Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The Centers for Medicare and 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 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 plan 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.

B. Justification

1 . Need and Legal Basis

A. Need

The collection of Medicare HOS is necessary to hold Medicare managed care contractors 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 is the only outcomes measure in Medicare managed care and therefore remains a critical part of assessing health plan quality. In addition, CMS includes the Medicare HOS results as one component of their performance assessment program.

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

Standard Reporting Requirements for Medicare Advantage Organizations: Health Plan Employer Data and Information Set (HEDIS®) Measures that Include the Medicare Health Outcomes Survey (HOS) and the Medicare Consumer Assessment of Health Plans Study (CAHPS® 2.0H).

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 and reward top performing health plans with regulatory relief, 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-in and computer assisted telephone interviewing (CATI) techniques for survey administration. Other than the manual reply necessary for mail-in 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 parties and the resulting data is aggregated electronically. Beneficiaries complete the survey either manually (accounting for roughly 83% at baseline and 91% at follow-up), as this is the most cost

effective means to collect information from them, or through CATI (accounting for roughly 17% at baseline and 9% at follow-up) as a non-response follow-up measure. 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. None of the TEP membership is aware of duplicative information being collected on the Medicare population in a meaningful way, nor are they aware of any other survey that duplicates the efforts of the Medicare HOS. In addition, both CMS and its data collection contractor have undertaken exhaustive reviews of the literature and other data sources. In no instance has CMS identified 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. To collect the data less frequently would actually increase burden because the program would lose the efficiencies gained by using a standardized, industry accepted and commonly used measurement set, which makes it possible for MCOs to meet the data reporting requirements of Medicare and other private purchases using the same instrument and submission process. In addition, 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 will not identify beneficiaries in any way. For example, 2-year HOS performance measurement data are included at the MAO-level in Medicare Options Compare 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 June 4, 2010. A copy of the notice is not attached, but can be found on Page 31790 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.

The System of Records Notices associated with this data collection effort are as follows:
1) Health Plan Management System (HPMS) [August 12, 1998 (Volume 63, Number 155) Pages 43187-43190] [Attachment 9]
2) Health Plan Management System (HPMS) – Notice of a Modified or Altered System of Records [January 14, 2008 (Volume 73, Number 9) Pages 2257-2263] [Attachment 10]

All respondent related material contains the following Privacy Statement: All information that would permit identification of any person who completes this survey is protected by the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA). This information will be used only for purposes permitted by law and will not be disclosed or released for any other purposes. If you have any questions or want to know more about the study, please call [vendor name] at [toll-free number].

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.

1) MAOs with fewer than 500 members are exempt from HOS reporting;
2) MAOs with populations of 500 to 1,200, all eligible members are included in the sample;
3) MAOs with populations of 1,201 or greater, members (1,200) are randomly selected for the Baseline Survey. To eliminate any unintended potential bias, members who were sampled for and returned a completed survey the previous year are not excluded from sampling in the following year.

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.

Experience has shown that the average time to complete the survey is 20 minutes. The target response rate for HOS baseline and HOS-M is 70% and the expected HOS follow-up response rate is 80%. There is a significant degree of variation between number of eligible plans and their eligible membership size from year to year. As a consequence, it is impractical to use one specific year’s response counts to represent future collection year efforts. This burden projection is considered a liberal estimate.

Based on a plan sample size of 1,200 and total plan participation in 2009, the total estimated burden upon the beneficiaries is .33 hours x [695 MCOs x (840 baseline + 672 follow-up

responses per MCO) + 58 PACE organizations x 840] = 366,520 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 of a completed survey is $18. Therefore, the estimated cost burden to an MCO for HOS is: $18 x (840 baseline + 672 follow-up completed surveys) = $27,216. Similarly, the estimated cost burden to a PACE organization for HOS-M is: $18 x 840 completed surveys = $15,120. See (Attachment 8) for a tabular breakdown of burden estimate calculations.

13. Capital Costs

All costs associated with this effort are reported in Items 12 and 14.

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 $$2,000,000 per year: $1,000,000 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	2010 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

With a targeted baseline response rate of 70% and a targeted follow-up response rate of 80%, a sample of 1,000 at baseline roughly translates to 560 follow-up responses. Historically the follow-up response rate has remained consistently around 80%. Over the past five years the overall baseline response rate has fallen short of the 70% target (2005, 65%; 2006, 64%; 2007, 60%; 2008, 55%; 2009, 60%). This is not saying that all plan by plan baseline response rates were below 70%, but that as a whole the overall baseline response rate has fallen below 70% consistently over the past five years.

The goal of the HOS is to gather valid, reliable and clinically meaningful data that have many uses. Drastically increasing respondent burden has adverse implications to future response rates so the following adjustment to the sampling methodology was developed to moderately increase the number of responses where appropriate and eliminate the burden where prudent.

The following are changes to this collection effort that will impact burden level:
1) MAOs with fewer than 500 members are exempt from HOS reporting;

2) MAOs with populations of 500 to 1,200, all eligible members are included in the sample;
3) MAOs with populations of 1,201 or greater, members (1,200) are randomly selected for the Baseline Survey. To eliminate any untended potential bias, members who were sampled for and returned a completed survey the previous year are not excluded from sampling in the following year.

The new methodology replaces the following sampling methodology:
1) MAOs with fewer than 1,000 members, all eligible members are included in the sample;
2) MAOs with populations of 1,001 to 2,999, members (1,000) are randomly selected for the Baseline Survey. To ensure a sample size of 1,000, 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 population 3,000 and greater, members (1,000) are randomly selected for the Baseline Survey. Members who were sampled for and returned a completed survey the previous year are excluded from sampling.

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

06/2010	Disseminate Cohort 12 Baseline QIO and MA Report
07/2010	Disseminate Cohort 12 Baseline QIO Data
08/2010	Disseminate Cohort 10 QIO and MA Performance Measurement Report
09/2010	Disseminate Cohort 10 Performance Measurement QIO and MA Data
11/2010	Disseminate 2009 HOS-M PACE Report and Data
04/01/2011	Data collection begun for Medicare HOS Cohort 14 Baseline and HOS-M
05/01/2011	Data collection begun for Medicare HOS Cohort 12 Follow-Up
06/2011	Disseminate Cohort 13 Baseline QIO and MA Report
07/2011	Disseminate Cohort 13 Baseline QIO Data
08/2011	Disseminate Cohort 11 Performance Measurement QIO and MA Report
09/2011	Disseminate Cohort 11 Performance Measurement QIO and MA Data
11/2011	Disseminate 2010 HOS-M PACE Report and Data
04/01/2012	Data collection begun for Medicare HOS Cohort 15 Baseline and HOS-M
05/01/2012	Data collection begun for Medicare HOS Cohort 13 Follow-Up.
06/2012	Disseminate Cohort 14 Baseline QIO and MA Report
07/2012	Disseminate Cohort 14 Baseline QIO Data
08/2012	Disseminate Cohort 12 Performance Measurement QIO and MA 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

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
7	2004 *Summer 2005*	2006 *Fall 2007*	2004-2006 *Fall 2007*
8	2005 *Summer 2006*	2007 *Fall 2008*	2005-2007 *Fall 2008*
9	2006 *Summer 2007*	2008 *Fall 2009*	2006-2008 *Fall 2009*
10	2007 *Summer 2008*	2009 *Expected Fall 2010*	2007-2009 *Expected Fall 2010*
11	2008 *Summer 2009*	2010 *Expected Fall 2011*	2008-2010 *Expected Fall 2011*
12	2009 *Expected Summer 2010*	2011 *Expected Fall 2012*	2009-2011 *Expected Fall 2012*

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.

18. Certification Statement

There are no exceptions to this certification statement.