Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

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

The 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. This name change was intended 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 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 health outcomes measures, the HOS is used to collect the Management of Urinary Incontinence in Older Adults, Physical Activity in Older Adults, Fall Risk Management, and Osteoporosis Testing in Older Women HEDIS® measures

The Medicare HOS uses the Veterans 12-item Health Survey (VR-12) (a self-reported measure of health status) to assess an 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, or group, 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 (taking risk adjustment factors into account) the member's physical and mental health status is 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.

Collected since 2005, the Medicare Health Outcomes Survey-Modified (HOS-M) is administered to vulnerable Medicare beneficiaries at greatest risk for poor health outcomes. These beneficiaries are enrolled in Program of All-Inclusive Care for the Elderly (PACE) programs. The HOS-M instrument is a shorter, modified version of the Medicare HOS 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 (Health Plan Data and Information Set) and CAHPS (Consumer Assessments of Health Plan Study) and Supporting Regulations 42 CFR 417.470 and 42 CFR 417.126 was submitted as a revised collection under OMB number 0938-0732 and was approved by OMB on July 20, 1998 through January 31, 1999.
- HEDIS (Health Plan Data and Information Set) and CAHPS (Consumer Assessments of Health Plan Study) 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.
- Health Plan Employer Data and Information Set (HEDIS) and Health Outcomes Survey (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.
- Medicare Health Outcomes Survey (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.

B. Justification

1 . Need and Legal Basis

A. Need

The collection of Medicare HOS is necessary to hold Medicare managed care organizations accountable for the quality of care they are delivering. 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.

B. Statutory and Regulatory Basis

Section 722(a)(3)(A)(i) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 mandates the collection, analysis and reporting of health outcomes information in the Medicare Advantage program. This legislation also specifies that data collected on quality, outcomes and beneficiary satisfaction to facilitate consumer choice and program administration must utilize the types of data collected prior to November 1, 2003. This provision was enacted by the agency at 42 CFR 422 Subpart D. Collected since 1998, the Medicare HOS has collected outcome measures in the Medicare managed care setting and remains a critical part of assessing health plan quality. In addition, CMS includes the Medicare HOS results as part of the Plan Ratings and is included in the Quality bonus Payment ratings for MA contracts.

These regulatory requirements are also contained within Chapter 5, Section 40 of the Medicare Managed Care Manual.

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 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 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 thirty party survey vendors and the resulting data are aggregated electronically. Beneficiaries complete the survey either manually (accounting for roughly 84% at baseline and 90% at follow-up), as this is the most cost effective means to collect information from them, or through CATI (accounting for roughly 16% at baseline and 10% 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 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

This information collection 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 contractor have not been able to identify another source of data, which 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 MCOs 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 MCOs are renewable on an annual basis, so the Agency needs these performance data for program management and contracting decisions.

7. Special Circumstances

Any publicly reported data that CMS makes available is aggregated and does not identify

beneficiaries in any way. For example, 2-year HOS performance measurement data are included at the MAO-level in Medicare Plan Finder on the Medicare.gov web site. The Medicare HOS individual level file is available only to requesters who, for confidentiality reasons, must sign a Data Use Agreement with CMS and must meet CMS's data policies and procedures that include, but are not limited to, submitting a research protocol and study purpose. For information about Data Use Agreements, contact the Division of Privacy Compliance, Enterprise Architecture and Strategy Group, within CMS's Office of Information Services.

8. Federal Register/Outside Consultation

A 60-day Federal Register Notice was published on April 27, 2012. A copy of the notice is included as Attachment 1, and can be found on Page 25181 of the FR Notice. Since this collection is not new, CMS has not gone out to solicit outside consultation; however, during the 60-day Federal Register Notice the public is free to comment.

9. Payments/Gifts to Respondents

There are no provisions to provide any payment/gift.

10. Confidentiality

All Contractors and HOS survey vendor staff directly involved in HOS data collection and/or analysis activities are required to sign confidentiality agreements. Furthermore, all HOS patient-level data are protected from public disclosure in accordance with the Privacy Act of 1974, as amended.

11. Sensitive Questions

CMS is not asking questions which would be considered of a sensitive nature. The Medicare HOS (a functional status survey) 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 managed care organization types, with a minimum of 500 members, that had a Medicare contract in effect on or before January 1 of the year prior are required by CMS to administer the current baseline survey: (1) all coordinated care contractors, including health maintenance organizations (HMOs), local preferred provider organizations (PPOs) and regional PPOs; (2) private fee-for-service (PFFS) contracts; (3) medical savings account (MSA) contracts; and (4) continuing 1876 cost contracts with open enrollment.

Organizations eligible to report also include MA contracts with exclusively special needs plan benefit packages, regardless of institutional, chronically ill, or dual-eligible enrollment.

Furthermore, all MCOs with contracts in place on or before January 1 of three years prior, and which administered a Baseline Survey two years prior are required to administer the current 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 following year.
3) MAOs with populations ≥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 sampling.

The HOS-M sample size is 1,200 for programs with at least 1,400 participants. For PACE organizations with less than 1,400 enrollees, the entire eligible enrollment is included.

Table 12 A.

	HOS Baseline	HOS Follow-Up	HOS-M	Total
Sample Size [1]	1,200	840	1,200	
Estimated Response Rate	70%	80%	70%	
Number of Estimated Respondents	840	672	840	
Survey Timing by Instrument	0.33	0.33	0.33	
Time Burden in Hours	277.20	221.76	277.20	
Number of Participating Plans [2]	471	330	58	
Total Time Burden in Hours	130,561	73,181	16,078	219,820
Average Hourly Wage Rate [3]	$ 21.35	$ 21.35	$ 21.35	
Cost to Respondents	$ 2,787,481.62	$ 1,562,410.08	$ 343,256.76	$ 4,693,148.46

1 The HOS Follow-up sample size is based on a 70% response rate at Baseline.
2 The number of participating plans is based on the 2010 participating plan list.
3 Based upon the average mean wages, "National Occupational Employment and Wage Estimates in the United States", May 2010, 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 63% at baseline, 82% 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 and HOS-M is 70% and the expected HOS follow-up response rate is 80%. Based on a plan sample size of 1,200 and total plan participation in 2010, the total estimated burden upon the beneficiaries is .33 hours x [(471 Baseline MCOs x 840 average baseline response rate) + (330 Follow-up MCOs x 672 average follow-up response rate) + (58 PACE organizations x 840)] = 219,819.60 hours.

MCO's will be contracting directly with an HOS-certified third party vendor to administer the Medicare HOS. The MCOs will not experience an hourly burden, but will absorb the cost of the CMS contracted third party administrator. The average cost borne by an MCO or PACE organization for a completed survey is $20. Therefore, the estimated cost burden to an MCO for HOS is: $20 x (840 baseline + 672 follow-up completed surveys) = $30,240. Similarly, the estimated cost burden to a PACE organization for HOS-M is: $20 x 840 completed surveys = $16,800.

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 Medicare HOS activities are $2,415,000 per year: $1,207,500 for each of two contracts, respectively. CMS personnel involved in Medicare HOS include approximately 2.0 FTEs at the GS 13/14 level.

Grade	FTE	2012 Annual Salary	Cost to Government
GS13 step 5	1.5	$100,904	$151,356
GS14 step 5	0.5	$119,238	$59,619
Travel		$2,000	$2,000
Total			$154,034

15. Changes to Burden

The goal of the Medicare HOS is to gather valid, reliable and clinically meaningful data that have many uses. With the introduction of the Five Star Rating system by the CMS, the Medicare program now requires an ever increasing ability to provide accurate and measureable, side-by-side comparisons between each MAO. Consequently, several questions have been added to meet this need, while other questions have been removed to offset the increase in burden.

Additionally, to meet the new requirements stipulated in Section 4302 of the Affordable Care

Act, the race, ethnicity, sex, language and disability questions outlined by the OMB have been adopted. While in some instances this translates into rewording of existing questions and thus does not impact the overall burden, there are instances in which the question is new to the instrument and by adding it to the survey will marginally increase the time burden placed on the respondent and on the cost for collection.

For a crosswalk of all survey instrument changes to include new questions being added, current questions being replaced or removed see Attachment 4. In some instances we are adding a question where a similar question will remain. An example of this is can be seen with current question 10 (Because of a health or physical problem,…) and recommended question 19 (Do you have difficulty dressing or bathing?). In this case we want to retain question 10 while complying with Section 4302 requirements to include wording found in question 19. It is important for the HOS to collect information at a more granular level than what some Section 4302 questions permit. The Survey Notes column of Attachment 4 will specify if the question recommended is simply being added or if it is replacing a current question and if the current HOS question is being removed.

16. Publication/Tabulation Dates

Three major types of analyses are planned: descriptive, explanatory and predictive. A number of published studies have already been conducted (Attachment 2). In addition, data files will continue to be prepared over the course of the survey, see (Table 16 A).

Table 16 A. Schedule for information collection and dissemination

06/2012	Disseminate Cohort 14 Baseline QIO and MA Report
07/2012	Disseminate Cohort 14 Baseline QIO Data
08/2012	Disseminate Cohort 12 QIO and MA Performance Measurement Report
09/2012	Disseminate Cohort 12 Performance Measurement QIO and MA Data
11/2012	Disseminate 2011 HOS-M PACE Report and Data
04/01/2013	Data collection begun for Medicare HOS Cohort 16 Baseline and HOS-M
05/01/2013	Data collection begun for Medicare HOS Cohort 14 Follow-Up
06/2013	Disseminate Cohort 15 Baseline QIO and MA Report
07/2013	Disseminate Cohort 15 Baseline QIO Data
08/2013	Disseminate Cohort 13 Performance Measurement QIO and MA Report
09/2013	Disseminate Cohort 13 Performance Measurement QIO and MA Data
11/2013	Disseminate 2012 HOS-M PACE Report and Data
04/01/2014	Data collection begun for Medicare HOS Cohort 17 Baseline and HOS-M
05/01/2014	Data collection begun for Medicare HOS Cohort 15 Follow-Up
06/2014	Disseminate Cohort 16 Baseline QIO and MA Report
07/2014	Disseminate Cohort 16 Baseline QIO Data
08/2014	Disseminate Cohort 14 Performance Measurement QIO and MA Report
09/2014	Disseminate Cohort 14 Performance Measurement QIO and MA Data
11/2014	Disseminate 2013 HOS-M PACE Report and Data
04/01/2015	Data collection begun for Medicare HOS Cohort 18 Baseline and HOS-M

05/01/2015 Data collection begun for Medicare HOS Cohort 16 Follow-Up

B. Medicare HOS research data files

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; however, 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) that are not included in an LDS file. A signed Data Use Agreement with CMS is required to obtain either LDS or RIF data files. (Table 16 B) summarizes data collection year and availability of baseline, follow-up and analytic research files for the past three and next three cohorts.

Table 16 B: Data Collection and Availability

HOS Cohort	Baseline Data	Follow-Up Data	Analytic Data
9	2006 *Summer 2007*	2008 *Fall 2009*	2006-2008 *Fall 2009*
10	2007 *Summer 2008*	2009 *Fall 2010*	2007-2009 *Fall 2010*
11	2008 *Summer 2009*	2010 *Fall 2011*	2008-2010 *Fall 2011*
12	2009 *Summer 2010*	2011 *Expected Fall 2012*	2009-2011 *Expected Fall 2012*
13	2010 *Summer 2011*	2012 *Expected Fall 2013*	2010-2012 *Expected Fall 2013*
14	2011 *Expected Summer 2012*	2013 *Expected Fall 2014*	2011-2013 *Expected Fall 2014*

17. Expiration Date

CMS would like an exemption from displaying the expiration date as the collection of Medicare HOS is an ongoing endeavor. Therefore, an expiration date is not practical.