DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5004–N]

Medicare Program; Voluntary Chronic Care Improvement Under Traditional Fee-for-Service Medicare

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

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply to implement and operate a chronic care improvement program as part of Phase I (CCI–I) of the Voluntary Chronic Care Improvement Under Traditional Fee-for-Service (FFS) Medicare initiative as authorized by section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173).

Eligible Organizations: Organizations eligible to apply to implement and operate chronic care improvement programs under CCI–I include: (1) Disease management organizations; (2) health insurers; (3) integrated delivery systems; (4) physician group practices; (5) a consortium of entities; or (6) any other legal entity that meets the requirements of this notice.

FOR FURTHER INFORMATION CONTACT: For information concerning this initiative, contact Raymond Wedgeworth, CMS Project Officer, at (410) 786–6676, or *ccip@cms.hhs.gov*.

DATES: Applications must be received on or before 5 p.m. e.s.t. on August 6, 2004, to be considered.

ADDRESSES: Mail applications to: Centers for Medicare & Medicaid Services, Attention: Raymond Wedgeworth, Mail Stop: C4–15–17, 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. Although this is not a demonstration, CCI–I will contain study elements, such as a control group and an evaluation. For this reason, we have decided to use the Medicare Waiver Application as the most appropriate available tool at this time. Application forms may be found online at: *http://www.cms.hhs.gov/medicarereform/ccip/default.asp*. Please refer to the file code CMS–5004–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 notice.

SUPPLEMENTARY INFORMATION:

I. Background

Section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173, adds a new section 1807 ''Voluntary Chronic Care Improvement Under Traditional Fee-for-Service (FFS) Medicare'' to the Social Security Act (the Act). Section 1807(a)(1) of the Act specifies that the Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. Each program shall be designed to improve clinical quality and beneficiary and provider satisfaction and achieve spending targets with respect to expenditures for targeted beneficiaries with one or more threshold conditions. Section 1807(c)(1) of the Act requires the Secretary to enter into agreements to expand the implementation of CCI programs or components to additional geographic areas, which may include the implementation of CCI on a national basis, if CCI–I programs meet certain statutory requirements. This initiative represents one of multiple strategies that the Department of Health and Human Services (DHHS) is developing and testing to improve chronic care, accelerate the adoption of health information technology, reduce avoidable costs, and diminish health disparities among Medicare beneficiaries nationally.

In CCI–I, the Centers for Medicare and Medicaid Services (CMS) plans to test programs in approximately ten areas in which in the aggregate at least 10 percent of the Medicare FFS population resides. In these initial programs, we will focus primarily on implementing and evaluating programs for beneficiaries with congestive heart failure (CHF) and/or diabetes with significant co-morbidities (hereafter referred to as complex diabetes). In one or two areas, we may focus on beneficiaries with chronic obstructive pulmonary disease (COPD). The Secretary will define the selection criteria and prospectively identify at least 30,000 beneficiaries in each area, split between intervention and control groups.

One awardee will be selected per area to offer intervention group beneficiaries services in CCI–I. Organizations will provide support in improving beneficiaries' self-care and provide them and their providers enhanced information and information tools to increase adherence to evidence-based care. As specified in sections 1807(a)(3) and section 1807(d)(3) of the Act, participation in the programs will be voluntary and will not change the amount, duration or scope of participants' FFS Medicare benefits. FFS Medicare benefits will continue to be covered, administered and paid under the traditional FFS Medicare program. Programs will be of no charge to the beneficiary. Awardees 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 doctors in a network.

We are particularly interested in applications for programs in geographic areas (for example, States, metropolitan statistical areas) that have a high prevalence of CHF and/or diabetes, or COPD among Medicare FFS beneficiaries and poor Medicare quality rankings compared to national averages. Applicants may propose to serve one or more areas, but we may request that applicants adjust their proposed service areas to ensure that the population is of an appropriate size and does not interfere with current FFS chronic care demonstrations.

As specified in section 1807(f)(2)(A) of the Act, awardees will be paid a monthly fee per participant; however, payment 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 CCI–I is three years.

CCI–I programs will be evaluated by an independent evaluator per section 1807(b)(5) of the Act.

The principal objectives of CCI–I are to develop and test new strategies to improve quality of care and beneficiary and provider satisfaction cost-effectively for chronically ill FFS Medicare beneficiaries that are scalable, replicable and adaptable nationally.

A. Program Authorization

Section 1807(b) of the Act requires the Secretary to provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs. The purpose of Phase I, the developmental phase of the Voluntary Chronic Care Improvement Under Traditional FFS Medicare initiative (CCI), is to develop and test, through randomized controlled trials, the cost-effectiveness of programs for target populations that may benefit from program participation. The Secretary will evaluate whether quality of care

and satisfaction improve for targeted beneficiaries with threshold conditions and will ensure that Medicare expenditures, including CCI fees, for these programs do not exceed what estimated Medicare expenditures would have been for the targeted populations in the absence of the CCI programs.

B. Concerns

Widespread failings in chronic care management 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 typically have multiple chronic health problems. (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. *http://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: Medicare beneficiaries with five or more chronic conditions represent 20 percent of the Medicare population but 66 percent of program spending.

Congestive Heart Failure (CHF) and diabetes are among the five most common chronic diseases in the Medicare population. Beneficiaries with these diseases tend to have complex self-care regimens and medical care needs. In addition, many of these beneficiaries have other chronic conditions that add to their self-care burdens and risks of developing co-morbid conditions, complications, and acute care crises. The health risks of these beneficiaries depend heavily on how effectively they are able to control their conditions in their daily lives and whether or not they receive appropriate medical care and effective coordination of their care. Controlling their conditions successfully may require ongoing guidance and support beyond individual provider settings.

According to findings from the 1999 Medicare Current Beneficiary Survey, individuals with CHF represent 14 percent of non-institutionalized FFS Medicare beneficiaries and account for 43 percent of Medicare expenditures, including treatment for all their health problems. Individuals with diabetes represent 18 percent of beneficiaries and 32 percent of FFS Medicare expenditures. (Foote, S. Population-based Disease Management in Fee-For-Service Medicare. *Health Affairs*, Web Exclusive, 30 July 2003, W3–350.). Each year, 10 percent of the Medicare population accounts for two-thirds of all Medicare FFS program payments. (Centers for Medicare and Medicaid Services. CMS Chart Book June 2002 edition, Section III. A, p. 29.) Many of these high-cost beneficiaries suffer from progressive chronic diseases, such as CHF and/or diabetes, and most of the Medicare expenditures for their care are for multiple and often preventable hospitalizations.

Prevalence rates of diabetes and CHF are even higher among minorities than among all Medicare beneficiaries. For example, the Centers for Disease Control and Prevention reports that 23.0 percent of black males and 23.5 percent of Hispanic males ages 65–74 have diabetes compared to 16.4 percent of white males and 15.4 percent of all individuals in that age group. Black and Hispanic females in that age group have diabetes prevalence rates of 25.4 percent and 23.8 percent, respectively, compared to 12.8 percent for white females and 15.4 percent for all individuals in that age group. (Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Diabetes Surveillance System. *See www.cdc.gov/diabetes/statistics/prev/national/f5dt2000.htm.* Given these prevalence figures, improving quality and adherence to evidence-based care should also improve outcomes and thus reduce racial and ethnic disparities, which is consistent with HHS' Healthy People 2010 goals.

The Institute of Medicine's landmark report *Crossing the Quality Chasm: A New Health System for the 21st Century* (National Academy Press, 2001) highlighted the challenges of assuring that patients with major chronic conditions such as CHF and diabetes 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 progressive chronic diseases. Providers of care are organized and paid for services provided in discrete settings (for example, hospitals, physician offices, home health care, long-term care, preventive services, etc.). 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 is rare.

Fragmentation of care is a particularly serious problem for Medicare beneficiaries. The average Medicare beneficiary sees seven different physicians and fills upwards of 20 prescriptions per year. (Anderson, G. *Chronic Conditions: Making the Case for Ongoing Care*. Partnership for Solutions and the Robert Wood Johnson Foundation, p. 4). In a recent survey, 18 percent of people with chronic conditions reported having duplicate tests or procedures and 17 percent received conflicting information from providers. (Anderson, p. 32) Providers reported feeling ill-prepared to manage chronically ill patients and reported that poor coordination of care led to poor outcomes. (Anderson, p. 36).

The gap between what we know is appropriate care for patients with chronic diseases and the care they actually receive is significant. According to findings of a recent national study, only 56 percent of patients with chronic diseases received recommended care based on well-established guidelines referenced by the researchers. Among patients in the study sample who had CHF, only 64 percent received recommended care, and among those with diabetes, only 45 percent received recommended care. Specifically, only 24 percent of diabetes patients in the study received three or more glycosylated hemoglobin tests over a two-year period. (McGlynn, E., Asch, S., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., Kerr, E. The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine.* 2003; 348:26:2635–2645). Similarly, in a recent study of practice patterns under Medicare, researchers found that, across all States, an average of 66 percent of Medicare beneficiaries with heart failure received ACE inhibitors and 16 percent with diabetes received a lipid test. (Jencks, S., Huff, E., Cuerdon, T. Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001. *Journal of the American Medical Association.* 2003; 289; 305–312).

Quality of care is not a function of regional spending levels under FFS Medicare. In a carefully controlled national study, Fisher *et al.*, found that, "quality of care in higher-spending regions was no better on most measures and was worse for several preventive measures.'' (Fisher, E.S., Wennberg,

D.E., Stukel, T.A., Gottlieb, D.J., Lucas, F.L., Pinder, E.L. The implications of regional variations in Medicare spending. Part 1: The content, quality, and accessibility of care. *Ann Intern Med.* 2003; 138:273–87). Thus, managing care in a cost-effective manner may in fact raise the quality of care delivered if incentives are properly designed.

Moreover, health information technology is expected to improve quality and fundamentality change the way health care is provided (Institute of Medicine, IOM 2004) by providing actionable evidence at the point of care, reducing errors, duplicate tests, unnecessary admissions, adverse events, and rejected claims.

C. Current Chronic Care Improvement Initiatives

Many payers in the private sector have begun sponsoring chronic care improvement initiatives, such as disease management and intensive case management programs, in an attempt to address pervasive problems in ensuring that chronically ill individuals receive appropriate care. The intensive case management programs are typically designed to assist patients who develop costly and complex medical care needs and who need help arranging for appropriate care. Private sector disease management programs often include: Patient self-care support, provider information support, and use of integrative clinical information systems to collect and synthesize patient information from the fragmented segments of the health care delivery system. These disease management programs are often designed to—

- Supply providers with timely, actionable clinical information regarding their patients;
- Provide clinical decision support for patients and providers based on evidence-based guidelines;
- Promote care coordination; and
- Guide and encourage patients in adhering to prescribed care management plans and self-care regimens.

The programs are also typically designed to ensure that preventive measures are taken when appropriate (for example, screening tests) and to prevent or mitigate complications that may result in costly hospitalizations or emergency room visits. In most programs, individual participants are assessed and stratified by their risk levels and self-care concerns, permitting interventions to be targeted based on individual needs. Some programs also provide social services, transportation, and tracking of prescription medications.

While many private sector disease management programs initially had a single-disease focus, many organizations today are attempting to support patients in managing their self-care holistically, including all their co-morbid conditions, regardless of the threshold condition that triggered eligibility for the program.

Many of the current private sector disease management programs are population-based, meaning that organizations are held accountable to improve quality and cost outcomes for prospectively identified target populations. Organizations often agree to put some of their fees at risk if they fail to achieve savings. Organizations often stratify individuals according to risk and tailor interventions to reflect the intensity of changing individual needs; however, the programs are responsible for achieving performance standards across the identified population, regardless of which interventions are provided.

The National Committee for Quality Assurance (NCQA), the American Accreditation Healthcare Commission/URAC and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) have developed quality standards and certification programs for disease management programs.

The chronic care improvement programs to be tested under CCI–I will have some program characteristics in common with the aforementioned private sector disease management programs, but will need to be adapted to suit the unique needs of beneficiaries in the FFS Medicare environment.

II. Provisions of This Notice

A. Purpose/Design

Section 1807 of the Act authorizes the Secretary to begin building chronic care improvement programs under the Medicare FFS program, incorporating relevant features from private sector programs, but allowing sufficient flexibility for us and the awardees to adapt the design of CCI–I programs to meet the unique needs of the Medicare population. For example, applicants will need to consider how to serve individuals with complex problems that might typically be referred for case management under private sector plans since FFS Medicare does not operate an intensive case management program. Organizations will have the latitude to stratify targeted beneficiaries according to risk and need and to tailor interventions to the unique needs of FFS Medicare beneficiaries, including self-care and caregiver support, care coordination, education, and use of in-home monitoring devices as appropriate.

As specified in section 1807(f)(3)(B)(ii) of the Act, the organizations will also 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. We have established that financial risk is fee risk. Thus, we believe that the chronic care improvement organizations in CCI–I will have strong incentives to reach the targeted beneficiaries and their providers on a continuing basis to help them improve chronic care management. The CCI–I organizations will be expected to track and improve the health outcomes of all identified members of their intervention group, not just those who seek treatment during a given time period.

1. Eligible Organizations

Section 1807(a)(2)(B) of the Act defines the organizations eligible to apply to implement and operate chronic care improvement programs under CCI–I. These include:

(1) Disease management organizations;
(2) Health insurers;
(3) Integrated delivery systems;
(4) Physician group practices;
(5) A consortium of entities; or
(6) Any other legal entity that the Secretary determines to be appropriate.

The Secretary has determined an appropriate legal entity is one that meets the requirements of this notice.

2. Identification of Intervention Groups

Section 1807(d) of the Act requires the Secretary to identify targeted beneficiaries who may benefit from CCI–I. Section 1807(a)(2)(E) of the Act defines a targeted beneficiary for a CCI program as a FFS beneficiary with a threshold condition covered under the program.

Threshold condition is defined in section 1807(a)(2)(D) as a chronic condition, such as CHF, diabetes, or COPD, or other diseases or conditions selected by the Secretary as appropriate for the establishment of a CCI program. For CCI–I, we have chosen to focus initially on beneficiaries who have CHF and/or complex diabetes, or Chronic Obstructive Pulmonary Disease (COPD) because they are major population subgroups within Medicare with significant health risks and disproportionately high health care

costs that are not being consistently well managed. Evidence from research and private sector experience suggests that chronic care improvement programs may produce measurable improvements in quality and health status and yield net reductions in health care spending for these subgroups by lowering their hospital admission rates and emergency service use, but the population-based programs have not been rigorously tested in large populations of people aged 65 and older or with severely disabling conditions in a FFS context. CCI–I will permit us to implement and rigorously test these programs under Medicare FFS.

Section 1807(d) of the Act requires the Secretary to establish a method for identifying eligible beneficiaries for CCI–I. Thus, we have established that eligible beneficiaries will be those beneficiaries who meet the inclusion and exclusion criteria established by us and who are identified by us for randomization. Through analysis of Medicare historical claims data, we initially plan to prospectively identify eligible beneficiaries in each CCI–I geographic area (henceforth referred to as a ''target population''). To be eligible for inclusion in a target population under CCI–I, Medicare beneficiaries must be enrolled in Parts A and B, have CHF and/or complex diabetes, or COPD, and have Medicare as primary payer.

Beneficiaries with CHF and/or complex diabetes will be identified using a combination of two or more professional visits on separate dates for CHF or complex diabetes (or a hospitalization for CHF) based on 1 year of historical claims data. Based on literature reviews and extensive input from the private sector, we have decided to focus on eligible beneficiaries with these threshold conditions who have moderate to high Hierarchical Coexisting Condition (HCC) risk adjustment scores in order to achieve our clinical and financial objectives within the 3-year program window (see our Web site, *http://www.cms.hhs.gov/medicarereform/ccip/default.asp,* for further information on HCC risk adjustment scoring).

Because of the high prevalence of COPD in the Medicare population, we will consider testing programs targeting beneficiaries with COPD in one or two geographic areas if an applicant(s) presents a strong proposal(s). For these program(s), beneficiaries with COPD will be identified using two or more professional visits on separate dates for COPD or a hospitalization in the year based on 1 year of historical claims data. Eligible beneficiaries with COPD will have moderate to high HCC risk adjustment scores as well.

As part of the process for identifying beneficiaries who might benefit from CCI–I, we have established that the following groups of beneficiaries will be excluded from CCI–I. We will not consider beneficiaries if they are currently or become enrolled in any of the following:

- Medicare End-Stage Renal Disease (ESRD) program;
- Hospice;
- Medicare Advantage (Medicare+Choice) plan; or
- A CMS FFS chronic care demonstration.

Detailed documentation on the inclusion and exclusion criteria above, and a more detailed explanation of the identification methodology, including the HCC risk score cut-off for each threshold condition, will be included with the dataset we will provide for bidding purposes. (*See* Section II.B. of this notice for further details on the bidding process.)

As specified in section 1807(b)(1) of the Act, CCI–I requires randomized controlled trials for Phase I. Our expectation is to randomize beneficiaries in the target population in each area into intervention and control groups at the beneficiary level. Randomization is intended to ensure comparability on factors that could affect performance improvement and overall health care costs.

In addition, we may request the applicant to adjust the size of the proposed geographic area to ensure that the population is of the appropriate minimum size to meet the requirements specified in section 1807(b)(3)(A) of the Act, that CCI–I in the aggregate cover areas in which at least 10 percent of the Medicare population resides or address other issues like conflicts with Medicare FFS demonstrations. If the applicant and CMS cannot come to an agreement on the size of the geographic area, that could be a basis to reject the proposal. Effects on clinical quality, beneficiary and provider satisfaction and total Medicare costs for individuals with CHF, for those with diabetes and CHF, and for those with complex diabetes will be evaluated. Programs targeting beneficiaries with COPD will be evaluated separately.

3. Identification of Potential Geographic Areas

We are interested in applications that target areas with higher than average prevalence of CHF or complex diabetes, or COPD, and low Medicare quality rankings.

We are particularly interested in applications for geographic areas that do not conflict with a currently operating FFS chronic care demonstration designed to reduce Medicare expenditures through care coordination, disease management or other care management efforts (*see* chart containing a list of the FFS chronic care demonstration areas). Running a CCI–I program in the same geographic area as the demonstration, even if enrollees in CCI–I cannot participate in the demonstration, could confound the results of the CCI–I study by cross-contamination of control groups. Chronic care improvement programs would be measured against the results of organizations running other demonstrations. To the extent that these demonstrations are successful in reducing the costs of their enrollees, chronic care improvement 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 for potential enrollees in order to assign populations of beneficiaries to CCI–I programs. However, applicants who are interested in proposing an area where a demonstration exists in part of a State are encouraged to contact us for further details concerning how they might structure their CCI–I proposals in a manner that will not cause cross-contamination with an ongoing FFS chronic care demonstration.

State	Medicare fee for service beneficiaries [a]	Percent diabetes [b]	Percent CHF [c]	Percent COPD [d]	Medicare quality rank [e]	Geographic areas with conflicting demonstraions [f]
United States	34,717,973	17	12	12		
Alabama	661,747	20	14	15	42	
Alaska	45,728	9	6	6	33	
Arizona	474,227	12	9	10	29	AZ
Arkansas	436,271	15	13	12	48	NW AR

State	Medicare fee for service beneficiaries [a]	Percent diabetes [b]	Percent CHF [c]	Percent COPD [d]	Medicare quality rank [e]	Geographic areas with conflicting demonstraions [f]
California	2,557,305	7	5	5	44	CA
Colorado	339,159	12	11	12	7	CO
Connecticut ...	454,662	18	12	12	9	S Central CT
Delaware	114,806	22	14	12	14	
DC	73,382	11	7	4	37	DC
Florida	2,240,227	18	12	15	41	N FL
Georgia	927,667	20	13	13	47	
Hawaii	116,160	2	2	1	16	
Idaho	158,301	13	10	9	22	
Illinois	1,535,043	17	13	11	46	Rural/E IL
Indiana	854,548	19	14	14	27	Central/Western IN
Iowa	474,090	16	11	11	6	NE IA, NW IA
Kansas	371,539	15	12	11	30	
Kentucky	622,181	19	13	16	40	
Louisiana	543,327	20	15	12	51	Corridor I–49
Maine	225,477	16	11	14	3	ME
Maryland	651,698	18	12	11	25	Mont. Cnty, DC Suburbs, Baltimore
Massachusetts.	768,883	17	12	12	15	
Michigan	1,376,774	22	14	14	26	MI
Minnesota	596,098	14	10	8	10	E Rural MN, S Central MN
Mississippi	430,625	19	13	11	50	
Missouri	764,550	17	14	13	28	SW MO, St. Louis
Montana	142,428	11	10	11	13	SE MT
Nebraska	251,062	15	12	10	12	
Nevada	176,387	12	9	11	35	
New Hampshire.	176,330	16	11	12	1	SW NH
New Jersey ...	1,089,135	21	16	13	43	
New Mexico ..	211,363	14	9	11	36	NM
New York	2,327,080	21	16	12	24	NYC
North Carolina	1,141,084	20	12	12	23	NW NC
North Dakota	104,775	14	10	9	4	
Ohio	1,497,640	20	15	14	38	
Oklahoma	473,529	16	14	13	45	
Oregon	336,477	10	7	7	11	
Pennsylvania	1,623,162	20	14	13	31	Eastern PA, Central NE PA
Rhode Island	117,890	19	13	13	17	
South Carolina.	597,582	22	13	12	32	
South Dakota	122,324	13	11	10	20	SD
Tennessee	829,852	19	13	14	39	NE TN
Texas	2,112,410	19	14	12	49	Houston, Urban/S TX
Utah	210,115	15	11	6	5	
Vermont	92,798	15	10	11	2	E VT
Virginia	914,745	19	12	11	18	SW VA, Richmond
Washington ...	616,018	13	10	9	19	W Central WA
West Virginia	324,294	22	14	17	34	
Wisconsin	769,142	16	11	9	8	N Central WI
Wyoming	67,139	13	11	13	21	N WY

Sources:

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

[b] Health Insurance Reform Project, George Washington University: Analysis of 5 percent SAF, All Physician-Supplier Claims, Percent of FFS Enrollees in State with Diabetes Diagnosis Reported.

[c] Health Insurance Reform Project, George Washington University: Analysis of 5 percent SAF, All Physician-Supplier Claims, Percent of FFS Enrollees in State with CHF Diagnosis Reported.

[d] Health Insurance Reform Project, George Washington University: Analysis of 5 percent SAF, All Physician-Supplier Claims, Percent of FFS Enrollees in State with COPD Diagnosis Reported.

[e] Jencks, S., Huff, E., Cuerdon, T. Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001. *Journal of the American Medical Association*. 289; 305–312; 2003.

[f] CMS, Office of Research, Development and Information, Listing of Demonstrations.

4. Outreach to Intervention Group

Beneficiary participation in CCI–I will be strictly voluntary. Eligible beneficiaries who are randomized to be contacted by us for potential participation in a CCI–I program (henceforth referred to as "intervention group'') will be notified of the opportunity to participate through a letter from the Medicare program including the information specified by section 1807(d)(2) of the Act. The letter will provide a description of the program and give the beneficiary an opportunity to decline to be contacted by the CCI–I organization. The letter will detail how the beneficiary can obtain further information about the program. We will then expect each awardee to contact the intervention group beneficiaries in its area who did

not decline to be contacted to describe the program, confirm participation, and initiate support 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 awardee or us that they no longer want to be contacted by the awardee. Participation is still voluntary and the beneficiary may terminate participation at any time.

We will provide awardees with historical Medicare claims data and other information on the intervention group beneficiaries who did not decline to be contacted in their geographic areas. Awardees will use the data for outreach and preliminary assessment of beneficiary risk levels and support needs. Our data will not include beneficiary phone numbers.

We will expect applicants' proposals to specify detailed descriptions about their outreach protocols, including for example, frequency and number of outreach attempts, and how the applicant will assure that outreach efforts are respectful of the beneficiary. The ''outreach period'' will consist of 6 months. We reserve the right to negotiate limits on the number and/or frequency of outreach attempts during the outreach period, and may specify that awardees will be required to cease further outreach efforts after the outreach period.

Under our authority in section 1807(e)(4)(B) of the Act, awardees will be required to maintain records of beneficiary contact and confirmation of their participation in the program. We will also require awardees to share beneficiary eligibility and participation status (that is, whether a beneficiary declined to participate or terminated participation) with us on a regular basis.

We will expect applicants to provide projections as to the percent of intervention group beneficiaries confirming participation, the percent of beneficiaries declining to be contacted (to the awardee or to us), the percent of beneficiaries they expect they will be unable to reach, and the percent of participants terminating participation.

Private sector experience has shown that this approach to program start-up facilitates ramping up participation levels rapidly and reaches individuals who are likely to benefit significantly from participating but who are not otherwise likely to take the initiative to seek this assistance. Programs will be evaluated based on health and cost outcomes of their entire intervention group, including those beneficiaries who chose not to be contacted, beneficiaries who dropped out of the program at any time, and those beneficiaries the awardee was unable to reach, over time and as compared to control groups. Beneficiaries in the control groups will not be contacted to inform them of the program, and therefore will not have the opportunity to decline to participate.

5. Program Characteristics

As specified in section 1807(a)(3) of the Act, participation in CCI–I will not—

- Expand the amount, duration or scope of a beneficiary's FFS Medicare benefits;
- Provide an entitlement for participation in a CCI program;
- Provide for any hearing or appeal rights with respect to a CCI program; or
- Provide benefits under a CCI program for which a claim may be submitted to the Secretary by any provider or supplier of services.

Additionally, Medicare beneficiaries will continue to have access to care and the same freedom of choice of providers as they do currently. Participants can drop out of the program at any time. Awardees must track and inform us of all participants who drop out of programs. Awardees must be able to demonstrate that they conduct their CCI–I programs in accordance with section 1807(e) of the Act.

As specified in section 1807(e)(1) and (e)(2) of the Act, CCI–I programs must develop a care management plan with each participant. In carrying out the care management plan and other CCI–I activities, chronic care improvement organizations shall:

1. Guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

2. Use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary (see the paragraph below for details on other criteria); and

3. Develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

We plan to provide monthly or quarterly claims data to awardees for their assigned populations to support these activities.

Section 1807(e)(4)(B) of the Act specifies that the Secretary also has the discretion to establish additional program requirements beyond those specified in section 1807(e) of the Act. We are particularly interested in programs that have a track record of success in engaging beneficiaries' physicians and other providers in information sharing and in working with community organizations, local and state agencies, and other organizations that serve the proposed target populations. Many chronic care improvement programs have developed integrative information infrastructures, new applications of information and communication technologies, expert clinical systems that incorporate evidence-based guidelines for multiple conditions, and predictive modeling capabilities to support their operations. Others have been working to develop interoperative electronic health records and other health information technology used at the point of care to improve quality and safety. We are interested in receiving applications from organizations that have proven to be successful in applying tools to meet the individual needs of participants and their providers, reduce fragmentation in patient information, and facilitate better communications between chronically ill 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 CCI–I to understand how the programs operate and assess their effectiveness. Transparency is essential. Therefore, awardees must agree to the following statement: ''At any phase in CCI–I, including at its conclusion, the awardee, if so requested by the project officer, must deliver to us all chronic 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 CCI–I, to be used by us solely to further the purpose of CCI–I.'' The data 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, without limitation, the specific proprietary algorithms used by the awardee for CCI–I) is and remains 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.

CCI–I programs 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

Section 1807(f)(2)(A) of the Act specifies that each awardee will be paid a fee for each participant per month in CCI–I. The fee amounts to be paid to awardees may vary because we envision testing a range of program models that may have different cost structures. We will establish fee amounts by agreement with each awardee.

Claims for medical services provided to participants will continue to be covered, administered, and paid under the Medicare FFS program. The monthly rate paid to awardees for providing chronic care improvement support to participants will be considered a programmatic administrative fee, and no beneficiary coinsurance amount or deductible liability will be applied. During the outreach period, we will pay a per beneficiary monthly payment for all intervention group beneficiaries, except those who declined to be contacted either to us or to the awardee. After the outreach period, we will pay a per participant monthly fee for all beneficiaries who confirm participation, until they become ineligible or terminate their participation in the program. We will not pay any per participant monthly fees for beneficiaries who have not been reached by the time the outreach period comes to a close unless agreed to by us and the awardee and specified in the CCI–I agreements. No program start-up funds will be allowable for costs incurred prior to program implementation. No added payments will be made to awardees for their program evaluation costs, travel, capital investments, data collection, or any activity related to CCI–I. All program costs must be factored into the per-participant fee. The bid should not include CMS programmatic costs as the standardized satisfaction survey or collection of information on control group beneficiaries, etc.

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

Section 1807(f)(3)(A) of the Act specifies that each agreement with an awardee will specify performance standards for improving clinical quality, improving beneficiary and provider satisfaction and achieving savings. As part of the application process, we will expect applicants to set forth their projections for improvement on clinical quality and savings on a year-to-year basis in the intervention group and as compared to the control group. The projections set forth by awardees in their applications and agreed upon by us may be included in their CCI–I agreements as standards that will be used in monitoring performance.

Section 1807(f)(3)(B)(i) of the Act also specifies that each agreement will provide for adjustment in payment rates in the event the Secretary determines that the awardee failed to meet its agreed-upon performance standards.

Applicants will be expected to propose performance guarantees for the first two performance standards, quality improvement and beneficiary 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 for quality improvement can relate to achievement of agreed-upon standards collectively rather than on individual measures. 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 a program after 18 months of operation if the Secretary determines the program is not demonstrating significant progress in improving clinical quality and beneficiary 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 CCI–I agreements. It is important to reiterate that awardees' performance will be measured on the entire intervention group (which includes those beneficiaries who chose not to be contacted, beneficiaries who dropped out of the program at any time, and those beneficiaries the awardee was unable to reach, for all months in which they were eligible to participate).

For the third performance standard, savings, section 1807(f)(4) of the Act requires the Secretary to ensure budget neutrality. To ensure that neutrality, we are specifying that each awardee will also be required to guarantee that the total of Medicare claims payments for beneficiaries in the intervention group and chronic care improvement fees under CCI–I paid for participants will be no more than 95 percent of the amount that total Medicare claims payments would have been absent CCI–I, as measured by claims for the corresponding control group over a 3-year period (applicants will be given the opportunity to propose multiple payment and savings guarantees structures, as described further in section II.B.6 of this notice). Beginning in 2006, beneficiaries will have the opportunity to purchase Medicare prescription drug coverage under Pub. L. 108–173. We intend to include Medicare drug expenditures in the calculation of total Medicare expenditures.

Section 1807(f)(1)(B)(ii) of the Act specifies that organizations must assume financial risk for performance under CCI–I 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 CCI–I, up to the full amount of the total chronic care improvement fees paid to the awardee. We may require awardees to make refunds to the government based on interim performance monitoring results or we may specify in agreements with awardees some other mechanisms to limit our exposure, but the final financial settlement will be based on 3-year program performance.

Throughout CCI–I, CMS and our contractor, in conjunction with the awardee, 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 be contacted, those who could not be reached or those who terminated participation) to the average Medicare expenditures per person per month for beneficiaries in the control group in the geographic area. 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. Net savings calculations will include appropriate claims run-out for both the intervention and control groups.

8. Reconciliation Process

We will hire an independent contractor to 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 refunds due to the government from awardees in the event awardees fail to achieve agreed-upon

performance guarantees over the 3-year program window.

As noted previously, awardees are to assume financial risk related to fees, not insurance risk. Awardees will be required to establish a system to compensate Medicare (up to 100 percent of the applicant's chronic care improvement fees) in the event that they fail to achieve their performance guarantees. Applicants will need to demonstrate financial solvency to assure us of their capacity to refund us up to 100 percent of their fees if this situation occurs, through available reserves, reinsurance, withholds, or other appropriate means. Awardees will be required to agree in writing to performance standards, guarantees, and liability calculation methodology as a condition of acceptance of CCI–I awards, and will have an opportunity to review the annual and final calculations when completed.

9. Program Monitoring

We will conduct ongoing formative program monitoring throughout the period of program operations. The formative evaluation will be conducted in collaboration with CMS and awardees to help identify and address operational problems, foster continuing improvement in program operations, and inform us as to how we might expand the program as specified by section 1807(c) of the Act if Phase I is successful.

Section 1807(f)(1)(B)(i) of the Act specifies that the Secretary may establish other requirements as appropriate. Thus, awardees will be required to cooperate with our implementation contractor, 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). Awardees will be expected to provide us with ongoing program monitoring information by tracking various measures of program performance and operational metrics. Awardees will be expected to track clinical quality, satisfaction, utilization, and cost measures on participants on a continuing basis and to analyze trends quarterly. The requirements for data exchange and reporting will be established in CCI–I agreements to satisfy our need for program monitoring and the independent evaluator's needs for program analysis.

10. Independent Formal Evaluation

Pursuant to section 1807(b)(5) of the Act, 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 (as specified by section 1807(b)(5) of the Act). Awardees 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. Detailed definitions of the indicators, measures, and calculation methods to be used in determining performance will be agreed upon by us and specified in the CCI–I agreements. 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. Awardee Selection Process

We will select awardees for CCI–I in a staged process. In the first stage, we will provide prospective applicants with a de-identified data set of Medicare claims information for a national sample of beneficiaries who meet the inclusion and exclusion criteria for CCI–I. 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 us a Data Use Agreement that will be posted on our Web site in advance of the publication of this notice. The applicant will analyze the data and submit an application and bid, including proposed target population (CHF, complex diabetes, or COPD), geographic area, per participant per month fees and performance guarantees. Applicants should base their proposals on 20,000 beneficiaries in the intervention group. Applicants may propose to serve a larger size population as well, but, for comparability, applicants must submit at least one proposal based on 20,000 beneficiaries in the intervention group. We reserve the right to negotiate and limit the size of the population. Applicants may propose adjustment factors to account for any differences between the nationally representative sample population and the actual population in their proposed geographic area that may warrant changes in performance projections, payment structure, or guarantees. We reserve the right to reject proposed adjustment factors. Applicants will have 90 days from the date the data are made available to submit applications.

In the second stage, our review panel will evaluate all submitted applications based upon the application evaluation criteria listed in section II.C. of this notice and will recommend applicants to be considered for the second stage of the awardee selection process. We may conduct site visits to selected applicants based upon review panel recommendations.

For applicants who are selected as finalists, we will provide the actual historical data for the applicable target population in the applicant's proposed geographic area. Finalists will analyze the data to determine if originally proposed and agreed upon adjustment factor(s) apply. (Adjustment factors must be specified in the initial application in order to be applied at this point.) If the applicant finds that an adjustment in the proposed payment or savings guarantees applies due to the differences in the data, we will verify the analysis and findings prior to entering into an agreement with the awardee.

The Administrator will make the final selections. Only one awardee will be selected for any given geographic area, and will be provided with HIPAA compliant identified data once selected. We may add to the intervention group individuals who meet the eligibility criteria for the original cohort.

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. Although this is not a demonstration, CCI–I will contain study elements, such as a control group and an evaluation. For this reason, we have decided to use the Medicare Waiver Application. The application is available online at: *http://www.cms.hhs.gov/medicarereform/ccip/default.asp.* 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 CCI–I notice will be reviewed.

Additional information about CCI–I, for example, fact sheets, press releases, question and answer documents, and information about the bidders' conference will be posted on the Web site. All questions must be submitted to us in writing; all responses will be posted on our Web site.

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, etc.). 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 p.m. EST on August 6, 2004. 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 specify which target population they intend to serve (CHF and/or complex diabetes, or COPD). Applicants should specify the size of the population they intend to serve if it differs from the required proposal based on 20,000 beneficiaries in the intervention group. Applicants should describe the demographics of the Medicare FFS population in the area, utilization rates, prevalence rates of CHF and complex diabetes or COPD in the Medicare population, and Medicare quality rankings (as defined by Jencks, S., Huff, E., Cuerdon, T. Change in the Quality of Care Delivered to Medicare Beneficiaries, 1998–1999 to 2000–2001. *Journal of the American Medical Association.* 2003; 289; 305–312) for the area with comparisons to national averages. The current health care delivery system and access to care in the proposed geographic area should be briefly described. Obstacles to providing chronic care improvement 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 CCI–I.

5. Chronic Care Improvement Program 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 program will address each of the following activities (*see* section II.C. of this notice 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 about outreach protocols, including for example, frequency and number of outreach attempts.
- Describe how program will assure that outreach efforts are respectful of beneficiaries. Describe how program will overcome language or cultural barriers, or cognitive impairment in outreach.
- Describe how the program plans to reach out to physicians to inform them of the program.
- *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 the stratification tool and whether it was validated.
- Describe how the program will screen each participant for conditions other than threshold 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 as specified in section 1807(e) of the Act.
- 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 chronic care improvement interventions as specified in section 1807(e)(2) of the Act, 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, and end-of-life care, etc.
- Describe how the program will increase use of preventive services.
- Describe how the program will guide the participant in managing his/her health, including all co-morbidities, relevant health care services and pharmaceutical needs. Describe how the program will improve efficiency and effectiveness of utilization of Medicare services.
- *Appropriate services and educational materials for participants.*
- Describe how the program will ensure that all chronic care improvement services provided are tailored to meet the needs of all participants, including those with limited reading skills, with diverse cultural and ethnic backgrounds, with sensory/physical/mental disabilities or cognitive impairment, or primary languages other than English.
- Describe how the program will use decision-support tools to ensure adherence to evidence-based medicine and monitoring of quality standards.
- Describe how the program will ensure use of clinical protocols or evidence-based medicine to guide care delivery and management.
- *Adequate mechanisms for ensuring physician integration with the program.*
- Describe the program's strategy to encourage physicians and other providers to actively participate in the program.
- Describe how the program will integrate beneficiaries' 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 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 physician to adopt or use decision-support tools or other health information technology, describe the basis and impact of these incentives.
- *Adequate mechanisms for ensuring coordination with State and local agencies.*

• Describe how the program will coordinate, if applicable, with State and local agencies, as well as other organizations that serve the target population.

• *Adequate mechanisms for supporting participants with more intensive needs.*

• Describe strategies for supporting participants with more intensive needs (for example, describe whether there will be a care coordination or intensive case management program as part of the overall CCI–I program or some other mechanism for supporting this population).

• *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 data analyses.

• 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, physicians 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 will anticipate 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.

Applicants do not need to describe how beneficiaries will be assigned to intervention and control groups, as we will be responsible for that function under CCI–I.

6. Organizational Structure and Capabilities

Applicants should demonstrate that they have the management capacity and organizational infrastructure to carry out CCI–I.

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 notice for further details on the application evaluation process) and how their programs could be expanded or replicated over time.

• *Staff.*

• Describe type of staff, level of staff, level of effort required to provide the service.

• Describe staff 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 all handoffs and coordination arrangements).

• 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 CCI–I.

• Describe typical hours of operation (EST) 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 who provide care to program participants or representatives from physician associations who have worked with the organization and who will serve as references.

• *Strong working relationships with community organizations in the area.*

• Describe how the organization interacts with local community organizations (such as Quality Improvement Organizations, among others).

• Provide contact information for at least two community organizations 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 us.)

• 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.

• With respect to data flows between organizations and us and within organizations, identify participating organizations, their covered entity status and the relationships among the partners. Indicate these data flows, detailing who is receiving what information and for what purpose.

• *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 threshold condition.

• *Ongoing performance monitoring.*

• Specify additional clinical and services indicators other than the performance standards specified in section II.B.7 of this notice 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, including 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.

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

• Indicate the numbers of beneficiaries now under active management by the applicant for CHF, for complex diabetes, and for each other type of 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 notice.

• *Accreditation.*

• Describe accreditation for disease management or chronic care improvement programs, if any. Section 1807(e)(5) of the Act specifies that the Secretary may consider deeming accredited organizations as meeting the CCI–I requirements. In the interest of encouraging proposals from a broad array of organizational models, we are not deeming accredited organizations at this time; however, we will consider accreditation as a factor.

Applicants who are selected as finalists in the second stage of the awardee selection process 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

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 large target populations of individuals with CHF, complex diabetes, COPD, or other 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.

Performance Projections

As discussed in section II.A of this notice, 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 CCI–I agreements as standards for monitoring performance. As mentioned in section II.B. of this notice, we have created a database of one year of historical data on a nationally representative target population. As appropriate, the organization should use this database as a point of reference to project performance improvements. The organization should also describe to what baseline values its projections apply and what adjustment factors would apply if the true baseline values were outside of the anticipated range.

• We have identified a core set of clinical quality indicators. The applicant should provide projected rates of improvement the awardee expects to achieve in each year of CCI–I on each proposed quality performance measure in the intervention group as compared to the prior year and as compared to the control group. The applicant should also include additional measures it could track. For each measure, the applicant should indicate its ability to track the measure, data sources that would be used, and projected improvement rates. Further information will be posted on our Web site. The measures presented here are subject to change.

• 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 notice.

• 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 declining to be contacted (to us or to the awardee), the percent of beneficiaries they expect they will be unable to reach, and the percent terminating participation.

Measure	Data source*	Projected % improvement in intervention group over prior year			Projected % change compared to control group		
		1YR	2YRS	3YRS	1YR	2YRS	3YRS
Heart Failure							
Assessment of left ventricular ejection fraction							
Blood Pressure controlled (< 130/85)							
Use of angiotensin converting enzyme inhibitors (ACE–I)/angiotensin receptor blockers (ARB) or hydralazine/isosorbide for patients with LVEF < .4							
Dose of ACE–I							
Use of beta-blockers for patients with LVEF < .4							
Monitoring daily weights							

Measure	Data source*	Projected % improvement in intervention group over prior year			Projected % change compared to control group		
		1YR	2YRS	3YRS	1YR	2YRS	3YRS
Sodium intake counseling							
Compliance with medication regimen							
Spironolactone for patients with AHA/ACC III or IV classification							
Daily aspirin, other antiplatelet or anticoagulant							
Diabetes							
Annual Hemoglobin A1c test							
Lipid profile performed once every year							
Eye exam performed once every year							
Monitoring for nephropathy (test for microalbumin) or receiving treatment for nephropathy							
Annual foot exam performed							
HbA1c controlled (≤7.0)							
Lipids controlled (LDL <130 mg/dl) within past 2 years							
Poor HbA1c control (>9.0 percent)							
Blood pressure controlled (<130/80)							
Patients with microalbuminuria on ACE or ARB							
Compliance with medication regimen							
Daily aspirin							
COPD							
Systemic corticosteroids for acute exacerbation							
Oxygen therapy							
Smoking quit rate							
Annual spirometry testing							
Oxygen status							

Condition	Measure	Data source*	Projected % improvement in intervention group over prior year			Projected % change compared to control group		
			1YR	2YRS	3YRS	1YR	2YRS	3YRS
Other Co-Morbid Conditions (Specify by Condition)								

Measure	Data source*	Projected % improvement in intervention group over prior year			Projected % change compared to control group		
		1YR	2YRS	3YRS	1YR	2YRS	3YRS
Preventive Measures							
Receipt of pneumococcal vaccine ever							
Annual flu shot							
Cigarette smoking cessation counseling							
Nutrition screening/counseling							
Depression screening							
Utilization of Health Care Services							
Hospital admission rates							
Hospital re-admission rates							
Emergency service utilization rates							
Rate of hospitalizations for lower extremity complications (for diabetes patients)							

*Data Source: C=Claims, SR=Self-Report, VSR=Validated Self-Report, P=Provider, S=Survey, PBM=Pharmacy Benefit Manager, L=Labs, CR=Chart Review

8. Payment Methodology & Budget Neutrality

Using the historical claims database of a representative target population that we provide (available on CD-ROM), applicants must provide a fee proposal in the format of Model 1 below for comparability across applications. We will also entertain applications that propose up to two additional payment proposals. All applicants must propose a payment structure that guarantees 5 percent net savings and places chronic care improvement fees at 100 percent risk for savings shortfalls relative to that target. For comparability, in this model, applicants should base this payment structure on 20,000 beneficiaries in the intervention group. All applicants must submit this bid in the format specified in Model 1. In addition, applicants may also include up to two alternative payment structures for programs in which organizations guarantee more than 5 percent net savings and/or propose to serve larger populations. In these scenarios, the applicant could propose to limit its fee risk associated with any shortfall relative to the proposed savings guarantee. Under these alternatives, however, an awardee would still be responsible for refunding us the full amount of its fees if net savings fall below 5 percent.

	Model 1 5% net savings	Alternate fee structure > 5% net savings
Per participant fee/month	$_____/month	$_____/month.
Percent net Medicare savings guaranteed	5%	___%.
Percent fees at risk for guaranteed savings	100%	100% on 5% net savings; Define fee risk for net savings > 5% and < guarantee.

An applicant should describe the components of its monthly fee. The proposed fee should include the projected cost for each chronic care improvement service, including any ancillary services, such as transportation or provision of equipment, and administrative costs in aggregate and per participant. All administrative costs relating to CCI–I should be included in this budget, including 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.

In addition, in conjunction with each bid, the applicant should:

- Describe what differences, if any, in the demographic composition or claims experience of the population in the selected geographic area relative to the national sample would require adjustment in the proposed fees or savings guarantees (for example, hospital admission rates); and
- Specify the proposed adjustment factor to be used to calculate final fees and performance guarantees if the identified values in the actual target population falls outside the corridor for which the proposed fees apply.

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

Medicare Expenditure Projections

The applicant should estimate the expected total yearly Medicare expenditures for the population in the sample dataset and give projections for the intervention group with and without CCI–I, and the resulting net savings to Medicare by major service category, for example, inpatient hospitalizations, outpatient services, emergency department utilization and physician office visits. While we do not have historical claims data available for drug costs, we will include Medicare prescription drug expenditures in cost comparisons between the intervention and control groups beginning in 2006. The applicant should explain any differences it projects in drug costs between the intervention and control group and how these differences (if any) are accounted for in its 3-year net savings projection. Estimates of expenditures with CCI–I should include chronic care improvement fees as well as the payments for traditional Medicare benefits provided to the intervention group as described in section II.A Purpose/Design (Billing and Payment section) of this notice.

An applicant should show the basis for the assumptions used in its proposed payment methodology and budget. The strength of the evidence supporting these estimates will be considered in evaluating the proposals. Further, applicants selected for award will be required to submit data supporting their utilization and financial assumptions prior to award. CMS or its financial contractor will use the information provided by the applicant, as well as Medicare claims and other data, to determine an estimate of what we would pay to provide care for a population similar to the projected intervention group both with and without CCI–I.

9. Implementation Plan

An applicant should provide the implementation information requested in the waiver application as well as those 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 us for CCI–I.

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. Rationale for 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 notice, including:

- Demographics and socio-economic characteristics.
- Access to and utilization of health care services, and Medicare quality ranking.
- Characteristics of the health care delivery system.
- Prevalence of CHF and complex diabetes, or COPD.
- Obstacles to providing chronic care improvement services.

b. Chronic Care Improvement Program (25 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 notice, including:

- A plan for outreach to the intervention group.
- A plan to assess, stratify, and screen participants.
- Frequency and type of interventions, including plan for development and implementation of care management plans.
- Appropriate services and educational materials for participants.
- Adequate mechanisms for ensuring physician integration with the program.
- Adequate mechanisms for ensuring coordination with State and local agencies.
- Adequate mechanisms for handling participants with more intensive needs.
- Data to be collected, data sources, and data analyses.

c. Organizational Capabilities and Structure (25 Points)

The proposal describes or demonstrates clear and convincing evidence that the organization has the structure and capacity to conduct the chronic care improvement program effectively as specified in section II.B. of this notice, including:

- Staff.
- Facilities.
- Equipment.
- Clinical protocols to guide care delivery and management.
- Strong working relationships with local providers.
- Strong working relationships with community organizations in the area.
- Appropriate information and financial systems.
- Ongoing performance monitoring.
- Organizational background and references.
- Accreditation, if any.

d. Performance Results: Past Performance and Performance Projections (25 Points)

The proposal describes or demonstrates clear and convincing evidence that the organization 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 notice, 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 us to determine data to be collected and procedures for submission of those data.
- Willingness to cooperate in independent formal and formative evaluations of CCI–I.

e. Payment Methodology & Budget Neutrality (20 Points)

The proposal describes or demonstrates clear and convincing evidence that the proposed fees 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 notice, including:

- Justification and explanation for the proposed chronic care improvement fees.
- Reasonableness of the proposed chronic care improvement fees and savings guarantees.
- Reasonableness of applicant's estimates of the expected net Medicare savings and the expected total yearly Medicare expenditures for the intervention and control groups.
- Financial solvency and an ability to compensate Medicare in the event the organization fails to meet its performance targets, including reinsurance, withholds, unreserved assets or some other means.

2. Final Selection

The CMS Administrator will make the final selection of organizations for CCI–I 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 approaches for delivering services, targeting beneficiaries, payment, and using integrative information and communications tools). 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. We reserve 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. We expect to make the awards in the fall of 2004. Once awarded, CCI–I will be phased in over a period of time.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues that contain information collection requirements:

This notice informs interested parties of an opportunity to apply for a pilot program agreement for the Voluntary Chronic Care Improvement Under Fee-for-Service Medicare initiative. If interested, applicants must submit a completed Medicare Demonstration Waiver Application that can be found online at: *http://www.cms.hhs.gov/medicarereform/ccip/default.asp.*

Requirements for this submission are described in Section B of this notice.

The burden associated with this information collection is estimated to be 1,200 hours annually (80 hours per response × 15 respondents).

This information collection requirement is subject to the PRA; however, the burden associated with this requirement is currently approved under OMB control number 0938–0880 entitled "Medicare Demonstration Waiver Application'' with a current expiration date of 7/31/2006.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: Dawn Willinghan, CMS–5004–N, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be emailed to the following address: e-mail: *baguilar@omb.eop.gov;* or faxed to OMB at (202) 395–6974.

Authority: Section 721 of Pub. L. 108–173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(Catalog of Federal Domestic Assistance Program No. 93.779, Health Care Financing Research, Demonstrations and Evaluations).

Dated: March 3, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–9127 Filed 4–20–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1273–N]

Medicare Program; Public Meetings in Calendar Year 2004 for New Durable Medical Equipment Coding and Payment Determinations

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

ACTION: Notice of meetings.

SUMMARY: This notice announces the dates and location of public meetings to be held in calendar year 2004 to discuss our preliminary coding and payment determinations for new durable medical equipment (DME). These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and pricing recommendations for DME that have been submitted using the Healthcare Common Procedure Coding System coding modification process. Discussion is directed toward response to our specific preliminary recommendations, and will be limited to items on the new DME public meeting agenda.

DATES: The public meetings are scheduled for Tuesday, June 29; Wednesday, June 30; and Thursday, July 1, 2004. Each meeting day will begin at 9 a.m. and end at 5 p.m., e.d.t. A meeting will only be held on July 1, 2004, if the number of agenda items cannot be managed in two meeting days.

ADDRESSES: The public meetings will be held in the Centers for Medicare & Medicaid Services (CMS) Auditorium, located at 7500 Security Boulevard, Baltimore, MD 21244.

Web site: Additional details regarding the public meeting process for new DME, along with information on how to register and guidelines for an effective presentation, will be posted at least one month before the first meeting date on the official HCPCS Web site, and can be accessed at *http://cms.hhs.gov/medicare/hcpcs/default.asp*.

Individuals who intend to provide a presentation at a public meeting for new DME need to familiarize themselves with this information. This Web site also includes a description of the HCPCS coding process, along with a detailed explanation of the procedures used to make coding and payment determinations for DME and other items and services that are coded in the HCPCS.

A summary of each public meeting for new DME will be posted on the above Web site within one month after the meeting.

FOR FURTHER INFORMATION CONTACT: Jennifer Carver, (410) 786–6610.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Public Law 106–554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice for new DME are in response to the mandate of section 531(b) of BIPA.

We published a notice in the November 23, 2001, **Federal Register** (66 FR 58743) with information regarding the establishment of the public meeting process for DME.

II. Registration

Registration Procedures: Registration may be completed online at *http://cms.hhs.gov/medicare/hcpcs/default.asp*, or you may contact the DME Public Meeting Coordinator, Jennifer Carver at 410–786–6610, to register by phone. The following information must be provided when registering: Name, company name and address, telephone and fax numbers, e-mail address and special needs information. Registrants must also indicate whether they are the "Primary Speaker'' for an agenda item, designated by the entity that submitted the HCPCS coding request. A CMS staff member will confirm your registration by mail, e-mail or fax.

Registration Deadline: Individuals must register for each date they plan to attend and/or provide a presentation. The deadline for registration for all of the meetings dates is Tuesday, June 15, 2004.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that submitted the HCPCS coding request for an item that appears on the Public Meeting agenda may designate one person to be the "Primary Speaker'' and make a presentation at the meeting. We will post guidelines regarding the amount of time allotted to the speaker, as well as other presentation guidelines, on the official HCPCS website at least a month before the first public meeting in 2004 for new DME. Persons designated to be a Primary Speaker must register to attend the meeting using the registration procedures described above and, at least 15 days before the meeting, contact the DME Public Meeting Coordinator, Jennifer Carver at 410–786–6610. At the time of registration, Primary Speakers must provide a brief, written statement regarding the nature of the information they intend to provide, and advise the meeting coordinator regarding needs for Audio/Visual Support. In order to avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accommodate tapes and disk files that are received by the DME Public Meeting Coordinator 7 or