we agree with CMS that the focus on "identified participant groups" is useful for priority-setting or when funds are inadequate for national implementation.

IOM also should recommend that CMS should provide funding for research and developmental projects to field test new quality improvement methods on new clinical topics. Once intervention strategies prove effective in a special project, subsequent funding should be provided to expand to the level required for widespread implementation of the project across the country.

STRENGTHENING THE QIO PROGRAM

AHQA recommends that the federal government capitalize on the tremendous strengths of the QIO program—including its national reach and extensive local infrastructure, performance-driven competitive contracting, essential partnerships with local providers and other stakeholders, rich history of developing and publishing evidence of health care quality shortcomings and quality improvement methods, and extensive experience influencing behavior change—by strengthening and expanding the program.

To achieve this, the federal government should better align the QIO program's quality improvement topics with those priority areas recommended by IOM for which valid and reliable quality indicators exist to measure care. CMS also should expand upon its successful initial efforts to reach out early and actively to stakeholders (consumers, purchasers, professional societies, health plans, providers, practitioners, suppliers of products and services, etc.) to identify priority topic areas best-suited for cooperative efforts.

Consistent with IOM's recommendations in its study of federal health care quality programs, federal agencies should, whenever possible, align their quality improvement efforts with the areas recommended by IOM, and we believe, implement them through the shared federal quality infrastructure represented by the QIO program. By doing so, the federal government would send an important message about the clinical areas requiring the greatest attention, and thereby reduce the burden on providers who often are asked to concentrate on various topic areas for quality improvement. To achieve gains in these priority areas, the QIO program should continue to take actions in accordance with the IOM's six identified aims for health care quality improvement.

As outlined in this testimony, there are a number of recommendations that IOM can make for CMS and the federal government to significantly improve the effectiveness of the QIO program. And while those recommendations would be helpful to improve current efforts, we strongly

encourage IOM and CMS to take advantage of ways to expand the QIO program to capitalize on the ever-increasing momentum around improving quality in health care delivery.

One of the greatest opportunities to assess and then improve quality of health care is under the Medicaid program. While the fragmented administrative system of Medicaid certainly presents challenges, it seems that the QIOs' defining characteristics of being state-based entities with national direction is a readily available improvement infrastructure model for Medicaid. In addition, many QIOs already are known quantities among state governments after years of providing utilization review services for states under Medicaid. A number of QIOs also have experience researching and addressing health care quality issues ubiquitous to the dually-enrolled Medicare-Medicaid population.

With a few exceptions (e.g. New York and Massachusetts), Medicaid programs typically ask QIOs to perform research studies that document problems, but rarely ask for action to improve care. Recently, however, a few state Medicaid programs have turned to QIOs to conduct quality improvement projects with providers to address devastating health problems prevalent among Medicaid beneficiaries, such as asthma and diabetes. For the non-Medicare-eligible population covered by Medicaid, IOM should recommend that CMS establish a set of national quality improvement priorities or require as a condition of FFP a state process for identifying state priorities. Congress also should provide matching rates to encourage these Medicaid improvement efforts and require that states use common quality measures and active clinical improvement programs aligned with those underway in the Medicare program (where appropriate for the population).

IOM also should urge the federal government to explore ways to better utilize the QIOs' knowledge and expertise in other federal health care programs and services where quality gaps persist, such as Veterans Affairs, TRICARE, programs under the Health Resources and Services Administration, and End-Stage Renal Disease services. FMQAI, the Florida QIO, already has

broken new ground by earning the ESRD Network 7 quality improvement contract, which should serve as a model for joint efforts between the two programs.

IOM should encourage CMS to examine ways to expand QIO efforts into additional health care settings, following up on the thus far successful QIO experience moving into nursing homes and home health care. Opportunities clearly exist for QIOs to apply their proficiency in collecting and analyzing quality data, and then designing care improvement interventions in rehabilitation facilities, psychiatric hospitals, and other sectors such as long-term care hospitals where QIOs could marry their existing quality assurance activities with new quality improvement efforts.

Furthermore, the Committee should recommend that CMS encourage QIOs to pursue external public and private funding, particularly to develop and test new areas and techniques for quality improvement.

CONCLUSION

Thank you for the opportunity to submit written testimony to accompany oral remarks during the BPPI Committee's first hearing. We are very excited about your analysis of the QIO program and its potential to highlight the groundbreaking work currently underway and share the appropriate direction for the program's future. We have the highest regard for the work of both the Committee and its staff, and we eagerly anticipate hearing your recommendations for the program's direction and future. AHQA's members and staff are at your disposal as you prepare this report.

We encourage you to take every opportunity to attend AHQA meetings to converse with QIO staff and visit QIOs in their home offices. I understand that your travel budget is limited, but I am certain that making site-visits will enhance your understanding and appreciation for the men and women that are dedicating their lives to improving the health care delivered to our country's Medicare beneficiaries. Meeting with the thousands of hard-working and intelligent nurses, physicians, analysts, IT specialists, communications officers, reviewers, and administrative staff

employed by QIOs can generate valuable information about the QIO program at the operational level.

In sum, the QIO program is committed to maintaining and enhancing its application of the recommendations and findings made by the expert resources of IOM and other respected bodies. We are confident that QIOs are demonstrating their value to American taxpayers by helping to save lives everyday through better, safer health care. But like the health care system IOM asked QIOs to begin improving in 1990, the program itself is in need of some changes to improve its effectiveness and efficiency. We are looking forward to working together with this IOM Committee, CMS, and other relevant stakeholders.

As a community of QIOs, we are proud of our accomplishments and committed to accelerating the pace of our progress for the betterment of America's seniors and the entire health care system. We anxiously anticipate the report of this distinguished panel, as we are certain your insights on the program's past, present, and future will advance the revolution IOM set in motion in 1990.

ATTACHMENT 1: AHQA suggested IOM recommendations

ATTACHMENT 2: Bibliography of QIO-authored research articles.