Supporting Statement For Paperwork Reduction Act Continuation Submission

Table of Contents

A. Background:

This document contains the data collection instrument and information supporting its use for the Second Generation Social Health Maintenance Organization(S/HMO-II) Demonstration. The purpose of this submission is to request OMB authorization to continue to collect information from S/HMO-II demonstration participants.

The data collection has been continuing since 1996. The survey is an integral part of the system. The purpose of the data collection is to: (1)collect the necessary data elements from members of the treatment group for the risk-adjusted S/HMO -payment methodology; and (2)gather information from members of the treatment group to enable the participating S/HMO-II site to identify high-risk beneficiaries. We request a one year extension of the currently approved collection because, Congress through the Balanced Budget Refinement Act of 1999(BBRA), has extended the S/HMO Demonstration until 18 months after the S/HMO Transition Report is submitted by the Secretary to Congress. BIPA continued the demonstration until 30 months after the S/HMO Transition Report is submitted by the Secretary to Congress. The previous Centers for Medicare & Medicaid Services (CMS)Administrator has further extended the demonstration through December 31, 2004 using discretionary authority. The current CMS Administrator, using discretionary authority, has extended the demonstration in a phase-down process through December 31, 2007. The payment blend includes the S/HMO demonstration payment method and the MA risk adjusted payment, with the demonstration portion decreasing over time.

The purpose of this submission is to request OMB authorization to continue to collect information from S/HMO-II demonstration participants.

B. Justification:

1. Need and Legal Basis

Section 2355 of Public Law 98-369, the Deficit Reduction Act of 1984 required the Secretary of the Department of Health and Human Services to approve, with appropriate terms and conditions, applications and protocols submitted to waive certain requirements of titles XVIII and XIX of the Social Security Act so as to demonstrate the concept of a

Social Health Maintenance Organization (S/HMO). The S/HMO is designed to integrate health and social services and reduce fragmentation of care through better coordination and more appropriate use of services. The S/HMO model of care combines the features of HMOs,with those of long-term-care demonstration projects and offers Medicare beneficiaries the opportunity to receive a wide range of services to meet both acute and long-term-care needs. Four applicant organizations were selected as S/HMO projects and began operation in 1985. Three of the four sites are still in operation. Section 4018(b) of P.L. 100-203, the Omnibus Budget Reconciliation Act (OBRA) of 1987, extended the S/HMO demonstration through September 30, 1992. Section 4207(b)(4) of P.L. 101-508, OBRA-90, extended the demonstration through December 31, 1995. In addition, the legislation further required approval of not more than four additional projects (S/HMO-II).

The purpose of the S/HMO-II demonstration was to refine the targeting and financing methodologies and benefit design of the S/HMO model. The legislation further allows that the effectiveness and feasibility of operating a more geriatrically-oriented S/HMO project, and S/HMO projects that target special populations (minority and dually-eligible beneficiaries, and rural populations) could also be tested. In 1993, section 5079 of P.L. 103-66, OBRA-93, further extended the demonstration through 1997 and required that one of the four new projects examine the feasibility of developing a S/HMO project for beneficiaries with end-stage renal disease (ESRD). The Balanced Budget Act of 1997 continued the demonstration through December 2000. The Balanced Budget Refinement Act of 1999 (BBRA)continues the demonstration until 18 months after the S/HMO Transition Report is submitted by the Secretary to Congress. The Beneficiary Improvement and Protection Act(BIPA)continued the demonstration until 30 months after the S/HMO Transition Report is submitted by the Secretary to Congress. The previous Centers for Medicare & Medicaid Services(CMS)Administrator has further extended the demonstration through December 31, 2004 using discretionary authority. The current CMS Administrator, using discretionary authority,has extended the demonstration in a phase-down process through December 31, 2007. The payment blend includes the S/HMO demonstration payment method and the MA risk adjusted payment, with the demonstration portion decreasing over time.

In January 1995, HCFA selected six applicant organizations to implement the various non ESRD S/HMO-II projects delineated in the OBRA-90 legislation. One Site became operational, the Health Plan of Nevada, Las Vegas, Nevada.(1)

The purpose of the S/HMO-II demonstration is to refine the targeting and

financing methodologies, and benefit design of the S/HMO model. Four primary components of the S/HMO-II demonstration are: (1) a geriatric care approach that will be applied across the entire spectrum of S/HMO-II enrollees; (2) expanded community care coordination through links between chronic care case-management and acute care providers; (3)provision of long-term-benefits; and (4) an AAPCC-based risk-adjusted payment methodology.

2. Information Users

The data collection needs of the S/HMO-II demonstration are listed and discussed below.

A. Collect the necessary data elements from members of the treatment group for the risk-adjusted S/HMO-II payment methodology;

The authorizing S/HMO legislation mandates the use of an adjusted average per capita costs (AAPCC)-based methodology. The AAPCC is a table of relative cost factors or underwriting ratios that establish different payment rates for groups based on their relative risk of incurring health care costs in the Medicare fee-for service (FFS) program for the geographic area that the HMO services. Medicare risk contract HMOs were reimbursed at 95 percent of the AAPCC for their enrolled population. However, the authorizing S/HMO legislation mandates that participating S/HMO sites be paid 100 percent of the AAPCC.(S/HMOs are paid at the published Medicare county rate book

(1)Design and selection of the ESRD S/HMO project was conducted as a separate activity.

amount for risk plans, augmented by the implicit 5 percent discount that is built into the risk plan rates.) Providers are then required to provide the core set of Medicare-TEFRA benefits (now Medicare Advantage), as well as extended and long-term-care benefits.

In recent years, a great deal of concern has been expressed over whether HMOs over-enroll healthy persons from their market areas. There is some evidence suggesting that Medicare risk plans are experiencing favorable selection, and consequently, HCFA is spending more than they would have under FFS care for the enrolled beneficiaries (Brown 1992). Since the AAPCC only accounts for 0.6 percent of the variance in individual Medicare costs, it does not adequately adjust reimbursement for the health differences that exist between HMO enrollees and Medicare FFS clients,resulting in overpayments for healthier HMO enrollees and little incentive for HMOs to enroll

Medicare beneficiaries with complex medical needs.

> Michael Finch,Ph.D.(previously from the Univ.of Minnesota)and William Manning,Ph.D.,from the Universityof Minnesota,and Liz Mauser,Ph.D., from the former Office of Research and Demonstrations have worked together to refine the S/HMO-II payment methodology using data from the Medicare Current Beneficiary Survey (MCBS). Mauser, Finch, and Manning have developed a regression-based model which includes a series of self-reported medical conditions, self-reported health status, limitations in several activities of daily living (ADLs), and limitations in several instrumental activities of daily living (IADLs). This model accounts for close to 6 percent of the variance in individual Medicare costs. The estimated co-coefficients from this regression model are used to adjust upward or downward the county per capita costs to account for the health status differences across enrollees.

We will not be using a rate cell approach due to the number of variables included in the regression model. However, from the regression model it was estimated how per capita costs for beneficiaries with a given set of characteristics differ relative to the average beneficiary. For example, if it were estimated through the regression model that individuals reporting to have diabetes and need help bathing have 10 percent higher costs on average, we will adjust the county rate upward by 10 percent for these types of enrollees.

The AAPCC took into account several factors: age, sex, welfare status, working aged disabled, and institutional status. These AAPCC adjustment factors are common data elements stored in CMS'common working file (CWF)for each Medicare beneficiary. Therefore, the factors are easily retrieved for payment determination upon beneficiary enrollment into an HMO. However, under S/HMO-II, a much more complex array of factors are being used for risk adjustment which require significant primary data collection.

Under the S/HMO-II regression-based payment model, each enrollee in the treatment group will be assigned a rate based on the presence or absence of individual characteristics that were included in the development of the model (such as ADLS, IADLS, medical conditions,etc). These individual characteristics also are important in providing the participating sites with information necessary for care-planning and targeting clinical resources. Currently an independent third party contractor surveys a sample of enrolled beneficiaries in order to gather the data necessary to determine an individual's risk adjusted payment rate. In 2004,the S/HMO II payment was determined by the CMS-Hierarchical Condition Category(CMS-HCC)risk adjustment model with a frailty adjuster employing a 90/10 percent

blend. The blend was 90 percent of the payment based on the methodology in prior use during the demonstration and 10 percent based on the new risk adjustment system with the additional frailty adjustment. In 2006, this payment blend is 50 percent of the payment based on the methodology in prior use during the demonstration and 50 percent based on the MA risk adjustment system with the additional frailty adjustment.

B. Gather information from members of the treatment group to enable the participating S/HMO-II site to identify high-risk beneficiaries.

The traditional HMO service delivery systems do not currently collect information appropriate to determine the need for long-term care services. Under S/HMO-II, information concerning functional status, income, psycho-social functioning, access to informal supports, caregiver burden, etc., will be gathered in a timely and consistent manner in order to adequately assess a beneficiary's full range of needs and arrange an appropriate care system.

C. Data Collection Instrument

In an attempt to consolidate the various data collection needs of the S/HMO-II demonstration, a data collection instrument has been developed. The S/HMO-II instrument was designed to gather data or information from the S/HMO-II treatment group members.

For treatment group members, the S/HMO-II data collection instrument was designed to provide the information necessary to adjust the capitated payment rates at the individual level for "at-risk" characteristics; The instrument is an initial screening instrument;

This instrument is included in Appendix B.

Initial Screening Instrument

The initial screening instrument (Appendix B) will be administered to all treatment group enrollees at baseline and annually thereafter. Currently an independent third party contractor surveys a sample of enrolled beneficiaries in order to gather the data necessary to determine an individual's risk adjusted payment rate. The initial screen includes such information as demographics, health status and functioning, presence of various medical conditions, service utilization, health habits, mental status, and living arrangements.

The different items on the initial screen serve functions for S/HMO-II treatment group members. Some items, particularly questions pertaining to health and functioning, service utilization, and medical conditions assist the S/HMO-II site to identify at-risk beneficiaries that may require

clinical intervention or further assessment. Some items on the initial screen provide information necessary to calculate the individual risk - adjustment factors for the S/HMO-II payment methodology. Lastly, all items on the initial screen will form the baseline and follow-up data. However, because it is also used to support clinical care planning, other circumstances such as a referral or an irregular utilization pattern may trigger intermittent administration of the initial screen for treatment group members. In such instances, the initial screen shall be administered by the respective plan and will serve to only determine the need for further treatment group intervention on behalf of the health plan (2).

The initial screening instrument will be administered to treatment group members on a sample basis by the third party contractor. Upon survey completion, the independent third party contractor will forward data collected from treatment group members to the respective health plan for care planning. This information will become part of the treatment beneficiary's medical record. Treatment group data will also be forwarded to CMS for payment purposes. CMS(formerly HCFA)awarded a contract to Mathematica Policy Research to perform the data collection function. The data is collected via telephone interview (Computer Assisted Telephone Interview) with in-person follow-up (when necessary).

3 . Information Technology

The patient interviews are being conducted using computer-assisted telephone interviewing or CATI. CATI has been reported to alleviate respondent burden. This largely occurs through the reduction of interviewer errors. Correcting such errors requires additional respondent time, particularly if the respondent must be telephoned again to obtain information not ascertained in the original interview.

In addition, the independent third party contractor shall work collaboratively with each individual site to minimize respondent burden.

Approximately forty percent of the interview process is electronic. A signature is not required from the respondents.

4. Duplication of Efforts

The purpose of this data collection effort is to consolidate the various information needs of the demonstration. Under this demonstration, individual level data is needed for rate-setting, and care-planning. Through implementation of an initial and annual survey for treatment group members, and access to medical records and patient charts, data may be collected to serve these functions without extraordinary burden being placed upon the enrolled beneficiaries.

5. Burden on Small Businesses

Not applicable. The data collection effort does not involve data collection from small businesses.

6. Less Frequent Collection

Data collection will take place on an annual basis for the treatment group members. Currently an independent third party contractor surveys a sample of enrolled beneficiaries in order to gather the data necessary to determine an individual's risk adjusted payment rate. This frequency is critical to effectively monitor enrollee health status for purposes of appropriate rate-setting.

7. Special Circumstances

None of the relevant special circumstances are applicable to this data collection effort. No data will be collected more than quarterly. The S/HMO-II instrument will be administered via telephone or in-person interview, therefore, respondents will not be required to provide written response in fewer than 30 days after receipt of a form. Respondents will not be required to submit multiple copies of any document. Respondents will not be required to maintain records. The statistical surveys are designed to provide reliable and valid results and will be administered to the sample of enrolled beneficiaries. Respondents are not required to use a statistical data classification. The pledge of confidentiality to patients is supported by authority established in statute, and confidential information received from agencies will be protected.

8. Federal Register notice/Outside Consultation

The 60-day Federal Register notice was published on October 27,2006.

A number of individuals outside CMS have been consulted on the development of the screening instrument. The instrument was developed in conjunction with CMS staff and researchers from the University of Minnesota and the University of California, San Francisco. These individuals are researchers or health care professionals who have conducted similar data collection efforts. The instrument was also shared with the participating sites who also had significant input into their development. The University of Minnesota and University of California, San Francisco researchers are: Robert Kane,M.D.,University of Minnesota; Michael Finch,Ph.D.,formerly of U.of Minnesota;Robert Newcomer,Ph.D.,University of California,San Francisco; and Charlene Harrington,Ph.D.,University of California,San Francisco.

9. Payment/Gifts to Respondents

No payments or gifts will be provided to respondents.

10. Confidentiality

All S/HMO-II participants are informed that their participation is voluntary and that their responses to the survey will be kept strictly confidential. Treatment group members will also be informed that their responses become part of their medical record. See Appendix C for a model letter informing beneficiaries of the data collection activities and introductory survey language. All willing participants will: (See Appendix C for model beneficiary notification letter); receive a detailed explanation of the survey and why they are being administered; be made aware that the survey will be in complete compliance with the Privacy Act of 1974; be assured that their responses will be kept confidential, except for specified uses, and that their decision to participate in the survey will not affect their Medicare coverage or services.

11. Sensitive Questions

The initial and annual survey contains the types of questions that are generally asked in obtaining a patient history or assessing the need for care and would not commonly be considered private when asked in that context. Nonetheless, there are some questions that some individuals may consider to be private when asked in the context of a research interview. This survey includes questions on living situation, and socioeconomic status. Functional status measures an individual's ability to complete basic activities of daily living and self-care. A question regarding continence is also included and may be perceived as sensitive. There are also questions regarding mental status (depression and dementia) and substance abuse. However, all questions are critical to gain an accurate and comprehensive picture of both the functional and health status of beneficiaries and adequately plan for their care.

12. Burden Estimates (Hours & Wages)

We estimate that there will be a total of approximately 57,000 S/HMO-II enrollees. We expect that approximately 57,000 will be assigned to the treatment group. For enrollees assigned to the treatment group a 30 percent sample will be taken in the Las Vegas area and a 40 percent sample in the Reno area and an attempt will be made to obtain the items on the initial screening instrument. Therefore, there will be approximately 17,624 respondents.

Table A and Section 12.A present and discuss the treatment group burden estimates for the screening instrument.

The data collected via the initial screening instrument by the independent third party contractor will be transmitted to the health plan for care planning (for treatment group members),and to CMS for payment purposes (for treatment group members).

TABLE A

ANNUAL BURDEN ESTIMATES
Treatment Group

Data Collection Instrument	Estimated Number of Completes	Hours Per Complete	Burden Hours
Screening Instrument	17,624	12min.	3,525
Total	17,624		3,525

A. Screening Instrument

As Table A indicates, we estimate that the total annual burden associated with the screening instrument to be 3,525 hours. These burden hours are based on the assumptions of a 95 percent completion/response rate and an average of 30.92% sample,17,624 completed screens per year. We also estimate that the average interview time will be approximately one-fifth hour, 12 minutes. The one-fifth hour interview time assumes a 95 percent response rate via Computer-Assisted Telephone Interview (CATI) and a 5 percent in-person follow-up. Participants will be interviewed upon enrollment and annually there after by MPR. This is an average estimate across the tenth year of the demonstration. Enrollees receive an annual survey and follow-up surveys. The S/HMO-II site will probably reach enrollment targets by the end of year ten. Those entering the demonstration in year ten will receive an initial screen and only follow-up interviews.(57,000 enrollees X 30.92% x 12min. = 3,525 annual burden hours)

13. Capital Costs

There are no direct costs to respondents other than their time to participate in the initial screen. For the initial screening instrument, MPR will contact respondents via telephone.

14. Cost to the Federal Government

The estimated cost to the Federal Government for the data collection effort under the demonstration for the extended period is $1,142,563.92. This amount reflects the cost for the independent contractor to continue the initial screening instrument (with annual follow-up),using a sampling basis, to the enrolled treatment group beneficiaries. The average cost per completed interview for the extended period is $64.83.

15. Changes to Burden

The change in burden is due to an increase in the universe,and the number of respondents because of sampling.

16. Publication/Tabulation Dates

A contractor was selected to analyze the data. Some analysis of certain aggregate data from the screening instrument was included in the S/HMO II report which was released in February 2003.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. We will display, if required, the expiration date of the OMB approval in the letters sent to all S/HMO II participants notifying them that they will be contacted to participate in a survey.

18. Certification Statement

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

C. Collections of Information Employing STATISTICAL METHODS

I . Respondent Universe and Sampling Methods

The respondent universe will be approximately 57,000 enrollees. An average 30.92 percent sample is taken and used for collecting the necessary data for the calculation of the monthly risk adjusted payment using the payment methodology.

A large random sample of enrollees could be used to produce estimates of the average cost factor that are quite close to the average for the full population. This estimated average factor for enrollees in the county ($\overline{CF}$) would then be multiplied by the county rate (r) and the number of

enrollees in the county (N_e) to determine total payments to the plan [Payment = $\overline{CF}$ * r *N_e]. Because the sample would be random, the estimated average cost factor would be an unbiased estimate of the population rate, so we would expect the sample on average to produce a payment factor (and therefore, total payments) that are close to that which would be obtained from the full population. However, we must draw a large enough sample to ensure a very low probability that chance differences between the particular sample we draw and the population are not large.

Sample Size Needed

Based on calculations that MPR has done on the payment factor data, a random sample around 30.92 percent of the population would ensure a very low probability that the estimated average cost factor would deviate by more than 1 percent (in either direction) from the population value. Each month MPR would calculate the payment factor for each sample member and compute the average for each county. CMS would then multiply this factor by the total number of beneficiaries enrolled in HPN from that county for that month. In these calculations we would use the data from the most recent interview for each enrollee in the sample. Average payments would change from month to month because some sample members would die or disenroll, new enrollees would join, and some fraction of enrollees would have updated data from an interview on their anniversary date. Total payments would change as the average monthly payment changed and as total enrollment changed.

Selecting the Random Sample

In selecting the 30.92-percent random sample, the contractor uses a simple method that makes monthly sampling easy and automatic and that yields a sample with the same average payment rate as the population at the outset. This would be to select the sample based on the final digit of the beneficiary ID number, and choose the three digits that yield a sample with an average payment factor as close as possible to the population value. The sample is defined to consist of all beneficiaries whose final digit is a 4, 5, or 8.

2. Procedures for Collection of Information

In an attempt to consolidate the various data collection needs of the S/HMO–II demonstration, a data collection instrument was developed. The S/HMO–II instrument is designed to gather data or information from the S/HMO–II treatment group members.

For treatment group members, the S/HMO–II data collection instrument was designed to provide the information necessary to adjust the capitated payment rates at the individual level for "at–risk" characteristics. The instrument is an initial screening

instrument and is included in Appendix B.

Initial Screening Instrument

The initial screening instrument (Appendix B-1) will be administered to treatment group enrollees at baseline and annually thereafter.

The initial screen shall serve the following functions for S/HMO-II treatment group members: (1) identify at-risk beneficiaries that may require clinical intervention or further assessment by the respective health plan. 2) provide information necessary for the SHMO-II risk-adjusted payment; and (3) provide baseline and follow-up data. While the initial screen will be administered annually, other circumstances, such as a referral or an irregular utilization pattern may trigger intermittent administration of the initial screen for treatment group members.

The initial screening instrument is administered to a sample of treatment group members by an independent third party contractor. Upon survey completion, the independent third party contractor will forward data collected from treatment group members to the respective health plan for care planning. This information will become part of the treatment beneficiary's medical record. Treatment group data will also be forwarded to CMS for payment determination. CMS awarded a contract to Mathematica Policy Research to perform the data collection function. The data are being collected via telephone interview (Computer Assisted Telephone Interview) with in-person follow-up (when necessary). The annual screen (versus intermittent administration) is the only mechanism that impacts a treatment individual's payment rate.

3. Maximizing Response Rates

Data will be collected using a sample at the time of enrollment and annually thereafter for the duration of the demonstration project. The clinical, and operational needs of the S/HMO-II demonstration demands a high response rate for the treatment members. While obtaining a 95 percent response rate is onerous, the independent third party contractor will be expected to work collaboratively with the participating SHMO-II site to initiate aggressive data collection techniques designed to maximize the response rate. For treatment group members, the participating S/HMO-II site will issue a letter informing them that they will be contacted to provide information needed to appropriately plan for their health care needs (see Appendix C for model letter). The advance letter and continued cooperation between the independent third party contractor and the participating site in locating members and converting refusals should minimize non-response. Moreover, the mode of data collection shall also contribute to a high response rate. Telephone coverage is very high for the elderly.

Ninety-seven percent of households with a member age 65 or older have telephones (U.S. Bureau of the Census, 1995).

4. Pretesting

The procedures to be used for the S/HMO-II data collection instrument has been utilized on previous telephone and in-person surveys among the elderly and have worked successfully.

5 . Statistician/Contractor

Mathematica Policy Research, Inc. is the contractor conducting the interviews.