DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
[CMS-5017-N]

Medicare Program; Solicitation for Proposals for the Medicare Health Care Quality Demonstration Programs

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice for solicitation of proposals.

SUMMARY: This notice informs interested parties of an opportunity to apply to participate in the Medicare Health Care Quality demonstration. The goal of the demonstration is to improve the quality of care and services delivered to Medicare beneficiaries through system redesign that fosters best practice guideline usage; continuous quality and patient safety improvement; shared decision making between providers and patients; and the delivery of culturally and ethnically appropriate care. The demonstration will encourage coordination of Medicare services and reward eligible health care groups for improving health outcomes.

A competitive process will be used to select 8 to 12 health care organizations (i.e. physician group practices, integrated delivery systems, and regional coalitions of physician group practices and integrated delivery systems) to participate in the 5-year demonstration. The application solicitation will be conducted in two phases.

DATES: For the initial solicitation phase, applications will be considered timely if we receive them on or before 5:00 P.M. EST on January 30, 2006. For the second solicitation phase, applications will be considered timely if we receive them on or before 5:00 P.M. EDT on September 29, 2006**.** Applicants intending to submit a proposal for the second phase review should forward a letter of intent to the same address no later than January 30, 2006. The letter of intent should include an outline of the demonstration proposal, a description of the proposed organizational structure, a timeline for development and implementation of the proposed model, and a projected or desired date for submission of the application. This will enable us to better plan for the second phase of the solicitation, keep prospective applicants apprised of any new developments over the course of the solicitation process, and ensure that they have the latest information for preparing their applications.

ADDRESSES: Applications should be mailed to the following address: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Attention: Cynthia Mason, Project Officer, Office of Research, Development and Information, MDPG/DPPD, Mail Stop: C4-17-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

General Information: Please refer to file code CMS-5017-N on the application. Applications (an unbound original and 2 copies plus an electronic copy on CD-ROM)

must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of cover letter, the executive summary, resumes, forms, and supporting documentation.

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission. Applications postmarked after the closing date, or postmarked on or before the closing date but not received in time for the panel review, will be considered late applications.

Eligible Organizations: As stipulated in the enabling legislation, physician groups, integrated delivery systems, or organizations representing 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. Eligible organizations and coalitions may form a new corporate entity for the purpose of representing provider organizations or eligible organizations may designate an existing entity as their representative. However, the entity organizing the coalition and developing the demonstration proposal must be an eligible provider organization.

FOR FURTHER INFORMATION CONTACT: Cynthia Mason at (410) 786-6680, or by e-mail at mma646@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Requirements

Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amends title XVIII (42 U.S.C. 1395 et seq.) of the Social Security Act by establishing the Medicare Health Care Quality (MHCQ) Demonstration Programs.

The MHCQ demonstration will test major changes to improve quality of care while increasing efficiency across an entire health care system. Broadly stated, the goals of the MHCQ demonstration are to:

- Improve patient safety;
- Enhance quality;
- Increase 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.

As stipulated under the MMA, the MHCQ demonstration projects are intended to "...examine health delivery factors that encourage the delivery of improved quality in patient care, including -- (1) the provision of incentives to improve the safety of care provided to beneficiaries; (2) the appropriate use of best practice guidelines by providers and services by beneficiaries; (3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research; (4) encourage shared decision making between providers and patients; (5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources; (6) the appropriate use of culturally and ethnically sensitive health care delivery; and (7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources."

The MMA mandate creates an opportunity to implement a demonstration that addresses gaps in care quality and efficiency by combining system redesign – improvements in clinical and non-clinical processes and structures within systems and organizations – with payment changes that alter the financial incentives and disincentives faced by providers.

B. Studying the Issue

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 MHCQ demonstration 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 draft report of this environmental scan is available online at www.cms.hhs.gov/researchers/demos/mma646. 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.

In April 2005, we issued a Request for Information and held an Open Door Forum to solicit comments on the MHCQ demonstration design. Numerous industry representatives responded to our request. Their responses covered a broad range of subjects including definitions of eligible organizations, identification of beneficiary populations, and design and implementation of the demonstration models. Many of those comments have been incorporated into this solicitation.

C. Linking Quality and Financial Incentives

In recent years there has been an increased focus on the relationship between quality and cost. Managed care incentive-based payment models evolved as a means to combat rising health care costs, initially focusing on rewarding physicians for financial performance, and have recently focused on incorporating incentives for quality performance. Public and private organizations that provide health care benefits, individually and collectively, are using their purchasing power to affect improvement in the safety and quality of health care. Examples include The Leapfrog Group and Bridges to Excellence. In addition, the IOM report, entitled *Crossing the Quality Chasm: A New Health System for the 21st Century* (published by Health Care Services, National Academy Press in 2001), found that quality-related problems can result in waste and lead to inefficiencies, directly conflicting with incentives designed to reduce costs. Many of the report's 20 priority areas apply to a Medicare population (see section II.A. below).

Hence, we are interested in exploring the impact of a more direct alignment between provider compensation methods and quality improvement initiatives. Various methods have been proposed in the private and public sectors to accomplish this needed alignment and include pay-for-performance programs, population-based performance payment models, and shared-savings models. The MHCQ demonstration explicitly addresses this issue by providing the opportunity to identify, test, and evaluate aligning health care providers' compensation models with quality improvement goals for the Medicare population.

II. Medicare Health Care Quality Demonstration Programs

A. Purpose/Design

The MHCQ demonstration will test the ability of health care groups to implement major system changes that reallocate resources to improve quality and reduce costs of Medicare Parts A, B, and C. Each proposal is expected to address all of the IOM's Six Aims for Improvement.

- The proposed system redesign should include steps to improve patient safety in the delivery of care.
- The redesign should increase the effectiveness of the health care delivered, minimizing the over- and under-utilization of services through the use of best practice guidelines and other measures.
- Patient-centeredness in the delivery of care should be a priority with primary focus on patients' needs and comfort, including increased emphasis on patient education and development of self-care skills.
- The system redesign should improve the timeliness of care, significantly reducing delay in the delivery of needed health care services.
- The system redesign should emphasize ways of improving efficiency in care delivery and thus improving quality.
- The proposed system redesign should assure equity of care for all persons.

We are persuaded that such system redesign should include 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.

We would expect that a significant component of major system redesign would be the adoption and use of health information technology within practice settings and the promotion of clinical data exchange across and among practices within a community, prototypes for a national health information network.

Further, we would expect major system redesigns to incorporate significant improvements in various business processes to enhance the coordination and delivery of care.

The IOM report categorizes health care system 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. We are seeking proposals to implement broader system redesigns. For example, one frequently discussed need is the total system redesign for patient transitions across components of an integrated delivery system. While facets of the redesign might include enhancement of medical services in extended care facilities and use of electronic medical records to ensure consistency of care following transfers, the overall objective of the redesign would be the coordination of care for all patients regardless of where they might be receiving services at any given time across the entire system.

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.

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.

- 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. Applicants must include a detailed definition of the population targeted by the proposed project.

- We seek innovative approaches to system redesign. Projects should not duplicate the models of any of the existing Medicare care management demonstrations or pilot programs (see table in section II.A.4. below).

- We are willing to consider demonstration models that involve multiple payers. Applicants themselves will be responsible for developing a proposal for the participation of other payers in the demonstration and for enlisting their cooperation.

- 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. In turn, awardees must be willing to share system designs and findings with other organizations.

- In Section II.A.6., we have included some examples of possible payment arrangements under this demonstration, but other proposals will be considered. Alternative payment models should be designed to streamline care delivery and reward enhanced performance. 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.

- Participating organizations must 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, or 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.

1. Eligible Organizations

As stipulated in the legislation, organizations eligible to apply to implement and operate programs under the MHCQ demonstration are:

- Physician groups;

- Integrated delivery systems; or

- Organizations representing regional coalitions of physician groups or integrated delivery systems.

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.

Eligible organizations and coalitions may form a new corporate entity for the purpose of representing provider organizations, or eligible organizations may designate an existing entity as their representative. Therefore, a broker, a payer coalition, or another non-provider entity would not be eligible to apply unless it represents a regional coalition of physician groups or integrated delivery systems. We believe that Congress intended these demonstration programs to be initiated by the providers that would furnish services under the demonstration. We further believe that this demonstration can yield successful models only if providers and provider organizations drive the shape of this demonstration because, ultimately, it is they who must embrace delivery system redesign efforts and be committed to making them work.

2. Identification of Demonstration Population

The population to be served by this demonstration will be identified by the individual applicants. Populations may be defined by geography, enrollment, or some other form of methodological assignment to a demonstration organization. Given the fact that this is a demonstration testing system redesign, we would expect the population to encompass most, if not all, of the applicant's client base, as opposed to a subset of patients with a particular medical condition.

We are not establishing a minimum size for the demonstration population. The available beneficiary population will vary depending upon geographic location and provider group size. We are requiring that the population be of sufficient size to provide statistically valid results and that the identified population involve the entire provider system as opposed to only one facet of the organization.

If the organization intends to use some form of an enrollment model, the organization should fully describe the proposed model in the application, and enrollment by beneficiaries should remain voluntary. Even where no beneficiary enrollment is involved, beneficiaries should be notified of the organization's participation in the demonstration. Applicants should describe how beneficiaries will be notified of the demonstration.

3. Identification of Comparison Populations

In order to permit CMS to conduct an evaluation of the MHCQ demonstration, each site will need to have a comparison population. The most feasible means of identifying control groups will vary depending upon the type of model being tested. Control groups may be internal, identified via random assignment, or external to the demonstration population. Given the emphasis upon system-wide projects, we assume that many of the demonstration populations will entail the provider groups' entire patient base, thus

requiring a similar external population for evaluation of the program. Therefore, applicants should identify the population that they believe will be most similar to their demonstration population for purposes of program evaluation.

4. Identification of Geographic Areas

We are interested in a mix of proposals focusing upon both urban and rural areas and would like to test system redesign models in both types of communities. All geographic areas will be considered. However, we are interested in applications that do not conflict with currently operating fee-for-service (FFS) care management demonstrations or Chronic Care Improvement Program (CCIP) sites. Patients already assigned to a population-based model such as CCIP cannot be covered and have services paid for under two Medicare demonstrations or pilot programs. Depending upon the demonstration model proposed, running a MHCQ project in the same geographic area as CCIP or another FFS care management demonstration, even if the MHCQ enrollees cannot participate in the other demonstrations or programs, could confound the results of the MHCQ study by cross-contamination of control groups. MHCQ would be measured against the results of organizations running other demonstrations or programs. To the extent that these other projects are successful in reducing the costs of their enrollees, MHCQ organizations would have a more difficult time demonstrating measurable quality improvement, beneficiary and provider satisfaction, and savings. Moreover, we believe it would be inappropriate to cut into the potential enrollee pools of existing demonstrations or pilot programs to assign populations of beneficiaries to MHCQ organizations. Finally, if organizations participating in existing demonstrations or pilot programs apply for the MHCQ demonstration, they would have to terminate those projects when the new demonstration takes effect or explain how MHCQ would overlay or complement the existing projects.

The following table lists the current fee-for-service (FFS) care management demonstrations and pilot programs by state. Applicants who are unsure whether their proposed geographic area and/or model will conflict with an existing demonstration or CCIP site should contact CMS for more detail so they can eliminate any geographic or population overlaps prior to submission of their proposals.

FFS Medicare Care Management Demonstrations and Pilot Programs

State	*Demonstration/Pilot Program
Alabama	
Alaska	
Arizona	BIPA DM, MCCD
Arkansas	PGP, MCMP
California	BIPA DM, CMHCB, MCCD, MCMP
Colorado	
Connecticut	PGP
Delaware	
District of Columbia	CCIP, MCCD

Florida	LifeMasters, CCIP, CMHCB, MCCD
Georgia	CCIP
Hawaii	
Idaho	
Illinois	CCIP, MCCD
Indiana	MCCD
Iowa	MCCD
Kansas	CMHCB
Kentucky	
Louisiana	BIPA DM
Maine	MCCD
Maryland	CCIP, MCCD
Massachusetts	CMHCB, MCMP
Michigan	PGP
Minnesota	MCCD, PGP
Mississippi	CCIP
Missouri	CMHCB, MCCD, PGP
Montana	PGP
Nebraska	
Nevada	
New Hampshire	PGP
New Jersey	CMHCB
New Mexico	
New York	CCIP, CMHCB, MCCD
North Carolina	PGP
North Dakota	
Ohio	
Oklahoma	CCIP
Oregon	CMHCB
Pennsylvania	CCIP, MCCD, PGP
Rhode Island	
South Carolina	
South Dakota	MCCD
Tennessee	CCIP
Texas	BIPA DM, CMHCB, MCCD, PGP
Utah	MCMP
Vermont	PGP
Virginia	MCCD
Washington	CMHCB, PGP
West Virginia	
Wisconsin	PGP
Wyoming	PGP

* BIPA DM – Medicare BIPA Disease Management Demonstration
CCIP – Chronic Care Improvement Program
CMHCB – Care Management for High Cost Beneficiaries Demonstration
LifeMasters – Medicare Disease Management Demonstration

MCCD – Medicare Coordinated Care Demonstration
MCMP – Medicare Care Management Performance Demonstration
PGP – Physician Group Practice Demonstration

5. Program Characteristics

We are interested in receiving applications from organizations that have proven to be successful in applying innovative information and decision-making tools to meet the individual needs of participants and their providers, reduce fragmentation in patient information, and facilitate better communications between beneficiaries and their providers at the point of care.

We recognize that some of these tools and capabilities may be proprietary. We are not seeking ownership of the tools, protocols, materials, and capabilities, and we will work with awardees to ensure that the ownership of proprietary tools and capabilities is protected. Nonetheless, it is essential that we be able to conduct a thorough evaluation of the MHCQ demonstration to understand how the programs operate and assess their effectiveness. Therefore, awardees must agree to the following statement: "At any phase in the MHCQ demonstration, including at its conclusion, the awardee, if so requested by CMS, must deliver to the project officer all care management software, algorithms and associated documentation, as well as beneficiary health information, program operational methods, and other data used by the awardee in the course of performing the services pursuant to the MHCQ demonstration, to be used by CMS solely to further the purpose of MHCQ." These deliverables will not be subject to use for any other purpose without written permission of the awardee. All proprietary information and technology of the awardee (including the specific proprietary algorithms used by the awardee for MHCQ) are and remain the sole property of the awardee. We do not acquire (by license or otherwise, whether express or implied) any intellectual property rights or other rights to the proprietary information or technology.

Organizations must comply with all applicable laws, unless waived, and all waivers must be justified. In addition, it will be the responsibility of the MHCQ awardee to fulfill all requirements of any Institutional Review Board (IRB) to which the organization is subject.

6. Payment Methodologies

Medicare demonstrations are opportunities for providers to provide services to Medicare beneficiaries – either services modifying the existing Medicare benefit package or services that are paid differently or under different conditions from the regular Medicare benefit package. Payments under the MHCQ demonstration will be made for services rendered to Medicare beneficiaries and will be tied to cost savings, as well as improvements in process and outcome measures, increases in efficiencies, and reductions in costs 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. In addition, all proposals must assure budget neutrality and no duplication of payments for any existing benefits provided under Parts A, B, C or D. Current benefits available under any plan will be reviewed to make sure all demonstration payments represent a true augmentation of Medicare benefits, including prescription drugs. We will not be providing funding for start-up or other costs.

Some examples of payment arrangements include a shared-savings model, a guaranteed-savings model, and a capitation (or partial capitation) model. Below is a brief summary of these models. However, the 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, up to 50 percent of the 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. Performance payments will only be made to a single entity, the awardee. The awardee will be responsible for allocating any performance payments among affiliated organizations.

- 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 assure 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 assure 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 achieve budget neutrality and reward performance on quality measures.

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

7. Performance Standards

Under this demonstration, the focus will be on linking financial incentives to improvements in structure, process and outcome indicators of quality. This is consistent with the MMA mandate and encourages applicants to employ quality indicators most easily measured, commonly used, and most relevant to the medical care operations of the MHCQ organizations. We believe that the applicant's ability to manage patient care, especially clinical conditions afflicting Medicare beneficiaries, is critical to their ability to generate savings under the demonstration.

Demonstration participants will select a group of core quality indicators for use in measuring performance. Measures must be valid, relevant, peer reviewed, and commonly used. For example, the National Quality Forum (NQF) recommended national health care quality measurement and reporting priorities involving measures of infrastructure (i.e., information technology, patient safety), processes of care (i.e., care coordination and communication, care at end of life, immunizations, pain management, self-management, health literacy), and clinical conditions (i.e., asthma, cancer, pneumonia, depression, diabetes, hypertension, etc.).

8. Reconciliation Process

We will monitor clinical quality, beneficiary and provider satisfaction, utilization, and costs for purposes of interim payment adjustments and to perform final financial reconciliation at the end of the 5-year program period to determine any additional payment due to the organization or any refund due to the government from awardees in the event awardees fail to achieve agreed-upon performance guarantees over the 5-year program window. CMS reserves the right to track financial and non-financial performance on a periodic basis and to adjust payment if specified performance objectives are not being achieved.

9. Program Monitoring

CMS will conduct ongoing formative program monitoring throughout the period of program operations. The formative evaluation will be conducted collaboratively by CMS and MHCQ demonstration organizations to identify and address operational problems, and foster continuing improvement in program operations.

Organizations will be required to comply with CMS requests, including submitting program monitoring data and operational metrics, as well as hosting site visits. Program monitoring includes performance monitoring (on clinical quality, beneficiary and provider satisfaction and savings targets) and operational metrics. Organizations will be expected to provide CMS with ongoing program monitoring information by tracking various measures of program performance and operational metrics.

In addition, participating organizations will be expected to take part in learning laboratories or evaluation activities sponsored by CMS, AHRQ and/or the National Institutes of Health (NIH) for this demonstration and to share demonstration findings with other organizations.

10. Independent Formal Evaluation

We will hire an independent contractor for the formal evaluation of program results. The independent evaluator will study the experience of the participating beneficiary group in each area compared to the relevant control group to ascertain the ability of each program and individual element of each program to improve clinical quality, achieve high levels of beneficiary and provider satisfaction, promote efficient use of health care services, and produce savings for Medicare in the effected beneficiary group. Organizations will be expected to cooperate with the independent evaluator, to participate in case studies of their programs, and to track and provide agreed-upon performance data for participants as needed for the independent contractor's performance evaluation. A commonly acceptable standardized beneficiary and provider satisfaction survey instrument will be developed to compare satisfaction levels between the control groups and the participating beneficiary groups.

B. <u>Requirements for Submission</u>

1. Selection Process

A CMS review panel will evaluate all submitted applications based upon the application evaluation criteria listed in section II.C. of this solicitation and will recommend applicants to be considered for MHCQ demonstration awards. CMS may conduct site visits to selected applicants based upon the review panel recommendations.

The CMS Administrator will make the final selection of participants from among the most highly qualified candidates. Sites will be selected based on a variety of factors including organizational structure, operational feasibility, and geographic location.

Awardees will be subject to standard CMS terms and conditions, and may be subject to special terms and conditions that are identified during the review process. We expect to select up to 12 organizations to participate in the demonstration.

2. Application Requirements

Applicants must submit their applications in the standard format outlined in CMS's Medicare Waiver Demonstration Application in order to be considered for review by the technical review panel. Applications not received in this format will not be considered for review.

The Medicare Waiver Demonstration application follows this demonstration notice.

We must receive applications (an unbound original and 2 copies plus an electronic copy) as indicated in the **DATES** and **ADDRESSES** sections of this notice. Only applications that are considered "timely" will be reviewed and considered by the technical review panel. Applications must be typed for clarity and must not exceed 40 double-spaced pages, exclusive of the cover letter, executive summary, resumes, forms, and supporting documentation. An unbound original and 2 copies plus an electronic copy on CD-ROM must be submitted. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receive an application in the manner intended by the applicant (for example, collated, tabulated, color copies). Hard copies and electronic copies must be identical. Applicants must designate one copy as the official proposal.

At a minimum, applicants should ensure that their applications and supplemental materials include the information requested below by section of the application:

1. Cover Letter

2. Application Form

3. Executive Summary

The applicant should submit an Executive Summary that provides a summary of the key elements of the proposal (not to exceed four pages).

4. Rationale for Proposed Demonstration (Problem Statement)

Applicants should present the background and need for the proposed demonstration, and discuss the system-wide problems the proposal is intended to address. Applicants should describe the specific goals of the program and explain why and how the proposal will address the stated problems. Applicants should describe the demographic and other characteristics of the population that will be impacted by the proposed project. A discussion of potential problems that can arise in the process of implementing such a demonstration project should also be included.

5. Description of the Proposed MHCQ Demonstration Design

Applicants should describe the proposed program and how the proposed system changes will improve quality of care by increasing patient safety; improving the effectiveness, timeliness, and efficiency of that care; providing patient-centered care focused upon the needs and comfort of the patient; and assuring equity and cultural competence in the delivery of services. Also, the applicants should describe how the program will achieve savings or, at a minimum, budget neutrality. Applicants should address each of the following:

- Describe the proposed delivery system redesign and how such a redesign, in concert with changes in payment methodology and any other specific Medicare program waivers sought, will achieve the objectives of this demonstration.
- Describe the specific system changes to be undertaken and the circumstances under which they will be employed.
- Explain how the proposed design is unique and does not duplicate existing care management demonstrations or programs.
- Explain how the beneficiary population will be identified.
- Describe how a control group population for the evaluation will be identified.
- Describe the role the health care information system will play in the demonstration to improve access to necessary patient information and facilitate improvements in quality of care.
- Describe how the proposal will enhance patient-centered care and improve patient safety.
- Describe how the proposal will ensure culturally and ethnically appropriate care.
- Describe how data will be managed for this project.
- Describe the quality measures that will be used.
- Discuss the specific analyses to be undertaken.

6. Organization Structure and Capabilities

The proposal should describe how the applicant will organize and manage the project, how tasks will be sequenced and in what time frames, and what management control and coordination mechanisms will be used to assure the timely and successful conduct of this project. In particular, the proposal should address each of the following:

- Identify resources, indicate all tasks that will be subcontracted and how subcontracted work will be monitored, and demonstrate a well-developed approach for ensuring successful implementation, operation, and completion of the project.
- Describe the structure and functionalities of the health care information system to be employed in the demonstration.
- Indicate organizational capacity to effectively conduct this project, show availability of and access to requisite resources and facilities, including staff, consultant, and computer and technical equipment.
- Identify the authors of the proposal to ensure that the capability demonstrated by the thought and substance of the proposal will be applied to the study.

- Describe the anticipated functions and duties with respect to key personnel. Include a brief description of relevant training, experience, publications, and the anticipated degree of availability of key personnel for the duration of the project.
- Demonstrate buy-in of all caregivers and/or providers.
- Describe the formal relationship between individuals, organizations, partners, coalitions, etc., including documentation of agreement to participate by all parties involved.

7. Process and Outcome Improvement/Quality Assurance

Applicants must define the structure of quality indicators they are proposing to employ in the demonstration and describe how those indicators are to be used to improve patient care, describe the process for evaluating and monitoring performance (including examples of reports and profiles), and identify how aggregated Medicare claims data could be used. Applicants should describe the role of their health information system in measuring improvements in the quality of care provided. Applicants should also describe their process for monitoring and managing their quality assurance programs, including the structure and operation of the relevant oversight board. Finally, applicants should describe all quality goals they intend to achieve under this demonstration.

The applicant should develop and maintain a tracking system, required data collection instruments, reimbursement and savings experience, and periodic utilization reports. The proposal should, at minimum:

- Describe the systems and processes for monitoring clinical, financial, and operational performance;

- Identify key metrics collected; and

- Describe how the organization will use this information to continuously improve the proposed system redesign, correct deficiencies, and satisfy beneficiaries, providers, and/or payers.

The reports should be in a format agreeable to the CMS project officer.

8. Payment Methodology and Budget Neutrality

Applicants may propose a variety of payment methodologies for services rendered through the demonstration program. An organization may also propose more than one methodology.

- Applicants must explain the rationale and justification for the proposed rates and payment methodologies, assuring no duplication of payments for existing services.

- Applicants must describe how financial incentives will align with quality outcomes and how performance payments will be distributed.

- Applicants must assure budget neutrality based upon a comparison of Medicare claims for the target population to those of the comparison group.

- Applicants must supply documentation and assumptions supporting their projections of budget neutrality.

- In the event that budget neutrality is not achieved, applicants must explain how demonstration payments will be refunded up to the total amount of payments made to the demonstration organization in excess of Medicare payments made on behalf of the control group.

9. Demonstration Implementation Plan

An applicant should provide the implementation information requested in the waiver application as well as those items listed below.

- Provide a detailed schedule with timelines for all essential tasks.

- Describe modifications to protocols, services, outreach, education initiatives, timelines, etc., if any.

- Describe what process improvements the organization has made in the last 12 months as part of continuous quality improvement related to providers, patients, communication, health education and/or training, and information systems.

- Among the staff named and biographies provided, identify the person who will be the liaison to CMS for the MHCQ demonstration.

An applicant must be willing to participate in shared learning activities with other demonstration participants, other health care organizations, and HHS agencies. The applicant should describe plans for disseminating demonstration findings and for communicating with the CMS Project Officer to assure timely exchange of information and produce analyses and data reports to the specification of the Project Officer.

10. Supplemental Materials

The applicant may submit staff resumes, component participation agreements or other supporting materials relevant to the application proposal.

11. Evaluation Criteria

Technical review panelists will assess and score (using a scale of 100 total points possible) applicants' responsiveness using the following evaluation criteria.

a. Rationale for Proposed Demonstration (Problem Statement) (5 points)

The applicant clearly presents the background and need for the proposed demonstration. The proposal discusses the system-wide problems, the specific goals of the program and why and how the proposal will address the stated problems. The description includes the demographic and other characteristics of the population that will be impacted by the proposed project, and identifies any potential problems that can arise in the process of implementing such a demonstration project.

b. Proposed MHCQ Demonstration Design (25 points)

The proposal provides clear and convincing evidence that the demonstration proposed will improve quality of care through increased efficiency across an entire health care system. The proposal has been developed by the medical care providers who will be instituting the system-wide changes. The targeted beneficiary population encompasses the entire health care system and will likely benefit from the changes. The role of enhanced information systems has been thoroughly described.

The application describes how the proposed model will integrate health information technology, decision support and shared decision-making tools to:

- Improve patient safety;
- Increase the effectiveness of care delivered;
- Refocus delivery systems to enhance patient-centered care;
- Improve timeliness in the delivery of care;
- Improve the quality of care through increased efficiency in care delivery; and
- Ensure care is equitable as well as culturally and ethnically appropriate.

c. Organization Structure and Capabilities (20 points)

- The organizational structure is in place to successfully implement and operate the proposed program.

- The organization has sufficient staff, systems, and other resources to organize, plan, implement, and evaluate all of the proposed clinical and financial components of the program.

- The leadership has demonstrated the ability to influence and direct clinical practice to improve efficiency, processes and outcomes.

- The organization has effective procedures to monitor use of appropriate health services and to control costs of health services to achieve demonstration objectives.

- The organization has in place and makes effective use of health information technology to improve efficiency and quality of care.

- Administrative arrangements are in place to distribute financial incentives to

affiliated entities.

d. Process and Outcome Improvement/Quality Assurance (20 Points)

- A physician-directed component oversees an ongoing action-oriented quality assurance program. The component is accountable for the quality assurance program and any delegated functions, and has processes for communicating activities to relevant parties.

- The quality assurance program establishes system-wide performance standards for safety, quality of care and services, cost effectiveness, and process and outcome improvements.

- The quality initiatives are clearly defined, and dedicated personnel are responsible for implementing, monitoring, and integrating changes into practice. Health information systems are used effectively to monitor and measure changes in quality of care.

- Processes are in place for implementing and monitoring corrective action plans.

- Relevant process and outcome measures are monitored, performance assessed, and processes for sharing results and promoting accountability are in place.

- Patient safety and equity of care is a focus of the organization with executive responsibility for the demonstration.

e. Payment Methodologies (15 points)

The proposal describes or demonstrates clear and convincing evidence that the proposed demonstration payments, shared savings arrangements, and performance guarantees are appropriate to improve quality of care and to reduce aggregate costs to Medicare, including:

- Justification and explanation of any proposed demonstration fees or payments;

- Reasonableness of the proposed demonstration fees, shared savings arrangements, and savings guarantees;

- Reasonableness of the applicant's estimates of the expected net Medicare savings; and

- Financial solvency and an ability to compensate Medicare in the event the organization fails to meet its performance targets.

The application includes information and assumptions supporting budget neutrality to enable CMS to prepare waiver cost projections for submission to the President's Office

of Management and Budget (OMB).

f. Demonstration Implementation Plan (15 Points)

- The organization understands demonstration principles and goals and objectives.

- The organization has clearly defined an implementation plan with measurable goals and objectives to improve patient safety, increase effectiveness of care, enhance patient-centered care, improve timeliness of care, improve the quality of care through increased efficiency, and ensure care is equitable.

- The organization has sufficient infrastructure (for example, staff and systems) to implement, monitor, evaluate, and report on the demonstration.

- The organization has provided convincing evidence of successful results in implementing similar activities.

- The organization is committed to exchanging information with other demonstration participants and is willing to share information with other health care entities.

12. Final Selection

The CMS Administrator will select participants from among the most highly qualified candidates. Sites will be selected based on a variety of factors including organizational structure, operational feasibility, and geographic location. Under no circumstances will candidates be selected if they cannot demonstrate that their proposals are, at a minimum, budget neutral. Awardees will be subject to our standard terms and conditions, and may be subject to special terms and conditions that are identified during the review process. We reserve the right to conduct site visits before beginning the demonstration. We expect to select up to 12 health care groups to participate in the demonstration.