Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

We have examined the impact 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 in any 1 year). This notice does not reach the economic threshold and thus is not considered a major rule.

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. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

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. 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

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 have no consequential effect on the governments mentioned or on the private sector.

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. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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

Authority: Section 1834(a)(12) and 1842 of the Social Security Act

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program.)

Dated: December 23, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–3729 Filed 2–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4088–N]

Medicare Program; Part D Reinsurance Payment Demonstration

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

ACTION: Notice.

SUMMARY: This notice informs interested Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations of an opportunity to participate in the Part D Reinsurance Payment Demonstration beginning in contract year 2006.

FOR FURTHER INFORMATION CONTACT: Mark Newsom, (410) 786–3198; *mnewsom@cms.hhs.gov.* Jennifer Harlow, (410) 786–4549; *jharlow@cms.hhs.gov.*

Application Requirements: Organizations intending to offer a stand alone prescription drug plan must submit an application in accordance with the instructions found in the Solicitation for Applications from Prescription Drug Plans posted on the CMS website on January 21, 2005.[1] Organizations intending to offer a prescription drug benefit in combination with a Medicare Advantage plan must submit a completed Medicare Advantage Prescription Drug application in accordance with the Solicitation for Applications from Medicare Advantage Sponsors posted on the CMS Web site on January 21, 2005.[2] Applications are due to CMS on or before March 23, 2005.

Eligible Organizations: All PDP sponsors may participate in option one as described below.[3] Medicare Advantage organizations offering Prescription Drug Plans (MA–PD plans) are eligible to participate in options one and two (as described below)[4] with the exception of the following: Program of All Inclusive Care for the Elderly (PACE), MA employer only plans, and employer direct contract plans.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority

Section 402(a)(1)(A) of the Social Security Amendments of 1967 authorizes the Secretary to conduct demonstrations designed to test whether methods of payment or reimbursement will have the effect of increasing the efficiency and economy of programs without adversely affecting the quality of those programs' services.

Section 402(b) of the Social Security Amendments of 1967 authorizes the Secretary to waive requirements in title XVIII that relate to reimbursement and payment in order to carry out demonstrations authorized under section 402(a). Section 1860D–42(b) of the Act provides that the provisions of section 402 of the Social Security Amendments of 1967 apply with respect to Part D and Part C in the same manner as they apply to Parts A and B, except that any reference with respect to a trust fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part will be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

B. Issue

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Conference Report notes that provisions of the new Part D benefit

[1] See *http://www.cms.hhs.gov/pdps/.* See section 2 of the application.

[2] Id.

[3] See II(A) Demonstration Design—Two Part D Reinsurance Options.

[4] *Id.*

that relate to the out-of-pocket (OOP) threshold established in section 1860D–2(b)(4)(B) of the Social Security Act (the Act) may create a disincentive for Part D plans to provide supplemental prescription drug benefits through the enhanced alternative coverage option. Reinsurance benefits provided for in the MMA are not available until this OOP threshold is reached. The provision of supplemental coverage thus might prevent Sponsors or MA organizations offering Part D benefits from benefiting from reinsurance. This concern was also strongly voiced among the commenters to the proposed rule.

The reinsurance demonstration proposal allows for a budget neutral alternative payment approach, over a 5-year period, that may provide an incentive for private sector plans to offer supplemental prescription drug coverage to Medicare beneficiaries.

C. MMA Part D Reinsurance

Reinsurance begins at the annual OOP threshold, defined by section 1860D–2(b)(4)(B) of the Act and § 423.104(d)(5)(ii) of 42 CFR as $3,600 for 2006 (which, under the defined standard benefit, would equal $5,100 in total drug expenditures). The enhanced alternative benefit with supplemental coverage, as defined by 1860D–2(a)(2) of the Act and § 423.104(f)(1)(ii) of the regulation, could have the effect of changing the catastrophic attachment point for reinsurance, or preventing it from attaching altogether.

D. MMA Conference Committee

The MMA Conference Committee noted that ''the conditions under which the government provides reinsurance subsidies may create significant disincentives for private sector plans to provide supplemental prescription drug coverage.'' [5] To address this concern, the conferees suggested use of Medicare demonstration authority to ''allow private sector plans maximum flexibility to design alternative prescription drug coverage.'' [6]

Our authority to conduct Medicare demonstrations is provided in section 402 of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1). Under section 402(b), the Secretary is authorized to waive requirements in title XVIII that relate to reimbursement and payment. As noted above, this authority applies for Parts C and D in the same manner as Parts A and B under the provision of section 1860D–42(b) of the Act. The conferees specifically recommended that we demonstrate the effect of filling in the gap in coverage by reimbursing participating plans a capitated payment that is actuarially equivalent to the amount that plans would otherwise receive from the government in the form of specific reinsurance when an individual plan enrollee reaches the catastrophic attachment point ($3,600 in OOP costs for 2006).[7]

The conferees specified that we are not permitted to waive the minimum benefits provided by the plans.[8]

In summary, the MMA conference report urged CMS to conduct a demonstration for the purposes of creating an incentive for plans to offer supplemental benefits filling in the coverage gap. Consequently, in the proposed rule published on August 3, 2004 (69 FR 46633), we stated that we were considering establishing a demonstration to evaluate possible ways of achieving extended coverage. During the subsequent public comment period, we received support from key stakeholders for conducting a demonstration in this area, and in the final rule, we agreed to conduct this demonstration.

II. Provisions of the Notice

A. Demonstration Design

This reinsurance demonstration proposal represents an alternative payment approach; however, unless specifically noted, all other Part D rules will apply. This demonstration will be limited to a 5-year period. Participation in this Part D reinsurance demonstration will require the provision of supplemental benefits through an enhanced alternative benefit package, as well as payment based on either one of the two reinsurance options described below.[9]

Enhanced Alternative Coverage: Under this Part D reinsurance demonstration, eligible participants must provide supplemental benefits through enhanced alternative coverage. Under Part D rules, enhanced alternative coverage may include a supplemental benefit covering non-Part D drugs, reducing cost sharing, increasing the initial coverage limit, reducing the deductible, or any combination of these actions. For this demonstration, however, the supplemental benefit may only fill in part or all of the coverage gap. To clarify, other supplemental benefits that are part of enhanced alternative coverage (as defined in § 423.104(f)) are not included in this demonstration. Thus, a PDP Sponsor or MA organization offering an MA–PD plan under this demonstration would provide coverage between the initial coverage limit and the out of pocket threshold ($3,600 of True Out-of-Pocket (TrOOP) in 2006). The coverage gap may be filled in part or completely. The Sponsor or MA organization must provide catastrophic coverage.

Two Part D Reinsurance Options: Under our demonstration authority, two Part D reinsurance options will be made available. Again, note that unless otherwise stated, all other Part D payment rules apply.

- *Option One:* Eligible PDP Sponsors, including organizations offering MA–PD plans, could offer an enhanced alternative drug benefit package and receive a capitated drug reinsurance payment, inaddition to the normal direct subsidy, low income subsidy, and risk sharing payments. This reinsurance payment would be capitated (instead of specific reinsurance payments of 80 percent of drug costs after the beneficiary incurred $3,600 in TrOOP drug costs). The plan specific capitated reinsurance payment will be negotiated during the bidding process.
- *Option Two:* For organizations offering MA–PD plans that use MA premium rebates to cover the additional cost of enhanced alternative drug coverage, this option would permit enrollees to count supplemental benefit payments toward meeting the TrOOP spending requirement for Part D catastrophic coverage. For this option, all the supplemental benefit must be funded by MA Part A and Part B rebate dollars. To clarify, MA–PD plans may not include a supplemental premium for the supplemental benefit under this option. This is because it is not possible to distinguish A and B rebate dollars that would count toward TrOOP under this option from beneficiary premium dollars that would not count toward TrOOP.

For more details regarding the payment options one and two, please see the Part D Reinsurance Payment Demonstration Fact Sheet on the CMS Web sites *http://www.cms.hhs.gov/pdps/* and *http://www.cms.hhs.gov/researchers/demos/*.

Bid Submission Process: PDP sponsors or MA organizations wishing to participate will submit a bid following the bid submission protocol for the Part D benefit. The bidding

[5] U.S. House of Representatives, 108th Congress (November 21, 2003). *Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Conference Report to accompany H.R. 1. Report* 108–391. Washington DC: Government Printing Office. Available online at *http://www.gpoaccess.gov/serialset/creports/index.html.*

[6] *Id.*

[7] Id.

[8] *Id.*

[9] *See Two Part D Reinsurance Options* in this section.

process will be the same as for Part D, with the exception of including information relating to the demonstration model selected. There will be no additional burden associated with the submission of a bid.

B. Demonstration Evaluation Design

An evaluation of the CMS reinsurance demonstration will examine the impacts on beneficiaries, PDP sponsors, and MA organizations. From the beneficiary perspective, the analysis will focus on the availability of, and enrollment in, enhanced alternative benefit packages offered by PDP sponsors and MA organizations, as well as patterns of utilization of enrollees. The evaluation will also explore the advantages and disadvantages of participation from the organizations' perspectives.

C. Budget Neutrality

This demonstration must be budget neutral. This means that the expected Medicare costs under the demonstration can be no more than expected costs to the Medicare program in the absence of the demonstration. In order to ensure budget neutrality, PDP sponsors and MA organizations participating in the demonstration will have their capitation payments offset. The amount will be dependent on the demonstration reinsurance payment option chosen by the plan.

The CMS Office of the Actuary prepared an analysis of the demonstration for CY 2006 and determined that this demonstration is budget neutral if the capitated payments are reduced by at least $3.13 per member per year for option one and at least $7.57 per member per year for option two. Budget neutrality could be at risk under this demonstration if employer groups are allowed to participate, because this demonstration could provide an incentive for employer groups to drop their provision of drug coverage and encourage individuals to seek coverage under Part D. Further, in order to ensure budget neutrality for this demonstration initiative, we will consider prior year(s) of data and bidding information in establishing capitation amounts. Note that CY 2006 offsets are based on first-year impacts. The amounts shown may increase annually in a similar manner as other Part D costs for the duration of the demonstration.

III. Collection of Information Requirements

Other than a simple affirmation, as discussed below, no additional data will be collected from plans for the purpose of this demonstration.

Pursuant to this demonstration, plans must affirm to CMS that any funding of premiums will not come from any respective employer or union with whom the plan conducts business.

Whereas, this notice does not impose information collection and record-keeping requirements, it does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (PRA). Further, it is not subject to the PRA as stipulated under 5 CFR 1320.3(h)(1).

Authority: Section 402 of the Social Security Amendments of 1967.

Dated: February 11, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 05–3621 Filed 2–18–05; 4:24 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4089–N]

Medicare Program; Meeting of the Advisory Panel on Medicare Education—March 22, 2005

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix 2, section 10(a) (Pub. L. 92–463), this notice announces a meeting of the Advisory Panel on Medicare Education (the Panel) on March 22, 2005. The Panel advises and makes recommendations to the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program. This meeting is open to the public. This meeting replaces the February 24, 2005 meeting that was canceled.

DATES: The meeting is scheduled for March 22, 2005 from 9 a.m. to 4 p.m., e.s.t.

Deadline for Presentations and Comments: March 15, 2005 12 noon, e.s.t.

ADDRESSES: The meeting will be held at the Wyndham Hotel, 1400 M Street, NW., Washington DC 20005, (202) 429–1700.

FOR FURTHER INFORMATION CONTACT: Lynne Johnson, Health Insurance Specialist, Division of Partnership Development, Center for Beneficiary Choices, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop S2–23–05, Baltimore, MD 21244–1850, (410) 786–0090. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free)/(410–786–9379 local) or the Internet (*http://www.cms.hhs.gov/faca/apme/default.asp*) for additional information and updates on committee activities, or contact Ms. Johnson via e-mail at *ljohnson3@cms.hhs.gov.* Press inquiries are handled through the CMS Press Office at (202) 690–6145.

SUPPLEMENTARY INFORMATION: Section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended, grants to the Secretary of the Department of Health and Human Services (the Secretary) the authority to establish an advisory panel if the Secretary finds the panel necessary and in the public interest. The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7849) and approved the renewal of the charter on January 14, 2005. The Panel advises and makes recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on opportunities to enhance the effectiveness of consumer education strategies concerning the Medicare program.

The goals of the Panel are as follows:

- To develop and implement a national Medicare education program that describes the options for selecting a health plan under Medicare.
- To enhance the Federal government's effectiveness in informing the Medicare consumer, including the appropriate use of public-private partnerships.
- To expand outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of a national Medicare education program.
- To assemble an information base of best practices for helping consumers evaluate health plan options and build a community infrastructure for information, counseling, and assistance.

The current members of the Panel are: Dr. Drew E. Altman, President and Chief Executive Officer, Henry J. Kaiser Family Foundation; James L. Bildner, Chairman and Chief Executive Officer, New Horizons Partners, LLC; Dr. Jane Delgado, Chief Executive Officer, National Alliance For Hispanic Health; Clayton Fong, President and Chief Executive Officer, National Asian