

RATIONALE FOR OMB CLEARANCE FOR MEDICARE WAIVER DEMONSTRATION APPLICATION

A. Background

The Centers for Medicare & Medicaid Services (CMS) is requesting an extension of a currently approved collection (Medicare Waiver Demonstration Application, OMB# 0938-0880) from the Office of Management and Budget under the Paperwork Reduction Act (PRA). The currently approved application has been used for several Congressionally mandated and Administration high priority demonstrations including the Physician Group Practice Demonstration, High Cost Case Management Demonstration and the ESRD Disease Management Demonstration. We would like to request for OMB to approve the extension of the Medicare Waiver Demonstration Application so that it can be used for upcoming solicitations for proposals that are either congressionally mandated or Administration high priority demonstration initiatives which would be used to strengthen and modernize the Medicare program. We estimate that we will issue 3 solicitations annually, each with 25 responses for a total of 75 proposals a year. OMB approval of the Medicare Waiver Demonstration Application does not constitute approval of the demonstrations.

The standardized proposal format is not controversial and will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable CMS to select proposals that meet CMS objectives and show the best potential for success.

The demonstration solicitations will not be controversial because CMS will first consult with key stakeholders. In fact, these solicitations often reflect comments and suggestions offered by stakeholders during the consultative process. CMS has previously obtained the approval of the OMB for solicitations in this standard format.

Demonstrations that will use the standard application format are either Congressionally mandated or part of the Administration's Demonstration Initiative and will test innovations that have proved to be successful in the private sector in improving quality and access and lowering health care costs. CMS will use Section 402 demonstration authority (authorized under P.L. 92-603) or alternative authority outlined in a statute by Congress to test these innovations.

Proposals are requested in identical format regardless of the focus of the demonstration. The solicitations will use the Medicare Waiver Demonstration Application to request information about an applicant's organizational structure and management team; previous success in operating the model on which the demonstration is based; evidence that the model is likely to be successful in terms of health care quality, access and costs; and an implementation plan that covers all of the tasks required to operate the demonstration models. Proposals from all solicitations must be submitted in the user-friendly format outlined in the Medicare Waiver Demonstration Application.

Independent evaluators will use the submitted proposals to assess the success of these demonstration models in terms of health care quality, access and cost. Results will be used to guide the future of the Medicare program and to inform Medicare reform initiatives.

The justifications provided below show that proposed collections for information pose minimal risk to the Agency, Administration and/or the Public.

OMB approval of the Medicare Waiver Demonstration Application does not constitute approval of the demonstrations themselves. The demonstrations will only be implemented upon OMB approval of the waiver package.

B. Justification

1. Need and Legal Basis

The demonstration initiatives for which this request for clearance is being sought are considered high priorities. The demonstrations are intended to strengthen the Medicare program by offering innovative models to people on Medicare that improve quality and access and lower costs. As a result, people on Medicare will directly benefit from these innovative models.

The demonstrations will be undertaken under Section 402 demonstration authority or additional specific authority given us by the Congress.

2. Information Users

The collections of information to be used under the clearance are in identical formats. Information will be collected for all solicitation for proposals using the Medicare Waiver Demonstration Application. The collected information will be used to assess proposals and select organizations that are qualified to participate in the demonstrations. All of the solicitations pertain to demonstrations that are new to the Medicare program and therefore constitute collections of information that are new and distinct from each other.

This collection of information is strictly voluntary in nature. Only organizations (i.e. managed care organizations, providers, commercial health care vendors, etc.) that are interested in participating in the demonstrations will respond. Moreover, CMS will not be using these solicitations for proposals to regulate and/or sanction.

3. Improved Information Technology

The collection of information does not involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. In light of the limited amount of information to be collected and the limited frequency of collection, the use of such techniques and technology are not warranted at this time. No reduction in paperwork burden hours is assumed.

4. Duplication of Similar Information

The collected information will be used by CMS to offer new models to the Medicare program. CMS does not anticipate the occurrence of a duplication of effort or information collected because all of the solicitations pertain to demonstrations that are new to the Medicare program. As a precaution, CMS will implement an internal review process that will examine each solicitation to be disseminated and prevent internal duplication of effort.

5. Small Businesses

Not applicable. The collection of information will not affect small businesses or other small entities since these demonstration focus on large, established, high volume health care organizations.

6. Less Frequent Collection

The information is to be collected on an as needed basis. If the information were collected less frequently, CMS would not be able to obtain the information necessary to implement the congressionally mandated or Administration Demonstration Initiatives.

7. Special Circumstances

Each applicant will be required to submit an original and 2 copies plus an electronic copy. Applicants will also be given the option, but are not required, to submit 10 copies to assure that each review panel member receives the application in the manner intended by the applicant (e.g., collated, tabulated, color copies, etc.).

Applicants may regard their proposals to be confidential. CMS will protect the confidentiality of the requested information to the fullest extent of the law. The collected information will be stored in a locked area with restricted access. Any reports pertaining to the collected information by an independent evaluator will be in aggregate and anonymous form.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice pertaining to this collection of information was published on March 23, 2007.

9. Payments/Gifts to Respondents

There will be no payments or gifts to respondents for any of the collection of information.

10. Confidentiality

As a matter of policy to protect the proprietary information of applicants, CMS will prevent the disclosure of individually identifiable information contained in the applications to the fullest

extent of the law. Any reports pertaining to the collected information by an independent evaluator will be in aggregate and anonymous form.

11. Sensitive Questions

Other than the proprietary information noted above in section 10, there are no sensitive questions included in the information request.

12. Burden Estimate (Total Hours and Wages)

The total annual estimated public cost is \$300,000 for all demonstrations, assuming an estimated response time for each proposal of 80 hours, a total of 75 respondents to all demonstration solicitations, and salaries of the respondents to be \$50.00 per hour.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs required for the collection of information.

14. Cost to Federal Government

The total direct salary cost to the government per demonstration is \$44,400 assuming an estimated 30 senior level CMS staff involved in the review for 40 hours for a total of 1200 hours and an hourly rate of \$37.00.

15. Program Changes

There are no program changes.

16. Publication and Tabulation Dates

There are no publication and tabulation dates.

17. Expiration Date

CMS intends to display the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

No statistical methods will be employed.