

Voluntary Chronic Care Improvement under Traditional Fee-for-Service Medicare

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 newly added section 1807-Voluntary Chronic Care Improvement Under FFS Medicare initiative as authorized by section 721 of the Medicare Prescription Drug, Improvement, and Modernization Act (MPDIMA) of 2003.

Eligible Organizations (Awardees): Disease Management organizations, Health insurers, Integrated delivery systems, Physician group practices, A consortium of entities, or Any other legal entity that the Secretary determines to be appropriate.

Background:

Widespread failings in chronic care management are a major national concern. The failing systems are from systemic problems rather than lack of effort or intent by providers to deliver high quality of care. Medicare beneficiaries are disproportionately affected because they typically have multiple chronic health problems that add to their self-care burdens and risks of developing co-morbid conditions, complications, and acute care crises. Those with multiple chronic diseases are a large and costly subgroup of the Medicare population, representing 2/3 of all Medicare FFS program payments. The health risks of those beneficiaries depends 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.

Each program of the CCI-I 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. 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. The duration of this CCI-I program shall be three years.

HHS is particularly interested in application for programs in geographic areas that have a high prevalence of CHF and or diabetes, two of the most common chronic diseases in Medicare FFS population or chronic obstructive pulmonary disease (COPD) and poor Medicare quality rankings. Beneficiaries with these diseases tend to have complex self-care regimens and medical care needs. Complex self-care regimens also entail fragmentation of medical services, because beneficiaries see up to seven different physicians and fill upwards of 20 prescriptions per year, resulting in duplication of procedures and tests and conflicting information.

The program shall test in ten areas in which the total population represents at least 10 percent of the Medicare FFS beneficiaries. Primary focus will be on implementation and evaluation of programs for chronic heart failure (CHF) and/or diabetes, and COPD with significant co-morbidities. Selection criteria and identification of at least 30,000 beneficiaries in each area will be defined by the secretary of HHS, and then split between intervention and control groups.

Adjustments maybe made to applicants to ensure that the service area is proportional in size and services.

One designated award winner will be selected per area to offer intervention group services. Efforts must be coordinated with the providers of the beneficiaries regarding self-care and information to increase adherence to evidence-based care. Participation in the program will not change the amount, duration or scope of participants' FFS Medicare benefits.

Awardees will be paid a monthly fee per participant, contingent on improvement in clinical quality of care, beneficiary and provider satisfaction, and savings to Medicare in the intervention groups compared to the control groups.

Current Chronic Care Improvement Initiatives

Payers in the private sector have begun to sponsor chronic care improvement initiatives in the form of disease management (DM) and intensive case management programs. The purpose is to address pervasive problems in ensuring that chronically ill individuals receive appropriate care. The intensive care programs are designed to assist patients who develop costly and complex medical care needs. The disease management programs typically target a single-disease, including: patient self-care support, provider information support, and use of integrative clinical information systems to collect and synthesize patient data from the delivery of health care. The programs are designed to ensure that preventive measures are taken when appropriate and to prevent or lessen complications, as well as:

- Supply providers with timely, actionable clinical information
- Provide clinical decision support for patients and providers based on evidence-based guidelines;
- Promote care coordination; and
- Guide and encourage patients in adhering to the required regimens.

At a broader level, the National Committee for Quality Assurance (NCQA), the American Accreditation Healthcare Commission/URAC and the Joint commission on Accreditation of Healthcare Organizations (JACHO) have developed quality standards and certification programs for DM programs.

Provisions:

The initiatives to be tested under CCI-I will have some characteristics in common with the aforementioned private sector DM programs but will be adapted to suit the unique needs of the Medicare FFS beneficiaries environment. Organizations will have the latitude to stratify targeted beneficiaries according to risk and need and to tailor interventions to the unique needs of the recipients, including self-care, care coordination, education, and use of in-home monitoring devices. Additionally, the organizations involved shall assume some financial (fee) risk in the event of failure to meet agreed performance guarantees for clinical quality, beneficiary and provider satisfaction and savings targets. It is believed that the CCI-I organizations will have strong incentives to reach the targeted beneficiaries and their providers on a continuing basis.

Eligible Beneficiaries

Eligible beneficiaries will be those who meet the inclusion and exclusion criteria established by HHS and who are identified randomization. Beneficiaries will be prospectively identified in each CCI-I geographic area. Inclusion beneficiaries must be enrolled in Parts A and B, have CHF

and/or complex diabetes, or COPD, and have Medicare as primary payer. Excluded beneficiaries shall be currently enrolled in any of the following:

- Medicare ESRD program
- Hospice;
- Medicare Advantage (Medicare+ Choice); or
- A CMS FFS chronic care demonstration.

Beneficiaries with CHF and/or complex diabetes, and COPD will be identified based on two or more professional visits on separate dates for CHF or complex diabetes based on 1 year of historical claims. Because of high prevalence of COPD in the Medicare population testing will be considered in one or two geographic areas if the proposals are strong.

Targeted areas shall be randomized for control groups to ensure comparability on factors that could affect performance improvement and overall health care costs. As mentioned above rejection is possible if an applicant is not willing to adjust the size of its population base to include 10 percent of Medicare FFS beneficiaries.

Identification of Geographic Area

Area of interest must not conflict with a currently operating FFS chronic care demonstration. Results may be confounded because of cross-contamination of control groups. HHS further believes it to 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. Applicants who would still like to pursue an area where a demonstration already exists is encouraged to contact the department for further explanation.

Outreach to Intervention Group

Beneficiary participation shall be strictly voluntary. Notification of eligibility for the CCI-I program will be through a letter from the Medicare program. The letter shall include a description of the program and an opportunity to decline or obtain further information about the program. Each awardee shall be required to contact the intervention group beneficiaries in its area who did not decline, confirmed participation, and initiated support services. Beneficiary may terminate participation at any time.

For outreach, preliminary assessment of risk levels and support needs, Medicare shall provide awardees with all historical claims data and other necessary information on the intervention group, except phone numbers. It is expected that all applicants' proposals specify detailed outreach protocols, including examples and frequencies. Outreach shall last for a period of six months; Medicare reserves the right to negotiate limits on the number and/or frequency of attempts. Once the period is over, awardees must provide projections as to the percentage of beneficiaries confirming participation, those who declined, those unable to reach, and those who terminated participation.

Program Characteristics

The main attribute as stated before is to expand the amount, duration or scope of beneficiary's FFS Medicare benefits through cost effective measures. Beneficiaries will continue to have access to care and the same freedom of choice of providers as they do currently.

Awardees must be able to demonstrate that they conduct their CCI-I programs in accordance through the development of a care management plan with each participant. Each awardee shall:

1. Guide participants in managing his/her health
2. Use decision-support tools (evidence-based guidelines)
3. Develop a clinical information database to track and monitor participants across settings

The Secretary of CMS also has the discretion to create additional program requirements beyond those specified, particularly to track the record of success in engaging other providers, state and local agencies, and community organizations in information sharing of the targeted population.

The agency is aware that many organizations have developed their own electronic health records and other health information technology used at the point of care to improve quality and safety. However because of the nature of this project it must be understood that ***Transparency is essential***. 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 the agency all chronic care management software, algorithms and associated documentation, as well as beneficiary health information, program operational manuals, and other data used by the awardee in the course of performing the services pursuant to CCI-I, to be used by the agency solely to further the purpose.”

Applicants must comply with all applicable laws, including but not limited to privacy laws and the Health Insurance Portability and Accountability Act (HIPAA).

Billing and Payment

The testing range of program models will vary in cost structures, therefore fee amounts shall be determined per awardees. Claims for medical services will continue to be covered, administered, and paid under Medicare FFS. During the outreach period Medicare will pay per beneficiary monthly payment for all intervention group beneficiaries, except those who declined.

No start-up funds will be allowable for costs incurred prior to program implementation. No added payments will be made for program evaluation costs, travel, capital investments, data collection, or any activity related to CCI-I. However, all program costs will be factored into the per participant fee and the applicants payment proposal should explain the rationale.

Performance Standards

Applications must set forth projections for improvement on clinical quality and savings on a year-to-year basis in the intervention group and as compared to the control. Standards shall also provide for an adjustment in payment rates if it is determined that the awardee failed to meet its agreed-upon performance standards.

Reconciliation Process

Independent contractors will be hired to monitor clinical quality, beneficiary and provider satisfaction, utilization, and costs for purposes of interim payment adjustments. The contractors will also perform final financial reconciliation at the end of the 3-year program to determine if any refunds to the government are necessary if the awardee fails to achieve agreed-upon performance guarantees.

Because awardees assume the fee risk not insurance risk, awardees shall be required to establish a system to compensate Medicare (up to 100% of the applicant's chronic care fee) if they fail to meet agreed results. Applicants must demonstrate financial solvency in submitted application via reserves, reinsurance, withholds, or other means.

Program Monitoring

Program monitoring includes both performance and operational metrics. The agency shall conduct ongoing formative monitoring throughout the project. Awardees will be expected to track various performance and operational metrics. Some performance metrics must be analyzed quarterly. The evaluation will be conducted in collaboration with CMS and awardees to identify and address operational problems, foster continuing improvement, and inform the agency as to how they might expand the program.

Independent Formal Evaluation

The independent evaluator will study the experience of the intervention group in each area compared to the control group to analyze the ability and individual elements of each program base on the performance measurements. Awardees must cooperate with evaluator and participate in case studies and track and submit performance data.

A standardized beneficiary and provider satisfaction survey will be developed to compare satisfaction levels between the control and intervention groups.

Requirements for Submission:

Awardee Selection Process

The process for selection shall be done in two stages. During the 1st stage, prospective applicants will be provided with a de-identified data set of Medicare claims information of beneficiaries who meet the inclusion and exclusion requirements. Applicants must analyze the data and submit an application and bid, including proposed target population (CHF, complex diabetes, or COPD), per participant per month fees and performance guarantees. Proposal must be based on 20,000 beneficiaries in the intervention group. Applicants will have 90 days to submit applications from the date the data is made available.

In the 2nd stage, a review panel will evaluate applications based upon the application evaluation criteria (for a complete list see section II.C of the notice) and will recommend applications to be considered for the second stage. Site visits may be conducted based upon review panel recommendations.

The Administrator will make the final selections. Finalist will be given the actual historical data for the applicable target population and asked to analyze the data to determine if originally proposed and agreed upon adjustment factor (s) apply.

Application

Applicants must submit completed applications following the standard format outlined in the Medicare Waiver Application available at <http://www.cms.hhs.gov/medicarereform/ccip/default.asp>

Applications will be reviewed by the technical review panel only if they are received on or before 5: 00 p.m. EST on August 6, 2004. Applications should include the following sections in the proper order. The necessary sections shall be evaluated by the panelists with a numerical rating based on the evaluation criteria.

1. Cover Letter
2. Application Form
3. Executive Summary
4. Rationale for proposed geographic area and target population (problem statement) (5 pts)

Applicants should specify which targeted population they intend to serve (CHF and/or complex diabetes, or COPD). The description must include demographics of the Medicare FFS population in the area, utilization rates, prevalence rates CHF and complex diabetes or COPD in the Medicare population, and Medicare quality ranking. The current health care delivery system and access to care in the area must also be included in the description.

5. Chronic Care Improvement Program Design (25 pts)

A description and explanation is required of how the program and how the proposed interventions will improve clinical quality, beneficiary and provider satisfaction, and achieve savings for the intervention group. This section also requires the applicant to address the following activities:

- A plan for Outreach
- A plan to assess and stratify participants
- Frequency and type of interventions
- Appropriate service and education materials for participants
- Adequate mechanisms for ensuring physician integration with the program
- Adequate mechanisms for ensuring coordination with the State and local agencies
- Adequate mechanisms for supporting participants with more intensive needs
- Data source, collection and analysis

To learn more about each activity, view section II C of the proposal

6. Organizational Structure and Capabilities (25 pts)

It must be demonstrated that the applicant has the management capacity and organizational infrastructure to carry out CCI-I. Explanation is also required for the following areas:

- Staff
- Facilities
- Equipment
- Working relationship with local providers
- Working relationships with community organizations
- Appropriate information and financial systems
- Clinical protocols for delivery of care and management
- Ongoing performance monitoring
- Organizational background references

- Accreditation

To learn more about each area of explanation, view section II C of the proposal

7. Performance Results: Past and Future Projections (25 pts)

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. Evidence of positive outcome from prior and current efforts should be reported.

Applicants must lay out projections for improvement in a year to year format. The projections must include in the CCI-I agreements as standards for monitoring performance.

The original proposal provides examples of projection tables for CHF, diabetes, COPD, other chronic illnesses, preventive measures, and utilization of health care services

8. Payment Methodology & Budget Neutrality (20 pts)

Based on the sample historical data provided, applicants must outline a fee proposal in a specified format for comparability across applications. HH will entertain applications that propose up to two additional payment proposals. All payment structures must guarantee 5 percent net savings and place chronic care improvement fees at 100 percent risk for savings shortfalls relative to that target. A description of the monthly fee is required and should include projected costs for each chronic care improvement service.

Medicare Expenditure Projections: Applicants must 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.

9. Implementation Plan

Applicants must provide the following information:

- A schedule with timeline for all essential tasks
- Modification to protocols, services, outreach, education initiatives, timelines, ect.
- Process improvements made by the organizations in the last 12 months as part of continuous quality improvement related to providers, patients, health plans, communication, and health education.