Deadline for Grant Submission: Grant applications must be submitted by July 15, 2003 to be considered under the 2004 annual funding cycle. Applications for these grants are not subject to review under Executive Order 12372—Intergovernmental Review by Federal Agencies (45 CFR part 100).

ADDRESSES: *Application Materials:* Standard application forms and related instructions are available from the Web site, *www.cms.hhs.gov/researchers/priorities/grants.asp* or from Judith Norris, Centers for Medicare & Medicaid Services, Office of Internal Customer Support, Acquisition and Grants Group, C2–21–15 Central Building, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–5130, e-mail: *Jnorris1@cms.hhs.gov*. Application materials must be formally submitted to Judith Norris.

Please note: State agencies are only required to submit an original application and two copies.

Web site: You may access up-to-date information about the Medicaid Infrastructure Grants and obtain information from the full grant solicitation grant at: *http://www.cms.hhs.gov/twwiia*.

FOR FURTHER INFORMATION CONTACT: Questions about the grants may be directed to: Joe Razes, TWWIIA Program Manager, Disabled and Elderly Health Programs Group, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Room S2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, (410) 786–6126, e-mail: *Jrazes@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION: This notice is the fourth such notice announcing the availability of funds for Medicaid infrastructure grants authorized by the Ticket to Work and Work Incentives Improvement Act. A total of 38 States currently have been awarded Medicaid infrastructure grants under the Ticket to Work legislation that provides Federal grant funding for 11 years through 2011. This notice is consistent with the three previous notices in soliciting States to apply for grants that will expand services and supports for workers with disabling conditions. States that wish to apply for these grants and desire further detailed information, such as application requirements, review procedures, an explanation of a timely submission, necessary forms, and other relevant information, should refer to the above listed Web sites.

Approval for Collection of Information: The collection of information requested in the application for grants funding has been approved by the Office of Management and Budget under the approval number 0938–0811. The current approval expires on November 30, 2003.

Authority: Section 203 of the Ticket to Work and Work Incentives Improvement Act of 1999, Pub. L. 106–170. (Catalog of Federal Domestic Assistance Program No. 93.768, Centers for Medicare and Medicaid Services Research, Demonstration, and Evaluations)

Dated: December 23, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–4733 Filed 2–27–03; 8:45am]

BILLING CODE: 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5002–N]

RIN 0938–ZA39

Medicare Program; Demonstration: Capitated Disease Management for Beneficiaries With Chronic Illnesses

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

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for a cooperative agreement to participate in a Capitated Disease Management Demonstration. This demonstration uses disease management interventions and payment for services based on full capitation (with risk sharing options) to (1) improve the quality of services furnished to specific eligible beneficiaries, including dual eligibles and the frail elderly, and (2) 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, such as stroke, congestive heart failure, or diabetes. We intend to use a competitive application process to select organizations to participate in this demonstration.

DATES: Applications will be considered timely if we receive them on or before May 29, 2003.

ADDRESSES: Mail applications to: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of Research Development and Information, Demonstration Program staff, Attn: Raymond Wedgeworth, Mail Stop: C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244. 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. 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: For information concerning this demonstration, contact Raymond Wedgeworth, CMS Project Officer, at (410) 786–6676, or *rwedgeworth@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Eligible Organizations

Potentially qualified applicants are provider sponsored organizations, academic medical centers, Medicare+Choice organizations, or disease management companies, who can demonstrate ability to effectively supply disease management services applicable to the Medicare population, which may include dual eligibles and frail elderly, specific to select chronic conditions.

Administrator Initiative

The clearest statement of the Administration's priorities for Medicare is found in the White House document, ''21st Century Medicare,'' issued on July 12, 2001. In that document, the Administration made a series of proposals for modernizing Medicare benefits so that they would better meet the needs of its beneficiaries. One of the important proposals in the document is to improve the current limits of the program on innovative treatment. The report notes that ''Medicare's traditional approach to paying only for discrete visits and services has denied many seniors the opportunity to take advantage of the advances that have been pioneered by integrated health delivery in coordinating care for complex conditions and chronic diseases. These programs can lead to better health outcomes and reduce total medical costs by avoiding complications.''

In line with the above goals, the Administration is undertaking a series of disease management demonstration projects to explore a variety of ways to improve beneficiary care in the traditional Medicare plan. These demonstrations provide beneficiaries with greater choices, enhance the quality of their care, and offer better

value for the dollars spent on health care.

The purpose of this demonstration is to test capitated payment arrangements with qualified organizations for the case management of specific diseases. The targeted populations include Medicare beneficiaries with chronic illnesses and special populations, such as dual eligibles and frail elderly. The payment models employed are intended to reduce costs and improve the coordination and quality of care for Medicare beneficiaries with select chronic diseases. In addition, the models may be applied to organizations that target dual eligibles or the frail elderly. Specifically, we will pay predetermined rates for each month for which an individual chooses to receive disease management services under this demonstration, according to a disease-specific risk adjustment approach currently being developed. (Disease specific risk adjusters are being developed as part of the model for M+C Risk adjustment. The legislative mandate for implementation of the risk adjustment model is January 1, 2004 for all plans. This risk adjuster, which will factor a greater number of comorbidities into the payment, is to be announced March 2003.)

There will also be a risk sharing option available (that is, a symmetrical risk sharing on profit and losses around a Medical-Loss-Ratio).

In exchange for the capitation amount, the applicant would be required to cover all Medicare-covered services for an individual participating in the demonstration, in addition to the disease management services. The applicant would be required to make such services available to beneficiaries participating in the demonstration, either directly or through arrangements with other Medicare-certified providers. Medicare beneficiaries participating in this demonstration would be informed that it is a condition of such participation that they receive services through the provider of disease management that has received a payment on behalf of the participant. For non-M+C organizations, only traditional Medicare fee-for-service (FFS) beneficiaries are eligible to participate in the demonstration. The intent of the demonstration is to attract traditional Medicare FFS beneficiaries, however, we will consider, on a case-by-case basis, allowing M+C organizations to market the demonstration to their current M+C beneficiaries and permit participation in the demonstration by one M+C beneficiary for every 2 traditional Medicare FFS beneficiaries they get to participate. Current M+C beneficiaries would have to disenroll from their current M+C plan in order to participate in the demonstration. Organizations allowed to sign up current M+C beneficiary who disenrolled from an M+C plan to participate in the demonstration would have to agree to the monitoring of their Medical-Loss-Ratio (MLR).

The capitated payment method will require the collection and submission of simplified encounter data. The demonstration will use the Group Health Plan Payment System to pay the sites.

Under this demonstration, selected organizations would provide the clinical management of patients with high cost diagnoses such as stroke, congestive heart failure, and diabetes. (Applicants may propose a project that seeks to intervene with disease management services for Medicare eligible beneficiaries who have the potential for renal failure but who are not yet in dialysis. Randomization may be required for a proposal with this model.) The demonstration would be especially appropriate for provider sponsored organizations (PSOs), but is also open to other types of organizations such as disease management organizations, academic medical centers (AMCs) or M+C organizations. By targeting or encouraging the formation of integrated delivery systems and paying a single risk payment rather than reimbursing services on a fee-for-service basis, we hope to improve communication and coordination of services between patient, physician, disease management organizations, and other providers.

I. Background

A. Legislative Background

Section 402(a)(1)(A) of the Social Security Amendments of 1967 (Pub. L. 90–248), 42 U.S.C. 1395b–1(a)(1)(A), authorizes the Secretary to develop and engage in demonstrations ''to determine whether, and if so which, changes in methods of payment or reimbursement * * * for health care and services under health programs established by the Social Security Act, including a change to methods based on negotiated rates, would have the effect of increasing efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services. * * *''

Under section 402(b) of the Social Security Act Amendments of 1967, the Secretary is authorized to waive requirements in title XVIII that relate to reimbursement and payment in order to carry out demonstrations authorized under section 402(a) of the Social Security Act Amendments of 1967.

Under this demonstration, we would use the authority in section 402(b) to waive the ''fee-for-service'' (FFS) payment rules that would ordinarily apply to a beneficiary who has elected the ''Original Medicare plan'', and would substitute the methodology discussed in this notice, and agreed to in the demonstration contract.

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 FFS 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 these individuals are expected to grow dramatically.

In addition, dual eligibles and special populations account for a large proportion of Medicaid and Medicare expenditures. The 1998 Medicare Chart Book reported that in 1995, the 6 million dually eligible beneficiaries accounted for 30 percent Medicare spending, though they only represented 16 percent of the Medicare population. Moreover, the dually eligible accounted for 35 percent of Medicaid spending, though they only made up 17 percent of the Medicaid population.

When services furnished to individuals with chronic illness are reimbursed on a FFS basis, health care 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 where they have limited accountability for the outcomes of care.

Many M+C organizations and private insurers have realized the importance of effectively coordinating the care of services for persons with select chronic conditions. The quality of care, as well as the cost of care, can be improved through better integration of the delivery system. In order to create incentives to maintain costs, encourage the coordination of services, and

improve the quality of care, M+C and private insurers have developed alternative payment systems that put the provider of disease management organizations at full or partial risk for the cost of care.

Concerning dual eligibles, integration across the continuum of primary, acute, and long-term care services for vulnerable populations has gained attention in recent years as an approach that could produce both cost efficiencies and more appropriate decisions on the settings in which care is delivered.

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,'' highlights the challenge of managing chronic conditions within a system that was designed to treat acute illness. Major national organizations such as the Disease Management Association of America (DMAA) have been formed to advance the practice of disease management, and the National Committee for Quality Assurance (NCQA) has established standards for disease management programs.

Early efforts at disease management occurred mainly in managed care settings, as 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 FFS system oriented around episodic care. The most obvious of these systems are called PSOs.

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 programs tend to 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 a 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.

Certain common features are found 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 their treatment plan. Examples of these 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 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 between face-to-face encounters with chronically ill patients. Programs that address comorbid 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 such as specialized software, data registries, automated decision support tools, and callback 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 FFS 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 FFS program.

In our recent study aimed at investigating and benchmarking case management and disease management efforts, the suggestion was made that case and disease management organizations provide services aimed at addressing one or more of the following goals: improving patient self-care, improving physician prescribing and treatment practices, improving communication and coordination, and arranging and providing for services. 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 others may emphasize access to additional services.

D. CMS Demonstrations of Management of Chronic Diseases

We have made three awards pursuant to section 121 of the Medicare, Medicaid, and Benefits Improvement and Protection Act (BIPA)(Pub. L. 106–554, enacted on December 21, 2000) that directs us to conduct a demonstration project for the Medicare FFS population to determine the impact on costs and health outcomes of applying disease management services. Demonstration sites plan to start enrollment in the spring of 2003. Under this BIPA demonstration, services will be supplemented with coverage for prescription drugs provided to beneficiaries with advanced-stage congestive heart failure, diabetes, or coronary heart disease. A key feature of the demonstration is that the selected organizations must guarantee either through reinsurance or some other means, net savings to the Medicare program.

In the past, we have conducted several demonstrations of case management for chronic illnesses, including the national channeling demonstration and the Alzheimer's Disease demonstration. The evaluations of these demonstrations found that none of them showed 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 into 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. The disease management demonstration Web site *www.cms.hhs.gov/healthplans/research/DMDemo.asp* contains

additional information about these demonstrations.

We are currently conducting other demonstrations that test either case or disease management. In one 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 involving 15 sites authorized by the Balanced Budget Act (BBA) of 1997 (Pub. L. 105–33, enacted on August 5, 1997) to evaluate methods such as 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. More information about the Coordinated Care Demonstration can be found on our Web site *www.cms.hhs.gov/healthplans/research/coorcare.asp.*

E. The Capitated Disease Management Demonstration

This demonstration will provide clinical management of—

(1) Patients with high cost diagnoses such as stroke, congestive heart failure, and diabetes, (2) people who receive both Medicare and Medicaid, or (3) frail elderly patients that would benefit from a greater coordination of services. The project will allow us to build on the experiences of existing clinical disease management organizations. The delivery system will be targeted to PSOs but is open to other types of organizations such as disease management organizations, AMCs, or M+C organizations. Participation by qualified beneficiaries currently in the traditional fee-for-service Medicare program is the intended objective, however, we will consider allowing M+C organizations, on a case-by-case basis, to accept one M+C beneficiary for participation in the demonstration for every 2 traditional Medicare FFS beneficiaries that participate. Organizations allowed to accept a current M+C beneficiary (who must actively disenroll in the plan first) must allow the monitoring of their Medical-Loss-Ratio (MLR).

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 from its predecessors in that the focus is on paying a risk adjusted capitated rate with negotiated risk sharing arrangements to qualified organizations in order to create incentives to improve the quality and coordination of care. Moreover, we will be using the recently developed risk-adjustment payment methodology that will apply to all M+C organizations beginning in 2004. It is a selected significant disease model, which includes many chronic illnesses that are relevant to predicting future expenditures.

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

Eligible Population

Beneficiary participation in this demonstration is strictly voluntary. Each beneficiary must be fully informed about the demonstration and must sign an informed consent form in order to participate. In addition to indicating informed consent, Medicare beneficiaries must satisfy the following conditions in order to be able to participate in the demonstration project:

Eligibility Criteria

- Must be a Medicare beneficiary enrolled in Part A and Part B.
- Medicare must be primary payer.
- Must have a chronic disease, such as stroke, congestive heart failure, or diabetes (except for dual eligible or frail elderly).

Medicare beneficiaries will be excluded from eligibility if they:

- Are currently enrolled in a M+C plan; however, we will consider allowing M+C organizations to allow participation in the demonstration by one M+C beneficiary for every 2 traditional Medicare FFS beneficiaries.
- Are receiving hospice or end stage renal disease benefits.
- Are currently participating in another CMS demonstration.
- Are unable to participate in self-care activities due to severe dementia or other serious mental illness.

Payment

A contracting provider or provider organization will be paid for the services it provides to demonstration participants (without regard to the frequency and intensity of the services received by a given individual) on a monthly capitation basis. In exchange for this payment, the contractor would be responsible for furnishing or arranging for all covered Medicare Part A and Part B services. A listing of the beneficiaries who have elected to receive disease management services through the demonstration will be furnished to us on a monthly basis, which will be submitted to the Group Health Payment System to process payments for the services furnished to these beneficiaries.

The capitated payment rate will be based on the higher of the rate paid under the M+C program or 99 percent of a county-level fee-for-service base rate that will be calculated using a method developed by our Office of the Actuary. The payment rate will be fully risk adjusted using the new risk-adjustment methodology.

In compliance with the legislative mandate in BIPA, we have announced a draft risk adjustment model that includes inpatient and ambulatory diagnosis data, which will be implemented in January 1, 2004. The specific payment methodology will be announced in March 2003. We have chosen a selected significant disease model with approximately 61 condition groups. This model incorporates multiple chronic diseases into the payment system. Although the new risk adjustment payment methodology will not be implemented for the M+C program until January 2004, demonstration payment amounts will be calculated using the new risk-adjustment payment methodology, and will be fully risk adjusted, rather than being phased-in as is the case in the M+C program. (M+C organization payments are subject to the congressionally mandated phase-in of risk adjustment whereby only a portion of the payment is risk adjusted and the other portion of the payment is calculated using demographic factors. Under this demonstration, the payment amount will be fully risk adjusted.)

The following example is for applicants to estimate risk scores based on the current model of the selected significant condition model. This example is for illustrative purposes only.

Our example is a female, age 76, and she is Medicaid eligible. She has the following conditions:

- Chronic obstructive pulmonary disease (COPD).
- Congestive heart failure (CHF).

Go to illustrative table found at *www.cms.hhs.gov/healthplans/encounter/RAmodels.pdf* for determining estimated payments. Use the draft coefficient under the ''61-condition'' model column to find estimates.

Payment estimate = Female, age 76 ($2,500) + Medicaid ($1,000) + COPD

($2,000) + CHF ($2,300) + CHF*COPD Interaction ($1,400) = $9,200.

In determining the risk score, notice that all the coefficients are added together (demographic characteristics and risk factors). Also, there is additional payment in the model for the interaction between COPD and CHF.

The total predicted expenditures equal $9,200, which is divided by $5,300 to arrive at a 1.74 risk factor estimate. The $5,300 amount is average cost for a Medicare beneficiary in fee-for-service.

An actual payment estimate requires a ratebook that is not available until May 2003. If that rate book were available, you would multiply the risk factor by the rescaled county capitation amounts for the enrollee (Part A and Part B amounts). For more information on this model go to *www.cms.hhs.gov/healthplans/riskadj/*.

If the applicant is proposing risk sharing, the arrangement must be described in detail. The applicant should include examples that illustrate the risk sharing arrangement. The shared risk of gain and loss between us and the participating organization must be symmetrical, and the organization must always remain at significant financial risk.

Because we intend to implement any approved demonstrations as soon as possible, we do not intend to make any significant changes to the payment system used under the M+C program, which would be used to make payments under this demonstration. Thus, we will use the same risk-adjustment method developed for M+C plans to be used beginning in January 2004, except the payment amount will be fully risk-adjusted. The reporting systems used under the M+C data will also apply. If the applicant believes it is necessary to modify any aspects of the payment process, the application should request the modification and provide a detailed justification for the request.

Network

Since the key to a successful disease management product is the composition of the provider network employed by the applicant, and the effectiveness of the network providers' care management, the applicant should describe the structure of the proposed network it would use, and the structure of its existing networks, to the extent applicable. If possible, the applicant should illustrate with a diagram the layering of networks (PSO, HMO, etc.) and describe the important differences in contracting provisions in each network. For the proposed capitated disease management demonstration, the applicant should describe which networks would be used, how existing networks would be modified for Medicare users, and if necessary, how existing networks will be expanded.

As noted above, beneficiaries electing to receive case management through this demonstration would agree, as a condition for doing so, to receive services through the case management provider.

Claims Processing

The application should contain a discussion of the methods for processing and paying claims in the demonstration, including in-network and out-of-network services. The applicant should indicate whether existing claims processing systems used in commercial business will be used or whether new systems must be developed for the Medicare demonstration.

If there are any interface requirements for Medicare intermediaries and carriers, this should be noted and discussed. Estimates of effort required to establish payment protocols should also be included.

Budget Neutrality

This demonstration must be budget neutral. This means that the expected costs that we incur under the demonstration can be no more than the expected costs were the demonstration not to occur. The applicant must submit a budget neutrality calculation in the application. Using the proposed payment methodology (including any risk sharing arrangements), the applicant should estimate our payments with and without the demonstration for each year of the demonstration. Applicants must use both FFS and M+C expenses calculated on a county basis for the without-demonstration baseline for comparison to the with-demonstration costs. The calculation should indicate how the estimates were derived. If risk sharing is proposed, there should be three calculations of budget neutrality—optimistic or best-case assumptions, expected or normal assumptions, and pessimistic or worst-case assumptions. The risk-sharing proposal must include a 2 percent full-risk corridor above and below a targeted Medical-Loss-Ratio. In addition, prior to awards, CMS will work with applicants to determine whether the proposed Medical-Loss-Ratio is set at a level where the risk-sharing arrangement is projected to be budget neutral.

The applicant should include a revenue and expense statement showing calendar year 2003 estimated per member per month Medicare revenue and member premium; benefit expenses (hospital inpatient, hospital outpatient, professional, other Medicare services, and non-Medicare services); and administrative expense. The statement should show any copay credits for the various services.

If risk sharing is proposed, we will share risk only on medical benefit expenses. Administrative expense must be reasonable and consistent with prior practices. The applicant should describe a reconciliation process to be used to determine savings or losses. The administrative cost will not be guaranteed and should be recovered from savings. A reconciliation based on the participating organizations' accumulated medical claims expenses must include an independent audit, funded by the organization, verifying the calculations.

Medigap Issues

Many Medicare beneficiaries have health insurance that supplement Medicare, such as a Medicare supplement (Medigap) policy or coverage through an employer-sponsored group plan. Thus, to be enrolled in the demonstration, beneficiaries must be informed about supplemental health insurance, including Medigap policies and protections. With respect to Medigap policies, a beneficiary who enrolls in the demonstration would generally have the following protections:

- Under section 1882(s)(3)(B)(iii) of the Social Security Act, if an individual is enrolled in an organization operating under demonstration project authority and enrollment ceases under the same circumstances that would permit an individual to disenroll from a Medicare+Choice plan as set forth in 1851(e)(4), (for example, contract termination, moving out of the service area), the individual has a right to purchase certain Medigap policies (generally Plan A, B, C, or F) on a guaranteed issue basis.
- Under section 1882(s)(3)(B)(v) of the Social Security Act, if an individual has a Medigap policy and drops the Medigap policy to enroll, for the first time, in a M+C plan or *any similar organization operating under demonstration project authority* (emphasis added) and the beneficiary disenrolls during the first 12 months of such enrollment, the individual has the right to buy his or her former Medigap policy, if it is still available from the same insurance company. If the former policy is not still available, the individual has the right to buy Plan A, B, C, or F.

While a beneficiary is free to keep his or her Medigap policy, there may be little benefit in doing so, as these policies are designed to complement payments under Original FFS Medicare payment rules.

State Insurance Commission Licensure

Depending on the design of the demonstration, programs under this demonstration may be considered to fall within State laws regulating insurance, and State licensure thus may be required before an applicant can participate. The applicant should discuss State-licensing issues for the proposed demonstration site, and indicate any potential problems in obtaining the appropriate license to participate in the capitated disease management demonstration. If potential problems exist, there should be a discussion of methods for their resolution. The applicant should also discuss any other requirements from local jurisdictions that could impact on the implementation of the capitated disease management demonstration. We will work closely with organizations and their respective States to ensure that all of the State requirements are met before the demonstration is implemented.

Other Features

Applicants will also be expected to follow additional features that include—(1) Identification and assessment of patients, and documentation of their decision to elect to receive disease management through the demonstration, following the rules that apply under the M+C program; (2) Implementation of an appropriate treatment plan based on clinical guidelines; (3) Monitoring, feedback, and communication concerning the patient's condition; and (4) Arranging for and/or providing needed services, including preventive services.

I. Provisions of This Notice

This notice solicits applications for demonstration projects that use disease management to improve the quality of services furnished to specific beneficiaries and manage expenditures under Parts A and B of the Medicare program. Demonstration awardees will receive a capitated payment for all Medicare-covered services for beneficiaries with select diseases electing to receive disease management through the demonstration. 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 chronic conditions in which they have demonstrated expertise and ability.

Through this solicitation, project awards will be made to qualified organizations. PSOs, M+C organizations, AMCs, or disease management companies, may propose one or multiple sites for any of their targeted diseases or for multiple diseases. The demonstration projects will operate for 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. A project officer will be assigned to each selected project that 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.

II. Requirements for Submissions

We are seeking innovative proposals from qualified organizations that can test whether capitated models for disease management using a newly developed disease-specific risk-adjustment model will improve clinical outcomes and appropriate use of Medicare-covered services for targeted Medicare beneficiaries, while managing Medicare expenditures under Parts A and B to achieve reduced aggregate Medicare expenditures.

Models that are targeted specifically at the traditional FFS 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 comorbidities into account in the services provided.

Applicants must submit their applications in the standard format outlined in CMS's Medicare Waiver Demonstration Application in order to be considered for review by the technical review panel. Applications not received in this format will not be considered for review.

The Medicare Waiver Demonstration Application may be accessed at the following Internet address: *http://www.cms.hhs.gov/healthplans/research*. The application outlines all application requirements including the format and content requirements.

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.

A. Evaluation Criteria and Weights

1. Statement of the Problem (5 Points)

The proposal describes—

- The population;
- Patterns of health care;
- Incidence of disease in the geographic area to be served by the disease management program;
- Enhancements planned in the disease management program; and
- Obstacles to providing disease management services.

2. Targeting the Appropriate Population (15 Points)

- The proposal provides details on how the applicant plans to identify, recruit, and obtain participation by eligible Medicare beneficiaries into the demonstration.
- The strategy and plan for recruiting the required number of patients in the control and experimental groups appear reasonable and achievable.
- The applicant describes the process by which it will ensure that participation in the demonstration is voluntary, and the beneficiary is fully informed of all aspects of the demonstration. A draft consent form is included in the proposal and is sufficient. If applicable, the form should include, but not be limited to, information about the randomization process, and use of the patient's medical records (for example, for monitoring quality of care and for evaluating the demonstration project).
- Applicant explicitly states how its referral sources will use common or readily available information, tests, or instruments to properly identify appropriate candidates before soliciting participation in the demonstration in order to reduce the incidence of beneficiary rejection due to ineligibility.
- The applicant provides sufficient information on how many beneficiaries it expects to treat each year at each site.

3. Description of Disease Management Intervention Services (20 Points)

- The proposal provides clear and convincing evidence and supporting materials that proposed disease management services are appropriate for the targeted population, likely to improve the quality of care for these individuals, and likely to result in savings from efficiencies in the use of medical services/products.
- There are adequate mechanisms for ensuring the medical necessity and reasonableness of the disease management services furnished under the demonstration.
- There are adequate mechanisms for ensuring that beneficiaries' physicians are integrated with the project.
- The proposal provides sufficient detail on exactly how each service will be provided, the type and level of staff that will be providing the service, the proposed level of effort required, and a discussion of any special equipment, such as monitoring or electronic input devices.
- 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.

4. Organizational Capabilities (20 Points)

- The proposal provides evidence of the availability and adequacy of the following components, which are necessary to ensure adequate service delivery and the provision of high quality of care:
  + Facilities.
  + Equipment.
  + Trained staff.
  + Clinical protocols to guide care delivery and management.
  + Linkages to providers and services necessary to deliver care.
  + Appropriate information systems including the ability to collect and submit data for risk adjustment.
  + Appropriate financial systems.
- The proposal includes a detailed implementation plan describing tasks, time lines, and costs associated with implementing the demonstration program.
- If any modifications to the applicant's current structure are proposed, they have been sufficiently described and justified. Modifications may involve protocols, services, outreach, education initiatives, timelines, etc.
- The organizational and reporting structure of personnel are provided.
- The application should contain a discussion of the methods for processing and paying claims in the demonstration, including in-network and out-of-network services.
- The application provides a detailed plan of all tasks necessary to implement the disease management project, a schedule with timelines for all essential tasks, a listing of key personnel for the project, including an overall point of contact for the demonstration, and a break out of the responsibilities for persons working on the project.
- The applicant expresses willingness to cooperate in an independent formal evaluation of the demonstration, including submission of cost and other program data and site visits, conducted by us and/or our contractor.
- The proposal does not include targeting or treatment protocols that are proprietary in nature, or, if proprietary protocols are included, the proposal clearly indicates the applicant's agreement to the following statement:

''At any phase in the project, including at the project's conclusion, the awardee if so requested by the project officer, must deliver to CMS materials, systems, or other items applied, developed, refined or enhanced in the course of or under the award to be used to further the purpose of this demonstration project. These materials, systems, or other items shall not be subject to use for any other purpose.''

5. Effectiveness of Intervention(s) (20 Points)

- For existing disease management programs, the applicant demonstrates prior experience in operating successful disease management programs.
- For existing disease management programs, the applicant shows evidence of positive outcomes from prior and current efforts. Claims of prior success must include definitions of the outcomes measures used, as well as explanations of the length of time over which they were measured and how the measures were calculated. Results from similar projects are cited.
- The applicant expresses a willingness to work with us, the evaluation contractor, and the consortium of awardee sites to determine the specific data to be collected across sites for each disease category, as well as to develop consistent measurement strategies between sites.
- The proposal provides convincing evidence that the intervention will likely increase the appropriate utilization of evidence-based and guideline-recommended therapies, as well as improve patient outcomes.
- Existing information systems and/or proposed new data collection are adequate to meet the quality of care reporting requirements. Applicants should list data to be collected in demonstration.
- The proposal reports strong, credible likelihood of savings and improved patient outcomes calculated from data collected during implementation of similar disease management interventions by the applicant.

6. Payment for Disease Management Services and Reduction of Medicare Expenditures (20 Points)

- The proposal provides justification and explanation for the proposed payment methodology.
- The proposal provides clear, convincing evidence that, over the three years of the demonstration, the aggregate Medicare expenditures under Parts A and B (including incentives and start-up funding, if made) will be less than expected Medicare expenditures in the absence of the demonstration.

B. Final Selection

From among the most highly qualified applicants, the final selection of projects for the demonstration will be made by our Administrator and will take into consideration a number of factors, including operational feasibility, geographic location, and program priorities (such as testing a variety of approaches for delivering services, targeting beneficiaries, and payment). CMS reserves the right to determine the scope of the project, which includes limiting the number of awards and beneficiaries covered under the demonstration. In evaluating applications, we rely on our past experience with successful and unsuccessful demonstrations. We expect to make the awards in 2003.

IV. Collection of Information Requirements

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we are publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to

minimize the information collection burden. However, the collection requirements associated with this notice have been approved by OMB, under control number 0938–0880, with a current expiration date of 3/31/2003.

Authority: Section 402 of the Social Security Act Amendments of 1967 (42 U.S.C. 1395b–1)

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

Dated: September 9, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 03–3879 Filed 2–24–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3099–N]

Medicaid Program; Annual Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)

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

ACTION: Notice.

SUMMARY: This notice solicits interested parties to submit requests for review of the appropriateness of the payment amount for a particular intraocular lens furnished by an ambulatory surgical center.

DATES: Requests for review must be received at the address provided no later than 5 p.m. E.S.T. on April 18, 2003.

ADDRESSES: Mail requests for review (one original and three copies) to the Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: Betty Shaw, Mailstop C1–09–06, 7500 Security Blvd., Baltimore, Maryland 21244–1850.

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

SUPPLEMENTARY INFORMATION: On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103–432) were enacted. Section 141(b) of SSAA 1994 requires us to develop and implement a process under which interested parties may request, for a class of new technology intraocular lens (NTIOLs), a review of the appropriateness of the payment amount for IOLs furnished by ambulatory surgical centers (ASCs) under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act).

On June 16, 1999, we published a final rule in the **Federal Register** titled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' (64 FR 32198), which added subpart F to 42 CFR part 416. That rule set forth the process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established a flat rate payment adjustment of $50 for intraocular lenses (IOLs) that we determine are NTIOLs. This payment adjustment is good for a 5-year period that begins when we recognize a payment adjustment for the first intraocular lens in a new subset of an existing class of intraocular lens or a new class of technology, as explained below. Any subsequent IOL with the same characteristics as the first IOL recognized for a payment adjustment will receive the adjustment for the remainder of the 5-year period established by the first recognized IOL. After July 16, 2002, we may change the $50 adjustment amount through a notice with comment period. There will be no adjustment change for calendar year 2003.

Review Process for Establishing Classes of New Technology Intraocular Lenses

We evaluate requests for the designation of an IOL as an NTIOL by doing the following:

(1) Publishing a notice in the **Federal Register** announcing the deadline and requirements for submitting a request for us to review payment for an IOL.

(2) Receiving requests to review the appropriateness of the payment amount for an IOL.

(3) Compiling a list of the requests we receive and identify the IOL manufacturer's name, the model number of the IOL to be reviewed, the interested party or parties that submit requests, and a summary of the interested party's grounds for requesting review of the appropriateness of the IOL payment amount.

(4) Publishing a notice in the **Federal Register** listing the requests, and giving the public 30 days to comment on the IOLs for which a review was requested.

(5) Reviewing the information submitted with the request to review, and requesting confirmation from the Food and Drug Administration (FDA) about labeling applications that have been approved on the model lens under review. We also request a recommendation from the FDA about whether or not the lens model represents a new class of technology that sets it apart from other IOLs.

Using a baseline of the date of the last determination of new classes of intraocular lenses, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses that are classified by a predominant characteristic as reducing the risk of intraoperative or postoperative complications or trauma, or demonstrating accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

(6) Determining which lenses meet the criteria to qualify for the payment adjustment based on clinical data and evidence submitted for review, the FDA's analysis, public comments on the lenses, and other available information.

(7) Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class.

(8) Publishing a notice in the **Federal Register** (within 120 days after we publish the notice identified in paragraph (4) of this section) announcing the IOLs that we have determined are ''new technology'' IOLs. These NTIOLs qualify for the following payment adjustment:

(a) Determinations made before July 16, 2002—$50.

(b) Determinations made after July 16, 2002—$50 or the amount announced through proposed and final rules in connection with ambulatory surgical center services.

(9) Adjusting payments effective 30 days after the publication of the notice announcing our determinations described in paragraph (8) of this section.

Who May Request a Review

Any party who is able to furnish the information required in § 416.195 (A request to review) may request that we review the appropriateness of the payment amount provided under section 1833(i)(2)(A)(iii) of the Act for an IOL that meets the definition of a new technology IOL in § 416.180 (Definitions).

Requests To Review

A request to review must include all of the following information:

- The name of the manufacturer, the model number, and the trade name of the IOL.
- A copy of the FDA's summary of the IOL's safety and effectiveness.