SUPPORTING STATEMENT A
MEDICARE HEALTH OUTCOMES SURVEY
CMS-10203, OCN 0938-0701

Introduction

The Centers for Medicare & Medicaid Services (CMS) requests a revision to a previously approved survey from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 for the Medicare Health Outcomes Survey (HOS). CMS received current approval on 11/7/2012, which expires on 11/30/2015.

Background

The Centers for Medicare & Medicaid Services (CMS) has a responsibility to Medicare beneficiaries to require that care provided by managed care plans under contract to CMS is of high quality. One way of ensuring high quality in Medicare managed care organizations, more commonly referred to as Medicare Advantage Organizations (MAOs), is through the development of standardized, uniform performance measures that enable CMS to gather the data needed to evaluate the quality of care provided to Medicare beneficiaries.

Collected annually since 1998, the Medicare Health Outcome Survey (HOS) is the first outcomes measure used in Medicare managed care. The goal of the Medicare HOS program is to gather valid, reliable, clinically meaningful health status data in Medicare managed care for use in quality improvement activities, plan accountability, public reporting, and improving health. All plans with Medicare Advantage (MA) contracts in effect must participate.

CMS, in collaboration with the National Committee for Quality Assurance (NCQA), launched the Medicare HOS as part of the Effectiveness of Care component of the former Health Plan Employer Data and Information Set, now known as the Healthcare Effectiveness Data and Information Set (HEDIS®). This measure was initially titled Health of Seniors, and was renamed the Medicare Health Outcomes Survey during the first year of implementation to reflect the inclusion of people with Medicare who are disabled and under age 65 in the sampling methodology.

The HOS measure was developed under the guidance of a Technical Expert Panel (TEP) comprised of individuals with specific expertise in the health care industry and outcomes measurement. The measure includes the most recent advances in summarizing physical and mental health outcomes results and appropriate risk adjustment techniques. In addition to the core health outcomes measures, the HOS is used to collect four HEDIS Effectiveness of Care measures: Fall Risk Management, Management of Urinary Incontinence in Older Adults, Osteoporosis Testing in Older Women, and Physical Activity in Older Adults.

The Medicare HOS uses the Veterans 12-item Health Survey (VR-12) (a self-reported measure of health status) to assess a MAO's ability to maintain or improve the physical and mental health of its Medicare members over time. Twelve hundred Medicare beneficiaries are randomly sampled from each contract and surveyed every spring (i.e., a survey is administered to a new baseline cohort each year). Two years later, these same respondents are surveyed again (i.e., follow-up measurement). For each member who completes a baseline and a follow-up survey, a two-year change score is calculated, and after taking risk adjustment factors into account, the member's physical and mental health status are categorized as better, the same or worse than expected. (Members who are deceased at follow-up are included in the "worse" physical outcome category.) Summary Medicare HOS results are calculated for each MAO based on aggregated member outcomes.

The Medicare Health Outcomes Survey-Modified (HOS-M) is administered to Medicare beneficiaries who are enrolled in Program of All-Inclusive Care for the Elderly (PACE) programs and has been collected since 2005. The HOS-M instrument is a shorter, modified version of the Medicare HOS and is used by CMS to assess the frailty of the population in these health plans in order to adjust annual capitated plan payments.

The chronology of all Medicare HOS OMB clearances is outlined below:

- Beginning on December 24, 1997 the Medicare HOS was approved by OMB for collection under HEDIS 3.0 (Health Plan Data and Information Set) and CAHPS (Consumer Assessments of Health Plan Study) and Supporting Regulations 42 CFR 417.470. This collection was cleared through December 31, 2000 under OMB number 0938-0701.
- Due to a change in statutory authority as a result of the Balanced Budget Act of 1997, HEDIS and CAHPS and Supporting Regulations 42 CFR 417.470 and 42 CFR 417.126 was submitted as a revised collection under OMB number 0938-0732 and approved by OMB on July 20, 1998 through January 31, 1999.
- HEDIS and CAHPS and Supporting Regulations 42 CFR 417.470 and 42 CFR 417.126 was approved for extension by OMB on January 4, 1999 through January 31, 2002 under OMB number 0938-0732.
- Health Plan Employer Data and Information Set (HEDIS) and Health Outcomes Survey (HOS) and Supporting Regulations at CFR 422.152 was submitted as a reinstated collection requested under OMB number 0938-0701. The collection was approved on March 29, 2002 through September 30, 2003.
- HEDIS and HOS and Supporting Regulations as CFR 422.152 was approved by OMB on January 28, 2004 through January 31, 2007 under OMB number 0938-0701.
- Medicare Health Outcomes Survey (HOS) and Supporting Regulations at 42 CFR 422.152 was approved by OMB on September 1, 2007 through August 31, 2010 under OMB number 0938-0701.

- HOS and Supporting Regulations at 42 CFR 422.152 was approved by OMB on February 1, 2011 through January 31, 2014 under OMB number 0938-0701.
- HOS and Supporting Regulations at 42 CFR 422.152 was approved by OMB on November 7, 2012 through November 30, 2015 under OMB number 0938-0701.

Based on requirements in the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA), CMS has collected health status data from Medicare beneficiaries enrolled in Medicare managed care through annual implementation of the HOS since 1998. Earlier, requirements in the Balanced Budget Act of 1997 established Medicare Part C and required CMS to collect quality information about Medicare health plans available under what were then known as the Medicare + Choice plans and provide this information to beneficiaries to assist them in their selection of a Medicare plan. The MMA renamed the Medicare's managed care program "Medicare Advantage," and under Section 1860D-4 (Information to Facilitate Enrollment), continued the collection and reporting requirements and also requires CMS to provide results to Medicare beneficiaries prior to the annual enrollment period.

CMS uses a data collection model similar to the one used for the Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey, commercial health plan CAHPS, Hospital CAHPS, and Home Health Care CAHPS. CMS contracts with the National Committee for Quality Assurance (NCQA) to approve and train survey vendors to collect and submit data on behalf of the MA, section 1876 cost, and PACE contracts and with the Health Services Advisory Group (HSAG) to analyze the data. All contracts that are required to conduct HOS need to contract directly with an approved vendor. NCQA is responsible for approving and training vendors, providing technical assistance to vendors, overseeing vendors to ensure that they are following the data collection protocols, providing the samples directly to the survey vendors, and collecting the data. HSAG is responsible for analyzing the data for public reporting and producing reports that the plans can use for quality improvement.

This request for approval is for CMS to continue conducting the Medicare HOS survey annually to meet the requirements outlined above. This request adds 2 questions focusing on sleep quality to the 2015 HOS, revises 8 existing questions, and removes 6 questions. There are no changes to the 2015 HOS-M. The additional questions and their placement in the survey are as follows:

Added items	**HOS Item**
How many hours sleep per night	53
Overall sleep quality	54

A. Justification

1. Necessity of Information Collection

The collection of Medicare HOS is necessary to hold Medicare managed care contracts accountable for the quality of care they deliver to beneficiaries. This reporting requirement allows CMS to obtain the information necessary for proper oversight of the Medicare Advantage program. It is critical to CMS' mission that the Agency collect and disseminate valid and reliable information that can be used to improve quality of care through identification of quality improvement opportunities, assist CMS in carrying out its oversight responsibilities, and help beneficiaries make an informed choice among health plans.

2. Information Users

The primary end users of HOS data are CMS, MAOs, and Quality Improvement Organizations (QIOs). The data are used by CMS to monitor health plan performance, to construct a frailty adjuster for payment purposes, and to inform other agency programs and priorities (e.g. disabled, poor, chronically ill, etc.). MAOs and QIOs use the HOS results to target quality improvement activities and resources. Other stakeholders (i.e., other federal agencies, advocacy groups, health policy scholars, and health services researchers) use HOS data to monitor the health of the Medicare population and vulnerable subgroups, and to evaluate treatment outcomes and procedures.

3. Use of Improved Information Technology

The Medicare HOS collects self-reported information through a combination of mail and computer assisted telephone interviewing (CATI) techniques for survey administration. Other than the manual reply necessary for mail survey instruments, there are no barriers or obstacles that prohibit the use of improved technology for this information collection activity. The Medicare HOS instrument is distributed to beneficiaries by independent third party survey vendors and the resulting data are aggregated electronically. Most beneficiaries complete the survey either manually (accounting for roughly 79% at baseline and 87% at follow-up), which is the most cost effective means to collect information from them, or through CATI (accounting for roughly 21% at baseline and 13% at follow-up). Mail surveys are processed using scanned image readers to enhance coding accuracy and increase production speed. The CATI program records collected information, which reduces respondent burden by minimizing the potential for double reporting and inconsistent responses. CATI also enables the interviewer to move through skip patterns quickly, which reduces respondent burden by shortening the interview and eliminating the need for call backs to correct errors. This collection does not require a signature from the respondent.

4. Duplication of Efforts

Collection of the Medicare HOS does not duplicate any other effort and the information cannot be obtained from any other source. The Medicare HOS is the first outcomes measure used in Medicare managed care. The Medicare HOS measure was developed under the guidance of a Technical Expert Panel comprised of individuals with specific expertise in the health care industry and outcomes measurement. CMS and its data collection and data analysis contractor have not been able to identify any other source of data that would be an effective substitute for the Medicare HOS. Continuing interagency collaboration insures against the likelihood of duplicative data collection processes now and in the future.

5. Small Businesses

The burden on small MAOs is reduced by requiring a standardized and commonly accepted measure set in the managed care industry, with which MAOs can meet requirements of Medicare and some private purchasers for reporting performance. In order to help control costs, CMS only surveys a sample of beneficiaries from each Medicare managed care plan. There is no way to further reduce the burden and still ensure the reliability of the information collected.

6. Less Frequent Collection

CMS collects the Medicare HOS data annually. Contracts between CMS and MAOs are renewable on an annual basis, so the Agency needs the annual performance data for program management and contracting decisions.

7. Special Circumstances

There are no special circumstances associated with this information collection request.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on February 28, 2014 (79 FR 11434). While comments were received, there have not been any program changes or burden adjustments as a result of those comments. The comments and our response have been added to this PRA package.

9. Payments/Gifts to Respondents

There are no provisions to provide any payment/gift.

10. Confidentiality

Individuals and organizations contacted are assured of the confidentiality of their replies under 42 U.S.C. 1306, 20 CFR 401 and 422, 5 U.S.C.552 (Freedom of Information Act), 5 U.S.C.552a (Privacy Act of 1974), and OMB Circular No.A-130. In instances where respondent identity is needed, the information collection fully complies with all respects of the Privacy Act. The System of Records is HPMS No. 09-70-4004.

11. Sensitive Questions

CMS is not asking questions which would be considered of a sensitive nature. The Medicare HOS is a functional status survey that does request information about one's capability to perform certain physical and mental activities. However, the core component of the HOS instrument, the VR-12, is a standardized instrument that has been used in both clinical practice and research for a number of years. Demographic information in the survey, including income and race, is requested for the purpose of risk adjustment.

12. Burden Estimates (Hours & Wages)

The following organization types, with a minimum of 500 members and a Medicare contract in effect on or before January 1 of the previous year are required by CMS to administer the current HOS Baseline survey: 1) all Coordinated Care contracts, Private Fee-For-Service (PFFS) contracts, and Medical Savings Account (MSA) contracts; (2) all Section 1876 cost contracts; and 3) Employer/Union Only Direct PFFS contracts.

Additionally, all MAOs with current contracts in place which administered a Baseline survey two years earlier are required to administer the current HOS Follow-Up Survey. In addition, all Program of All Inclusive Care for the Elderly (PACE) organizations with a contract effective date of on or before January 1 of the previous year are required by CMS to administer the HOS-M.

The HOS sampling strategy is designed to reduce burden on survey respondents. Because of variations in health plan population size, three sampling approaches are used. (MAOs with fewer than 500 members are exempt from HOS reporting.)

1) MAOs with populations of 500 to 1,200: all eligible members are included in the sample;
2) MAOs with populations of 1,201 to 2,999: 1,200 members are randomly selected for the Baseline survey. To ensure a sample size of 1,200, members who were sampled for and returned a completed survey the previous year are not excluded from sampling in the current year.
3) MAOs with populations greater than 3,000: 1,200 members are randomly selected for the Baseline survey. To reduce burden on survey respondents, members who were sampled for and returned a completed survey the previous year are excluded from the current year sampling.

The HOS-M sample size is 1,200 for programs with at least 1,200 participants. For PACE organizations with less than 1,200 enrollees, the entire eligible enrollment is included.

Table 12 A.

	HOS Baseline	HOS Follow-Up	HOS-M	Total
Sample Size	1,200	840[1]	300	
Estimated Response Rate	70%	80%	75%	
Number of Estimated Respondents	840	672	225	
Survey Timing by Instrument	0.33	0.33	0.33	
Time Burden in Hours	277.20	221.76	74.25	
Number of Participating Plans [2]	496	452	87	
Total Time Burden in Hours	137,491	100,236	6460	244,187
Average Hourly Wage Rate [3]	$ 22.77	$ 22.77	$ 22.77	
Cost to Respondents	$ 3,130,670.07	$ 2,282,373.72	$ 147,094.20	$ 5,560,137.99

[1] The HOS Follow-up sample size is based on a 70% response rate at Baseline.
[2] The HOS-M sample size is based on actual PACE enrollment statistics. Previous versions of this table used the maximum sample size, which inflated burden potential beyond actual population size.
[3] The number of participating plans is based on the 2014 participating plan list.
[4] Based upon mean hourly wages, "National Compensation Survey: All United States December 2009 – January 2011," U.S. Department of Labor, Bureau of Labor Statistics.

Tests have shown that the average time to complete the survey is 20 minutes. The average response rate over the past five years is 60% at baseline, 80% at follow-up, and 75% for the HOS-M; however, for the purpose of this clearance package we will use the following figures so as to illustrate the greatest burden potential. The calculated response rate for HOS baseline is 70%, the expected HOS follow-up response rate is 80%, and the expected HOS-M response rate is 75%. Based on a plan sample size of 1,200, 70% percent baseline response rate, and total plan participation in 2014, the maximum total estimated burden upon the beneficiaries is .33 hours x [(496 Baseline MAOs x 840 average baseline response) + (452 Follow-up MAOs x 672 average follow-up responses) + (87 PACE organizations x 225)] = 244,187 hours.

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

There are costs to the Federal government in terms of its contracts with NCQA to administer the Medicare HOS data collection and with HSAG to provide data file preparation, analysis, and dissemination. Average contract costs for the Medicare HOS activities are $2,415,000 per year: $1,207,500 for each of two contracts, respectively.

15. Changes to Burden

As demonstrated in the previously stated burden estimate calculations, changes to burden are the result of growth of Medicare Advantage program, including increases in enrollment, the number of contracts, and contract size, rather than changes to the HOS survey instrument proposed herein.

On average, the burden to Medicare beneficiaries to complete a HOS or HOS-M survey has not changed; the survey burden remains at .33 hour. However, the number of MAOs required to report HOS Baseline has increased slightly, by 25 contracts, and the number of MAOs that remain in the MA program and are required to report HOS Follow-Up has increased significantly, by 122 contracts. As a result, the number of respondents has gone up by approximately 21,000 respondents for Baseline and 81,984 respondents for Follow-up, increasing HOS survey burden by approximately 33,985 hours. The burden to PACE was recalculated using a sample size based on actual enrollment. Although the number of participating PACE organizations has increased 50%, by 29 contracts, the revised total survey burden decreased by approximately 9,618 hours. Thus, the total survey burden for HOS and HOS-M combined increased approximately 24,367 hours.

For a crosswalk of all survey instrument changes that includes new questions being added and current questions being removed or revised, see Attachment A.

16. Publication and Tabulation Dates

Three major types of analyses are planned: descriptive, explanatory and predictive. A number of published studies have already been conducted. In addition, data files and reports will continue to be prepared over the course of the survey, as illustrated in the schedule of information collection and dissemination below:

06/2014	Disseminate Cohort 16 Baseline QIO and MA Report
07/2014	Disseminate Cohort 16 Baseline QIO Data
08/2014	Disseminate Cohort 14 QIO and MA Performance Measurement Report
09/2014	Disseminate Cohort 14 Performance Measurement QIO and MA Data
11/2014	Disseminate 2013 HOS-M PACE Report and Data

04/2015	Data collection begins for Medicare HOS Cohort 18 Baseline and HOS-M
05/2015	Data collection begins for Medicare HOS Cohort 16 Follow-Up
06/2015	Disseminate Cohort 17 Baseline QIO and MA Report
07/2015	Disseminate Cohort 17 Baseline QIO Data
08/2015	Disseminate Cohort 15 Performance Measurement QIO and MA Report
09/2015	Disseminate Cohort 15 Performance Measurement QIO and MA Data
11/2015	Disseminate 2014 HOS-M PACE Report and Data
04/2016	Data collection begins for Medicare HOS Cohort 19 Baseline and HOS-M
05/2016	Data collection begins for Medicare HOS Cohort 17 Follow-Up
06/2016	Disseminate Cohort 18 Baseline QIO and MA Report
07/2016	Disseminate Cohort 18 Baseline QIO Data
08/2016	Disseminate Cohort 16 Performance Measurement QIO and MA Report
09/2016	Disseminate Cohort 16 Performance Measurement QIO and MA Data
11/2016	Disseminate 2015 HOS-M PACE Report and Data
04/01/2017	Data collection begins for Medicare HOS Cohort 20 Baseline and HOS-M

In addition, several types of Medicare HOS data files are available for research purposes. Medicare HOS data files are available as public use files (PUFs), limited data sets (LDSs), and research identifiable files (RIFs).

Medicare HOS PUFs contain the majority of the survey items collected on the Medicare HOS instrument (excluding beneficiary identifying information), as well as selected additional administrative variables. Medicare HOS PUFs are constructed to prevent the identification of any single beneficiary or plan and only respondents to the survey are included in the files. Medicare HOS PUFs are available at no cost and can be downloaded directly from the CMS website.

Medicare HOS LDSs and RIFs are comprised of the entire national sample for a given cohort (including both respondents and non-respondents), and contain all of the Medicare HOS survey items. The Medicare HOS LDSs include plan identifiers as well as several additional variables describing plan characteristics. They also contain protected beneficiary-level health information such as date of birth, but specific direct person identifiers (i.e., name and health insurance claim number) are not included in LDSs.

The RIFs contain all of the variables in an LDS as well as specific direct person identifiers (i.e., name and health insurance claim number) not included in an LDS file. A signed Data Use Agreement (DUA) with CMS is required to obtain either LDS or RIF data files.

The table below summarizes data collection year and availability of baseline, follow-up, and analytic research files for the past three and next three cohorts:

HOS Cohort	Baseline Data	Follow-Up Data	Analytic Data
11	2008 *Summer 2009*	2010 *Fall 2011*	2008-2010 *Fall 2011*
12	2009 *Summer 2010*	2011 *Fall 2012*	2009-2011 *Fall 2012*
13	2010 *Summer 2011*	2012 *Fall 2013*	2010-2012 *Fall 2013*
14	2011 *Summer 2012*	2013 *Expected Fall 2014*	2011-2013 *Expected Fall 2014*
15	2012 *Summer 2013*	2012 *Expected Fall 2015*	2010-2012 *Expected Fall 2015*
16	2013 *Expected Summer 2014*	2013 *Expected Fall 2016*	2011-2013 *Expected Fall 2016*

17. Expiration Date

No exemption is being requested. CMS would like to continue its exemption from displaying an expiration date. The collection of Medicare HOS is an ongoing endeavor and an expiration date is not practical.

18. Exceptions to Certification Statement 19

There are no exceptions taken to item 19 of OMB Form 83-1.

Attachments

A. Crosswalk of Changes to HOS Proposed Questionnaire
B. HOS Response Rates
C. HOS Proposed Survey Questionnaire
D. HOS-M Survey Questionnaire
E. Mailing Materials
F. Case-mix Coefficients