Non NPL Petitioned Sites

None.

Dated: February 14, 2002.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4030–N]

Medicare Program; Solicitation for Proposals for the Demonstration Project for Disease Management for Severely Chronically Ill Medicare Beneficiaries With Congestive Heart Failure, Diabetes, and Coronary Heart Disease

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

ACTION: Notice for solicitation of proposals.

SUMMARY: This notice informs interested parties of an opportunity to apply for a cooperative agreement for the Medicare Disease Management Demonstration. This demonstration uses disease management interventions to (1) improve the quality of services furnished to specific beneficiaries, (2) introduce full prescription drug coverage to encourage compliance with medical instructions and requirements, and (3) 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 are related to high costs to the Medicare program, namely, congestive heart failure, diabetes, or coronary heart disease. We intend to use a competitive application process to select up to three existing disease management organizations to participate in this demonstration.

Potentially qualified applicants are existing providers of disease management services applicable to the Medicare population specific to the three targeted chronic conditions.

DATES: Applications will be considered timely if we receive them on or before May 23, 2002.

ADDRESSES: Applications should be mailed to the following address: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Attention: Tamara Jackson-Douglas, Project Officer, Center for Beneficiary Choices, Mail Stop: C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244.

Please refer to the file code CMS–4030–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.

FOR FURTHER INFORMATION CONTACT: Tamara Jackson-Douglas at (410) 786–9417, or by e-mail at *TJackson2@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Our Disease Management Demonstration website (*www.hcfa.gov/research/dmdemo.htm*) contains additional information about these demonstrations and specific submission requirements for applications.

I. Background

A. Statutory Requirements

Section 121 of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA) requires the Secretary of Health and Human Services (the Secretary) to conduct a demonstration project for the Medicare fee-for-service population to demonstrate the impact on costs and health outcomes of applying disease management services, supplemented with coverage for prescription drugs, to specific Medicare beneficiaries with diagnosed, advanced-stage congestive heart failure, diabetes, or coronary heart disease. This demonstration project should result in a net reduction in aggregate Medicare expenditures. This project may include up to three organizations and cover up to 30,000 beneficiaries at a time. The project will last for 3 years.

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 individuals and estimated cost of care for high-cost beneficiaries is expected to grow dramatically.

In the fee-for-service environment, health care for individuals with chronic illness has often been fragmented and poorly coordinated across multiple health care providers and multiple sites of care. Evidence-based practice guidelines have not always been followed, nor have patients always been 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 in which providers have limited accountability for the outcomes of care.

The vast majority of disease management patients' issues center around a single disease or condition and fall into fundamental problems with their own behavior, access to appropriate prescription drugs, or the disease-specific care they receive. Patient behavior-based problems include poor medication compliance, lack of self-care skills, and lack of adherence to recommended lifestyle changes. Patients' general reluctance to make major adjustments to their ways of life tends to be reinforced when patients are unable to see the direct or immediate benefits resulting from these changes.

Further compounding this problem for Medicare beneficiaries is the fact that Medicare generally does not cover outpatient prescription drugs. Beneficiaries wanting drug benefits have to purchase supplemental insurance, or join a Medicare+Choice plan if they are not already covered under an employer-sponsored retirement plan or a publicly-funded program, such as Medicaid or the Department of Veterans Affairs. Our research shows that, as of 1998, a majority (73 percent) of Medicare beneficiaries had some drug coverage at one point or another within a given year, and that fewer than half have had uninterrupted coverage for 2 consecutive years. Furthermore, questions remain regarding extent, quality, and comparability of coverage across different programs. Appropriate, effective pharmaceuticals are a key part of a comprehensive treatment program, and effective disease management must include access to appropriate medications.

Provider-related 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.

C. Disease Management

The level of interest in, and knowledge about, disease management is growing dramatically. The Institute of Medicine's report, entitled *Crossing the Quality Chasm: A New Health System for the 21st Century* (published by Health Care Services, National Academy Press in 2001), highlights the challenge of managing chronic conditions within a system that was designed to treat acute illness. Major national organizations, such as the National Disease Management Association (NDMA), have been formed to advance the practice of disease management, and the National Committee for Quality Assurance (NCQA) has just released draft standards for disease management programs for public comment.

Early efforts at disease management occurred mainly in managed care settings, because the plan and the providers had clear incentives to manage care, and the patients were enrolled and ''locked into'' a delivery system. More recently, a variety of health care organizations, including physician group practices, private insurers, commercial firms, and academic medical centers, have developed programs designed to address the challenges inherent in managing chronic illnesses within the context of a fee-for-service system.

The NDMA, NCQA, and other organizations, such as the National Pharmaceutical Council, have put forward definitions of disease management that contain certain common elements. These definitions view disease management as an approach to delivering health care to persons with chronic illnesses that aims to improve patient outcomes while containing health care costs. These definitions generally focus on persons whose primary health problem is a specific disease, although certain co-morbid conditions are usually addressed as well. Patients with a similar level of severity of the disease tend to face similar problems and therefore receive similar treatment plans. These disease management interventions tend to be highly structured and emphasize the use of standard protocols and clinical guidelines.

There are certain common features in all of these definitions:

- Identification of patients and matching the intervention with need.
- Use of evidence-based practice guidelines.
- Supporting adherence to the plan of care.
- Supporting adherence to evidence-based medical practice guidelines by providing medical treatment guidelines to physicians and other providers, reporting on the patient's progress in compliance with protocols, and providing support services to assist the physician in monitoring the patient.
- Services designed to enhance patient self-management and adherence to his or her treatment plan. Examples of those services are patient education, monitoring and reminders, and behavior modification programs aimed at encouraging lifestyle changes.
- Routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling).
- Communication and collaboration among providers and between the patient and his or her providers. Related services include team conferences, collaborative practice patterns, and routine reporting and feedback loops. In addition, care managers are often used to relay communication and to coordinate care across providers and by face-to-face encounters with chronically ill patients. Programs that address co-morbid conditions extend their communication efforts to include all of the patient's providers and the entire spectrum of care.
- Collection and analysis of process and outcomes measures.

In addition to these standard features, programs may include use of information technology, for example, specialized software, data registries, automated decision support tools, and call-back systems. Although disease management services usually do not include actual treatment of the patient's condition, many disease management programs augment the services provided in the traditional fee-for-service system by adding such services as comprehensive geriatric assessment, social services, preventive services, transportation, including prevention services and necessary prescription drugs and outpatient medications. The interventions provided go beyond those services generally covered under the Medicare fee-for-service program.

In our recent study (Best Practices in Coordinated Care, Chen et al., March 22, 2000) aimed at investigating and benchmarking case management and disease management efforts, we suggested that case and disease management organizations provide services aimed at addressing one or more of the following goals:

- Improving patient self-care through such means as patient education, monitoring, and communication.
- Improving physician performance through feedback and/or reports on the patient's progress in compliance with protocols.
- Improving communication and coordination of services between patient, physician, disease management organization, and other providers.
- Improving access to services, including prevention services and necessary prescription drugs.

Programs vary in their relative focus on these areas. Some disease management programs may emphasize improving physician use of recommended clinical guidelines; others may focus on providing case managers to support and educate the patient and enhance communication; and still others may emphasize access to additional services.

D. Other CMS Demonstrations for Management of Chronic Diseases

In the past, we have conducted several demonstrations for case management of chronic illnesses, including the National Long-Term Care Demonstration (Final Report by Kemper et al., May 1966. NTIS Accession No. PB86–229119/AS) and the Medicare Alzheimer's Disease Demonstration Evaluation (Final Report October 1998). The evaluations of these demonstrations found that none of the demonstrations provided sufficient savings to cover the additional costs of case management.

There are several possible reasons for the lack of positive results. First, the most appropriate individuals were not always targeted and enrolled in the demonstration. In many cases, the sites enrolled patients with less severe, and therefore less costly, conditions, making it more difficult to achieve cost savings by avoiding normal utilization patterns of acute or long-term medical care. (See the Disease Management Demonstration website address at the beginning of the **SUPPLEMENTARY INFORMATION** section for additional information.)

We are currently conducting other demonstrations that test either case or disease management, both of which are designed for a smaller number of participants than Medicare's Disease Management Demonstration project. In one ongoing demonstration, Lovelace Health Systems, in Albuquerque, New Mexico, was chosen to operate demonstrations of intensive case management services for high-risk patients with congestive heart failure and diabetes to improve the clinical outcomes, quality of life, and satisfaction with services. The other is a larger scale demonstration authorized by section 4016 of the Balanced Budget Act of 1997 (BBA) to evaluate methods, for example, case management and disease management, that improve the

quality of care for beneficiaries with a chronic illness. The ''Coordinated Care'' demonstration was designed based on the findings of a review of best practices for coordinating care in the private sector. (See the Disease Management Demonstration website address at the beginning of the **SUPPLEMENTARY INFORMATION** section for additional information.)

E. This Disease Management Demonstration

In developing this demonstration, we reviewed the work and recommendations of organizations such as the NDMA and NCQA, and examined our prior and current experience with similar demonstrations.

This demonstration differs significantly from its predecessors in that the legislation stipulates that the demonstration must cover all prescription drugs, even those drugs not related to the beneficiary's targeted condition. The legislation also requires each demonstration organization to accept risk or have another entity agree to accept risk if certain Medicare budget provisions are not met, specifically if the demonstration does not reduce aggregate Medicare program expenditures. In addition, this solicitation highlights the need to target the severe and high-cost cases, and to match the intervention to the patient.

For the purpose of this demonstration, disease management is defined as a systematic approach to managing health care that aims to improve patient self-care, physicians' prescribing and treatment practices, communication and coordination of services between the patient, physician, disease management organization, and other providers, and access to needed services, and incorporates the following features:

- Patient identification, assessment, and enrollment.
- Patient instruction and empowerment regarding self-care.
- Implementation of an appropriate treatment plan based on clinical guidelines.
- Monitoring, feedback, and communication concerning the patient's condition.
- Arranging for and/or providing needed services, including prescription drugs and preventive services.

Disease management programs may also include additional services, such as nurse visits, access to special equipment, and coordination with specialty clinics.

II. Provisions of This Notice

A. Purpose

This notice solicits applications for demonstration projects that use disease management, along with coverage of prescription drugs, to improve the quality of services furnished to specific beneficiaries and to manage expenditures under Parts A and B of the Medicare program. The demonstration anticipates savings from more efficient provision and utilization of Medicare-covered services and the prevention of avoidable, costly medical complications. Applicants may propose to manage one, two, or all three of the advanced-stage, chronic conditions named in section 121 of BIPA (congestive heart failure, diabetes, and coronary heart disease). Even if the applicant focuses on one condition, the others should be treated as they relate to the targeted chronic condition. Beneficiaries may be subject to a modest cost-sharing arrangement pertaining to their prescription drug coverage. Applicants who offer demonstration services beyond the scope of traditional Medicare benefits are not to hold beneficiaries financially liable for demonstration services typically not covered by Medicare. Beneficiaries will continue to be subject to the same co-pays/coinsurance of the traditional Medicare fee-for-service program.

B. Randomization

The 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, a concurrent treatment group that receives disease management services and a control group that receives usual care with patient assignment occurring after agreement to participate in the demonstration is established). Applicants must submit evidence of their ability to recruit and serve a study population of at least 5,000 Medicare beneficiaries who will be randomly assigned to applicable treatment and control groups.

When characteristics of the proposed intervention or the population under study renders a randomized design infeasible, applicants must provide a justification for that conclusion, and must fully describe how the proposed treatment and comparison groups would be identified so that the selection bias usually avoided by randomization would be minimized. 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(s) to assign beneficiaries to the experimental and/or control groups; or

(2) Have their proposed procedures for assignment approved and monitored by us.

Beneficiaries who are already being served by an awardee's program (that is, beneficiaries who are participants at the time an award is made to the disease management organization) may not be recruited by that awardee for participation in the demonstration.

C. Evaluation

Through this solicitation, project awards will be made to up to three disease management organizations. An organization may propose one or multiple sites for any of its targeted diseases or for multiple diseases. The demonstration projects will operate for up to 3 years from implementation during which time a formal independent evaluation will be conducted. Each awardee is expected to fully cooperate in all phases of the evaluation. Our project officer will be assigned to each selected project. That project officer will serve as the point of contact with the demonstration project staff and will provide technical consultation regarding cooperative agreement procedures, monitor demonstration site activities, and forward feedback to the demonstration project's staff.

D. Requirements for Models

We are seeking innovative proposals from organizations that can test whether models of disease management improve clinical outcomes and appropriate use of Medicare-covered services for targeted Medicare fee-for-service beneficiaries, while managing Medicare expenditures under parts A and B to achieve reduced aggregate Medicare expenditures.

Models that are targeted specifically at the Medicare population and that take into account the beneficiaries' relative health and functional status, age, mental functioning, and other relevant factors, are of particular interest. Preference will be given to proposals that focus on beneficiaries most likely to benefit from disease management interventions and that take patient co-morbidities into account in the services provided. In selecting applicants for this demonstration project, we will also consider whether the applicant will serve the Medicare ethnic patient

populations disproportionately affected by the targeted diseases.

An organization that wishes to apply to participate in the demonstration should refer to the specific submission requirements at our Web site (listed in the **SUPPLEMENTARY INFORMATION** section of this notice).

E. Submission of Applications

Applications (an unbound original and 10 copies) must be received by us 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 4, 5, 6, 7, 8, and 9 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:

1. Cover Letter

Must include a brief description of the proposed project and indicate the target population, and urban site or rural site, and identify any and all CMS provider numbers assigned to the applicant, a contact person, and contact information.

2. ''Application for Federal Assistance''—Standard Form 424

Must include SF–424a ''Budget Information'' and SF–424b ''Assurances'' available on our Web site (*www.hcfa.gov/research/dmdemo.htm*).

3. Executive Summary

Must include a summary of the project, disease management experience, existence of adequate information systems, and willingness to share protocols for disease management.

4. Statement of the Problem

5. Targeting the Appropriate Population

6. Description of Disease Management Intervention Services

7. Organizational Capabilities

8. Effectiveness of Intervention(s): Quality

9. Payment for Disease Management Services, Reduction of Medicare Expenditures, and Reinsurance

10. Related Supplemental Materials

III. Evaluation Process and Criteria

A panel of experts will conduct a review of responsive proposals. 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 proposed projects to ensure that aggregate Medicare program expenditures are reduced.

Our Administrator will make the final selection of projects for the demonstration from among the most highly qualified applicants, taking into consideration a number of factors, including operational feasibility, geographic location, and program priorities (for example, testing a variety of approaches for delivering services, targeting beneficiaries, and payment). Applicants should be aware that proposals may be accepted in whole or in part. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We reserve the right to conduct one or more site visits before making awards. We expect to make the awards in 2002.

IV. Collection of Information Requirements

As this demonstration requires existing disease management organizations to (1) supplement their offerings with full prescription drug coverage, (2) provide reinsurance to guarantee reduced aggregate Medicare program expenditures, and (3) recruit and serve at least 5,000 appropriately-targeted Medicare beneficiaries, it is unlikely that many disease management organizations would be eligible to participate in this project. We expect fewer than 10 organizations to submit proposals. Therefore, the collection requirements referenced in this notice are not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), as defined under 5 CFR 1320.3(c).

Authority: Section 121 of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA).

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

Dated: February 5, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3061–FN]

RIN: 0938–AH15

Medicare Program; Disapproval of Alcon Laboratories' Request for an Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

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

ACTION: Final notice.

SUMMARY: This final notice announces our disapproval of Alcon Laboratories' request for a $50 adjustment in payment amount for lenses reviewed for determination as a new technology intraocular lens (NTIOL).

FOR FURTHER INFORMATION CONTACT: Betty Shaw, (410) 786–6100.

SUPPLEMENTARY INFORMATION: *Copies:* To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 (or toll-free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

In our regulations at 42 CFR part 416, subpart F, we describe the process an interested party must use to request that