Interested persons may submit to the Dockets Management Branch (address above) written comments on the plan. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 21, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–19046 Filed 7–27–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1115–N]

RIN 0938–AI26

Medicare Program; Solicitation for Proposals for the Medicare Coordinated Care Demonstration

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for a cooperative agreement for the Medicare Coordinated Care Demonstration. This demonstration uses existing models of coordinated care interventions to improve the quality of services furnished to specific beneficiaries and manage expenditures under Parts A and B of the Medicare program. We are interested in testing models aimed at beneficiaries who have one or more chronic conditions that represent high costs to the Medicare program.

Section 4016 of the Balanced Budget Act of 1997 requires a review of best practices and that the Medicare Coordinated Care Demonstration design be based on the findings of this assessment. We intend to select at least eight proposed projects for this demonstration through this competitive application process.

Eligible Organizations

Potentially qualified applicants are existing providers of coordinated care services applicable to the Medicare population. See section II.C.1. of this notice for additional details.

FOR FURTHER INFORMATION CONTACT: For information concerning this demonstration, contact Catherine Jansto, HCFA Project Officer, at (410) 786–7762, or cjansto@hcfa.gov.

For information regarding cooperative agreement procedures, fiscal matters, or guidance in completing the application forms, contact Nettie Faulkner, Grants Management Specialist, at (410) 786–6639, or nfaulkner@hcfa.gov.

General information regarding this project is available on HCFA's website (www.hcfa.gov/ord/coorcare.htm).

DATES: Applications will be considered ''on time'' if we receive them on or before October 11, 2000.

ADDRESSES: Mail applications to: Department of Health and Human Services, Health Care Financing Administration, Office of Internal Customer Support, Acquisition and Grants Group, Attn: Ms. Nettie Faulkner, Grants Management Specialist, Mail Stop: C2–21–15, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Applications must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of the executive summary, resumes, forms, and documentation supporting the cost proposal. Please refer to the file code HCFA–1115–N on the application.

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

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Requirements

Section 4016 of the Balanced Budget Act of 1997 (Pub. L. 105–33) requires the Secretary of Health and Human Services (the Secretary) to evaluate best practices in the private sector for methods of coordinated care. The statute also directs the Secretary to design a demonstration project for the original Medicare fee-for-service population based on this evaluation. The purpose of the demonstration is to evaluate models of coordinated care that improve the quality of services provided to specific beneficiaries with a chronic illness and manage expenditures under Parts A and B of the Medicare program so that, under the demonstration, Medicare expenditures do not exceed what they would have been in the absence of the demonstration.

Section 4016(b)(3) authorizes the continuation of demonstration projects that are cost-effective. That is, the evaluation of the demonstration projects conducted by HCFA establishes that these projects reduce Medicare expenditures or do not increase Medicare expenditures while increasing the quality of services furnished and beneficiary and provider satisfaction. This section also authorizes us to expand the number of demonstration sites if the models tested are shown to be cost-effective. In addition, we may issue regulations to implement, on a permanent basis, the components of the demonstration projects that are proven to be cost-effective for the Medicare program.

In July 1998, we competitively awarded a task order for conducting a review of best practices in coordinating care and for providing a recommendation of demonstration design options to Mathematica Policy Research, Inc. (MPR). We have evaluated the findings from the review of best practices and selected the following demonstration design.

B. Problem

Historically, a small proportion of Medicare beneficiaries has accounted for a major proportion of Medicare expenditures. For example, in 1996, 12.1 percent of all Medicare enrollees accounted for 75.5 percent ($126.1 billion) of all Medicare fee-for-service program payments. Many of these high-cost beneficiaries are chronically ill with certain common diagnoses, and most of the Medicare expenditures for their care are for repeated hospitalizations. During the next 30 years, as the population ages, the number of these individuals is expected to grow dramatically.

Health care for individuals with chronic illness is often fragmented and poorly coordinated across multiple health care providers and multiple sites of care. Oftentimes, evidence-based practice guidelines are not followed, nor are patients taught how best to care for themselves. These shortcomings are particularly true for patients served under reimbursement systems in which providers lack incentives for controlling the frequency, mix, and intensity of services, and have limited accountability for the outcomes of care.

A number of health care organizations, including health maintenance organizations, private insurers, commercial firms, and academic medical centers, have developed programs to support adherence (by both provider and patient) to evidence-based medical practices, to better coordinate care across providers and between face-to-face encounters with chronically ill patients, and to reduce costs. At best, the literature on the effectiveness of

these models is mixed. There is little hard evidence that these programs are effective. Hence, the applicability and cost-effectiveness of these programs, in general, for the original Medicare fee-for-service program and specifically to its beneficiaries who suffer from complex co-morbid conditions is uncertain.

C. Findings From the Review of Best Practices

On March 23, 1999, we published a notice in the **Federal Register** (64 FR 13998) announcing the opportunity to submit information on examples of best practices of coordinated care as well as to comment on potential aspects of the overall Medicare Coordinated Care Demonstration. Through a review of submitted information, electronic literature searches, and expert referrals, MPR identified programs self-reporting success in coordinating care for chronically ill patients. A multi-tiered approach focusing on structure, process, and outcomes was used to identify favorable characteristics of potentially successful programs and to develop a general framework that describes these coordinated care delivery models. The review emphasized the strength of the evidence supporting claims of success, the degree of impact on costs (hospitalizations and total costs), and the degree of impact on patient outcomes. A detailed discussion of the methodology, findings, and limitations of the best practices assessment is available in MPR's final report that can be accessed via our website (www.hcfa.gov/ord/coorcare.htm). A brief summary of the report's findings and limitations is presented below.

1. Findings

MPR identified two main types of coordinated care programs and a three-step conceptual framework applicable to these coordinated care delivery models. The two main types of programs differ in the patients they serve and the tactics they adopt to accomplish the three steps of the conceptual framework for coordinating care. Because of limitations in the submitted data, the cost-effectiveness of the reviewed programs could not be determined with certainty. There were 37 programs reporting credible evidence of impacts on hospitalizations or total costs. Twenty-five of these programs were interviewed in greater depth to obtain greater insight into the reasons for their success. These programs are referred to as ''identified potentially cost-effective programs'' in this notice.

a. *Models of Coordinated Care:* The identified potentially cost-effective programs tended to operate as one of the following two program types.

- Case Management (CM) Programs

These programs serve a select group of frail, disabled patients who suffer from severe illness, often multiple chronic health problems, and a high risk of recurrent, costly, adverse medical events. Each patient has a unique set of diseases, functional deficits, and social conditions. These programs follow a holistic approach to care and rely on case manager judgment and highly individualized approaches. Creative, innovative interventions are used to address individual care needs. Partnership with the patient, primary care physician (PCP), other providers, caregivers, and the social support system is integral to the interventions.

- Disease Management (DM) Programs

These programs target persons whose primary health problem is a specific disease, although certain comorbid conditions are usually addressed as well. Patients with a similar level of severity of the disease face similar problems. The care coordination interventions tend to be highly structured and emphasize the use of standard protocols and clinical guidelines. The PCP may not play an active role in the implementation of the interventions; however, successful collaboration with PCPs generally influences program outcomes.

Under both main types of coordinated care programs, the interventions provided go beyond those services for which payment under the original Medicare fee-for-service program is typically made. These interventions may include comprehensive geriatric assessment, intensive patient education, social services, telephone monitoring, medications, or transportation, among others.

Overall, there was variation among the identified potentially cost-effective programs within and between the two main types of programs. The scope, mix, and intensity of care coordination interventions varied as did the duration of the interventions, targeted disease(s), organizational structures, system and staff capabilities, outcomes, and other features. Notwithstanding this variation, there were many examples of programs that claim to have successfully combined particular practices to positively impact patient and cost outcomes.

b. *Goals of Successful Coordinated Care Programs:* In general, the identified potentially cost-effective coordinated care programs use a variety of interventions to accomplish the following goals:

- Ensure optimal medical management.
- Enhance and support patient self-management.
- Eliminate barriers to efficient and effective utilization of health care services.

To achieve these goals, the identified potentially cost-effective coordinated care programs of both types generally follow a three-step process that is described in the following conceptual framework.

c. *Conceptual Framework:* Care coordination programs identify the patients they serve through a range of methods. After defining the target population (and any exclusionary criteria), programs may identify potentially eligible clients through provider or self-referrals, claims data, special screening tools, or a combination of methods. Eligible and willing cases then receive the intervention.

Many care coordination programs ''risk-stratify'' their patients, attempting to identify from those meeting the basic eligibility criteria the subset that would benefit most from the intervention. Some programs use risk stratification to restrict the set of patients admitted to the program, while others use it to tailor the intervention to the estimated level of risk of adverse outcomes faced by the patient. However, the degree of structure imposed in stratifying patients may vary. Thus, the three-step process discussed below focuses on what programs do once targeted patients are identified, rather than how they are selected.

Step One: Assess and Plan: *Accurately assess patients' barriers to improved health and devise a feasible plan to overcome those barriers.* This step encompasses activities such as initial patient assessment, care plan development, establishing patient-specific goals, assessing patient education needs, and involving PCPs and other providers. The component tasks of Step One are as follows:

- *Uncover all important problems.* These are the problems that can keep the patient from better health and lead to unplanned hospitalizations. These problems vary for each patient.
- *Address all important problems and goals.* Every important problem and goal should have a plan and an intervention or interventions to address the problem.
- *Draw from a comprehensive arsenal of proven interventions.* A care coordinator must have a broad array of appropriate, proven interventions

available from which to choose the best ones to meet a patient's needs.

• *Produce a clear, practical plan of care with specific goals.* The first step concludes with a written, individualized plan of care. It is important that all concerned—patient, care coordinator, primary care physician—have a common, agreed-upon set of goals for the patient, and when and how the patient is going to achieve them.

Step Two: Implement and Deliver: Implement the plan and deliver the interventions. This step encompasses activities such as patient education, service arrangement and provision, and coordination with providers. The component tasks of Step Two are as follows:

• *Build ongoing relationships with the primary care physician (PCP) and with other providers.* This task enables care coordinators to coordinate care and facilitate communication among providers. Also, programs that fail to engage the physician may be limited in the degree to which they can address the medical aspects of care coordination.

• *Build ongoing relationships with patients and families.* The foundation for this relationship is often laid during the initial assessment in the first step.

• *Provide excellent patient education.* This intervention must be part of every plan of care. Programs must teach patients crucial self-care skills, such as proper diet for their condition, medical compliance, self-monitoring, emergency action plans, and skills to cope with the stresses of chronic illnesses.

• *Make certain that planned interventions are conducted.* This task involves monitoring to make sure each intervention is conducted.

Step Three: Reassess and Adjust: *Determine whether the interventions are working as intended. If not, adjust the plan by going back to Step One.* This step entails regular evaluation and monitoring of whether the plan of care developed in Step One and its implementation in Step Two are achieving the intended goals. The component tasks of Step Three are as follows:

• *Perform periodic reassessments.* The care coordinator must contact patients on a regular basis to make sure they continue to progress and have not encountered new problems.

• *Be accessible.* Patients must have an easy way to reach a care coordinator at all times.

• *Nurture the relationship with PCPs and providers.*

• *Nurture the relationship with patient and family.* This relationship and the relationship with the PCPs and providers must be maintained.

• *Make prompt adjustments to the plan of care as needed.* If the reassessment reveals a lack of progress, the plan of care may need to be changed. Several interventions may have to be tried and discarded before a successful solution is discovered. Changes in the plan of care also need to be made promptly, sometimes even urgently. Patients' level of risk for complications may change, necessitating a change in follow-up frequency.

Overlaying these three steps, at the program level, programs employ system-wide processes for assessing and improving the coordinated care delivery model as a whole. These continuous quality improvement processes ensure that lessons learned about failures and successes are disseminated to other care coordinators and program staff.

d. *Similarities Between Program Types:* The two main types of coordinated care programs are similar in several respects. First, the identified potentially cost-effective programs of both types accomplish the same three basic steps and address the same basic components under each of these steps, as described above. Both disease and case management programs have case managers who act as advocates for their patients to help them get the care and attention they need. Strong programs of both types stress the critical importance of having personable, knowledgeable case managers who are effective communicators. Programs of both types also provide thorough patient education focused on self-care and overcoming personal barriers to improved health. In addition, the potentially cost-effective programs of both types are proactive rather than reactive, developing written care plans based on evidence-based, disease-specific guidelines at the outset, and monitoring patients between office visits.

e. *Differences Between Program Types:* Despite these similarities, the two main types of coordinated care programs differ in the types of patients they serve and the tactics they adopt to accomplish the three steps and their component tasks. The major differences between disease management (DM) and case management (CM) programs seem to stem from the somewhat more limited set of problems that DM programs typically deal with. Patients in DM programs generally do not have as high a prevalence of difficult geriatric syndromes, such as incontinence, falling, cognitive impairments, delirium, or such social problems as inadequate family support, housing, or transportation. Instead, the vast majority of DM patients' problems center around a single disease or condition and fall into fundamental problems with either their own behavior or the disease-specific care they receive. Patient behavior problems contributing to their problems include poor medication compliance, lack of self-care skills, and lack of adherence to recommended lifestyle changes. Provider-based problems include failure to prescribe the most effective medications, poor coordination of care across providers and settings, lack of adherence to disease-specific guidelines based on evidence or expert panels, and inadequate follow-up and monitoring. Case management programs tend to serve patients with a more complex mix of problems and comorbidities. While they also face problems of poor self-care and compliance and inadequate prescribing and follow-up by their physicians, the patients are often frail and more prone to face adverse interactions from multiple prescription drugs that they may be taking for different conditions, or from conflicting advice about diet and exercise from different providers treating their multiple conditions.

As a result of the differences in characteristics of the patients served, disease management and case management programs differ in the emphases they place on different component tasks, and on how they accomplish these tasks. They also differ on the degree to which patient education and treatment is standardized. Case management programs tend to rely more heavily on the judgment of the case manager and less on protocols. Case management programs also take a broader perspective, involving family and other caregivers and arranging for services more often than the typical disease management programs. (See MPR's final report for more comprehensive lists of key features of potentially cost-effective disease management and case management programs.)

f. *Rural Programs:* A few of the identified potentially cost-effective programs served rural areas. Each of these programs was of the case management type and looked similar to nonrural case management type programs. However, having strong ties to the community helped rural case managers gain patients' trust and find ways of getting things done. Travel distance placed important constraints on case managers by limiting their caseloads, forcing them to spend much energy on transportation arrangements, and making it difficult for them to forge

collaborative relations with outlying physicians.

2. Public Comments

In response to the March 23, 1999 notice, we received 25 timely public comments on potential aspects of the overall demonstration. All but six of the comments were from providers that furnish coordinated care services. The commenters included for-profit vendors, tertiary hospitals, academic medical centers, health plans, and nonprofit groups. The comments related to the types of organizations that are appropriate providers of care coordination services, the care manager's role, desired features of care coordination programs, and reimbursement of care coordination services.

Commenters suggested a variety of organizational structures in which to provide care management including for-profit and nonprofit entities, integrated delivery systems, and stand-alone care management providers.

The majority of commenters believed that the care manager should be part of an interdisciplinary team and most believed that the care manager should be intimately involved in the provision of actual care to enrollees. One commenter stressed the need to define the care manager's role in relation to other providers of care coordination (such as discharge planners) in the current Medicare system. Commenters also suggested that programs need to integrate patients' physicians into the care coordination process.

Several providers credited their success to the use of patient risk stratification, evidence-based medicine, information systems, or Internet and telecommunications technologies. The latter two were mentioned by several commenters as being useful for rural populations.

There were many comments on the difficulties of providing care management services under the current Medicare fee-for-service payment system. Almost all respondents suggested some sort of risk bearing system in which providers would be paid a fixed fee per enrollee and would share in any savings to the Medicare system. Some also suggested that reimbursement be linked to patient outcomes.

3. Limitations

Through the study design, a number of exemplary or highly regarded coordinated care programs may have been excluded from the review of best practices. Only those programs that volunteered to submit information and that provided self-reported evidence of favorable impacts on costs or hospital admissions were considered in the review. However, a review of excluded programs would not likely alter our basic conclusions about the three basic activities that successful programs must accomplish and the component tasks that they must address. Nor would have examination of additional programs been likely to permit more definitive statements about minimum requirements for a successful care management intervention. Evidence from additional programs would have likely provided further proof that there are multiple ways to achieve the goal of coordinating care.

An additional limitation of the review is that the data were self-reported and it was not possible to validate the reported impacts on outcomes. Nonetheless, the quality of the evidence reported was evaluated, and this ranking was used in the identification of potentially cost-effective practices. Thus, absent fraudulent representation of the data or concealment of questionable evaluation practices, programs that reported large impacts are likely to have had sizeable positive effects, even if the effects are somewhat overstated. This conclusion is reinforced by the focus of the study on programs that also tended to have features that case management experts believe to be strongly associated with good care coordination. Another data-related limitation is that the cost-effectiveness of most programs could not be assessed due to the complete absence or poor quality of data on the costs of the interventions.

In the analysis phase of the assessment, some of the less successful programs (those that reported comparatively smaller impacts) were reviewed in an effort to better understand potential differences between these programs and programs with similar structure and process features that reported large impacts. While this effort yielded limited insight (due largely to the wide variability in the quality of the evidence and large confidence intervals), examination of three unsuccessful programs reinforced the findings described above. These ineffective programs failed to identify all important problems, and failed to set specific goals in creating care plans. They also had shortcomings in implementing and delivering the care. Two of the programs cited difficulties building relations with primary care providers. One program relied solely on pamphlets for patient education. They also failed to reassess patients adequately, lacked procedures for patients to reach case managers between scheduled contacts, and relied on staff with backgrounds in acute care rather than community nursing.

D. Discussion

The findings of the best practice assessment suggest two general conclusions. First, there are several, if not many, potentially effective ways of coordinating care, and second, the two delivery models identified (DM and CM) may have the potential to improve care for chronically ill Medicare beneficiaries. In general, these conclusions are sufficiently informative for the purposes of developing a demonstration design. A conceptual framework applicable to the identified coordinated care delivery models is provided, and it appears that implementation of each of these delivery models in the Medicare fee-for-service program under a demonstration is feasible.

In addition to the conceptual framework and favorable characteristics of potentially cost-effective programs found through the review of best practices, there are several key design details that must be specified in order to ensure the likelihood of a successful demonstration within the time frame required by the Balanced Budget Act. These design issues include: Eligibility requirements, organizational capabilities for providing coordinated care services and for participating in the research and evaluation aspects of the demonstration, experimental design, technical operational design features, and the payment methodology to be tested. In specifying these requirements, we rely on our past experience with successful and unsuccessful demonstrations.

II. Provisions of This Notice

A. Purpose

This notice solicits applications for demonstration projects that will use existing models of coordinated care to improve the quality of services furnished to specific beneficiaries and manage expenditures under Parts A and B of the Medicare program. These savings are to result from more efficient provision and utilization of Medicare-covered services and the prevention of avoidable, costly medical complications. The intention of this demonstration is not to expand the set of services that Medicare covers with the exception of coordinated care services for targeted beneficiaries. Applicants may propose to expend a portion of the payments received for coordinated care services on services

that are typically not covered by the Medicare program. These services are not to be considered Medicare-covered services to which demonstration participants are entitled under the demonstration. Examples of these services include (but are not limited to): Coordination with community-based services, transportation, medications, noncovered home visits, and equipment. Beneficiaries will not be financially liable for these services.

We are interested in testing a variety of delivery and payment models aimed at diseases that represent high costs to the original Medicare fee-for-service program. The number and type of models to be tested will be determined by the quality of the proposals received. Through this solicitation, we intend to award at least eight proposed projects. Five of the selected projects will be conducted in urban areas; three in rural areas. We intend to operate the demonstration projects for 4 years from implementation during which time a formal evaluation will be conducted. We will assign a project officer, to each selected project, who will serve as the point of contact with the demonstration project staff. Our project officer will provide technical consultation regarding cooperative agreement procedures, monitor demonstration site activities, and forward feedback to the demonstration project's staff.

B. Funding

Under the demonstration, using a monthly all-inclusive rate, we will pay for the proposed coordinated care services. As required in the Balanced Budget Act of 1997, aggregate Medicare payments for the costs of the demonstration must be budget neutral for the Medicare program. This requirement means that, over the course of the projects, the aggregate Medicare payment for the coordinated care services (and any start up funding and incentive payments, if made) may be no greater than the total expected Medicare program savings from the coordinated care services. In addition to the monthly payment amounts, applicants may propose and we are willing to consider testing well-constructed performance incentives for the coordinated care entity.

Applicants may request minimal financial assistance for initial implementation costs (one-time payment of up to $150,000 per demonstration project, subject to availability). If made, this funding will be considered as part of the project's budget neutrality estimate. We are willing to consider requests for assistance with the following kinds of initial implementation costs: Modification of existing protocols, services, outreach, and educational materials to address a Medicare fee-for-service population. Applicants' proposed project budget must show the applicant's share of start-up costs as well as the proposed HCFA share.

C. Requirements for Submissions

We are seeking innovative proposals from a variety of qualified organizations that test whether models of coordinated care improve clinical outcomes, satisfaction, quality of life, and appropriate use of Medicare-covered services for targeted Medicare fee-for-service beneficiaries, while managing Medicare expenditures under Parts A and B so that budget neutrality of the project is achieved. Preference will be given to proposals aimed at beneficiaries who have one or more chronic conditions that represent high costs to the Medicare program, such as congestive heart failure, other heart disease (heart attack, ischemic heart disease, angina, arrhythmia), diabetes, liver disease, chronic obstructive pulmonary disease or other chronic lung disease, stroke or cerebrovascular or other vascular disease, psychotic disorders, major depressive disorders, drug/alcohol dependence, Alzheimer's or other dementia, cancer, or HIV/AIDS. Applicants proposing to target beneficiaries with chronic conditions not listed above must provide evidence justifying their selection.

Applicants must describe, in detail, their experience with providing coordinated care services and the populations served. Enrollment and drop-out rates must be described. Applicants must submit evidence for the following required organizational capabilities: appropriately experienced clinical and management staff; accurate understanding of the original Medicare fee-for-service program coverage and payment policies; adequate data and information systems; capacity to capture and analyze relevant patient-specific data elements; willingness to submit data to our designated evaluation contractor; effective management oversight; and effective quality improvement processes.

We are interested in models that are specifically targeted to the Medicare population and that take into account the beneficiaries' relative health and functional status, age, mental functioning, and other relevant factors. We are interested in and will give preference to proposals that focus on beneficiaries most likely to benefit from coordinated care interventions and that take patient comorbidities into account in the services provided.

Many of the design elements of the proposed demonstration project will depend on the coordinated care delivery model and interventions offered by the applicant, as well as the proposed payment methodology. When appropriate, applicants must demonstrate capabilities consistent with the coordinated care conceptual framework described in section I.C. of this notice.

Applicants must explain how their proposed program addresses each of the following aspects of the demonstration:

1. Coordinated Care Services

We seek to test existing models of coordinated care that have at a minimum been pilot tested by the applicant, thus eliminating the need for a lengthy developmental time frame. The applicant must therefore be an existing provider of coordinated care services applicable to the Medicare population. For purposes of this notice, ''existing provider'' is defined as an entity that has provided coordination services similar to or identical to the coordinated care services proposed for the demonstration for at least 1 year prior to the date of this notice.

Applicants must serve a chronically ill Medicare population, define their target population precisely, and have a defined scope of coordinated care services to be provided over a defined service period. The proposed coordinated care services must be appropriate for the targeted population, and must be likely to improve the quality of care for these individuals. The proposed bundle of coordinated care services may not include services for which separate Medicare payment is typically allowed (for example, physician office visits, inpatient hospital stays, durable medical equipment, and other Medicare-covered services).

Proposals for models that rely on medication management regimens or services (to be furnished by a provider other than the coordinated care entity) that are not typically covered by the Medicare program must address issues related to the cost of the medications or services, beneficiaries' ability to afford the medications or services, implications for the applicant's protocols, and other pertinent details.

Detailed processes must be proposed for beneficiary participant identification, recruitment, selection, enrollment, and discharge from the program. Applicants must indicate how they plan to assess whether an individual has one of the targeted

diseases and what additional restrictions will be placed on eligibility (for example, qualifying conditions, excluded conditions, and mandated referral from a physician). Additional processes must include: Ensuring optimal medical management; enhancing and supporting patient self-management and patient and caregiver education; ensuring efficient and effective utilization of Medicare services; and ensuring adequate flow of patient information from setting to setting.

Preference will be given to proposals in which the intervention protocols are not proprietary in nature.

2. Evidence of Prior Success

Applicants must provide clear evidence that their program has achieved reductions in the use of medical services for the target population previously served. Applicants must provide estimates showing that Medicare savings from proportionately similar effects for the target Medicare population would be sufficient to cover the costs of the demonstration to the Medicare program (proposed aggregate payment for coordinated care services and any start up funding). For their claims of prior success, applicants must define the outcomes measures used, the length of time over which they were measured, and how the measures were calculated. Preference will be given to proposals that report strong, credible evidence of savings and improved patient outcomes calculated from actual data collected during past implementation of the proposed care coordination interventions by the applicant. Preference will also be given to proposals that will test protocols that have been shown to be cost-effective specifically with a Medicare population.

3. Experimental Design

The proposed demonstration project must provide for voluntary participation for targeted Medicare beneficiaries. Preference will be given to proposals that make use of a randomized experimental design (for example, concurrent treatment group (receives coordinated care services) and control group (receives usual care) with patient assignment occurring after agreement to participate in the demonstration is established). For a randomized design, applicants must submit evidence of their ability to recruit and serve a study population of at least 618 Medicare beneficiaries per year (309 in the treatment group and 309 in the control group). When characteristics of the proposed intervention or the population under study renders a randomized design infeasible, applicants must provide a justification for this conclusion, and must fully describe how the proposed treatment and comparison groups would be identified such that the selection bias usually avoided by randomization would be minimized. For a comparison group design, applicants must submit evidence of their ability to recruit and serve a large enough population to allow us to differentiate statistically between the two groups.

Details of the applicant's proposed experimental design must be specified in its proposal, including the expected number of eligible Medicare beneficiaries in the geographic area the program intends to serve and the proportion expected to volunteer for the demonstration. Applicants must either (1) allow us (or our contractor) to assign beneficiaries to the experimental or control/comparison groups, or (2) have their proposed procedures for assignment approved and monitored by HCFA. At the time enrollment begins, beneficiaries who are then being served by the applicant's program may not be recruited for participation in the demonstration.

Note: Beneficiaries participating in the demonstration must be enrolled in Medicare Parts A and B and Medicare must be the primary payor.

4. Payment and Budget Neutrality

Applicants must propose an overall payment methodology and project budget that are appropriate for their proposed coordinated care delivery model and budget neutral for the Medicare program. Applicants must submit evidence demonstrating the accuracy of the financial assumptions used in their proposed payment methodology and project budget. Applicants' accuracy in estimating the expected net Medicare savings, the expected total yearly Medicare expenditures for the treatment and control (or comparison) groups, and 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 to us data supporting their financial assumptions prior to finalization of the award. In addition, we may revisit the budget neutrality calculations periodically during demonstration implementation to assess if the projects are budget neutral to the Medicare program.

- All-Inclusive Rate

The applicant's payment methodology must propose an all-inclusive rate per enrolled beneficiary served per calendar month for the proposed bundle of coordinated care services. Under the demonstration, the coordinated care entity may bill for and be paid for each calendar month for which the beneficiary was enrolled in the coordinated care program and received coordinated care service furnished by that coordinated care entity. Enrollment begins the first day of the month following consent for participation from the beneficiary. Applicants may propose an alternative enrollment process with justification. For example, an applicant may propose an enrollment process that would allow for enrollment during the month in which the beneficiary consents to participate and for subsequent partial monthly payment.

This demonstration aims to give the care coordination entity increased flexibility in providing services and make participation in the care coordination program attractive to patients and providers. The monthly all-inclusive rate for coordinated care services furnished to participating beneficiaries will be considered an administrative fee; no beneficiary coinsurance amount or deductible liability will be applied. Further, the selected demonstration sites must submit bills for the coordinated care services furnished on an assignment basis (no balance billing will be permitted). Providing coordinated care services to beneficiaries without cost eliminates a potential financial barrier to willingness to participate, offers a modest incentive for beneficiaries to participate (without applicable supplemental insurance) and avoids a layer of complexity in the billing requirements both for us and the demonstration projects. In addition, applicants may propose to expend a portion of the payment for coordinated care services on other services to beneficiaries.

Applicants may also propose to expend a portion of the monthly administrative fee for coordinated care services on appropriate payments to providers whose services are essential to the success of their programs. For example, an applicant may propose to pay physicians for services furnished to demonstration participants for which separate Medicare payment is not allowed. The payment might be structured as a monthly payment for care oversight or payment for participation in a scheduled multidisciplinary team conference. Payments to physicians must be tied to services furnished to an enrolled beneficiary and cannot be based upon referrals to the program. These

payments, if any, will be included in the budget-neutrality calculations and in determining any Medicare savings.

The proposed payment amount must be reasonable given the scope of coordinated care services proposed and must be supported by prior evidence of cost savings. The derivation of the monthly all-inclusive rate from the component costs must be specified in the applicant's proposal. No separate payment will be made for recruitment, travel, capital investments, labor, administrative, implementation, operating, data collection, research, evaluation, or any other costs incurred by the demonstration selectees in the provision of the proposed coordinated care services. However, applicants may request minimal financial assistance for initial implementation costs (a one time payment of up to $150,000 per demonstration project, subject to availability). Applicants must submit a detailed project budget with documentation of how the requested start-up funds, if any, would be used.

- Case Mix

In proposing the monthly all-inclusive rate per beneficiary, applicants may propose a payment schedule (of up to six rates) that reflects the intensity of services provided to beneficiaries with varying severity of disease or functioning, or length of time enrolled in the coordinated care program. Under this type of payment methodology, applicants must specify the mix of cases anticipated in the treatment group and develop an average rate. This average rate will determine the maximum monthly payment amount permitted (average monthly rate per beneficiary multiplied by the number of beneficiaries enrolled during the month cannot exceed the aggregate case mix adjusted rate for that month).

- Formal Evaluation

The demonstration projects will be required to cooperate in an independent formal evaluation of the demonstration, including submission of cost and other program data and two site visits, conducted by HCFA or its contractor. No additional funding will be provided for these activities.

- Performance Incentives

The primary focus of the demonstration program is an all-inclusive rate payment methodology. For the first year, all demonstration sites will be paid in this manner. For the second year and beyond, an applicant may propose testing alternative models such as a financial incentives program for the coordinated care entity beyond the monthly all-inclusive rate. Proposed performance-based financial incentive fee payments may be in the form of a fixed fee (capped by a percentage of net Medicare savings), or a percentage of net Medicare savings (as calculated by HCFA or its contractor). Development of appropriate outcomes-based incentives can be a significant challenge. Thus, applicants must define precisely the target measures to be used to determine if the performance-based financial incentive fee will be paid and how these measures will be calculated. Final decisions on these alternatives will depend on: (1) The applicant's ability to demonstrate the effectiveness of the proposed incentives, and (2) the applicant's ability to measure savings attributable to the intervention. Applicants should be aware that our primary interest is in testing the effectiveness of an all-inclusive rate payment and that this will be the primary basis for evaluating proposals.

5. Ability To Carry Out the Demonstration

Applicants must demonstrate that they have the basic infrastructure to carry out the demonstration. At a minimum, the applicant must have adequate physical assets, trained staff, clinical protocols to guide care delivery and management, linkages to providers and services necessary to deliver care, and appropriate information and financial systems. Accordingly, applicants must have substantial experience in coordinating care.

Proposals must include a detailed implementation plan describing tasks, time lines, and costs associated with implementing the demonstration program. Since applicants must demonstrate prior experience in operating successful care management programs, the implementation plan should focus on tasks and a time line for modifying the existing system to fit the demonstration program features listed above. Applicants may need to modify case management models, including protocols, services, outreach, and education to address a Medicare fee-for-service population.

The implementation plan must also demonstrate how the organization will modify its existing data and claims systems in order to submit electronic claims for payment to the appropriate Medicare contractor(s), using standard claims formats, and to meet all data requirements for the project. The preimplementation start-up phase should not exceed 6 months. Within 12 months from the implementation date, at least 309 treatment patients must be served (for a randomized design.)

D. Submission of Applications

Applications (original and 10 copies) must be received by HCFA as indicated in the **DATES** and **ADDRESSES** sections of this notice. Only proposals that are considered ''on time'' will be reviewed and considered by the technical review panel. Applications must be typed for clarity and should not exceed 40 double-spaced pages, exclusive of the cover letter, executive summary, resumes, forms, and documentation supporting the cost proposal. That is, sections IV, V, VI, VII, and VIII below must be presented in 40 double-spaced typewritten pages. These sections make up the body of the proposal and must fully describe the proposed project.

Application Contents Outline

To facilitate the review process, the application should include the following contents in the following order:

I. *Cover Letter*—Must include a brief description of the proposed project and indicate the model to be tested (that is, DM or CM, target population, and urban site or rural site), and identify any and all HCFA provider numbers assigned to the applicant, a contact person, and contact information.

II. ''Application for Federal Assistance'' Standard Form 424 (including SF–424a ''Budget Information'' and SF–424b ''Assurances'', available on our website (www.hcfa.gov/ord/ordhp1.htm)).

III. *Executive Summary*—Must include a summary of the project, care coordination experience, existence of adequate information systems, and willingness to share protocols for care coordination.

IV. Statement of the Problem

V. Demonstration Design

VI. Organizational Capabilities

VII. Project Budget and Cost-Effectiveness Evidence

VIII. Implementation Plan

IX. Related Supplemental Materials

E. Evaluation Process and Criteria

A review of responsive proposals will be conducted by a panel of experts. This technical review panel will convene in the months following the due date for submission of proposals. The panelists' recommendations will contain numerical ratings based on the evaluation criteria, the ranking of all responsive proposals, and a written assessment of each applicant. In addition, we will conduct a financial analysis of the recommended proposals and evaluate the budget neutrality of these proposed projects.

Evaluation Criteria and Weights

• Soundness of the Demonstration Design (20 points)

A. The proposal provides clear and convincing evidence and supporting materials that proposed care coordination services are appropriate for the targeted population, likely to achieve reductions in the use of medical services, and likely to improve the quality of care for these individuals.

B. The proposed research design provides for voluntary participation of a sufficient number of Medicare beneficiaries. The research design provides for the enrollment of comparable treatment and comparison groups in order to allow for validity of the evaluation result. Preference will be given to applications that make use of an appropriate randomized design.

• Organizational Capabilities (30 points)

A. The proposal provides evidence of the availability and adequacy of facilities, equipment, personnel, and data systems to successfully conduct the proposed project.

B. The proposal provides evidence of the organizational capacity to ensure adequate service delivery and the provision of high quality of care.

C. Specific information is provided concerning how the personnel are to be organized in the project, to whom they will report, and how they will be used to accomplish specific objectives or portions of the project.

• Ability To Implement the Demonstration (35 Points)

A. The proposed project implementation strategy and plan are detailed and appropriate.

B. There are adequate mechanisms for ensuring the medical necessity and reasonableness of the coordinated care services furnished under the demonstration.

C. There are adequate mechanisms for ensuring that beneficiaries' physicians are integrated with the project.

D. The strategy and plan for recruiting the required number of patients in the control and experimental groups appear reasonable and achievable.

E. The data to be collected, data sources, and data analyses planned are specified in detail and are sufficient to ensure optimal medical management and efficient use of health care services.

F. The implementation plan supports an independent evaluation of the project.

G. The proposal provides evidence that effective continuous quality improvement processes are being employed and can be transferred to the demonstration.

• Strength of the Cost-Effectiveness Evidence (15 points)

A. The proposal provides justification and explanation for the proposed payment amount(s).

B. The proposed payment amount for the bundle of coordinated care services is reasonable considering the scope and nature of services included.

C. The proposal provides clear, convincing evidence that, over the 4 years of the demonstration, the aggregate Medicare expenditures under Parts A and B (including incentives and start-up funding, if made) will be no greater than expected Medicare expenditures in the absence of the demonstration.

Final Selection

From among the most highly qualified applicants, the final selection of projects for the demonstration will be made by the HCFA Administrator and will take in to consideration operational feasibility, geographic location, and program priorities (such as testing a variety of approaches for delivering services, targeting beneficiaries, and payment). We reserve the right to conduct (a) site visit(s) prior to making awards. We expect to make the awards in early 2001.

III. Collection of Information Requirements

The information collection requirements contained in this notice have been approved by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (42 U.S.C. 3501–3520) and assigned OMB control number 1938–0800. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Authority: Section 4016 of the Balanced Budget Act of 1997 (Pub. L. 105–33).

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

Dated: July 23, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–19159 Filed 7–27–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1144–N]

Medicare Program; Announcement of a Series of Regional Training Sessions To Provide Training to Medicare+Choice Organization Physicians, Medicare+Choice Organization Non-Physician Practitioners, and Medicare+Choice Organization Medicare Directors, As Well As Physician Organizations and Billing Associations Involved in the Timely and Accurate Submission of Physician Encounter Data To Support a Comprehensive Risk Adjustment Model

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of training sessions.

SUMMARY: This notice announces a series of regional training sessions to provide an opportunity for Medicare+Choice Organization (M+CO) physicians, M+CO non-physician practitioners, and M+CO medical directors, as well as physician organizations, billing associations, and other interested parties, to obtain information on the requirements placed on M+COs for submission of physician encounter data collection. HCFA and the Restuccio Healthcare Group will provide the physician encounter data training.

Regional Training Dates & Cities

The regional training sessions will be held as follows:

PHYSICIAN ENCOUNTER DATA TRAINING SCHEDULE 2000

Date	Location
August 23, 2000, Palo Alto, CA	Hyatt Rickeys, 4219 El Camino Real, Palo Alto, CA 94306–4493, (650) 493–8000.
August 29, 2000, Philadelphia, PA	Park Hyatt Philadelphia at the Bellevue, Broad and Walnuts Streets, Philadelphia, PA 19102, (215) 893–1234.