Supporting Statement for Collection of Medicare HOS Data

The Centers for Medicare and Medicare Services (CMS) requests a Revision of a Currently Approved Collection (OMB number 0938-0701), and three year clearance for the Medicare HOS data collection from the Office of Management and Budget.

A. BACKGROUND

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) 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 and reliable 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) (formerly Medicare +Choice) contracts must participate.

The Centers for Medicare & Medicaid Services (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 Health Plan Employer 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 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 MCO's ability to maintain or improve the physical and mental health of its Medicare members over time. One thousand Medicare beneficiaries, who were continuously enrolled in the same plan for six months, 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 Medicare MCO based on aggregated member outcomes.

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.

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 the proper oversight of the program. It is critical to CMS' mission that we 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 choose 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. 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 of the Medicare Managed Care Manual.

40 – 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).

40.4 – The Medicare Health Outcomes Survey (HOS) Requirements
(Rev. 78, Issued: 01-20-06; Effective / Implementation Date: 01-20-06)

A – Survey Process (Paragraph 3)
All Medicare Advantage organizations and continuing cost contracts that held §1876 risk and cost contracts, all Program of All-Inclusive Care for the Elderly (PACE) plans, as well as Social HMOs (SHMOs), with Medicare contracts in effect on or before January 1 of the previous year must comply with this survey requirement. In addition all Massachusetts Health Senior Care Options, Minnesota Senior Health Options, and Wisconsin Partnership Program plans regardless of contact effective date must comply with this survey requirement.

2) Information Users

The primary end users of HOS data are CMS, Medicare Advantage Plans, and 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.). Medicare Advantage Plans and Quality Improvement Organizations (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) Improved 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, as this is the most cost effective means to collect information from them, or through CATI 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, 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.

4) Duplication and Similar Information

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. Although membership changes, the TEP continues to provide input for developing the science of the Medicare HOS measure. (The names and organizations of current TEP membership are included in Attachment 1.)

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 have we 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 Business

The burden on small MCOs is reduced by requiring a standardized and commonly accepted measure set in the managed care industry, with which MCOs 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 we 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 we need this 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. 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 Data Liaison and Distribution, Enterprise Database Group, within CMS's Office of Information Services.

8) Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published on August 14, 2006. Since this collection is not new, we have not gone out to solicit outside consultation; however, during the 60-day Federal Register Notice the public is free to comment.

9) Payment/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) Estimates of Burden Hours and Wages

All Medicare Advantage organizations and continuing cost contracts that held §1876 risk and cost contracts and all Special Needs Plans, including Program of All-Inclusive Care for the Elderly plans, as well as Social HMOs with Medicare contracts in effect on or before January 1st of the year prior, are required by CMS to administer the current baseline survey. In addition, all Massachusetts Health Senior Options, Minnesota Senior Health Options and Wisconsin Partnership Program plans, regardless of contract effective date, must comply with this survey requirement. Furthermore, all MCOs with contracts in place on or before January 1st of three

years prior, and which administered a Baseline Survey two years prior are required to administer the current Follow-Up Survey.

The HOS sampling strategy is designed to reduce burden on survey respondents. One thousand (1,000) eligible members are randomly sampled for the baseline survey. In MCOs with populations greater than or equal to 3,000, members who were sampled and returned a completed survey for the previous year's baseline survey are excluded from the current year's sampling.

Experience has shown that the average time to complete the survey is 20 minutes. The expected baseline response rate is 70% and the expected follow-up response rate is 80%. Based on a plan sample size of 1,000, the total estimated burden upon the beneficiaries is .33 hours x 254 MCOs x (700 baseline + 560 follow-up responses per MCO) = 105,613 hours.

MCO's will be contracting directly with a 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 is: $18 x (700 baseline + 560 follow-up completed surveys) = $22,680.

13) Capital costs.

There are no capital costs.

14) Costs 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 $700,000 and $1,348,000 per year, respectively. CMS personnel involved in Medicare HOS include approximately 2.5 FTEs at the GS 13/14 level.

Grade	FTE	2006 Annual Salary	Cost to Government
GS13 step 5	1.5	$87,664	$131,496
GS14 step 5	1.0	$103,594	$103,594
			$235,090

15) Program and or Burden Changes

a. Questionnaire Changes

Based on results from an independent evaluation of the Medicare HOS conducted in 2003-2004 by the Delmarva Foundation and the University of Maryland Baltimore County, and additional analyses conducted by HOS Contractors in 2005, modifications were made to the HOS instrument that fall into three categories: (1) a reduction in the number of core items used for outcomes measurement, (2) a reduction in other items, and (3) the addition of new items.

The HOS program evaluation primarily found that while HOS results provide CMS, QIOs, MCOs, and its other data users with valid, reliable and clinically meaningful information, there were some recommendations for improvement. Direct feedback from HOS data users, including QIOs and MCOs, helped shape the final recommendations. These recommendations included increasing the effective sample size, shortening the survey instrument length, adding process measures, and increasing and fostering cooperation between primary data users.
With the evaluation recommendations in mind, the following changes were implemented in 2006: 1) a reduction in outcome items, the core 36- item instrument (SF-36®) was replaced by a 12 item instrument (VR-12) to decrease survey burden and potentially boost response rates; 2) a minor reduction in other collected items to eliminate redundancy and less useful information; and, 3) HEDIS® measures for osteoporosis testing in older women and fall risk management, and height and weight questions (for Body Mass Index calculations) were added to the survey to increase utility to MCOs and QIOs.

The change in the core HOS outcome measure from the SF-36® to the VR-12 is scientifically supported by both the HOS program evaluation and comparative analyses performed between the SF-36®, SF-12®, VR-36 and VR-12 health surveys by HOS contractors (i.e., Health Services Advisory Group, NCQA, Boston University School of Public Health). The VR-12 survey instrument has been applied and validated relative to both the VR-36 and the SF-36®. In an article by Jones et al., 2001, the VR-12 survey was shown to include fewer items than the SF-36® but provide 90% of the reliable variance in the two component summary measures used by both the VR-12 and SF-36®. Using independent results from the Veterans Health Study and the 1996 National Survey of Ambulatory Care Patients, the results for the Veterans SF-12 [VR-12] corresponded very closely with the results for the Veterans SF-36 (average difficulties of 0.06 points between them for PCS and 0.31 points for MCS) (Kazis et al., 1996; Kazis and Wilson, 1998; Kazis et al., 2006).

Adding process measures, to include measures for osteoporosis testing, fall management, and height and weight questions (for Body Mass Index calculations), enhance the overall power of the Medicare HOS. Although this does counteract some of the savings in respondent burden produced by the adoption of VR-12, MCOs and QIOs can now link process measures to health status changes. These additional questions produce a more desirable product for purposes of assessing the effectiveness of preventative efforts by providers.

In addition to changes implemented in response to the HOS program evaluation, note also that HEDIS® Effectiveness of Care measures for management of urinary incontinence in older adults and physical activity in older adults were added in 2004 and 2005, respectively. In 2004, three questions that assess health related quality of life were incorporated into the HOS from the Centers for Disease Control and Prevention's (CDC's) Behavioral Risk Factor Surveillance System (BRFSS) survey. The inclusion of these questions allows a link between HOS and BRFSS results and will assist healthcare providers to increase quality and years of healthy life and address health disparities.

b. Paperwork Reduction Act Submission Changes

As a HEDIS Effectiveness of Care measure, the Medicare HOS data collection effort has historically been included under the umbrella of HEDIS® for Paperwork Reduction Act (PRA) submissions to OMB. However, the Medicare HOS has been administered independently from HEDIS under a separate contract and in a different CMS component for several years. The current PRA clearance for HEDIS is scheduled to expire on January 31, 2007. For administrative simplification, two separate OMB clearance packages are being submitted for renewing HEDIS and HOS. HOS is being submitted as an existing collection and retaining the current OMB number of 0938-0701 and HEDIS is being submitted as a new collection effort for the purposes of obtaining a new OMB number.

16) Publication and Tabulation

Three major types of analyses are planned: descriptive, explanatory and predictive. A number of published studies have already been conducted (Attachment 3). In addition, data files will continue to be prepared over the course of the survey. For a listing of data files created, which are currently available through the CMS website (www.cms.hhs.gov/hos), refer to section 16) B. of this document.

A. Schedule for information collection and dissemination

04/01/2007	Data collection begun for Medicare HOS Cohort 10 Baseline.
05/01/2007	Data collection begun for Medicare HOS Cohort 8 Follow-Up.
06/2007	Disseminate Cohort 9 Baseline QIO and MA Report
07/2007	Disseminate Cohort 9 Baseline QIO Data
08/2007	Disseminate Cohort 7 QIO and MA Performance Measurement Report
09/2007	Disseminate Cohort 7 Performance Measurement QIO and MA Data
04/01/2008	Data collection begun for Medicare HOS Cohort 11 Baseline.
05/01/2008	Data collection begun for Medicare HOS Cohort 9 Follow-Up.
06/2008	Disseminate Cohort 10 Baseline QIO and MA Report
07/2008	Disseminate Cohort 10 Baseline QIO Data
08/2008	Disseminate Cohort 8 Performance Measurement QIO and MA Report
09/2008	Disseminate Cohort 8 Performance Measurement QIO and MA Data
04/01/2009	Data collection begun for Medicare HOS Cohort 12 Baseline.
05/01/2009	Data collection begun for Medicare HOS Cohort 10 Follow-Up.
06/2009	Disseminate Cohort 11 Baseline QIO and MA Report
07/2009	Disseminate Cohort 11 Baseline QIO Data
08/2009	Disseminate Cohort 9 Performance Measurement QIO and MA Report
09/2009	Disseminate Cohort 9 Performance Measurement QIO and MA Data

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 web (www.cms.hhs.gov/hos).

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. The table below summarizes data collection year and availability of baseline, follow-up and analytic research files for each cohort to date.

HOS Cohort	Baseline Data	Follow-Up Data	Analytic Data
1	1998 *Summer 1999*	2000 *Fall 2001*	1998 - 2000 *Fall 2001*
2	1999 *Summer 2000*	2001 *Fall 2002*	1999-2001 *Fall 2002*
3	2000 *Summer 2001*	2002 *Fall 2003*	2000-2002 *Fall 2003*
4	2001 *Summer 2002*	2003 *Fall 2004*	2001-2003 *Fall 2004*
5	2002 *Summer 2003*	2004 *Fall 2005*	2002-2004 *Fall 2005*
6	2003 *Summer 2004*	2005 *Expected Fall 2006*	2003-2005 *Expected Fall 2006*
7	2004 *Summer 2005*	2006 *Expected Fall 2007*	2004-2006 *Expected Fall 2007*
8	2003 *Summer 2006*	2005 *Expected Fall 2006*	2003-2005 *Expected Fall 2006*
9	2004 *Expected Summer 2007*	2006 *Expected Fall 2007*	2004-2006 *Expected Fall 2007*

17) Expiration Date

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.