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MATHEMATICA
Policy Research, Inc.

Supporting Statement for a Home Health Agency Survey on the Medicare Home Health Independence Demonstration

Paperwork Reduction Act Submission Supporting Statement

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Submitted to:

Centers for Medicare & Medicaid
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A. BACKGROUND

This application requests approval of a survey that will support the required evaluation of the Home Health Independence (HHI) Demonstration mandated under Section 702 of the Medicare Modernization Act (MMA) of 2003 (see Appendix A).

The Section 702 Demonstration, or the Home Health Independence (HHI) demonstration, represents an effort to clarify the definition of homebound by eliminating the homebound criterion for a defined group of Medicare beneficiaries. The demonstration allows beneficiaries who are permanently disabled and require substantial help to receive home health services regardless of the number, or frequency, and duration of their home absences. Specifically, the demonstration's clinical criteria for waiving the homebound requirement are that the patient (1) has a permanent and severe disabling condition that is not expected to improve (and a physician certifies this status); (2) needs permanent help with at least three of five activities of daily living (ADL); (3) needs permanent skilled nursing care other than medication management; (4) requires daily visits from an attendant to monitor, treat, or provide ADL assistance; (5) requires human or technological assistance to leave home; and (6) is not working outside the home.

Under the demonstration, Medicare beneficiaries who qualify for Medicare home health benefits and meet the demonstration criteria can leave their homes more frequently and for longer periods without risking the loss of those benefits. The Section 702 Demonstration and its evaluation were intended to assess the effect of removing the homebound requirement on beneficiary outcomes and costs/savings to the Medicare program.

1. **How does demand for home health services change after removal of the homebound requirement?** How many beneficiaries who would not otherwise be eligible seek care? How many beneficiaries receive more 60-day episodes of care than they otherwise would have?
2. **What is the likely cost or savings to the Medicare program?** What is the cost of additional episodes of care provided under the waiver? Do Medicare expenditures

for other services increase or decrease for beneficiaries receiving home health care under the waiver? Did the environment of the demonstration, or the way the agencies implemented the demonstration, suggest that actual national program costs could be higher or lower than costs predicted by the demonstration?

3. **How are beneficiaries who receive care as a result of the new policy affected?** Does the health and functioning of beneficiaries who receive care under the waiver improve relative to what it would have been otherwise? Do they leave their homes more often than similar beneficiaries who receive home health care? For what purpose? In what ways do their sources of care change?

4. **How did the demonstration affect home health agency staff behavior and resource use?** Did agencies' staff know about the demonstration, chose to participate, and actively encourage their patients to participate? How did they determine which patients met the demonstration criteria? Do demonstration participants have a different casemix distribution than typical home health patients? Do they use more resources, on average, then patients in the same casemix group?

The HHI demonstration, which is limited to 15,000 beneficiaries, is a 2-year demonstration and was implemented on October 4, 2004 in three states: Massachusetts, Missouri, and Colorado. Contrary to the original expectations of high enrollment, the agencies have reported that a total of only 25 participants have enrolled in the demonstration since its inception on October 2004.[1] As a result, an evaluation of the demonstration's impact upon the enrollees is not feasible. The focus of the demonstration evaluation has changed from examining the extent of the homebound problem and demonstration implementation process to understanding the reasons underlying the lack of enrollment.

B. JUSTIFICATION

1. Need and Legal Basis

The statute authorizing the demonstration mandates a report to Congress on the effects of the demonstration, to be submitted not later than one year after the date of completion of the

[1] This number is the total number of enrollees who were enrolled using the correct procedures. Agencies may have tried to enroll more participants, but used incorrect procedures, and thus are not included in the demonstration records.

demonstration (see Appendix A). The expected completion date of the demonstration was to be October 2006. In light of the low enrollment for the demonstration, the final report will instead evaluate the implementation of the demonstration outreach and enrollment efforts, and knowledge and perceptions of the major stakeholders towards the demonstration. With home health agencies (HHAs) as the major mediators of enrollment in the demonstration, this survey of HHAs is necessary to collect information on agency perceptions and recommendations regarding the home health eligibility criteria and the impact of the homebound provision waiver.

2. Information Users

This document seeks Office of Management and Budget (OMB) approval to collect these primary data using the mail survey instrument described below. Mathematica Policy Research, Inc. (MPR) will use the quantitative data collected with the home health agency survey to supplement the qualitative data collected from other central stakeholders to understand the reasons for the low enrollment rate for the demonstration and ways to change the home health eligibility requirements. MPR has designed this mail questionnaire to be completed in 30 minutes (see Appendix B) and to collect information from the home health agencies in the following domains: interpretation of the homebound rule, impact of the homebound rule upon their admissions and discharges, understanding of the demonstration eligibility criteria and determination of the eligibility status of their caseloads. This information will be used by Congress to understand why the demand within the Medicare population for the homebound waiver did not materialize as anticipated.

3. Use of Information Technology

There will be no use of information collection technology as the HHAs will receive a mail survey.

4. Duplication of Efforts

The information to be collected is uniquely related to this demonstration, and there are no similar data available. No other agencies or organizations are conducting any similar data collections.

5. Small Businesses

No small businesses will be involved in this study.

6. Less Frequent Collection

The proposed data collection will inform CMS about the factors related to the low enrollment of the demonstration and the role of the home health agencies in implementing the homebound rule and demonstration. Failure to collect the survey data would seriously hinder CMS's ability to explain why the demonstration failed to meet its stated objectives, to make recommendations regarding the need to modify home health requirements and to deliver a mandated report to Congress.

7. Special Circumstances

No special circumstances apply to this data collection. Respondents will not be required to retain any records. The statistical survey of home health agencies is designed to produce valid and reliable results that can be generalized to the universe of the study. The project will not use a statistical data classification not reviewed or approved by OMB. All project staff will follow MPR's confidentiality procedures (see Section A.10). Respondents are not required to provide any secrets or proprietary information.

8. Federal Register/Outside Consultations

The emergency notice soliciting comments on the proposed collection was published in the Federal Register on July 28, 2006. A copy of the notice appears in Appendix C. People outside CMS have been consulted about the availability of other data sources for this study and the data that need to be collected; these include the staff of the evaluation contractor, MPR, and the staff of the demonstration contractor, Abt Associates. The following people participated in the survey design:

- MPR Staff
  - Valerie Cheh (609) 275-2385
  - Karen CyBulski (609) 936-2797
  - Nancy Duda (609) 945-3340
  - Barbara Carlson (609) 275-2374
  - Daniel Kasprzyk (202) 264-3482
- CMS Staff
  - Ann Meadow (410) 786-6602

In addition, MPR has pretested the survey instrument by interviewing five home health agencies. Respondents in the pretest were asked to comment on any questions that were unclear. There are no unresolved issues regarding this data collection.

9. Payments/Gift to Respondents

The information that we are requesting from the home health agencies can only be provided by a representative who is knowledgeable about the agency's caseload and characteristics. We expect that this representative will be either the executive director or other senior manager at the home health agency. To compensate for the time spent filling out the questionnaire and to increase response we are proposing that compensation of $50 be provided to respondents.

10. Confidentiality

Notification of respondents regarding confidentiality, MPR's confidentiality procedures, and the basis for confidentiality assurances are discussed below.

a. Notification of Respondents

We will mail to sample members an advance letter from CMS informing them of the survey and asking for their cooperation. It will also inform them that their participation is voluntary. The letter will assure sample members that their responses will be treated confidentially. It will also describe the purpose of the study, provide information regarding the monetary compensation and an estimate of burden, give the name of the contractor conducting the survey, and provide a toll-free telephone number that the home health agencies can call if they desire more information about the study. A copy of the letter appears in Appendix D.

b. MPR's Confidentiality Procedures

MPR maintains extensive, tested procedures to ensure that confidentiality is maintained. As a condition of employment, all employees must sign a confidentiality pledge affirming that they accept their responsibility to protect the confidentiality of survey data. This pledge informs them that a violation may result in termination and possible legal action.

Survey data are maintained in MPR's Survey Operations Center, access to which is limited. During working hours, only MPR personnel have access to the Center. Visitors are required to report to the Center managers or supervisors upon entering the building. The Center is locked during nonworking hours, with access limited to the Center managers, supervisors, and MPR senior systems analysts. Interviewers and other MPR personnel do not have access to the center after working hours.

To ensure that data are protected and that the confidentiality of sample members is maintained, access to identifying information is limited to project personnel for the period of time it is needed. The Survey Operations Center is equipped with locked file cabinets for storing hard-copy questionnaires and other paper documents. Access to these storage units is limited to project managers and supervisors.

The respondents will provide patient-level medical data in a non-identifiable form. The survey requires agencies to provide medical information for specific patients. However, prior to the submission of the survey, the agency will remove all identifiers from the hard-copy questionnaire. Even after the questionnaires have been received at MPR, identifying information will neither be kept with completed survey data nor included on the data files provided to clients. Hard-copy questionnaires and other paper documents are routinely returned to the client or destroyed after completion of the project in accordance with contract specifications. Similarly, as required by contract specifications, data are purged from the computer system at the conclusion of a project or maintained for a set period of time.

c. Basis for Confidentiality Assurance

Assurance of confidentiality is made on the basis of the Privacy Act of 1974, as amended (45 CFR 5b), which stipulates that information may be released by the U.S. Department of Health and Human Services (DHHS) without written consent for a purpose compatible with the purpose for which the information was collected.

Respondent confidentiality will be ensured by adherence to Section 903(d) of the Public Health Services Act (42 USC 299 a-1(c)), as follows:

> "No information, if an establishment or person supplying the information or described in it is identified, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as

> determined under regulations or the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form."

No individually identifying information collected by the study will be released. Only aggregated data will be reported.

11. Sensitive Questions

The proposed survey does not contain any sensitive questions.

12. Burden Estimates

Table B.1 presents burden and cost estimates for respondents. We estimate that the total burden associated with the survey will be 75 hours. These estimates of burden are based on a pretest of respondents who are representative of the study population. The pretest completion time averaged 30 minutes for the respondents who completed the mail questionnaire. We estimate that the total cost to respondents for completion of the survey will be $17.50 per completed response based on hourly wage estimate of $35.

TABLE B.1

BURDEN AND COST ESTIMATES

Questionnaire	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden (Hours)	Total Cost to Respondents
Mail Survey	120	1	0.50	60	$2,100

13. Capital Costs

Respondents will incur no monetary costs in completing the survey. The advance letter will include a toll-free telephone number that sample members can call if they have any questions

about the survey or would like additional information. The sample will be selected from administrative files maintained by CMS. Thus, the selection of the sample will not impose any costs on the people participating in the survey.

14. Cost to the Federal Government

The total cost to CMS of conducting this survey is $178,776. These costs were estimated by projecting the number of hours to develop the survey instruments, as well as expected number of hours to conduct the survey. We multiplied these hours by wage rates of staff expected to complete the tasks, and added in equipment use costs.

15. Changes to Burden

This is the first submission for this survey; there are therefore no changes or adjustments.

16. Publication/Tabulation Dates

The demonstration began enrolling patients in October 2004. The evaluation of the HHI demonstration began in January 2005. Data collection for the agency survey will begin on July 2006 and end on October 2006. The data collected in the survey will be tabulated and analyzed in the Final Report due to Congress by January 2007.

The survey is designed to address the question of why the enrollment rate for the demonstration was much lower than originally anticipated. Was the failure to enroll beneficiaries in the demonstration due to: the stringency of eligibility criteria, the lack of knowledge and support by home health agencies, the extent to which homebound is a problem, or some other reason or combination of reasons? The survey data will be used for descriptive analyses, consisting of percentages and frequencies of the key variables to determine which factors limited enrollment. Table B.2 describes the use of the items in the agency survey.

TABLE B.2

DATA ELEMENTS

Question	Data Element
1-3	Implementation of Homebound criteria
4-9	Extent of homebound problem
10	Patient characteristics
11-14	Demonstration experience

For each state, we will tabulate agencies' responses to the questions and compare findings between states. Because we are not formally testing hypotheses, no power calculations or minimum detectable differences are required.

17. Expiration Date

The proposed data collection will display the OMB number and expiration date in the introductory letters to be sent to sample members, as well as on the mail version of the survey instrument.

18. Certification Statement

The proposed data collection does not involve any exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

C. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Below we describe the target population and sample frame, the sample design, the sample size, and the selection method. We also discuss postsurvey adjustments to the sample weights and variance estimation from survey data with a complex design.

a. Sample Design and Survey Implementation

Overview. The sample for the HHI is drawn in two stages: (1) agencies and (2) patients within agencies. The goal of the HHI sample design is to select a representative sample of 50 home health agencies that have patients who are potentially eligible for the demonstration in each of the three participating states (Colorado, Massachusetts, and Missouri), and to select a representative sample of such patients within each selected agency. Within each of the selected agencies, we plan to randomly select 5 patients who are potentially eligible for the demonstration, and for whom the agency will abstract the medical record information needed for this evaluation.

Eligibility. For sampling purposes, we have decided to include as "potentially eligible" those patients who have been receiving Medicare home health services from these agencies for two or more consecutive 60-day episodes, who use technical or human assistance to move, and who have three or more Activities of Daily Living (ADLs) for which they need assistance. An agency is considered to be eligible for this sample if it has five or more eligible patients.

Agency Sample. According to the most recent OASIS administrative data we have,[2] there are 60 eligible agencies in Colorado, 80 eligible agencies in Massachusetts, and 81 in Missouri. If these numbers are similar when looking at updated administrative data, we will randomly select 50 in each of the three states. Within each state, we will randomly sort the eligible agencies by zip code, and select a sample of 50 in each, with probability proportional to the number of potentially eligible patients. We will use a sequential sampling technique based on a

[2] From January 2004 to June 2005.

procedure developed by Chromy.[3] If an agency is so large that its probability of selection is one or greater, we will select that agency with certainty and remove it from the random selection process. Based on the current data, 20 to 30 agencies per state will be selected with certainty.

Patient Sample. Within each of the selected agencies, we will obtain a list of potentially eligible patients, with information about their gender and age. We will sort each agency's list by gender, and then by age within gender, and select a Chromy sequential sample of 5 patients per agency with equal probability.

b. Weighting and Precision

After data collection, we will produce agency-level and patient-level analysis weights. At the agency level, the base weight will be the inverse of the probability of selection of the agency. The certainty selections will have an agency-level base weight equal to 1. If there is any ineligibility or nonresponse at the agency level, this will be accounted for in the weights. This weight should be used for agency-level analyses.

At the patient level, the weight will be the inverse of the patient's probability of selection within agency. Should there be any missing medical record abstractions (for example, record not found), this will be accounted for in the weights as well. The cumulative patient-level weight, which should be used for patient-level analyses, will be the product of the agency and patient weights. For patients within non-certainty agencies, the cumulative weight should be approximately equal to 1.

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[3]The Chromy procedure offers all the advantages of the systematic sampling approach but eliminates the risk of bias associated with that approach. It makes independent selections within each of the sampling intervals while controlling the selection opportunities for units crossing interval boundaries. Chromy, J.R. "Sequential Sample Selection Methods." Proceedings of the Survey Research Methods Section of the American Statistical Association, 1979, pp. 401-406.

c. Variance Estimation

At the agency level, the variance of estimates must account for the unequal weights across agencies, due to the probability-proportional-to-size selection methodology. Table C.1 shows the standard errors and 95 percent confidence intervals around estimates using all 50 agencies in a state, and around estimates from a subgroup of half these agencies. For example, if the outcome measure of interest is the proportion of agencies that report a certain characteristic, the in Massachusetts, if that proportion is .4, the standard error would be about .085, and the confidence interval would be .4 ± .170.

Table C.1. Precision of Agency-Level Estimates

Outcome measure – proportion of sample equal to:		.1	.2	.3	.4	.5
		.9	.8	.7	.6	.5
Colorado						
design effect[a]	1.089					
Sample size=50	std. error	.045	.060	.068	.073	.075
	conf. intvl.[b]	.090	.120	.137	.147	.150
Sample Size=25	std. Err.	.064	.085	.098	.104	.107
	conf. intvl.	.132	.176	.201	.215	.220
Massachusetts						
design effect	1.462					
Sample Size=50	std. error	.052	.069	.079	.085	.086
	conf. intvl.	.104	.139	.159	.170	.174
Sample Size=25	std. error	.074	.099	.113	.121	.123
	conf. intvl.	.153	.204	.233	.250	.255
Missouri						
design effect	1.233					
Sample Size=50	std. error	.048	.063	.073	.078	.079
	conf. intvl.	.096	.128	.146	.156	.159
Sample Size=25	std. error	.068	.091	.104	.111	.113
	conf. intvl.	.140	.187	.214	.229	.234

[a] Design effect due to unequal weighting.
[b] This number represents the half-width of a 95% confidence interval.
N.B. These figures are based on the currently available data.

At the patient level, the variance of estimates must account for the unequal weights across patients, as well as the clustering effect of the multi-stage design (for patients selected within non-certainty agencies). Table C.2 shows the standard errors and 95 percent confidence intervals around estimates using all 250 patients in a state, and around estimates from a subgroup of half

these patients. For an estimated proportion of about .2 made from all 250 patients selected in Colorado, the standard error would be about .034, and the confidence interval would be .2 ± .067.

Table C.2 Precision of Patient-Level Estimates

	proportion=	.1	.2	.3	.4	.5
	or	.9	.8	.7	.6	.5
Colorado						
Sample Size=250	std. error	.026	.034	.039	.042	.043
	conf. intvl.[a]	.050	.067	.077	.082	.084
Sample Size=125	std. err.	.036	.048	.055	.059	.060
	conf. intvl.	.071	.095	.109	.117	.119
Massachusetts						
Sample Size =250	std. error	.028	.037	.043	.046	.047
	conf. intvl.	.055	.074	.084	.090	.092
Sample Size=125	std. error	.040	.053	.061	.065	.066
	conf. intvl.	.079	.105	.120	.129	.131
Missouri						
Sample Size=250	std. error	.026	.035	.040	.043	.043
	conf. intvl.	.051	.068	.078	.084	.086
Sample Size=125	std. error	.037	.049	.056	.060	.061
	conf. intvl.	.073	.097	.111	.119	.121

[a] This number represents the half-width of a 95% confidence interval.
N.B. These figures are based on the currently available data.

When analyzing data resulting from a complex sample design, it is important to account for the design when calculating the variance of an estimate. Because of the unequal weighting and clustering, a specialized approach (such as Taylor Series or replication techniques) must be used to properly calculate the variances. These techniques are available in statistical packages such as SUDAAN and Stata.

2. Procedures for the Collection of Information

There will be three mailings to the home health agencies. The first will contain an advance letter that explains the purpose of the study and provides MPR's toll-free telephone number for agencies that have questions, a contact person, and information about the monetary

compensation for participation. This letter will be mailed first class and sent one week before the first questionnaire mailing. A week later, a second mailing will be sent, containing a cover letter, the questionnaire, and a return FedEx envelope. The cover letter will contain content similar to that of the advance letter and will address confidentiality concerns. We will send a second questionnaire mailing one month after the first questionnaire mailing. The cover letter will be modified to address issues of nonresponse and will include letters, if available, from the appropriate state and national home health associations. Both questionnaire mailings will be sent by priority mail. Agencies that return completed questionnaires will receive $50 in compensation for their time.

After questionnaires have been received and entered into the system, they will be quickly routed for data entry. We will develop procedures for identifying critical items and conducting follow-up calls to collect missing or inconsistent information. We will begin the telephone phase two weeks after the second questionnaire mailing. This phase will consist of two major activities: (1) locating telephone numbers for HHAs, and (2) making telephone reminder calls to the agencies who have not return the mail instrument. We estimate that about 40 percent of the initial sample will be referred to the telephone phase for item follow-up and reminders. When we begin the telephone phase, we will update the telephone sample daily to eliminate, as much as possible, calls to respondents who have completed mail instruments.

3. Methods to Maximize Response Rates and Deal with Nonresponse

To assure the validity of the response to the survey, the survey seeks a response rate of 80 percent. To achieve the highest possible response, we will undertake the following steps for the collection of information:

1. ***Pretesting.*** We pretested the instrument to assure that the language, questions, pathing, and format are readily comprehensible to the targeted population.

Respondents are much less apt to refuse a question or, indeed, the entire questionnaire, when they can understand the task they are being asked to accomplish. We conducted this limited pretest of the entire questionnaire with 9 agencies resembling the targeted population.

2. ***Support of home health associations.*** A key to achieving this response rate will be the support of state and national home health associations. We discussed this with the state associations and asked them to provide a letter of support. We have provided the home health associations an opportunity to comment on the survey instrument.

3. ***Data collection materials.*** The focus of all respondent materials (advance and refusal conversion letters) will be to secure respondent cooperation through the clarity, simplicity, and thoroughness of the materials.

4. ***Data collection methods.*** Section C.2 described several data collection techniques that will minimize nonresponse: sending advance letters, offering an incentive, and calling agencies who have not returned completed questionnaires.

We will also assess and address any nonresponse in the postsurvey analysis phase. If the agencies which fail to respond to a survey would have provided systematically different answers from those who do respond, then the survey estimates obtained only from respondent data will be biased. We will calculate adjustments to the sampling weights to compensate for such bias.

Finally, survey data collected for this evaluation are subject to item nonresponse. Item nonresponse occurs when the beneficiary participates in the survey but is unable or unwilling to answer all the questions. Upon receipt of a completed survey, project staff will check the survey against a list of critical data elements. Any uncompleted items will trigger a call to the agency to obtain or clarify the missing/incomplete data. Remaining item non-response will be handled by including a missing category in the analysis.

4. Tests of Procedure or Methods to be Undertaken

To estimate completion time and uncover problems in questionnaire wording and logic, we conducted a pretest of the mail questionnaire with nine respondents. These respondents were representative of the full study sample. No significant problems were uncovered.

5. Persons Consulted on Statistical Aspects and Persons Collecting and/or Analyzing Data

Mathematica Policy Research, Inc. (MPR) is conducting this study, including collecting and analyzing the survey data, under contract to CMS (contract no: CMS 500-00-0033 (06)). The MPR person responsible for the statistical aspects of the sample design is Barbara Lepidus Carlson (609-275-2374). Karen CyBulski of MPR (609-936-2797) will direct the data collection effort. Valerie Cheh of MPR (609-275-2385) is the project director with overall responsibility for the project, and will lead the analysis. Ann Meadow of CMS (410-786-6602) is the technical Project Officer for the task order

APPENDIX A

APPLICABLE LEGISLATION

SEC. 702. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall conduct a 2-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if—

(1) the beneficiary has been certified by one physician as an individual who has a permanent and severe, disabling condition that is not expected to improve;

(2) the beneficiary is dependent upon assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the beneficiary's life;

(3) the beneficiary requires skilled nursing services for the rest of the beneficiary's life and the skilled nursing is more than medication management;

(4) an attendant is required to visit the beneficiary on a daily basis to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living;

(5) the beneficiary requires technological assistance or the assistance of another person to leave the home; and

(6) the beneficiary does not regularly work in a paid position full-time or part-time outside the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e). The report shall include the following:

(1) An examination of whether the provision of home health services to medicare beneficiaries under the project has had any of the following effects:

(A) Has adversely affected the provision of home health services under the medicare program.

(B) Has directly caused an increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification.

Deadline.

Deadline.
42 USC 1395x
note.

(2) The specific data evidencing the amount of any increase in expenditures that is directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program.

(3) Specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional costs to the medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(j) DEFINITIONS.—In this section:

(1) MEDICARE BENEFICIARY.—The term ''medicare beneficiary'' means an individual who is enrolled under part B of title XVIII of the Social Security Act.

(2) HOME HEALTH SERVICES.—The term ''home health services'' has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ''activities of daily living'' means eating, toileting, transferring, bathing, and dressing.

APPENDIX B

SURVEY INSTRUMENT

FORM APPROVED:

OMB No.
APPROVAL EXPIRES:

MATHEMATICA
Policy Research, Inc.

Survey of Home Health Agencies

May 9, 2006

Centers for Medicare & Medicaid Services (CMS)

INSTRUCTIONS

This questionnaire should be completed by the person or persons who know the most about the composition of the home health agency's caseload and activities related to CMS's Home Health Independence Demonstration. Even if your agency did not participate in this demonstration, it is very important that you complete this questionnaire. Please use black or blue ink to complete this questionnaire. Most questions can be answered by simply placing a check mark in the appropriate box. For a few questions you will be asked to write in a response. If you are unsure about how to answer a question, please give the best answer you can rather than leaving it blank.

If you have any questions, please contact Valerie Cheh, the study director, at Mathematica Policy Research, Inc. (609) 275-2385, Monday through Friday, between 9:00 a.m. and 5:00 p.m. (Eastern Time). Valerie Cheh is also available to answer your questions via email at: vcheh@mathematica-mpr.com.

Please return the completed questionnaire in the enclosed pre-paid Federal Express mailer by _____. If you need to arrange for Federal Express pick-up, you can call the toll-free 800 number on the mailer.

As a token of our appreciation you will receive $50 for completing this questionnaire.

The Home Health Independence Demonstration

The Medicare Home Health Independence Demonstration is a project being conducted by the Centers for Medicare and Medicaid Services (CMS) that allows qualifying Medicare beneficiaries who receive Medicare home health benefits in COLORADO, MASSACHUSETTS, and MISSOURI to leave their home more frequently and for longer periods without risking the loss of those benefits. You may know this demonstration as the **Homebound Exemption Demonstration**.

Who can participate in the Home Health Independence Demonstration?
To be eligible for the demonstration, the individual must be a Medicare beneficiary who is enrolled in Part B, meets all of the eligibility criteria for Medicare home health, and receives home health services under the traditional Medicare home health benefit and NOT through an HMO. In addition to these requirements, the individual must meet six additional criteria, which are as follows:

(a) Beneficiary has a permanent and severe disabling condition that is not expected to improve;

(b) Beneficiary requires skilled nursing services for the rest of beneficiary's life (not necessarily daily or with any fixed frequency) and the skilled nursing is more than medication management;

(c) Beneficiary requires technological assistance or the assistance of another person to leave the home;

(d) Beneficiary does not regularly work in a paid position full-time or part-time outside the house;

(e) Beneficiary is dependent upon assistance from another individual with at least 3 out of the 5 activities of daily living (eating, toileting, transferring, bathing and dressing) for the rest of beneficiary's life;

(f) An attendant is required on a daily basis to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living.

This ability to leave home more often, for any purpose, and for longer periods of time is the ONLY change under the demonstration. Beneficiaries must meet ALL the other usual eligibility and coverage criteria for Medicare home health care (including having limitations that make leaving home require a considerable and taxing effort). The Home Health Independence Demonstration began on October 4, 2004 and runs for two years. A maximum of 15,000 Medicare beneficiaries (across all 3 states) are allowed to participate.

Questions 1-3 are how your agency defines homebound.

1. Please check all the specific activities for which the "homebound" patient may leave the house without any limits on the frequency or length of absences without jeopardizing his or her homebound status and still be eligible for Medicare home health.

CHECK ALL THAT APPLY

1 ☐ Have dinner with family members
2 ☐ Visit the doctor or medical institutions
3 ☐ Go to religious services
4 ☐ Shopping for food
5 ☐ Shopping for clothes
6 ☐ Visiting friends
7 ☐ None of the above

For the next two questions, please exclude any activities that you marked in question 1.

2. Under normal circumstances, a homebound patient can leave the house no more than:

CHECK ONE BOX ONLY

1 ☐ Once a month
2 ☐ Once a week
3 ☐ Two or three times a week
4 ☐ Four or five times a week
5 ☐ More than five times a week
6 ☐ Can't leave the house for any other activities

3. Under normal circumstances, the maximum amount of time a homebound patient may be away from home is:

CHECK ONE BOX ONLY

1 ☐ Less than 30 minutes
2 ☐ 30-59 minutes
3 ☐ 1-2 hours
4 ☐ 3-4 hours
5 ☐ More than 5 hours
6 ☐ Can't leave the house for any other activities

Please answer questions 4 through 9 based on your agency's last fiscal year. Your state annual report may be helpful in answering these questions.

4. What was the total number of patients your agency served in the last fiscal year?

_____ NUMBER OF PATIENTS

5. Approximately what percent of these patients had Medicare as their primary payer?

|__|__|__| % MEDICARE

6. In the last fiscal year, approximately what percent of your total Medicare patients were discharged from receipt of home health care services?

CHECK ONE BOX ONLY

1 ☐ Less than 10 percent
2 ☐ 11-25 percent
3 ☐ 26-50 percent
4 ☐ 51-75 percent
5 ☐ 76-99 percent
6 ☐ 100 percent

7. Of the Medicare patients who were discharged, approximately what percent were discharged because they were no longer homebound?

CHECK ONE BOX ONLY

1 ☐ 0-2 percent
2 ☐ 3-10 percent
3 ☐ 11-25 percent
4 ☐ 26-50 percent
5 ☐ 51-75 percent
6 ☐ 76-100 percent
7 ☐ 100 percent

8. In the last fiscal year, approximately how many Medicare referrals did your agency not admit for home health services?

CHECK ONE BOX ONLY

1 ☐ 0 - 10
2 ☐ 11 - 25
3 ☐ 26 - 50
4 ☐ 51 - 75
5 ☐ 76 - 100
6 ☐ Over 100 *(Please estimate specific number)*

_____

9. Of the denied Medicare referrals, approximately what percent met all of the requirements for Medicare home health except the patient was not homebound?

CHECK ONE BOX ONLY

1 ☐ 0-2 percent
2 ☐ 3-10 percent
3 ☐ 11-25 percent
4 ☐ 26-50 percent
5 ☐ 51-75 percent
6 ☐ 76-100 percent
7 ☐ 100 percent

10. The last question is about patients who have received Medicare home health services from your agency within the past two years. We have identified 5 patients and have listed their Medicare ID number and name at the top of each column. To answer these questions, it is important to review the patient's medical record For each patient, please indicate whether or not the patient meets each eligibility criteria.

Eligibility Criterion	HIC # _____ Name_____	HIC # _____ Name_____	HIC # _____ Name_____	HIC # _____ Name_____	HIC # _____ Name_____
a. Has a permanent and severe disabling condition Specify medical conditions and ICD-9 codes	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____
b. Needs permanent skilled nursing care (not including medication management) Specify skilled nursing care	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____	1 YES ☐ 0 NO☐ _____ _____ _____
c. Needs permanent skilled nursing care for medication management only	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
d. Needs permanent help with ADL:					
1. Bathing	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
2. Dressing	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
3. Eating	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
4. Toileting	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
5. Transferring	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐

Eligibility Criterion					
e. Requires an attendant (not necessarily paid) on a daily basis to treat and monitor medical condition or provide ADL assistance for rest of beneficiary's life	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
f. Requires human or technological assistance to leave the home	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
g. Employment status: (CHECK ONE ONLY)	1☐ NOT EMPLOYED 2☐ EMPLOYED, ON SICK LEAVE 3☐ EMPLOYED, WORKS FROM HOME 4☐ DON'T KNOW	1☐ NOT EMPLOYED 2☐ EMPLOYED, ON SICK LEAVE 3☐ EMPLOYED, WORKS FROM HOME 4☐ DON'T KNOW	1☐ NOT EMPLOYED 2☐ EMPLOYED, ON SICK LEAVE 3☐ EMPLOYED, WORKS FROM HOME 4☐ DON'T KNOW	1☐ NOT EMPLOYED 2☐ EMPLOYED, ON SICK LEAVE 3☐ EMPLOYED, WORKS FROM HOME 4☐ DON'T KNOW	1☐ NOT EMPLOYED 2☐ EMPLOYED, ON SICK LEAVE 3☐ EMPLOYED, WORKS FROM HOME 4☐ DON'T KNOW
h. Medicare coverage:					
1. Part B	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
2. Medicare Advantage	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
3. Hospice Benefit	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐
i. Number of episodes of home health care received in the last 12 months	|___|	|___|	|___|	|___|	|___|
j. Able to leave the house if homebound requirement is waived	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐	1 YES ☐ 0 NO☐

Please remove the labels from the top of each column when you have completed this section.

11. How many patients did your agency enroll in the demonstration?

|___|___|___| NUMBER OF PATIENTS YOUR AGENCY ENROLLED IN THE DEMONSTRATION

12. Please use the space below to describe any problems your agency encountered enrolling patients into the demonstration or reasons why your agency decided not to participate in the demonstration?

_____

_____

_____

_____

_____

_____

_____

13. Do you think the homebound criteria is still a major issue for Medicare patients? 1 YES ☐ 0 NO ☐

14. Please describe the type of patients for whom you think the homebound criteria should be waived.

_____

_____

_____

_____

_____

_____

_____

Thank you for completing the survey. Please fill out your name, address and telephone number on the label below. We will use this information to send you the check for $50 for completing the survey. We will use the telephone number to call you if we have any questions regarding your responses. All of your information is confidential. We will remove the label from this form. Information reported to CMS will not be identified by person or agency.

APPENDIX C

FEDERAL REGISTER NOTICE

APPENDIX D

AGENCY INTRODUCTION LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard
Baltimore, MD 21244-1850

July 2006

«NameNew»
«Address1»
«Address2»
«City», «State» «Zip»

Dear «Salutation»:

I am writing to ask for your help with an important study sponsored by the Centers for Medicare and Medicaid Services (CMS) about the *Home Health Independence Demonstration.* Mandated under Section 702 of the Medicare Modernization Act (MMA) of 2003, the demonstration allowed beneficiaries meeting certain requirements to waive the homebound requirement while receiving home health services. The demonstration was implemented in the states of Massachusetts, Missouri and Colorado on October 4, 2004. You may also know the demonstration under the name of *Homebound Exemption Demonstration*.

The purpose of the survey is to learn about your agency's experiences with the homebound requirement and the home health independence demonstration. Specifically, the survey includes questions about the agency's understanding of the homebound requirement and the number of people who are affected by it, and characteristics of the agency's caseload and whether particular demonstration requirements kept otherwise qualified beneficiaries from participating. Results from this study are important to the development of policy related to the homebound requirement for home health patients, so we hope you will agree to participate.

CMS has hired Mathematica Policy Research, Inc. a private national research firm to conduct the survey. We assure you that all information collected will be totally confidential and will not be reported in any way that identifies you or your agency personally. ***We are only collecting this information for research purposes and to improve program operations—it will not be used for payment or any other purposes .***

Please help us by completing the enclosed survey, which should take about 30 minutes to complete. In appreciation of your time and effort, we will send a check of $50 upon receipt of your completed survey. ***If you have any questions, or wish to set up an interview time, please call Mathematica and say you are calling about the Home Health Independence Demonstration Survey. The toll-free number is XXX-XXXX.***

Thank you for your assistance.

Sincerely,

CMS Privacy Officer