REQUEST FOR INFORMATION

Medicare Health Care Quality Demonstration

Medicare Modernization Act
Section 646

As mandated by Section 646 of the Medicare Modernization Act (MMA), the Medicare Health Care Quality Demonstration will test major system changes to improve quality of care while increasing efficiency across the entire health care system. The Centers for Medicare & Medicaid Services (CMS) is in the process of developing a solicitation for demonstration proposals and is seeking public comment on the demonstration design. All comments regarding this initiative must be submitted in writing to **mma646@cms.hhs.gov** and must be received no later than **Friday, May 6, 2005**. For further information, please contact Cynthia Mason, Project Officer, at the same e-mail address or by calling 410-786-6680.

Background

The defects and failures in the current health care delivery system, as documented by the Institute of Medicine (IOM) in *To Err Is Human* and *Crossing the Quality Chasm*, are pervasive, and their consequences add to the burden of illness borne by Americans and their families. It is not a lack of caring, competent and dedicated professionals that is to blame for this state of affairs, but rather fragmentation that makes continuous care very difficult and a lack of systems designed to protect against the likelihood of human error. The Medicare Health Care Quality Demonstration, mandated by Section 646 of the MMA, will enable CMS to support major system changes to achieve effective, safe, and patient-centered care.

In preparation for this demonstration, CMS participated in a meeting of a group of subject experts convened by the Agency for Healthcare Research and Quality (AHRQ) in July 2004 to conduct a roundtable discussion on Health System Leadership and Design. Participants in that meeting recommended the redesign of delivery systems and health care organizations to take advantage of new developments in information technology, the implementation of practices that promote safety and quality, the provision of more patient-centered care, and the facilitation of preparedness for national emergencies. Participants recommended that the next steps should include harvesting state-of-the art design practices and identifying strategies to promote diffusion and adoption of these models and encourage further innovation.

In October 2004, CMS, AHRQ, the National Cancer Institute (NCI) and *Health Affairs* jointly convened a meeting of health care leaders and other experts in system design and payment to explore ways to organize health care delivery systems and put incentives in place to foster quality, efficiency, appropriate clinical processes, culturally and ethnically sensitive care, and shared decision-making. An environmental scan was conducted to lay the groundwork for discussion at this meeting; the report of this environmental scan is available online at www.cms.hhs.gov/researchers/demos/mma646/default.asp. Meeting participants focused on

the identification of promising system practices and prototypes for design change; the identification of strategies for disseminating the best designs within the current regulatory and payment environment; the identification of strategies for aligning financial and non-financial incentives to promote good design and promote the quality, safety, and efficiency of health care; and the promotion of partnerships within and beyond the Department of Health and Human Services to support the transformation of our nation's health care delivery systems. A report summarizing the presentations and discussion at the meeting can be found at www.cms.hhs.gov/researchers/demos/mma646/default.asp.

Using the extensive information gathered from these meeting as well as other discussions with industry experts, we have outlined the broad parameters of a demonstration design. We expect to issue a solicitation for demonstration applications later this year and to continue collaborative work with AHRQ and others to learn about ways to improve health systems. In the interest of ensuring that the requirements of the solicitation are not so narrow as to preclude worthwhile applications from being considered, we are issuing this request for information to solicit input from interested parties on a number of aspects of this demonstration.

Purpose and Vision

Summary of Law: Broadly stated, the goals of the Medicare Health Quality Demonstration are to:

- Improve patient safety;
- Enhance quality of care by increasing efficiency; and
- Reduce scientific uncertainty and the unwarranted variation in medical practice that results in both lower quality and higher costs.

The legislation anticipates that CMS can facilitate these overarching goals by providing incentives for system redesigns built on:

- Adoption and use of decision support tools by physicians and their patients, such as evidence-based medicine guidelines, best practice guidelines, and shared decision-making programs;
- Reform of payment methodologies;
- Measurement of outcomes; and
- Enhanced cultural competence in the delivery of care.

Vision of a Redesigned System: CMS has adopted "The Right Care for Every Person Every Time," in which the right care is, following the IOM's *Crossing the Quality Chasm*, safe, effective, efficient, patient-centered, timely, and equitable.

The Nature of System Redesign: The IOM report categorizes health care redesign at four levels: 1) the patient experience of care; 2) care delivery teams; 3) the organizations within which care delivery teams and patients interact; and 4) the regulatory and payment environment

within which the health care delivery system operates. Much can be and is being done by health care providers and organizations to redesign care delivery at the first two levels, within the existing regulatory and payment framework. For example, many hospitals are beginning to staff their intensive care units with intensivists to coordinate care across many consulting specialists who may be involved in the care of patients with very complex conditions. Some physician groups have adopted electronic patient records with such functionality as e-prescribing, registries, and automatic reminders for needed care. While such changes to the structure and processes of care are important and can make significant contributions to safety, quality and patients' overall experience of care; indeed, while they may be components of a redesigned system, they are not the focus of this demonstration.

Demonstration Design and Solicitation

Broad Design Features: CMS intends to use this demonstration to identify, develop, test, and disseminate major and multi-faceted improvements to the entire health care system. The focus will be on redesign projects that "bundle" multiple delivery improvements so as to introduce "system-ness" across the spectrum of care delivery – changes at the third level, across and even between organizations, supported by changes at the fourth level. Another way to say this is that redesign must make the system patient-focused and must undo the effects of a payment methodology that systematically fragments care while encouraging both omissions and duplication of care. While our environmental scan and the presentations at our October meeting showed that some organizations have managed to make some remarkable transformations despite the existing payment and regulatory system, there was also broad recognition that such successes will remain rare and tenuous without changes at this fourth level. At its "grandest," particularly if a demonstration project is conducted by a regional coalition and entails the participation of other payers besides Medicare, this demonstration affords CMS and awardees an opportunity to reinvent the health care delivery system.

Further, we are persuaded that such change cannot occur without the integration of health information technology consistent with the national health information infrastructure strategy and that:

- Informs clinical practice,
- Interconnects clinicians,
- Personalizes health care, and
- Improves population health.

In keeping with our view that this demonstration authority is intended to test models of basic health care system redesign, including payment reform, we note that the statute provides broad authority for us to waive both payment and non-payment provisions of the Medicare program. Therefore, we are not specifying particular models of health care systems that demonstration applicants must propose and test, but are looking to applicants to specify the models they believe they can successfully put into practice for the patients they serve in their communities.

Because we must be able to operationalize any demonstration project we choose to undertake, we have provided examples of a few of the payment models that we know we can implement. These are discussed briefly in a separate section below.

- We seek projects that will address a population that is defined either by geography, enrollment or some form of methodological assignment to a demonstration organization, not projects that are limited to subsets of patients, such as those with a particular medical condition. We are willing to consider demonstration models that involve multiple payers.

- Projects must be replicable and exportable to other locations or organizations and must have the ultimate potential to transform the health care delivery system in this country.

- We are also using this request for information to allow organizations that are considering applying for this demonstration to suggest alternative payment models for inclusion in our request for proposals. Because the projects conducted under this authority must be budget-neutral, such models must allow for comparison to what Medicare payments would have been in the absence of the demonstration. Alternative payment models should be designed to streamline care delivery and reward enhanced performance.

- We expect participating organizations to assume a degree of financial risk for failure to meet the budget neutrality requirements of the demonstration. This may be done through risk-sharing arrangements, putting fees at risk, providing spending target guarantees backed by reinsurance, escrow accounts or withholds.

- In accordance with the legislative mandate, the demonstration will focus on linking financial incentives to improvements in quality.

- Finally, we are specifically interested in those models of system redesign that require changes in the regulatory and/or payment environment or other aspects of the environment that CMS controls or influences to encourage enhanced performance.

Eligible Organizations: As stipulated in the enabling legislation, physician groups, integrated delivery systems, and regional coalitions of physician groups or integrated delivery systems are eligible to apply. Integrated delivery systems must include a full range of health care providers including hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent or contracted physicians.

Payment Models: Payments under the demonstration will be tied to cost savings, as well as improvements in process and outcome measures in the targeted population compared to a similar group or sample. Eligible organizations may propose a variety of payment methodologies as long as those methodologies are amenable to an evaluation methodology based upon Medicare claims data. Also, all proposals must guarantee budget neutrality.

Some examples of payment arrangements include a shared savings models, a guaranteed-savings model, and a capitation (or partial capitation) model. Below is a brief summary of these models. However, their descriptions here are for illustrative purposes only and are not meant to restrict the types of models that will be considered.

- Shared Savings – Under this model, savings to the Medicare program would be shared between the Medicare program and the demonstration site. Savings would be measured as the difference between the total costs under the demonstration for the targeted beneficiaries and total costs of beneficiaries assigned to a comparison group. Performance payments would be distributed based on a site's performance on quality measures. Any amount of the maximum quality bonus that is not earned by the participating organization would be retained by Medicare.

- Per Member Per Month Fee with Guaranteed Savings – Participating organizations would be paid a fee per beneficiary per month for services not currently covered under the Medicare program. Medicare savings would be calculated by comparing total Medicare payments, including the demonstration payments, for the targeted population to the total Medicare payments for the comparison group. To the extent that a demonstration organization fails to achieve the guaranteed savings, its fees would be at risk up to the amount of the savings shortfall.

- Capitation or Partial Capitation – Participating organizations might propose various forms of capitation for all or a portion of the Medicare services provided. Beneficiaries may or may not be enrolled in the system, but any enrollment would have to be voluntary on the beneficiary's part. Organizations would still have to demonstrate how the payment methodology would guarantee budget neutrality and reward performance on quality measures.

- Restructured Fee-for-Service Payments – Participating organizations might wish to propose alternative FFS payments in which, for example, monthly fees might be paid to physicians for managing the care of their patients coupled with reduced payments for individually billable services. Organizations would have to demonstrate how such a payment methodology would guarantee budget neutrality and reward performance on quality measures.

- Regional Capitation – Participating organizations may propose a regional capitation model whereby a single organization or regional consortium of organizations takes responsibility for and receives reimbursement for all clinical services to beneficiaries residing in their catchment area. Under this model, the organizations must demonstrate how they will be responsible for providing and/or coordinating services in the service area as well as how they will take responsibility for services rendered outside the service area or provided by organizations not part of the consortium. The organization or consortium must also demonstrate how the payment methodology would guarantee budget neutrality and reward performance on quality measures.

Applicants are welcome to propose their own payment methodologies as long as they explicitly define that methodology, how savings will be achieved, and how improvements in quality and efficiency will be accomplished. Also, all proposals must guarantee budget neutrality.

Demonstration Evaluation: The Medicare Health Care Quality Demonstration evaluation will be conducted by an independent evaluator.

Schedule: The solicitation of applications for this demonstration is being conducted in phases. After considering all comments received in response to this request for information, CMS will publish a solicitation or request for proposals. Two rounds of applications will be considered. For the initial round, proposals will be due 90-120 days after the solicitation is published, for implementation approximately 8 months later. Recognizing that some organizations forming new regional health care coalitions or newly implementing major system redesigns may require a longer period of time to develop a proposal, CMS will accept a second round of applications with a due date 11-12 months after the solicitation is published, for implementation about 8 months later. Over the two rounds, CMS plans to select 8-12 organizations to participate in this 5-year demonstration. We expect that no more than half of those will be selected for the first round.

Application Review: All applications will be reviewed by technical experts, and the Administrator will make the final selection of participants from among those applicants found to be the most highly qualified. All applications will be evaluated based upon criteria in the following areas:

- Problem statement
- Demonstration design
- Organizational structure and management
- Implementation plan
- Quality measurement and improvement
- Payment methodology and budget neutrality
- Project goals and feasibility of attaining objectives

Application Content

A proposal should address:

1. The payment system in fee-for-service treats all procedures as if they have equal merit and prices them exclusively on the basis of resources. Unsurprisingly, this leads to provision of an ever-growing number of services. The proposal should address how the proposed payment methodology leads to care that better fits the IOM goals for safe, effective, efficient, patient-centered, timely and equitable care.

2. Care of patients is extremely discontinuous across settings and even within settings. The proposal should consider mechanisms to make care more centered on the individual patient and integrative across providers, settings, and conditions. To that end, the proposal should contain a comprehensive description of how patients in the demonstration will be transitioned from one care setting to another.

3. Applicants should propose measures of quality and other outcomes that are evidence-based and widely used and are relevant to the areas in which they expect the demonstration project to have a measurable and significant effect. To facilitate cross-site learning and replicability, we will try to achieve as much congruity among measures as possible. Because participating

demonstration sites may propose somewhat different models and cover different types of clinical services, the quality and efficiency measures and metrics used by each site may vary somewhat. However, we encourage standardization of core measures across sites, to the extent this is feasible and will work with sites to encourage such standardization. We expect at least some of these measures to be chart-based and readily accessible from the sites' information technology systems. Others may be based on administrative data.

4. Health care information systems are inadequate within providers and even worse at the regional level. The project should incorporate adoption and use of information technology through means such as Regional Health Information Organizations (RHIOs) that will inform clinical practice, interconnect clinicians, personalize health care, and improve population health. Of particular interest are proposals to expand the interoperability of electronic health records (EHRs) across and among components of integrated delivery systems.

5. Different stakeholders lack mechanisms to collaborate effectively, leading to duplication and misalignment of requirements, overlapping but conflicting initiatives, and the absence of a common vision. The proposal should include mechanisms to enhance established partnerships, alliances, and collaboration and to set objectives and priorities for such collaboration.

6. Quality improvement tends very much to be an internal matter for providers, but there are strong indications that community-level efforts can be powerful and effective, especially in dealing with care transitions. We welcome proposals that build on collaborative community efforts to improve care and detail the quantifiable health improvements that the project will realize for specific identifiable patient populations.

7. Even with the growth of consumer information on quality, available information is not user-friendly, and few consumers understand it. Treatments are often based on provider preferences and training/specialty rather than a patient-centered and carefully considered choice among all available options. The proposal should address how the project will support patient decision-making to make it more informed.

8. The proposal should address how it will use payment incentives to encourage safer, more effective, more efficient, more patient-centered, more timely and equitable care.

Applications must include:

- A description of the project and the system redesign necessary to accomplish it, including the quantifiable health improvements for a specific and identifiable patient population

- Evidence in support of the redesign model being proposed and its ability to achieve the goals of this demonstration. This evidence should not only include findings from peer-reviewed journals, but should make reference to the cumulation of learnings, findings and tools (e.g., measurement instruments, intervention packages, training programs) that are being disseminated by CMS, AHRQ, NIH institutes, and other private and public organizations promoting the IOM goals

- A description of the waivers needed and why the project cannot succeed without them

- A description of the organization(s) participating in the project and the organizational framework within which they will operate so as to overcome the fragmentation that characterizes the current delivery system

- A description of the capability of the organization(s) to deliver the results the project is designed to achieve

- A plan for adoption, integration and use of health care information technology

- Evidence in support of budget neutrality and organizational willingness to assume financial risk for savings

- Evidence in support of potential generalizability of the findings to other organizations

- Evidence of willingness to freely share project information with other demonstration sites, the Department and other interested parties, and to participate in formal information exchanges

Requested Comments

We welcome your comments regarding this proposed demonstration solicitation. In particular, we are interested in your responses to the following questions:

- Are there particular delivery models that we should consider to achieve our goal of improving health care through system-wide change?

- How should a target population be defined and what role should enrollment play?

- Should area-level measures of performance be incorporated into the demonstration design and, if so, how?

- For the evaluation, how should comparison group members be identified?

- Are there other payment methodologies that we should consider?

- Is the timeline for submission of applications and implementation of programs reasonable?

- The language of Sec. 646 indicates that the Secretary "where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program." What types of information would applicants be willing to broadly disseminate to similar organizations? What roles would applicants envision for the Federal government and themselves if involved in a laboratory to study the implementation and effects of demonstrations? Federal roles might include provision of technical assistance,

provision of financial assistance for particular purposes, or convening of workshops for real-time learning and for sharing experiences, management tools, and methods. Applicant roles might include disseminating and teaching at gatherings of professionals from similar organizations.

- What services and tools might applicants benefit from using in planning and implementing their system changes, gathering information on progress toward goals, and learning from these findings and experiences? Should applicants search for and discover these tools and services on their own, or might they benefit from guidance from CMS, e.g., through web listing or referral to work by other agencies and organizations.

- CMS staff has met with representatives of many companies that have developed tools or services that they believe could enhance the health care provided to our beneficiaries, such as decision support tools, shared decision-making tools, and remote monitoring devices. Although we are not in a position to evaluate or endorse such products or services, we often refer these companies to CMS' partners (e.g., Medicare Advantage plans, disease management organizations, other demonstration sites). To the extent that such products or services may be useful to providers engaged in restructuring care delivery, we believe they might be most effectively incorporated into demonstration projects during the design phase. Therefore, we would consider collecting and posting on our website a limited amount of information from such companies about such tools and/or services.

    - Are vendors of such products and services interested in having such information posted?
    - Would such an inventory be helpful to prospective applicants?
    - What categories of services and tools would be useful to applicants (e.g., planning guides, diagnostic tools, measurement tools, shared decision-making tools, clinical decision support tools, electronic health/medical records, remote monitoring devices, cultural competence assessments)?
    - Is there information besides contact information and a brief (e.g., 100 words) description of the tool or service that applicant organizations would find useful?
    - Are there other sources of information that already exist and that might serve the same purpose and preclude the need to develop such an inventory? If so, what are they?