CARE MANAGEMENT FOR HIGH-COST BENEFICIARIES DEMONSTRATION SOLICITATION

This solicitation describes the process by which eligible health care organizations may apply to implement and operate a care management demonstration serving high-cost beneficiaries in the original Medicare fee-for-service (FFS) program. This voluntary demonstration is part of an effort to develop and test multiple strategies to improve the coordination of Medicare services for high-cost FFS beneficiaries.

Organizations eligible to apply to implement and operate a care management site under the demonstration include: (1) physician groups; (2) hospitals; and (3) integrated delivery systems. Other organizations may apply but only as part of a consortium that includes physician groups, hospitals, or integrated delivery systems.

For information concerning this initiative, contact Cynthia Mason, CMS Project Officer, at (410) 786–6680, or cmhcbdemo@cms.hhs.gov.

Applications must be received on or before 5:00 p.m. EST on January 4, 2005, to be considered.

ADDRESSES: Mail applications to:

Centers for Medicare & Medicaid Services,
Attention: Cynthia Mason,
Mail Stop: C4-17-27,
7500 Security Boulevard,
Baltimore, Maryland 21244.

Because of staff and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail.

FORMAT: Applicants must submit a completed Medicare Waiver Application. Application forms may be found online at: http://www.cms.hhs.gov/researchers/demos/cmhcb.asp. Please refer to the file code **CMS-5015-N** in the upper right hand corner on your application cover page. Detailed instructions for completing and submitting applications appear with the application form and are supplemented by information in the "Requirements for Submission" section of this solicitation.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Health and Human Services (DHHS) is developing and testing multiple strategies to improve the

coordination of Medicare services for beneficiaries with high-cost conditions. However, one approach which remains to be studied is intensive management for high-cost beneficiaries with various medical conditions to reduce cost as well as improve quality of care and quality of life for those beneficiaries. Therefore, the Centers for Medicare & Medicaid Services (CMS) is interested in proposals to restructure care or enhance the management of care for beneficiaries with costly medical conditions. It is anticipated that organizations will serve high-risk beneficiaries with a variety of medical conditions and that the vast majority of beneficiaries participating in the demonstration will have multiple conditions. One organization will be selected per area to offer services to eligible beneficiaries. Beneficiary participation in the programs will be voluntary and will not change the amount, duration or scope of participants' fee-for-service (FFS) Medicare benefits. FFS Medicare benefits will continue to be covered, administered and paid under the traditional FFS Medicare program. Programs will be offered at no charge to the beneficiary. Organizations chosen for the demonstration will not be able to restrict beneficiary access to care (for example, there can be no utilization review or gatekeeper function) or restrict beneficiaries to a limited number of physicians in a network.

Applicants may propose to serve one or more areas but must adjust their proposed service areas to ensure that the population is of an appropriate size to ensure statistically significant results. Also, to avoid any overlap between the current FFS care management demonstrations or the Chronic Care Improvement Programs (CCIP), it will be necessary to exclude from the Care Management for High-Cost Beneficiaries (CMHCB) demonstration population any beneficiaries who meet the criteria to participate in existing demonstrations or CCIP.

Organizations may be paid a monthly fee per participant and/or participate under a gain-sharing arrangement based on Medicare savings; however, fee and gain-sharing payments will be contingent on improvements in clinical quality of care, beneficiary and provider satisfaction, and savings to Medicare in the intervention groups compared to control groups. The planned duration of the CMHCB demonstration is three years.

Widespread failings in the management of care for high-cost beneficiaries are a major national concern. Many of these failings stem from systemic problems rather than lack of effort or intent by providers to deliver high quality care. Medicare beneficiaries are disproportionately affected, because they frequently experience complications and acute exacerbations of chronic diseases requiring care that can be

complex and very costly. (Anderson, G. Testimony before the Subcommittee on Health of the House Committee on Ways and Means, Hearing on Promoting Disease Management in Medicare. 16 April 2002. www.partnershipforsolutions.org/DMS/files/4_16_02_testimony.doc). Beneficiaries who have multiple progressive chronic diseases are a large and costly subgroup of the Medicare population and typically receive services from multiple providers. Controlling their conditions successfully may require ongoing guidance and support beyond individual provider settings.

The Institute of Medicine's landmark report, Crossing the Quality Chasm: A New Health System for the 21st Century (Nation Academy Press, 2001), highlighted the challenges of assuring that patients with major high-cost conditions receive adequate care. The current health care delivery system is structured and financed to manage acute care episodes, not to manage and support individuals with costly long-term diseases. Providers of care are organized and paid for discrete services (for example, visits, immunizations, tests) provided in discrete settings (for example, hospitals or physician offices). Some literature supports an argument that provider incentives favor focusing on each patient only while he or she is within the provider's care setting. (Todd, W. and Nash, T., eds. Disease Management, A Systems Approach to Improving Patient Outcomes). Patient care can be fragmented and poorly coordinated and patient information difficult to integrate among settings as patients move from one care setting to another. Providers may lack timely and complete patient clinical information to fully assess their patients' needs and to help prevent complications. Ongoing support to beneficiaries for managing their conditions outside their physicians' offices or even restructuring care to optimize both quality and satisfaction is rare.

II. Provisions of This Solicitation

A. Purpose/Design

This demonstration is intended to test models of care management for high-cost beneficiaries under the Medicare FFS program, incorporating relevant features from traditional disease management programs, but allowing sufficient flexibility for CMS and the awardees to adapt the design of CMHCB programs to meet the unique needs of the high-cost Medicare population. For some beneficiaries with high-cost conditions, the restructuring of the care management plan to integrate provider services in the program and to deliver those services in non-acute care locations such as the

beneficiary's home could significantly improve the beneficiary's quality of life while simultaneously reducing costs. Under the CMHCB demonstration, CMS hopes to test a variety of models such as intensive case management, increased provider availability, structured chronic care programs, restructured physician practices, and expanded flexibility in care settings to deliver care to high-cost beneficiaries with multiple conditions.

Organizations will have the latitude to stratify targeted beneficiaries according to risk and need and to tailor interventions to the unique needs of their targeted Medicare beneficiaries, including self-care and caregiver support, care coordination, education, and use of in-home medical services and monitoring devices as appropriate.

The organizations will be required to agree to assume financial risk in the event of failure to meet agreed upon performance guarantees for clinical quality, beneficiary and provider satisfaction and savings targets. That financial risk will include all fees and gain-sharing payments.

1. Eligible Organizations

Organizations eligible to apply to implement and operate care management programs under CMHCB include:

- Physician groups;
- Hospitals; or
- Integrated delivery systems.

Other organizations may apply, but only as part of a consortium that includes physician groups, hospitals, and/or integrated delivery systems which would play a major role in the operation of the proposed CMHCB demonstration. Eligible organizations must be capable of providing ambulatory health care services.

2. Identification of Intervention Groups

We will identify beneficiaries who may benefit from CMHCB. An eligible beneficiary for the CMHCB demonstration is defined as a FFS beneficiary within the group accounting for high Medicare expenditures and having high risk scores using the Hierarchical Coexisting Condition (HCC) risk adjustment model.

Through analysis of Medicare historical claims data, we will prospectively identify eligible beneficiaries in each geographic area served by an awardee. From this group, we

will then identify those beneficiaries who meet the parameters of the specific model proposed by the CMHCB organization (henceforth referred to as a "target population"). In order to achieve our clinical and financial objectives within the 3-year demonstration window, we have decided to focus on beneficiaries who have high HCC risk adjustment scores and were high-cost cases in the year prior to the commencement of the demonstration. Also, to be eligible for inclusion in a target population under CMHCB, Medicare beneficiaries must be enrolled in Parts A and B and have Medicare as primary payer.

While we have outlined our plans to identify target populations, organizations may propose their own approaches for targeting high-cost beneficiaries. However, in order to be considered, any alternative targeting proposal must be accompanied by a justification.

As part of the process for identifying beneficiaries who might benefit from CMHCB, we have established that the following groups of beneficiaries will be excluded from the demonstration, because coordination of Medicare services is already an integral component of these programs. We will not consider beneficiaries who are currently or become enrolled in any of the following:

- Medicare Advantage (Medicare+Choice) plan;
- Chronic Care Improvement Program (CCIP); or
- Another CMS FFS coordinated care, physician group practice or disease management demonstration.

Also, we will not consider beneficiaries who are currently enrolled in a hospice program although demonstration participants who subsequently enroll in such a program may continue in the demonstration.

Detailed documentation on the inclusion criteria above and a more detailed explanation of the identification methodology will be included with the dataset CMS will provide applicants to prepare their fee proposals. (See Section II.B. of this solicitation for further details on the fee proposal process.)

For each target population, we will randomize individual eligible beneficiaries into intervention and control groups. Random assignment is intended to ensure comparability on factors that could affect performance improvement and overall health care costs. Should random assignment be infeasible for certain care management models, we would consider identifying a matched population of eligible beneficiaries for the control

group. The size of the population assigned to the intervention group is expected to vary based on the size of the savings that the applicant credibly proposes to achieve and the variability of claims expenses within the target population. In general, the larger the savings proposed and the more homogeneous the claims experience of the target population, the smaller the group that will be required. Table 1 offers a guideline for applicants to consider when developing their proposals.

Table 1
Enrollment guidelines*

	Proposed Savings (Net of Fees)		
C.V.**	5%	10%	15%
0.6	1,789	448	199
0.8	3,180	795	354
1.0	4,969	1,243	553
1.5	11,179	2,795	1,243

* The table displays the size of the intervention group required to demonstrate a specified level of proposed savings given the variability of claims cost in the target population. Because both an intervention and a control group must be formed, the target population must be at least twice the figures displayed.

** Coefficient of variation (CV) of claims cost for the target population. The CV is simply the standard deviation of claims divided by the average claims cost for the target population. Thus, if the target population has an average claims cost of $1,500 per person per month with a standard deviation of $1,800, the CV would be 1.2.

As this table suggests, an applicant that proposes to achieve small savings for a population that exhibits large variability in claims experience will need to reach out to a large number of beneficiaries. Its application will need to demonstrate that there is a sufficiently large target population in the geographic area it proposes to serve to form both an intervention group and a control group, that it will be able to enroll a sufficient number of beneficiaries in its program, that it has the capacity to provide its services to the enrolled population, and that Medicare can credibly expect it to achieve the proposed reduction in claims expenses.

An applicant may be able to reduce the size of the population that it must enroll by targeting a population that shows a high degree of homogeneity in claims experience, by achieving a large percentage reduction in claims experience, or both. Applications should include credible evidence to support the

use of specific targeting criteria and savings assumptions. We anticipate that typical savings will be in the range of 10 percent and that the CV for the target population will be between 0.8 and 1.5, yielding an estimate for required enrollment in the intervention group of between 800 and 2,800.

In addition, we may request that the applicant adjust the size of the proposed geographic area to ensure that the population is of the appropriate minimum size for evaluation purposes or to address other issues like conflicts with Medicare FFS demonstrations and CCIP sites. If the applicant and CMS cannot come to an agreement on the size and boundaries of the target population, CMS will reject the proposal.

3. Identification of Geographic Areas

We are interested in applications that target populations that do not conflict with currently operating FFS care management demonstrations or CCIP sites. (See Table 2 which contains a list of the FFS care management demonstration areas. CCIP locations are not yet available.) Running a CMHCB project in the same geographic area as CCIP or another FFS care management demonstration, even if the CMHCB enrollees cannot participate in the other demonstrations or programs, could confound the results of the CMHCB study by cross-contamination of control groups. CMHCB 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, CMHCB 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 enrollee pools of existing demonstrations or programs for potential enrollees in order to assign populations of beneficiaries to CMHCB organizations. Applicants who are unsure whether their proposed geographic area will conflict with an existing demonstration or CCIP site should contact CMS for clarification so they can eliminate any geographic overlaps prior to submission of their proposals.

Table 2
Demonstration Areas

State	Medicare Fee for Service Beneficiaries (a)	Geographic Areas with Current Demonstrations (b)
United States	34,717,973	
Alabama	661,747	

State	Medicare Fee for Service Beneficiaries (a)	Geographic Areas with Current Demonstrations (b)
Alaska	45,728	
Arizona	474,227	AZ
Arkansas	436,271	AR
California	2,557,305	CA
Colorado	339,159	CO
Connecticut	454,662	S Central CT
Delaware	114,806	
DC	73,382	DC
Florida	2,240,227	N FL
Georgia	927,667	
Hawaii	116,160	
Idaho	158,301	
Illinois	1,535,043	Rural / E IL
Indiana	854,548	Central / Western IN
Iowa	474,090	NE IA, NW IA
Kansas	371,539	
Kentucky	622,181	
Louisiana	543,327	Corridor I-49
Maine	225,477	ME
Maryland	651,698	Montgomery County, DC Suburbs, Baltimore
Massachusetts	768,883	MA

State	Medicare Fee for Service Beneficiaries (a)	Geographic Areas with Current Demonstrations (b)
Michigan	1,376,774	MI
Minnesota	596,098	E Rural MN, S Central MN
Mississippi	430,625	
Missouri	764,550	SW MO, St. Louis
Montana	142,428	SE MT
Nebraska	251,062	
Nevada	176,387	
New Hampshire	176,330	SW NH
New Jersey	1,089,135	
New Mexico	211,363	NM
New York	2,327,080	NYC
North Carolina	1,141,084	NW NC
North Dakota	104,775	
Ohio	1,497,640	
Oklahoma	473,529	
Oregon	336,477	
Pennsylvania	1,623,162	Eastern PA, Central NE PA
Rhode Island	117,890	
South Carolina	597,582	
South Dakota	122,324	SD
Tennessee	829,852	NE TN

State	Medicare Fee for Service Beneficiaries (a)	Geographic Areas with Current Demonstrations (b)
Texas	2,112,410	Houston, Urban / S TX
Utah	210,115	UT
Vermont	92,798	E VT
Virginia	914,745	SW VA, Richmond
Washington	616,018	W Central WA
West Virginia	324,294	
Wisconsin	769,142	N Central WI
Wyoming	67,139	N WY

Sources:

Health Insurance Reform Project, George Washington University: Analysis of 5 percent Standard Analytic File (SAF), Denominator Files, Number of FFS Enrollees by State.

CMS, Office of Research, Development and Information.

4. Outreach to Eligible Beneficiaries

Beneficiary participation in CMHCB will be strictly voluntary. Eligible beneficiaries assigned to the intervention group for the site will be notified of the opportunity to participate through a letter from the Medicare program. The letter will provide a description of the program and give the beneficiary an opportunity to decline to be contacted by the CMHCB organization. The letter will detail how the beneficiary can obtain further information about the program. The list of those beneficiaries in the intervention group not declining to participate will then be forwarded to the CMHCB organization for follow-up. We will then expect each organization to contact the intervention group beneficiaries to describe the program, confirm participation, and initiate CMHCB services. Beneficiaries who confirmed participation will be presumed to be participants until they either become ineligible (for example, join a Medicare Advantage plan) or notify the CMHCB organization or CMS that they no longer want to be contacted by the organization. The beneficiary may terminate participation at any time.

We will provide CMHCB organizations with historical Medicare claims data and other information on the intervention group beneficiaries. Organizations will use the data for outreach and preliminary assessment of beneficiary risk levels and support needs. We will expect applicants' proposals to specify detailed descriptions about their organizations' outreach protocols, including for example, frequency and number of outreach attempts, and how the organization will assure that outreach efforts are respectful of the beneficiary. The initial "outreach period" will consist of 6 months. We reserve the right to negotiate limits on the number and frequency of outreach attempts during the outreach period, and may specify that organizations will be required to cease further outreach efforts after the initial outreach period.

Organizations will be required to maintain records of beneficiary contact and confirmation of their participation in the program. We will also require that awardees report beneficiary eligibility and participation status (that is, whether a beneficiary declined to participate or terminated participation) on a regular basis.

Programs will be evaluated based on health and cost outcomes of their entire intervention group, including those beneficiaries who chose not to be contacted, those beneficiaries who dropped out of the program at any time, and those beneficiaries the organization was unable to reach, over time and as compared to control groups.

5. Program Characteristics

Participation in CMHCB will not—

- Expand the amount, duration or scope of a beneficiary's FFS Medicare benefits;
- Provide an entitlement for participation in a CMHCB demonstration; or
- Provide for any hearing or appeal rights with respect to a CMHCB project.

Additionally, Medicare beneficiaries will continue to have access to care and the same freedom of choice of providers as they do currently. We also plan to provide regularly updated claims data to awardees for their assigned populations to support ongoing project operations.

We are particularly interested in programs that have a track record of success in providing care management, in engaging beneficiaries' personal physicians and other providers in information sharing and in working with beneficiaries' family members and with other organizations that serve the proposed target populations. We are interested in receiving applications from organizations that have proven to be successful in applying innovative information tools to meet the individual needs of participants and their providers, reduce fragmentation in patient information, and facilitate better communications between high-cost 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 confidentiality of proprietary tools and capabilities is protected. Nonetheless, it is essential that we be able to conduct a thorough evaluation of the CMHCB demonstration to understand how the programs operate and assess their effectiveness. Therefore, awardees must agree to the following statement: "At any phase in the CMHCB demonstration, including at its conclusion, the awardee, if so requested by the project officer, must deliver to CMS 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 CMHCB demonstration, to be used by CMS solely to be used to further the purpose of CMHCB." 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 CMHCB) 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, including but not limited to privacy laws and the Health Insurance Portability and Accountability Act (HIPAA).

6. Billing and Payment

We will consider various payment proposals based upon the organizations' demonstration models.

An applicant may propose to charge an administrative or care management fee on a per member per month (PMPM) basis.

An applicant may propose to share in the savings that it generates for Medicare.

An applicant may propose a combination of the above or other alternative.

Claims for medical services provided to beneficiary participants by non-demonstration providers as well as demonstration providers will continue to be covered, administered, and paid under the Medicare FFS program. Any monthly PMPM rate paid to CMHCB organizations for providing care management support to participants will be considered a program administration or care management fee, and no beneficiary coinsurance amount or deductible liability will be applied. No separate payments will be made for program start-up funds, evaluation costs, travel, capital investments, or data collection. All such expenses, along with any other program costs, should be factored into the PMPM fee or gain-sharing proposal.

7. Performance Standards: Clinical Quality, Beneficiary and Provider Satisfaction and Savings Guarantees

Each agreement with an organization will specify performance standards for improving clinical quality, increasing beneficiary and provider satisfaction and achieving savings. The performance standards for clinical quality should include any condition-specific performance measures that the National Quality Forum or CMS has endorsed for all patients with relevant diagnoses. As part of the application process, we will require applicants to set forth their projections for clinical quality improvement and savings in the intervention group on a year-to-year basis and as compared to the control group. The projections set forth by organizations in their applications and agreed upon by CMS may be included in their CMHCB agreements as standards that will be used in monitoring performance. Also, each agreement will provide for reduction in fee and gain-sharing payments in the event the Secretary determines that the organization failed to meet its agreed-upon performance standards.

Applicants will be required to propose performance guarantees for the first two performance standards, quality improvement and beneficiary and provider satisfaction, and propose payment adjustment amount(s) and methods of liability calculation to be applied in the event of failure to meet the proposed quality improvement and satisfaction guarantees. The proposed guarantees will be evaluated as part of the review of proposals. Performance guarantees, liability calculation methods, and payment amounts agreed upon by us will be

included in agreements with awardees. We may terminate or scale back the size of a program after 18 months of operation if the Secretary determines the organization is not demonstrating significant progress in improving clinical quality and beneficiary and provider satisfaction. Provisions relating to termination for non-performance, including the methodology used to determine any fees to be returned to us, will be specified in the CMHCB agreements. It is important to reiterate that awardees' performance will be measured on the entire intervention group (which includes beneficiaries who declined to participate, those who dropped out of the program at any time and those whom the organization was unable to reach, for all months in which they were eligible to participate).

For the third performance standard, savings, each organization will be required to guarantee that the total of Medicare claims and demonstration care management fees for beneficiaries in the intervention group will be no more than 95 percent of the amount that total Medicare claims payments would have been absent CMHCB, as measured by claims for the corresponding control group over a 3-year period (organizations will be given the opportunity to propose payment and savings guarantees structures, as described further in section II.B.8 of this solicitation). The Secretary will ensure that each organization's application satisfies the budget neutrality requirement. Beginning in 2006, beneficiaries will have the opportunity to purchase Medicare prescription drug coverage under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173). Therefore, effective January 1, 2006, we intend to include Medicare drug expenditures in the calculation of total Medicare expenditures for both the intervention and the control groups.

Organizations must assume financial risk for performance under CMHCB agreements. We are establishing that, in the event that 5 percent net savings is not achieved over the 3-year program window, the awardee will be required to refund to the government the amount of excess expenditures made under CMHCB, up to the full amount of the any care management fees paid to the awardee. By the same token, failure to achieve at least a 5 percent net savings will result in the forfeiture of all gain-sharing payments. Gain-sharing proposals will be considered only for net savings amounts in excess of 5 percent, and we reserve the right to cap the total amount of such payments. We reserve the right to withhold a portion of the organization's fee to ensure budget neutrality. Also, we may require organizations to make fee refunds to the

government based on interim performance monitoring results or we may specify in agreements with organizations some other mechanisms to limit our exposure, but the final financial settlement will be based on 3-year program performance.

Throughout the CMHCB demonstration, we, with the cooperation of each organization, will monitor Medicare benefit expenditures using Medicare administrative claims records. Net savings will be calculated by comparing the average Medicare expenditures per person per month, including program fees, for the identified intervention group (including those who declined to participate, those who could not be reached and those who terminated participation) to the average Medicare expenditures per person per month for beneficiaries in the control group for the targeted population. All months for which a beneficiary was eligible to participate in the intervention or control group will be included, regardless of the number of months a beneficiary actually participated in the program.

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 3-year program period to determine any gain-sharing 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 3-year program window.

9. Program Monitoring

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

Organizations will be required to cooperate with us, including submitting performance monitoring data and operational metrics, as well as hosting site visits as requested. Program monitoring includes both performance monitoring (on clinical quality, beneficiary and provider satisfaction and savings targets) and operational metrics (including but not limited to outreach and engagement rates, and management information). Organizations will be expected to provide us with ongoing program monitoring information by tracking various measures of program performance and operational metrics.

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 intervention group in each area compared to the relevant control group to ascertain the ability of each program and individual elements 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 intervention 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 contactor'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 intervention groups.

B. Requirements for Submission

1. Selection Process

To assist organizations in preparing their PMPM rate or gain-sharing proposals, we will provide them with a de-identified data set of Medicare claims information for a national sample of beneficiaries who meet the criteria for CMHCB. This data set will be available on CD-ROM. Prior to receiving the data on CD-ROM, applicants will be required to download, sign and mail to CMS a Data Use Agreement that will be posted on the CMS website. The applicant will analyze the data and submit an application and financial proposal, including proposed target population, geographic area, PMPM fees, gain-sharing arrangements and performance guarantees. Organizations should specify the size of their proposed intervention group and provide their statistical power calculations to support that number of beneficiaries. We reserve the right to negotiate and limit the size of the population. Organizations will have 90 days from the date the data are made available to submit applications.

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 a CMHCB demonstration award. CMS may conduct site visits to selected applicants based upon review panel recommendations.

The Administrator will make the final selections. Only one awardee will be selected for any given area, and will be provided with HIPAA compliant identified data once selected. The Administrator reserves the right to negotiate the size of the population and the number of areas.

2. Application

Applicants must submit completed applications following the standard format outlined in our Medicare Waiver Application in order to be considered for review by the technical review panel. The application is available online at: http://www.cms.hhs.gov/cmhcb. Applicants should also include in their applications the information requested below related to each section of the Application. Only applications that follow the standard Medicare Waiver Application format and include the information requested in the Application instructions and in this solicitation will be reviewed. All questions must be submitted to us in writing.

As noted in the Application instructions, applications must be typed using 12-point font with 1-inch page margins. The applications must not exceed 40 double-spaced pages, exclusive of the cover letter, executive summary, forms, and appendices. An unbound original, 2 copies, and 3 electronic copies on CD-ROM of the Application must be submitted. Applicants may, but are not required to, submit a total of 10 copies to assure that each reviewer receives 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.

Applications will be reviewed by the technical review panel only if they are received on or before 5:00 p.m. EST on January 4, 2005. 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

4. Rationale for Proposed Geographic Area and Target Population (Problem Statement)

Applicants should describe the geographic area(s) they propose to serve (for example, State, metropolitan statistical area) and explain the rationale for targeting each proposed

geographic area. Applicants should describe the demographics and other characteristics of the beneficiary population they intend to serve. Applicants should specify the size of the population they are able to serve. The current health care delivery system and access to care in the proposed geographic area should be briefly described. Obstacles to providing care management services in the area should also be explained.

Applicants need not provide a description of Medicare coverage and payment or discuss implications of changes as called for in the standard application instructions as neither coverage nor payment for Medicare benefits and services will change under CMHCB.

5. Description of CMHCB Demonstration Design

Applicants should describe the proposed program and explain how the proposed interventions will improve clinical quality, beneficiary and provider satisfaction, and achieve savings for the intervention group.

In this section, applicants should explain how the proposed demonstration will address each of the following activities (see section II.C. of this solicitation for further details on the application evaluation process):

A plan for outreach.

Describe how the program will actively engage participants and the rate at which the applicant expects to ramp up the program. Provide a detailed description of outreach protocols, including, for example, frequency and number of outreach attempts.

Describe how the program will assure that outreach efforts are respectful of beneficiaries. Describe how the program will overcome language or cultural barriers, or cognitive impairment in outreach.

Describe how the program plans to reach out to physicians, those within the organization as well as the beneficiaries' other regular providers, to incorporate them in the delivery of care management services.

A plan to assess and stratify participants.

Describe how the program will stratify participants by risk (including types and frequencies of interventions for beneficiaries at various strata and an explanation of when and how patients are transitioned between levels of intensity, if at all).

Describe any stratification tools to be used and how they will be validated.

Describe how the program will screen each participant for conditions such as impaired cognitive ability and co-morbidities.

Frequency and type of interventions.

Describe how the program will work with beneficiaries to develop and carry out their care management plans.

Describe how the intervention will work and how it will differ from traditional disease management models.

Describe how a beneficiary communicates with the program and how the program communicates with the beneficiary.

Describe how the program will determine the appropriateness of care management interventions, such as self-care education for beneficiaries or caregivers, education for physicians, the use of monitoring technologies, provision of information about hospice care, pain and palliative care, end-of-life care, etc.

Describe how the program will guide the participant in managing his/her health, including all co-morbidities, relevant health care services, preventive services and pharmaceutical needs. Describe how the program will improve efficiency and effectiveness of utilization of Medicare services.

Clinical protocols to guide care delivery and management.

Describe the clinical protocols used to guide interventions, as well as processes and responsibilities for updating them (clinical protocols must be derived from evidence-based medicine or nationally accepted practice guidelines). Describe how clinical protocols will support all of a participant’s co-morbidities, not just his/her primary condition.

Appropriate services and educational materials for participants.

Describe how the program will ensure that all care management services provided are tailored to meet the needs of all participants, including those with limited reading skills, diverse cultural and ethnic backgrounds, sensory/physical/mental disabilities or cognitive impairment, or primary languages other than English.

Describe how the program will ensure use of clinical protocols or evidence-based medicine to guide care delivery and management.

Adequate mechanisms for ensuring provider integration with the program.

Describe the program's strategy to encourage physicians and other providers to actively collaborate in the program.

Describe how the program will integrate beneficiaries' regular physicians and other providers into the program and ensure that the program enhances patient-provider relationships.

Describe how the program will ensure exchange of patient information with applicable providers, both within and outside the organization in an effective, timely, and confidential manner across care settings.

Describe how the program will facilitate access to timely and accurate patient information at the point of care. If the program includes incentives for the provider to participate in the demonstration, describe the basis and impact of these incentives.

Data to be collected, data sources, and data analyses.

Describe data to be collected and data sources.

Describe how the program will collect information on intervention group beneficiaries that are not available from claims data (for example, laboratory results, prescription drug data, clinical information from physicians).

Describe how the program will ensure privacy of participant information.

Describe how the program will develop a clinical information database to track and monitor patients' major chronic conditions and integrate management for participants who have multiple co-morbid conditions, such as diabetes and depression, across settings and to evaluate outcomes.

Describe the data exchange between the program, providers and beneficiaries. Describe whether physicians can access participant information on their patients. Describe process for sharing sensitive information between physicians (for example, HIV status or mental health diagnoses).

Describe how the program anticipates incorporating prescription drug data, including claims after 2006, to the extent possible.

In addition, applicants should provide sample communications and educational materials to be used with participants and providers and explain any plans to customize them for Medicare.

6. Organizational Structure and Capabilities

Applicants should demonstrate that they have the management capacity and organizational infrastructure to carry out the CMHCB demonstration in the proposed area.

At a minimum, in addition to the information requested in the application instructions, applicants should explain how the organization has demonstrated capacity in each of the areas listed below (see section II.C. of this solicitation for further details on the application evaluation process).

Staff.

Describe type of staff, level of staff, level of effort required to provide the service. Describe the mix of physician to non-physician staff.

Describe staff, both physician and non-physician, to participant ratios and required qualifications of staff that will be providing services to the participants.

Describe similar detailed information on any services to be performed on a sub-contracted or affiliated basis (List full name and address of any subcontractors involved in the services to be performed.)

Describe qualifications of the non-clinical staff that will be responsible for the information systems, data analysis, and other major program functions.

Describe organizational and reporting structure of personnel.

Provide a listing of key personnel.

Provide a breakout of staff responsibilities.

Facilities.

Describe locations that will be used to operate the CMHCB demonstration.

Describe typical hours of operation in terms of hours per day and days per week, including types of staff available during these hours of operation. (If the organization is not open 24 hours per day, 7 days a week, describe the process beneficiaries follow to contact professional staff.)

Equipment.

Describe equipment, including participant monitoring equipment or electronic input devices.

Strong working relationships with local providers.

Describe how the organization reaches out to local providers.

Provide contact information for at least two physicians outside the applicant organization who provide care to program participants or representatives from physician associations who have worked with the organization and who will serve as references.

Provide contact information for a hospital or health plan medical director who has worked with the organization and who will serve as a reference.

Appropriate information and financial systems.

Describe the organization's information and financial systems, including the organization's computer systems capabilities and how the applicant collects, integrates, analyzes, and reports data necessary to support program components. (Describe the data repository, and how the applicant's computer systems can transmit data to CMS.)

Provide samples of clinical, financial and management information reports used in program operations.

Describe the modification of its existing data systems, if necessary.

Describe how the organization ensures compliance with all applicable laws, including but not limited to privacy laws and HIPAA privacy and security standards.

With respect to data flows between awardees and CMS and within awardee organizations, identify participating organizations, their covered entity status under HIPAA and the relationships among the partners. Provide a diagram of these data flows, detailing who is receiving what information and for what purpose.

Ongoing performance monitoring.

Specify additional clinical and services indicators other than the performance standards specified in section II.B.7 of this solicitation and the timetable that the program proposes to use to monitor health status and quality of care by condition

and severity level for all conditions, including co-morbidities.

Organizational background and references.

Describe the organization's history (including how long the organization has been in business and any relevant predecessor companies), ownership, and current products and services.

For consortia, provide a history of the consortium and any supporting relevant experiences of the partners collectively and/or individually.

Describe the organization's capability and qualification to provide ambulatory health care services. Describe current services provided and current licensure by type of service and provider.

Provide references (including name, title, address and telephone number) for two organizations for which the applicant has developed and currently administers programs of similar scope and complexity as the proposed demonstration.

Indicate the numbers of beneficiaries now under active management by the applicant for each major chronic condition the applicant manages (including as a co-morbid condition).

Describe the organization's risk management history or demonstrated capability to operate with fee risk.

Indicate agreement to language regarding proprietary data, materials, systems, etc. in the Program Characteristics part of section II.A. of this solicitation.

Accreditation.

Describe any professional accreditations currently held by the organization.

Applicants will also be expected to provide detailed financial statements.

For consortia, applicants should describe how the new entity will achieve the organizational capacity functions listed below. Consortia may draw from the organizational qualifications of each of the partners, but applicants should emphasize the capabilities of the collective partnership. Consortia should describe the interrelationships between the partners, a plan for dedicated resources to develop infrastructure and seamless program cohesion (including integrated interventions, communications, information systems,

etc.), and a plan for governance and management structure with dedicated staffing and resources.

7. Performance Results

a. Past Performance: Clinical Quality, Beneficiary and Provider Satisfaction and Savings.

In addition to supplying the information requested in the application instructions, applicants should describe how their proposed interventions are likely to have a positive effect on clinical quality, beneficiary and provider satisfaction, and savings for the intervention group within the proposed geographic area. Applicants should show evidence of positive outcomes from prior and current efforts. Applicants must quantify their results for other target populations of individuals with major chronic conditions. Claims of prior success should include definitions of performance measures used, evaluation methods, as well as explanations of the length of time over which performance was measured. For savings, to the extent possible, applicants should include evidence of success in improving outcomes based on paid claims data. If a consortium has no prior experience to draw from, the applicant should, to the best of its ability, provide the relevant experiences of one or more of the components of the consortium.

b. Performance Projections

As discussed in section II.A of this solicitation, we will expect applicants to lay out their projections for improvement in clinical quality, beneficiary and provider satisfaction, and savings year to year in the intervention group and as compared to the control group. The projections set forth by awardees in their applications may be included in their CMHCB demonstration agreements as standards for monitoring performance. The organization should also describe to what baseline values its projections apply.

For the organization’s proposed set of clinical quality indicators, the applicant should provide projected rates of improvement the awardee expects to achieve in each year of the demonstration on each proposed quality performance measure in the intervention group as compared to the prior year and as compared to the control group. For each proposed measure, the applicant should indicate its ability to track the measure, data sources that would be used, and projected improvement rates.

The applicant should provide projected savings for each year of the program in addition to the aggregate savings projections specified in section II.B.8 of this solicitation.

The applicant should provide projections on operational metrics for each year of the program, including but not limited to, outreach and engagement rates. The applicants should provide detailed projections as to the percent of intervention group beneficiaries confirming participation, the percent of beneficiaries they expect they will be unable to reach, and the percent terminating participation.

8. Payment Methodology & Budget Neutrality

Using the historical claims database of a representative target population that CMS provides as well as their own data and knowledge of their respective target populations, applicants may provide a fee and/or a gain-sharing proposal. All payment proposals must guarantee a 5 percent net savings. Net savings will be calculated by comparing FFS payments for the control group to FFS payments and administrative or care management fees for the intervention group. In the event the actual net savings to Medicare is less than 5 percent, CMS will recoup administrative or care management fee payments up to the full amount of the savings shortfall. For net savings in excess of 5 percent, CMS will consider gain-sharing proposals. However, gain-sharing payments to an awardee will be limited to a maximum of 10 percent of the total claims expense of the target population, as measured by the Medicare claims payments for the control group. The reasonableness of any proposed gain-sharing will be evaluated based upon anticipated savings and the size of any monthly administrative or care management fee proposed. Under any alternative, CMS could withhold a portion of an organization’s fee to ensure budget neutrality, and an awardee will be responsible for refunding to CMS up to the full amount of its fees if net savings fall below 5 percent. Also, fee and gain-sharing payments will be at risk for failure to meet quality and satisfaction guarantees.

An applicant should describe the components of any monthly fee proposed. The fee may include the projected cost for each care management service, including any ancillary services, such as transportation or provision of equipment, and administrative costs. Components of the cost should be in aggregate and per participant. Administrative costs to be included in this budget may be costs for recruitment, travel, capital investments, data collection, profit, and any other relevant items or services. An applicant should describe the assumptions that underlie its price structure, including but

not limited to, expected outreach and engagement rates, assessment rates, levels of intervention intensity, drop-out rates, etc.

An applicant should also propose fee and/or gain-sharing adjustments in the event its program fails to achieve agreed-upon performance guarantees for clinical quality improvement and beneficiary and provider satisfaction. An applicant should provide a detailed explanation of its proposed adjustments and methods for calculating liability in the event of failure to meet agreed-upon performance guarantees.

9. Implementation Plan

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

Provide 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, health plans, communication, health education and/or training. Describe the organization’s plan for implementing process improvements.

Among the staff named and biographies provided, identify the individual who will be the liaison to CMS for CMHCB.

10. Supplemental Materials (Appendices)

C. Application Evaluation Process and Criteria

As noted in the Waiver Application instructions, a panel of experts will conduct a review of responsive proposals. The panelists’ evaluations will contain numerical ratings based on the application evaluation criteria, rankings for all responsive proposals, and a written assessment of each application.

1. Application Evaluation Criteria and Weights

a. Proposed Geographic Area and Target Population (5 points)

The proposal provides a thorough and convincing rationale for choosing the targeted population in the selected geographic area as specified in section II.B. of this solicitation, including:

- Demographics and socio-economic characteristics.
- Access to and utilization of health care services.
- Characteristics of the health care delivery system.
- Obstacles to providing care management services.

b. CMHCB Demonstration Model (35 points)

The proposal describes or demonstrates clear and convincing evidence that program design will improve quality of care for participating beneficiaries and reduce aggregate costs to Medicare (with any applicable supporting materials) as specified in section II.B. of this solicitation, including:

- A plan for provider outreach to the intervention group.
- A plan to assess, stratify, and screen participants.
- Frequency and type of interventions.
- Appropriate services and educational materials for participants.
- Adequate mechanisms for ensuring integration of patients' current providers into the program.
- Adequate mechanisms for handling participants with more intensive needs such as cognitive limitations.
- Data to be collected and data sources.

c. Organizational Capabilities and Structure (20 points)

The proposal describes or demonstrates clear and convincing evidence that the organization has the structure and capacity to conduct the CMHCB demonstration effectively as specified in section II.B. of this solicitation, including:

- Staff, both physician and non-physician.
- Facilities.
- Equipment.
- Clinical protocols to guide care delivery and management.
- Strong working relationships with local providers.

- Appropriate information and financial systems.
- Ongoing performance monitoring.
- Organizational background and references.

d. Performance Results: Past Performance and Performance Projections (20 Points)

The proposal includes clear and convincing evidence that the proposed provider-directed interventions can produce a positive effect on clinical quality, beneficiary and provider satisfaction, and savings with respect to the intervention group in the selected geographic area as specified in section II.B. of this solicitation, including:

- Positive outcomes from prior and current efforts, including quantified results for clinical quality, beneficiary and provider satisfaction and savings.
- Past success in performance standards data capture and management necessary to monitoring this type of program.
- Reasonableness of projections for quality improvement and beneficiary and provider satisfaction.
- Willingness to work with CMS to determine data to be collected and procedures for submission of those data.
- Willingness to cooperate in independent formal and formative evaluations of CMHCB.

e. Payment Methodology & Budget Neutrality (20 Points)

The proposal describes or demonstrates clear and convincing evidence that the proposed fees, gain-sharing arrangements, and performance guarantees are appropriate to improve quality of care for participating beneficiaries and reduce aggregate costs to Medicare as specified in section II.B.6 of this solicitation, including:

- Justification and explanation for any proposed care management fees.
- Reasonableness of the proposed care management fees, gain sharing arrangements, and savings guarantees.
- Reasonableness of applicant’s estimates of the expected net Medicare savings.

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

2. Final Selection

The CMS Administrator will make the final selection of organizations for the CMHCB demonstration from among the most highly qualified applicants, taking into consideration a number of factors, including operational feasibility, geographic location, and Medicare program priorities (for example, testing a variety of provider-directed approaches for delivering services, targeting beneficiaries, and payment). We will also conduct a financial analysis of these proposals and evaluate the proposed programs to ensure that aggregate Medicare program expenditures will be reduced. Applicants must be aware that proposals may be accepted in whole or in part. Awards may be subject to special terms and conditions that are identified during the review process. CMS reserves the right to conduct one or more site visits before making awards. The Administrator reserves the right to negotiate and limit the size of the population and the number of areas. CMS expects to make approximately four to six awards.