404–639–3091. Fax Number: 404–639–3838. E-mail address: *EBelay@cdc.gov.*

Dated: April 8, 2002.

Sandra R. Manning,

CFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 02–9010 Filed 4–12–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Availability of Draft Technical Report of a Feasibility Study of the Health Consequences to the American Population of Nuclear Weapons Tests Conducted by the United States and Other Nations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comments.

SUMMARY: In 1998, the Congress requested that the Department of Health and Human Services (HHS) conduct an initial assessment of the feasibility and public health implications of a detailed study of the health impact on the American people of radioactive fallout from the testing of nuclear weapons. This request resulted in a joint project by scientists at the Centers for Disease Control and Prevention (CDC) and at the National Cancer Institute (NCI).

This notice announces that a 2-volume Technical Report providing details on the scientific methods and conclusions of this feasibility project is now available for public comment. This project has, for the first time, estimated preliminary doses to representative persons in all counties of the contiguous United States for a set of important radionuclides produced as a result of nuclear weapons testing from 1951 through 1962 by the United States and other nations. The work that has now been completed demonstrates that it is feasible to conduct a more detailed study of the health impact on the American population as a result of exposure to radioactive fallout from the testing of nuclear weapons in the United States and abroad.

However, significant resources would be required to implement this project, and careful consideration should be given to public health priorities before embarking on this path. To assist in the process of deciding about future fallout-related work, this report contains five different options for consideration.

DATES: To be considered, comments on this draft Technical Report must be received August 13, 2002. Comments received after the close of the public comment period will be considered at the discretion of CDC on the basis of what is deemed to be in the best interest of the general public.

ADDRESSES: Requests for copies of the draft Technical Report should be sent to the Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, Mail Stop E–39, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone (404) 498–1800, e-mail NTS and Global Fallout Report@cdc.gov. Written comments regarding the draft Technical Report should be sent to the same address. Because of its large size, CDC reserves the right to provide only one copy of the draft Technical Report free of charge to a requester. The document may also be accessed via the Internet at *http://www.cdc.gov/nceh/radiation/default.htm.*

Written comments submitted in response to this notice should bear the title of the report, ''A Feasibility Study of the Health Consequences to the American Population of Nuclear Weapons Tests Conducted by the United States and Other Nations.'' Because all public comments regarding this draft Technical Report will be available for inspection, no confidential business information or personal medical information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Radiation Studies Branch, Division of Environmental Hazards and Health Effects, National Center for Environmental Health, Centers for Disease Control and Prevention, Mail Stop E–39, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

SUPPLEMENTARY INFORMATION: Before 1963, the United States and other countries tested more than 500 nuclear weapons in the atmosphere. Each of these tests inserted radioactive debris, commonly known as fallout, into the atmosphere. Depending on the size and type of weapon detonated, some of this fallout traveled great distances before depositing on the earth and exposing people to radiation. Any person living in the contiguous United States since 1951 has been exposed to radioactive fallout, and all organs and tissues of the body have received some radiation exposure. On the basis of the preliminary estimates of dose and risk developed in this feasibility study, fallout radiation appears to have the greatest impact on risks for thyroid tumors. Risks for leukemia would be lower. Risk for cancers of other organs or tissues could be assessed as well, but because of the smaller amount of information available about radiation-associated health effects and the lower doses to most organs, the uncertainties associated with these estimates would be extremely large.

Dated: April 8, 2002.

Joseph R. Carter,

Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 02–9011 Filed 4–12–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4042–N]

RIN 0938–ZA32

Medicare Program; Solicitation for Proposals for Medicare Preferred Provider Organization (PPO) Demonstrations in the Medicare+Choice Program

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 to develop a Medicare Preferred Provider Organization (PPO) Demonstration. We are interested in making the PPO health care option, which has been successful in non-Medicare markets, more widely available to people with Medicare. Our objective is to introduce more variety into the Medicare+Choice program so that Medicare beneficiaries have broader choice and more options available. We intend to use a competitive application process to select several organizations to develop PPO demonstrations beginning January 1, 2003.

DATES: Applications will be considered timely if we receive them on or before May 30, 2002.

ADDRESSES: Applications should be mailed to the following address: Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Beneficiary Choices, Demonstration and Data Analysis Group, Division of Demonstration Programs, Attn: Ron

Deacon, Mail Stop: C4–17–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Please refer to file code CMS–4042–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: Ron Deacon, CMS Project Officer, at (410) 786–6622, or *ppodemo@cms.hhs.gov.* General information regarding this initiative is available on CMS's web site (*www.hcfa.gov/research/ppodemo.htm*).

SUPPLEMENTARY INFORMATION:

Informational Meeting

We invite individuals from organizations interested in responding to this solicitation to attend an informational meeting to be held at CMS headquarters in Baltimore on April 24, 2002 from 1 p.m. to 4 p.m. e.d.t. We will answer questions and provide guidance for the application process. Telephone call-in will be available for organizations unable to attend the meeting. More information on this meeting will be available at our web site (*http:www.hcfa.gov/research/ppodemo.htm*). Please send any questions in advance to *ppodemo@cms.hhs.gov.* We will answer the questions at the informational meeting.

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.

B. Problem

Medicare currently provides a choice of alternatives to fee-for-service health care through its Medicare+Choice (M+C) program. While the program has grown since its introduction in the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), enacted on August 5, 1997, plans representing a wide range of options have not entered the program. The Congress intended that the BBA give people with Medicare the opportunity to choose, from a variety of private health plan options, the health care plan that best suits their needs and preferences. The options anticipated were coordinated care plans, including preferred provider organizations (PPOs) and health maintenance organizations (HMOs) (including HMOs with a point-of-service (POS) option); unrestricted private fee-for-service plans; provider-sponsored organizations (PSOs); and medical savings accounts. Currently, of the 179 M+C contracts, only 2 are PPO contracts, 1 is a PSO contract, and 2 are private fee-for-service plan contracts; the remainder are HMO contracts (a relatively small number of these offer a POS option).

Over the long term, the M+C program has the potential to reduce costs because of its strong emphasis on coordinated care and preventive health. Moreover, because of its risk-based capitation payment system, the program provides increased incentives over fee-for-service for plans to control and even decrease the rate of growth in health care expenditures. Several proposed Medicare reform initiatives include financial components that encourage competition among health care providers and plans to provide the best choice for Medicare beneficiaries and the best price to Medicare. Today, participation by plans nationally or locally in M+C is not sufficient to foster the positive effects of competition in some areas.

People with Medicare currently have access to fewer health plan models or choices than consumers with commercial insurance. Often, when individuals become eligible for Medicare, they are unable to continue medical coverage in widely available commercial options that were available when they were employed. The cost of supplemental insurance for fee-for-service Medicare is often much higher and the benefits are fewer than with commercial insurance.

Our challenge is to increase participation in alternatives to Medicare fee-for-service. Participation by plans in the M+C program is declining. While there are several activities occurring that may minimize this trend, we are placing a new emphasis on expanding options and choices in the M+C program for people with Medicare. We are conducting this demonstration initiative to facilitate this process.

Through independent contractors, we researched specific health care models in the non-Medicare market, attempting to ascertain whether they would be effective in the Medicare program. This research has guided the development of this special solicitation.

C. Findings

Our research indicates that the success of the PPO concept is not being replicated in the Medicare program. Several of the organizations interviewed reported significant success with the PPO model and high satisfaction from subscribers. While some M+C plans are currently operating with aspects of the PPO concept, they have had minor impact. Because there are so many variations of the PPO theme, clearly defining the different types of PPO models is difficult. Industry experts confirmed this difficulty, but also emphasized that the PPO concept offers the potential for innovation in benefit design and the ability to customize product offerings to customer needs.

These experts also stated that PPOs encourage efficient use of health services through coordinated care and various types of incentives. PPO enrollees may use any provider either within or outside the PPO network, but have a financial incentive to use in-network providers. Some interventions, for example, disease management, counseling, health education, and such additional benefits as prescription drugs, may be conditional upon use of providers within the network.

Many organizations reported that they also offer closed panel HMOs, and that PPOs are designed as an intermediate option to the traditional HMO and traditional fee-for-service offerings. PPOs are popular with employers who use that model to manage and stabilize costs and to provide employees more flexibility and choice than in an HMO.

Point-of-service (POS) plans combine elements of both HMO and PPO coverage. They maintain an integrated provider network, but also offer benefits for out-of-network services. Several HMOs offer a POS option within the HMO framework. An HMO enrollee has the option of staying in-network or going out-of-network for care. Like PPOs, with this HMO POS option, an individual who elects to go out-of-network will likely absorb additional costs (that is, higher copayments or deductibles) and less coverage. HMOs

with a POS option frequently use a gatekeeper to control out-of-network use or to limit the amount of out-of-network use. Most PPOs do not use a gatekeeper.

All PPOs or PPO-like models share one common characteristic—a network of health care providers who have agreed to provide care to patients subject to contractually established payment levels. Often these networks are not as comprehensive as HMO networks because members are not restricted to using in-network providers. Several organizations expressed reservations about introducing a PPO model in Medicare because of the current M+C payment system. Almost all organizations expressed dissatisfaction with current payment amounts. The additional risk associated with out-of-network service compounds the problem.

Our research asked organizations specific questions about barriers to contracting with us. The organizations noted several administrative and regulatory barriers in addition to low payment levels and the lack of opportunity to share risk for higher-than-anticipated costs. Most plans were familiar with constraints imposed by M+C regulations. Some referred to barriers resulting from past policy decisions within our agency. In summary, most plans wanted an opportunity to be more innovative to use PPO concepts from their non-Medicare business. They requested more flexibility on qualifying conditions, monitoring requirements, and reporting requirements. They requested that we consider the unique characteristics of a PPO model and that our flexibility decisions be based on PPO characteristics and not reflect only what occurs with HMOs, the predominant type of M+C plan.

D. PPO Demonstrations

Under this demonstration, we will be testing alternatives to the current rules for payment to M+C organizations in section 1853 of the Social Security Act (the Act). As noted above, these demonstrations would be conducted under the authority under section 402(a)(1)(A) of the Social Security Amendments of 1967, 42 U.S.C. 1395b1(a)(1)(A), to test ''changes in methods of payment'' for Medicare services which may be more efficient and cost effective without compromising the quality of services. We would be waiving rules that relate to payment pursuant to section 402(b) of the Social Security Act Amendments of 1967. These PPO demonstrations will be considered M+C plans, although they will not be subject to some of the usual M+C provisions.

We believe that the PPO model will introduce incentives that will result in more efficient and cost-effective use of medical services. Enrollees will experience incentives to select efficient providers and to utilize services more effectively. Providers of care will experience incentives to alter the mix and intensity of services to enrollees in a cost-effective manner.

Based on the information received from private sector organizations, we intend to use our waiver authority to overcome some of the recognized barriers to increased participation in Medicare by health care organizations. Our overall goal is to use these demonstrations to assess the effects of new delivery models on various aspects of the M+C program. We will determine how these new delivery models impact Medicare beneficiaries and Medicare program expenditures as well as administrative burden. Through a formal independent evaluation, we will determine whether increasing the options available to beneficiaries has a favorable impact.

II. Provisions of This Notice

A. Purpose

This notice solicits applications from organizations for demonstration projects to offer the PPO model as an additional M+C choice to people with Medicare. We are encouraging experienced organizations to contract with us on a capitated payment basis and to provide PPO products that will appeal to people with Medicare, both those already familiar with some form of managed care and those familiar only with fee-for-service. We are interested in increasing the number of plan choices available so that more beneficiaries have optimal opportunity to find and select a plan that meets their needs. We anticipate that premium and other out-of-pocket costs for the PPO product will be priced between HMO and fee-for-service supplemental costs so that individuals will weigh these costs against the benefit and provider access characteristics associated with currently available plans.

We encourage organizations to propose innovative PPO models with the appropriate payment requirements and operational processes required to successfully implement the models. The quality of the proposals received will determine the number and types of models to be tested. Through this solicitation, we intend to award demonstrations in up to 12 geographic areas.

We intend to conduct the demonstrations for up to 3 years from the date of implementation. For each selected demonstration, we will assign a project officer who will serve as the point of contact with the demonstration project staff and who will provide technical consultation regarding waiver requirements, implementation and monitoring activities, and also provide feedback to us on demonstration status.

B. Funding

Under this demonstration, payments will flow to contract organizations as monthly capitation based on enrollment. We will use the M+C payment system and are requesting that applicants become familiar with this system. We will determine the actual payment amount and any reconciled adjustments based on the unique characteristics of each demonstration's payment terms.

Applicants may request minimal financial assistance for initial implementation costs (one-time payment up to $100,000 per demonstration project, subject to availability). We will consider requests for assistance with the following initial implementation costs:

- Modification of existing network contracts.
- Adaptation of claims processing systems to incorporate Medicare fee-for-service amounts.
- Preparation of special education and outreach efforts required for PPOs.
- Development of expense reporting required for any risk sharing or reconciliation processes.
- Development of any special quality of care or patient satisfaction data collection efforts unique to the demonstration.

A proposed project budget must illustrate the applicant's share of start-up costs, as well as our proposed share.

III. Requirements for Submission

Organizations with current M+C plan contracts may submit applications; however, existing contractors should offer the PPO model as a new choice for Medicare beneficiaries in the area. We prefer that organizations with an existing HMO product continue to offer the HMO product while also making the PPO product available. Our intention is to increase the number and types of choices available to people with Medicare. In our evaluation process, we will assign higher priority to proposals that create ''additional'' rather than ''substitute'' options.

The required application format is specified later in this solicitation.

Within the application each of the following subjects must be addressed:

A. Qualifications

We are interested in transporting successful models to the Medicare program. Applicants must describe in detail their prior experience and success in operating a PPO product. We will use our existing M+C application review process, or modifications of the review process, to determine if that organization is qualified to operate a PPO demonstration. It is important that the applicant be familiar with existing M+C qualification criteria. If the applicant believes that a criterion or requirement should not apply to the demonstration, this must be explicitly stated and sufficient rationale included for us to make a decision on the request.

The applicant should discuss State licensing procedures for the proposed demonstration site and indicate any potential problems in obtaining the appropriate license for the PPO 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 Medicare PPO demonstration.

B. Networks

Since the key to a successful PPO product is the composition of the applicant's provider networks and the effectiveness of the network providers' care management, the applicant should describe the structure of the networks in its existing products. If possible, the applicant should illustrate with a diagram the layering of networks (PPO, HMO, PAR (participating network), etc.) and describe the important differences in contracting provisions for each network. For the proposed PPO demonstration, the applicant should describe which existing networks will be used, how networks must be modified for Medicare users, and if necessary, how networks will be expanded.

While PPOs in the private sector may not directly manage or coordinate care within preferred networks, managing or coordinating care within the Medicare population is likely to be productive and cost-effective. The application should discuss any coordinated care interventions planned by the PPO organization.

C. Payment Methodology/Risk Sharing

If the applicant proposes any variation from the traditional M+C payment amount in the demonstration, the application must describe in detail its proposed payment amount. Because we are maintaining budget neutrality, we will not pay an amount that is higher than either 99 percent of the fee-for-service payment amount or the M+C payment amount in an area. In addition, if the applicant is proposing any type of financial protection, such as risk sharing or reinsurance, this should also be described in detail. The applicant should include examples that illustrate the risk sharing arrangement. The shared risk of gain and loss between CMS and the PPO must be symmetrical and the PPO will 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 existing M+C payment system. Thus, we will use the existing blend methodology of risk-adjusted and demographic-adjusted payment. The usual M+C reporting systems will remain in place. 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.

D. Budget Neutrality

The PPO demonstrations awarded under this solicitation must be budget neutral. This means that the expected cost that we incur under the demonstration can be no more than the expected cost 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 CMS payments with and without the demonstration for each year of the demonstration. 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 applicant should include a revenue and expense statement showing CY 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 (administration and profit). 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. A reconciliation based on the PPO's accumulated medical claims expenses must include an independent audit, funded by the PPO, verifying the calculations.

We intend to carefully review each applicant's proposed payment methodology. Our primary goal in this demonstration is to increase choices for people with Medicare while maintaining budget neutrality. Thus, before we make final decisions on demonstration awards, we will negotiate with applicants the specific terms of their payment proposals including our payment amount and any risk sharing arrangement, if proposed. We will not pay an amount that is higher than the M+C payment amount in an area or higher than 99 percent of the fee-for-service payment amount. Following are some of the aspects of payment that we consider important.

- Whether the model is likely to draw enrollees from fee-for-service or existing M+C products by considering existing M+C enrollment penetration and the characteristics of supplemental insurance available.
- The potential for selection risk resulting from the benefits offered, including member premium and cost sharing requirements.
- The reasonableness of revenue and expense estimates, particularly the administrative component.
- Any special enhancements for people with Medicare, such as prescription drug coverage, broad preferred networks, and commitments for quality improvement.

E. Provider Payments

The applicant should discuss its policies and procedures on in-network contracting including its credentialing and recredentialing process, level of payment, quality and other types of reporting required, and financial incentives and rewards. The applicant should compare these approaches to those in its commercial contracts. Any special challenges to obtaining a sufficient network for Medicare enrollees should be noted along with proposed solutions.

The applicant should describe its method of payment for out-of-network providers for their care of PPO enrollees. The discussion should include numerical examples showing dollar contributions from the PPO organization and from the enrollee for Part A and Part B services. The example

should include specific Medicare allowable amounts, enrollee cost sharing, and the total amount received by the provider.

The applicant should also describe its method for conducting provider relations, including the means by which it will address questions, complaints, and appeals from out-of-network providers on payments received. In addition, the applicant should describe its procedures for enrollee complaints relating to any balance billing requests received from providers.

F. 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 required payment protocols should also be included.

G. Enrollment Potential

The applicant should state the reasons it believes that the PPO demonstration is a wise business decision, and in particular, the reasons it believes people with Medicare will enroll in the PPO product. If focus groups or other qualitative consumer-oriented studies were completed, the findings should be described. The applicant should also explain its method for computing enrollment projections. In addition, the applicant should describe and provide estimates of its target market including underlying enrollment trends, demographics, and origin of potential enrollees (that is, fee-for-service, Medigap supplement, Medicare managed care including M+C, employer group).

Benefits offered and cost-sharing requirements are important considerations for those considering PPO enrollment. The application should thoroughly describe the benefit design and cost-sharing requirements for in- and out-of-network services. To the extent possible, we encourage organizations to offer some level of prescription drug coverage. If out-of-pocket caps are included for in- and out-of-network services, the application should describe the methods of calculation and implementation. Since the incentives to use network services are critical to successful performance in a PPO environment, the application should discuss the manner in which the benefit design and cost-sharing characteristics contribute to the desired incentives.

The application should also contain a description of the marketing plan for the demonstration. We are interested in the approach that each applicant will take to inform people with Medicare about a new PPO option. Since the concept may be unknown to older Medicare beneficiaries, the applicant should explain how it would attempt to explain the unique features of the PPO, not only in the marketing plan, but also after enrollment, when members begin to use services.

The application should discuss how the PPO organization will advise its members of providers in the preferred network and how it intends to update information as network changes occur.

H. Organizational Capabilities

Applicants must demonstrate that they have the basic infrastructure to implement and carry out the demonstration. At a minimum, the applicant must have adequate physical assets, trained staff, information systems, and financial resources. Proposals must include a detailed implementation plan describing tasks, time lines, and resources required to implement the demonstration program. Since applicants must demonstrate prior experience in operating successful PPO or M+C programs, the implementation plan should focus on tasks and a time line for modifying or adapting the existing systems and networks to fit the Medicare demonstration program.

One of the tasks in the implementation plan must be preparation of a ''Medicare Plus Choice PPO Application'' (OMB number 0938–0470) which is different from this application for a PPO demonstration. If the application for a PPO demonstration is approved, the awardee must submit a M+C application before implementation of the demonstration. Organizations with existing M+C contracts are familiar with the M+C application process. We are requiring this information to assess the organizational, health service delivery, financial, and quality aspects of each PPO model before it becomes operational. We may suggest a site visit to assist the applicant.

We intend to simplify and streamline the existing application process and will require awardees only to supplement material and information already included in the demonstration application. As part of the application, applicants may request that normal M+C requirements be waived or modified in the PPO demonstration. If we approve an applicant's request, the qualification application should reflect any waivers or modifications. During the implementation planning process, the project officer and our staff will assist awardees in further defining the process. It is our intent to make the qualification process as streamlined as possible.

The plan must also include tasks and time lines associated with other required implementation planning activities, such as network contracting, claims processing design, risk-sharing reconciliation process, marketing, and data reporting. The pre-implementation planning phase should not exceed 4 months, since we anticipate that all demonstrations will begin no later than January 1, 2003.

I. Waivers

The applicant must list and discuss all waivers of M+C requirements that they have requested. The applicant should describe each waiver, give the legal reference of the M+C requirement to be waived, and present a rationale for the importance of the waiver to a successful demonstration outcome. The applicant must distinguish, if possible, between M+C requirements that are legally binding by statute or regulation and those that are current M+C policy.

It is important to note that, while our waiver authority is limited to provisions that relate to payment, we believe our existing waiver authority will provide the opportunity to demonstrate innovative PPO options that offer greater flexibility to plans. For example, while we cannot waive quality assurance requirements, our payment-related waiver authority could potentially have the effect of permitting an entity to operate a PPO product under this demonstration without being subject to quality assurance requirements that would otherwise apply. Some potential demonstration participants may be M+C organizations that have an HMO license. If so, they would not be eligible for the less prescriptive quality assurance requirements under section 1852(e)(2)(B) of the Act that apply to a PPO plan, since the definition of a PPO plan in section 1852(e)(2)(D) of the Act requires that the plan be ''offered by an organization that is not licensed or organized under State law as a health maintenance organization.'' Private fee-for-service plans, however, are subject to the same less prescriptive quality requirements in section 1852(e)(2)(B) of the Act, and there is no restriction on an entity with an HMO license offering a

private fee-for-service plan. Absent waiver authority under a demonstration, however, there would be an impediment to carrying out a PPO demonstration under the private fee-for-service plan rules, since there is a requirement that all providers receive the same payment amount for a service, without regard to whether they have a signed contract with the entity offering the private fee-for-service plan. Our authority to waive requirements that relate to reimbursement or payment could allow us to waive these rules, and thus allow the organization to have a different payment arrangement with a preferred provider network than with providers outside the network. This would allow an M+C organization with an HMO license to carry out the demonstration without being subject to the quality assurance requirements that apply to HMOs, while still establishing a PPO-type network for enrollees.

Other examples of M+C rules that potentially could be waived as relating to payment might be rules applicable to enrollee cost-sharing (for example, the current aggregate limit on cost-sharing under a particular plan), and requirements in section 1854 of the Act relating to the submission and approval of an ''adjusted community rate'' (ACR) proposal. Virtually any payment requirement in section 1853 of the Act could also be waived. We wish to emphasize, however, that we cannot waive non-payment related requirements under our authority in section 402(b) of the Social Security Act Amendments of 1967, 42 U.S.C. 1395b–1(b).

J. Submission of Applications

We must receive applications (original and 10 copies) as indicated in the **DATES** and **ADDRESSES** sections of this notice. Only proposals that are considered ''on time'' will be reviewed and considered for award. 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 budget.

Application Contents Outline

To facilitate the review process, the application should include the following:

1. *Cover Letter*—Must include a brief description of the proposed demonstration, the demonstration site, a contact person, and contact information.

2. *Funding Request*—If the applicant is requesting financial assistance for start-up costs, it must include Standard Form 424—Application for Federal Assistance (including SF–424a—''Budget Information'' and SF–424b—''Assurances''). The form and information are available at *www.hcfa.gov/research/sf424.pdf, www.hcfa.gov/research/sf424a.pdf,* and *www.hcfa.gov/research/sf424b.pdf.*

3. *Executive Summary*

4. *Statement of the Problem*

5. *Demonstration Design*

6. *Rationale for Waivers*

7. *Organizational Capabilities*

8. *Budget Neutrality Calculations*

9. *Implementation Plan*

10. *Related Supplemental Materials*

IV. Evaluation Process and Criteria

A panel of experts will conduct a review of responsive proposals. This technical review panel will convene in the month following the due date for submission of proposals. The panelist's 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 assess the budget neutrality of the proposed projects.

A. Evaluation Criteria and Weights

1. Understanding the Problem (10 points)

The proposal should provide the following:

- Discussion of the importance of creating additional choices for people with Medicare.
- Discussion of the health resource characteristics of the proposed demonstration site, including existing M+C options, and present a rationale for introduction of a PPO option.
- Documentation of existing M+C constraints preventing or discouraging PPO options in the proposed demonstration site.

2. Soundness of the Demonstration Design (25 points)

The applicant should provide an additional PPO option for Medicare beneficiaries rather than a substitution for an existing M+C product. In addition, the proposal should provide the following:

- Clear and convincing evidence with supporting materials that the proposed PPO option will be viable and will attract people on Medicare.
- Reasons that its benefit design and in-network and out-of-network cost sharing requirements will encourage enrollees to effectively utilize services and will not discourage enrollment or deter use of necessary services.
- Convincing evidence that the proposed payment arrangements, including any risk sharing provisions, will ensure financial stability and will be budget neutral.
- Sufficient justification for any M+C waivers that the applicant is requesting.
- Sufficient explanation of all on-going operational activities required in PPO models.
- Evidence that the PPO network will be sufficiently accessible and achieve the desired results.
- Assurance that all State requirements will be met before implementation.

3. Organizational Capabilities (20 points)

The proposal should provide the following:

- Evidence of the availability and adequacy of facilities, equipment, personnel, and data systems to successfully conduct the proposed demonstration.
- Sufficient information on the organization of personnel during the project, to whom they are to report, and the methods for using their services in implementation planning and in the operation of the demonstration.

4. Ability to Implement the Demonstration (25 points)

The proposal should—

- Present a thorough and well-documented implementation plan projecting timely completion of required start-up activities;
- Recognize the more difficult implementation issues requiring resolution by both the organization and by us, presenting a plan for that resolution; and
- Indicate the organization's familiarity with Medicare requirements in its qualification process and ongoing monitoring of M+C plans.

5. Strength of the Financial Analyses (20 points)

The proposal should—

- Provide a clear understanding of projected revenues and expenses during the demonstration;
- Provide sufficient examples and explanations of various financial scenarios; and
- Indicate that the applicant understands the budget neutrality constraints and that the estimates that the applicant uses in the budget neutrality calculations are sound.

B. Final Selection

Our Administrator will make final selections for demonstration projects from among the most highly qualified applicants. Factors including operational feasibility, special area

characteristics, and program priorities will be considered in the final selection process. 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 expect to make awards during CY 2002.

V. Collection of Information Requirements

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. We cannot reasonably comply with the normal clearance procedures because these demonstrations would not be implemented in a timely manner resulting in the potential loss of alternative and flexible benefits for beneficiaries. As a result, beneficiaries may not be provided health care choices that will produce the most beneficial health care outcomes. In addition, this demonstration will provide beneficiaries with an alternative health care choice that may alleviate the need for supplemental health care coverage resulting in more cost-efficient health care.

We are requesting OMB review and approval of this collection within 14 days of the date of this publication, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 14 days of this publication. During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Collection Request: New collection; *Title of Information Collection:* PPO Demonstration Proposal Solicitation Package; *Form No.:* CMS–10063 (OMB# 0938–NEW); *Use:* CMS intends to use the collection requirements referenced in this notice to collect information needed to implement a high priority demonstration designed to strengthen the Medicare program. The collection requirements will be used to gather information about the characteristics of the applicant organizations and the services and benefits they propose to offer; *Frequency:* On Occasion; *Affected Public:* Business or other for profit and not for profit; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours:* 400.

In addition, if an applicant is approved, the awardee must submit a Medicare+Choice PPO application, approved under OMB number 0938–0470, with a current expiration date of 11/30/2003, before implementation of the demonstration. We intend to simplify and streamline the existing application process and will require awardees only to supplement material and information already included in the demonstration application.

We have submitted a copy of this notice to OMB for its review of these information collections. A notice will be published in the **Federal Register** when approval is obtained.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below, within 14 days of the publication of this notice:

Centers for Medicare and Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Fax Number: (410) 786–0262, Attn: John Burke.

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Fax Number: (202) 395–6974 or (202) 395–5167, Attn: Allison Eydt, CMS Desk Officer.

VI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980 Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). We have determined that this notice is not a major rule because it does not impose a significant economic impact to preferred provider organizations or the Medicare program.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. For purposes of the RFA, most preferred provider organizations are considered to be small entities, either by nonprofit status or by having revenues of $5 to $25 million or less annually. (For details, see the Small Business Administration's regulation that set forth size standards for health care industries (65 FR 69432).) Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of

a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will not mandate any requirements for State, local, or tribal governments.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this notice under these requirements and have determined that it will not impose substantial direct requirement costs on State or local governments.

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

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: March 28, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 02–9196 Filed 4–12–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0007–N]

Health Insurance Reform: Standards for Electronic Transactions; Announcement of the Availability of a Model Compliance Plan

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice announces the availability of instructions for, and a model of, a compliance plan that covered entities may use to request an extension to the compliance deadline for standards for electronic transactions and code sets that covered entities must use for those transactions.

FOR FURTHER INFORMATION CONTACT: Elizabeth Holland, (410) 786–1309.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 1996 the Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191, which included provisions to address the need for standards for electronic health care transactions and other administrative simplification issues. Through subtitle F of this law, the Congress added to title IX of the Social Security Act (the Act) a new part C (consisting of sections 1171 through 1179 of the Act), entitled ''Administrative Simplification.'' The purpose of this part is to improve the Medicare program, the Medicaid program, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information.

Section 1172 of the Act makes any standard adopted under part C of the Act applicable to the following entities as defined in section 1171 of the Act:

- All health plans.
- All health care clearinghouses.
- Any health care provider who transmits any health information in electronic form in connection with transactions referred to in section 1173(a)(1) of the Act.

Section 1175(a)(3) of the Act establishes that each person to whom a standard or implementation specification applies is required to comply with the standard no later than 24 months (or 36 months for small health plans) following its adoption. With respect to modifications to standards or implementation specifications made after initial adoption, compliance must be accomplished by a date designated by the Secretary. This date may not be earlier than 180 days after the Secretary adopts the modification.

In the August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule entitled ''Health Insurance Reform: Standards for Electronic Transactions'' that implemented the provisions of sections 1171 through 1179 of the Act. These provisions established new national standards with which all covered entities must comply. The effective date of these standards for all covered entities, with the exception of small health plans is October 16, 2002, and the effective date for compliance by small health plans is October 16, 2003. In addition, the August 17, 2000 final rule established a definitions section at 45 CFR 160.103 that includes definitions for the following terms— (1) Covered entities; (2) health plans; (3) small health plans; (4) health care clearinghouses; and (5) health care providers.

However, on December 27, 2001, the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105) provided for a 1-year extension of the deadline for compliance with the electronic health care transactions standards and code sets for all covered entities, with the exception of small health plans, that request an extension on or before October 15, 2002. Covered entities that submit a request by the deadline will have until October 16, 2003 to come into compliance with the standards.

In addition, Pub. L. 107–105 required the Secretary to develop a model compliance plan by no later than March 31, 2002. In developing this model compliance plan, the Secretary consulted with organizations described in sections 1172(c)(3)(B) and (f) of the Act as organizations to be consulted in developing national electronic health care standards. One of these organizations, the Workgroup for Electronic Data Interchange (WEDI), developed a series of recommendations for the model plan. On February 7, 2002, these recommendations were discussed at a public hearing of the National Committee on Vital and Health Statistics (NCVHS).

II. Provisions of the Notice

This notice provides information to covered entities, with the exception of small health plans, that will not be compliant with the electronic health care transactions and code sets standards by October 16, 2002. As required by Pub. L. 107–105, we are providing a model compliance plan that covered entities may use to submit to request an extension. These entities may use one of the following options to file for a 1-year extension (that is, until October 16, 2003):

- Submit the on-line compliance plan, which is available on our website at *www.cms.hhs.gov/hipaa.*
- Submit a paper copy of the on-line compliance plan via mail.
- Submit their own version of a compliance plan that provides equivalent information.

The model compliance plan and instructions for its completion and submission are available via the Internet