

U. S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

MEDICARE WAIVER DEMONSTRATION APPLICATION



DISCLOSURE STATEMENT According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0880. The time required to complete this information collection is estimated to average 80 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850.

Medicare Waiver Demonstration Applicant Data Sheet	Date Submitted
Applicant Legal Name	Date Received by CMS
Address (city, county, state, zip code)	Name, telephone number and address of person to be contacted on matters involving the application.
Descriptive Title of Applicant's Project	Project Duration (MM/DD/YYYY) From _____ To _____
Proposed Project	Type of Applicant <input type="checkbox"/> Academic Institution <input type="checkbox"/> Individual <input type="checkbox"/> Profit Organization <input type="checkbox"/> Not for Profit Organization <input type="checkbox"/> Other, please specify
Areas Affected by Project (cities, counties, states)	
Applicant's Medicare Provider Number(s)	Applicant's Employer Identification Number
Is The Applicant a Medicare Provider/Organization in Good Standing? <input type="checkbox"/> Yes <input type="checkbox"/> No If "No", attach an explanation.	
<p><i>TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE TERMS AND CONDITIONS OF THE AWARD AND APPLICABLE FEDERAL REQUIREMENTS IF AWARDED.</i></p>	
Type Name and Title of Authorized Representative	Telephone Number
Signature of Authorized Representative	Date Signed

This application provides an opportunity for eligible organizations to apply to participate in Medicare-waiver-only demonstrations sponsored by the Centers for Medicare & Medicaid Services (CMS).

CMS conducts Medicare-waiver-only demonstrations to test innovations that have been shown to be successful in the private sector in improving access and quality and/or lowering health care costs. These demonstrations may involve new benefits, fee-for-service or Medicare+Choice payment methodologies, and/or risk sharing that are not currently permitted under Medicare statute.

Section 402 of Pub. L. 92-603 grants CMS the authority to waive Medicare payment and benefit statutes to conduct these demonstrations. Demonstrations may also be initiated as a result of Congressional mandate.

BUDGET NEUTRALITY Medicare-waiver-only demonstrations must be budget neutral. Budget neutrality means that the expected costs under the demonstration cannot be more than the expected cost were the demonstration not to occur. Applicants must supply information and assumptions supporting budget neutrality that CMS will use in preparing a waiver package for submission to the President's Office of Management and Budget (OMB). OMB must approve Medicare waivers before implementing the demonstration.

DUE DATE Applications will be considered timely if we receive on or before the due date specified in the "DATES" section of the demonstration

notice. Applications must be received by 5 P.M EST/EDT on the due date.

Only applications that are considered "timely" will be reviewed and considered by the technical review panel.

APPLICATION SUBMISSION An unbound original and 2 copies plus an electronic copy on diskette of the APPLICATION must be submitted; however, applicants may, but are not required to, submit 10 copies to assure that each review panelist receives the application in the manner intended by the applicant (e.g., collated, tabulated, colorized). If the applicant chooses to submit ten copies, they should deliver one (1) original and ten (10) copies plus an electronic copy on diskette. The applications should be MAILED to the following address:

**Department of Health and Human Services, Centers for Medicare & Medicaid Services, ATTN: Sid Mazumdar, End-Stage Renal Disease (ESRD) Disease Management Demonstration
Office of Research, Development, and Information, Division of Demonstration Programs, 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 cover letter, executive summary, forms, and supporting documentation.

Because of staffing and resource limitations, and because we require an application containing an original

signature, we cannot accept applications by facsimile (FAX) transmission.

FOR FURTHER INFORMATION

Please contact the project officer listed in the demonstration announcement and/or visit the CMS website at <http://www.cms.hhs.gov/healthplans/research>. Additional information about the demonstration, for example, fact sheets, design reports, press releases, and question and answer documents will be periodically posted on the website. Be sure to check the website frequently if applying for a demonstration to be sure you have the most current information available.

APPLICATION CONTENTS

OUTLINE To facilitate the review process, applications should be arranged in the following order:

1. Cover Letter
2. Medicare Waiver Demonstration Applicant Data Sheet
3. Executive Summary
4. Problem Statement
5. Demonstration Design
6. Organizational Structure & Capabilities
7. Performance Results
8. Payment Methodology & Budget Neutrality
9. Demonstration Implementation Plan
10. Supplemental Materials

CMS may provide start-up funds to cover implementation costs associated with the demonstration. If start-up funding is available, it will be announced in the demonstration solicitation. If requesting start-up funds, please include the Application for Federal Assistance Standard Form 424

after the Medicare Waiver Demonstration Applicant Data Sheet in the application and indicate the amount of funds requested in the cover letter.

APPLICATION REQUIREMENTS

We will use all the information you submit in the application review process. Your application must include the following information.

Cover Letter Please be sure to identify the demonstration, indicate the target population and geographic location of the demonstration (for example, urban or rural), the CMS provider numbers assigned to the applicant, contact person, and contact information.

Medicare Waiver Demonstration

Applicant Data Sheet Complete, sign, date, and return the Medicare Waiver Demonstration Applicant Data Sheet found at the beginning of this application.

Executive Summary Provide a 4 page summary of the key elements of the proposal (for example, Sections 3, 4, 5, 6, 7, 8, 9 under "Application Contents Outline").

Problem Statement Describe Medicare's current coverage and payment policy, and describe how or why changes to current policy would lead to reductions in Medicare expenditures or improvements in Medicare beneficiaries' access to and/or quality of care. Provide local examples. Describe the policy rationale for the proposal, who will benefit and why, and any previous experience with the proposed intervention.

Demonstration Design Describe the intervention including the scope of

services covered and/or benefit design, and payment methodology including financial incentives and/or risk sharing arrangements. Indicate how eligible beneficiaries will be identified, targeted, and enrolled in the demonstration (if applicable).

If applicable, describe the study design. Identify the intervention and comparison groups, and how Medicare beneficiaries will be assigned to each group. If a randomized study design is proposed, describe the process and provide a copy of the informed consent to be used.

Organizational Structure & Capabilities

Describe your governance structure and management and clinical teams, and their success before implementing the proposed intervention. Provide an organizational chart that describes the functional and reporting lines of major departments and/or entities.

Demonstrate that infrastructure exists to implement and carry out the demonstration project. Provide copies of reports from clinical, financial, and management information systems and describe how they are used.

Provide copies of applicable Federal and State licenses. Indicate if the applicant is a Medicare provider in good standing. Describe any other applicable accreditation, credentialing, and/or certification processes and results.

Provide documentation of your organization's financial viability that will enable it to participate actively and successfully in the demonstration, for example, as a formal audit opinion from the past 3 years or the balance sheet from the past 3 years with a summary

description. If there are any financial concerns, explain how your organization has addressed or will address these problems.

Performance Results Describe your systems and processes for monitoring clinical, financial, and operational performance. Identify key metrics collected and describe how you use this information to continuously improve the proposed intervention, correct deficiencies, satisfy beneficiaries, providers, and/or payers.

Payment Methodology & Budget

Neutrality Please indicate the proposed payment amount and method. Proposed payments may be based on fee-for-service or Medicare+Choice rates, methodologies, or some combination, and may involve risk sharing.

Describe in detail any risk sharing arrangements. Provide a revenue and expense statement by year for the life of the demonstration.

Demonstrate that the proposed intervention is budget neutral. Provide expected, best, and worse case scenarios. Include all supporting cost effectiveness, evidence, and assumptions used for the calculations.

If start-up funds are available as indicated in the demonstration announcement, please indicate the amount requested and include in your budget neutrality calculations. Note, if requesting start-up funds, applicants must complete an "Application for Federal Assistance" Standard Form 424 that can be found on the CMS website at <http://www.forms.psc.gov/forms/sf/sf.html> and submit with this application.

Demonstration Implementation Plan

Describe your implementation strategy, including tasks, resources, and timeline to implement the demonstration. Identify internal system and process modifications required to implement the demonstration. Describe your recruitment strategy and contingency plans for achieving beneficiary thresholds. Identify the individuals and staff responsible for implementing the demonstration and attach biographies.

Supplemental Materials Include in this section copies of supporting materials requested or referenced throughout the application.

EVALUATION PROCESS We will convene technical review panels consisting of outside experts and our staff to review all of the applications. Panelists will receive a copy of the application along with a technical summary. Panelists will be asked to numerically rate and rank the application using evaluation criteria contained in the demonstration announcement.

Applicants should review the demonstration announcement for the specific evaluation criteria to be used by panelists to assess proposals, as well as additional information on the evaluation process and selection of awardees.