

PRA Clearance Package

Prospective Evaluation of Evidence-Based Community Wellness and Prevention Programs

Part A. Justification

Version: September 5,
2014

Centers for Medicare & Medicaid Services

Table of Contents

Background	3
Part A. Justification	5
1. Circumstances That Make the Collection of Information Necessary	5
2. Purpose and Use of Information	5
3. Use of Improved Information Technology	7
4. Efforts to Identify Duplication	7
5. Involvement of Small Businesses	7
6. Consequences If Information Collected Less Frequently	8
7. Special Circumstances	8
8. Consultation Outside the Agency	8
9. Payments/Gifts to Respondents	9
10. Assurance of Confidentiality	9
11. Questions of a Sensitive Nature	10
12. Estimates of Annualized Burden Hours and Costs	10
13. Estimates of Annualized Respondent Capital and Maintenance Costs	11
14. Estimates of Annualized Cost to the Government	11
15. Changes in Hour Burden.....	11
16. Time Schedule, Publication and Analysis Plans	12
17. Exemption for Display of Expiration Date	16
List of Attachments.....	16

Background

The Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC and its partner, Westat, Inc., to (i) analyze beneficiary readiness to engage in community-based wellness and prevention activities and (ii) conduct a prospective evaluation of wellness program impacts on the health and wellbeing of participating beneficiaries and on potential cost outcomes for the Medicare program. Community-based wellness and chronic disease prevention programs (henceforth wellness programs) aim to promote healthier lifestyles, lower beneficiary health risks, and ultimately improve health outcomes. These effects could lead to reduced health service utilization and ultimately, costs, for program participants.

This effort is a critical component of a larger, ongoing evaluation of wellness programs mandated by Congress in the Affordable Care Act (ACA). In Section 4202, subsection (b) of the ACA, Congress mandated that CMS conduct an evidence review and independent evaluation of wellness programs focusing on the following four intervention areas:

- 1) Physical activity, nutrition, and obesity;
- 2) Falls Prevention;
- 3) Chronic disease self-management; and
- 4) Mental health.

In response to the ACA mandate, CMS adopted a three-phase approach to evaluate the impact of wellness programs on Medicare beneficiary health, utilization, and costs to determine whether broader Medicare beneficiary participation in wellness programs could lower future growth in Medicare spending. Phase I consisted of a comprehensive literature review and environmental scan to identify a list of wellness programs for further evaluation. Phase II involved a retrospective evaluation of 10 wellness programs in the targeted intervention areas mentioned above. The purpose of the Phase II evaluation was to use Medicare claims data to assess the 10 wellness programs' impact on Medicare beneficiary outcomes including health service utilization and medical costs. The findings in Phase II were promising in that several wellness programs demonstrated the potential to save medical costs among participating beneficiaries.

Phase III of CMS's evaluation, of which this work is the key component, aims to round out CMS's understanding of how wellness programs affect Medicare beneficiaries and what cost saving opportunities exist for the Medicare program. This Paperwork Reduction Act (PRA) package is for the data collection activities related to Phase III of CMS's evaluation efforts, which will involve a prospective evaluation of wellness programs. Specifically, this evaluation effort will 1) describe the overall distribution of readiness to engage with wellness programs in the Medicare population, 2) better adjust for selection biases of individual programs and interventions using beneficiary level survey data, 3) evaluate program impacts on health behaviors, self-reported health outcomes, and claims-based measures of utilization and costs, and 4) better describe program implementation, operations and cost in relation to the expected benefits. The results of these analyses will be used to inform CMS and CMMI wellness and prevention activities in the future.

To achieve the goals of this project, CMS and its evaluation contractor will be conducting a nationally

representative survey of Medicare beneficiaries to assess their readiness to participate in community-based wellness programs. National estimates of Medicare beneficiary demand for wellness services and benefits will be generated from this population-based readiness national survey. In addition, CMS and its evaluation contractor will partner with evidence-based wellness programs for the purposes of enrolling an estimated 2,000 participants per program. CMS has identified eight evidence-based wellness programs for potential participation in the evaluation. Wellness programs were selected based on evidence of impact on participant health and health care utilization; capacity to perform evaluation activities; and interest in participation in the evaluation. The eight wellness programs tentatively included in the study are crossmapped to the ACA intervention areas in Exhibit 1. Wellness programs may be excluded if program participant sample size goals cannot be achieved.

Exhibit 1: Wellness programs included in the evaluation by ACA intervention area

Wellness program	ACA Priority Areas			
	Physical Fitness, Obesity, & Nutrition	Falls Prevention	Chronic Disease Management	Mental Health
Chronic Disease Self Management Program (CDSMP)	S		P	S
Diabetes Self Management Programs (DSMP)	S		P	S
Enhance Fitness	P	S		
Enhance Wellness	S	S	P	S
Fit & Strong!	P			
A Matter of Balance	S	P		
Stepping On		P		
Walk with Ease	P			

P = Primary Focus
 S = Secondary Focus

Surveys of program participants will be conducted to assess program impacts on health and behavior; and ask about reasons for program non-completion among those participants who do not complete the full program. A comparison group will be derived from the population-based survey. In-depth interviews with wellness program staff will identify best practices in wellness program design and implementation strategies; outreach, targeting, and marketing efforts; and participant engagement and retention. Wellness program operational costs will be collected to perform a cost benefit analysis and determine the return on investment for wellness programs

Part A. Justification

1. Circumstances That Make the Collection of Information Necessary

This collection is part of CMS's overall response to Section 4202, subsection (b) of the ACA, which mandated that the Secretary of Health and Human Services and CMS conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries (Part A, Attachment 1). This prospective evaluation builds on CMS's previous efforts conducting a comprehensive literature review and evidence scan of wellness programs during Phase I of the evaluation; and a retrospective claims-based evaluation of outcomes and costs for Medicare beneficiaries participating in eight wellness programs conducted as part of the Phase II evaluation. The retrospective analyses in Phase II identified challenges in reaching definitive conclusions regarding the effects of program participation, suggesting that important unobserved health differences existed between the controls and wellness program participants.

This data collection for the Phase III evaluation aims to address the limitations of Phase II by collecting self-reported survey data on patient proactiveness in health care decision making (or patient activation), self-efficacy, health behaviors, demographics, and comorbidities, which will be used for improved matching between wellness program participants and a comparison group. This Phase III evaluation will integrate Medicare claims data with wellness participant survey data, and qualitative information about program implementation, operations and costs in a prospective study design to develop the "business case" for wellness program participation by Medicare beneficiaries. CMS contracted with Acumen, and its subcontractor, Westat, to partner with up to eight wellness programs to participate in this evaluation and to enroll new Medicare beneficiaries into their program and this evaluation study. These wellness evaluation partners will be selected by March, 2014.

Phase III also aims to assess demand for, or readiness to engage in, wellness programs in the general Medicare population. This data collection is a key component of CMS's overall efforts to improve its understanding of how wellness programs affect Medicare beneficiaries and the estimated cost saving opportunities for the Medicare program.

2. Purpose and Use of Information

As a new collection, CMS requests approval for the following data collection to respond to Section 4202, subsection (b) of the ACA and to inform future CMS and CMMI wellness and prevention efforts:

National Surveys of Medicare Beneficiaries

A national survey of non-institutionalized Medicare beneficiaries will: (i) provide national estimates of beneficiary readiness for lifestyle modifications to promote wellness and prevention, and (ii) provide a comparison group for the participants entering the wellness and prevention programs for impact evaluation analyses (Part A, Attachment 2). The national survey will be conducted by mail with telephone follow-up for nonresponse, during the enrollment year for the wellness programs (baseline). Six- and 12-month followup surveys with beneficiaries selected for the comparison group will obtain outcome measures comparable to those collected for the program participants. The 6- and 12- month followup national surveys contain identical questions to track measures over time.

Wellness Program Participant Surveys

Surveys of wellness program participants will be conducted to measure changes in health-related quality of life, functional status, social function, physical activity, medication adherence, confidence in balance, and other outcomes (Part A, Attachment 3). To evaluate program impact at 6- and 12-months post enrollment, a propensity score for each participant and each beneficiary from the comparison group, drawn from the national baseline sample, will first be estimated using key characteristics including age, gender, comorbidities, and level of patient activation. Then, an attempt will be made to match a comparison beneficiary with each wellness program participant based on the propensity score. Next, outcome measures of the matched participants and their comparisons will be collected in each follow-up period. Then, the average change of each outcome measure will be calculated per group for each follow-up period. Finally, the difference-in-differences estimator (i.e. the program impact measure) for the outcome measure of interest is calculated by subtracting the average change in the comparison group from the average change in the participant group. . Thus, the 6- and 12- month followup participant surveys contain identical questions to track outcome measures over time. The six- month follow-up survey of wellness program participants also includes questions to identify those participants who indicate that they stopped participation. This information will be used to identify samples for the average treatment effect on the treated (ATT) analysis (where only program completers will be compared with the matched control group) and the complier average causal effect analysis (where characteristics of the non-completers will be matched with those from the control group.)

To address self-selection bias, data will be collected on selected patient activation questions along with self-efficacy, demographic, health behavior, and other control measures. For each type of wellness program, matching between the participant group and the comparison Medicare beneficiaries group will be performed on these variables so that the two groups are as comparable as possible in program impact evaluation. Selected patient activation questions were derived from the Medicare Current Beneficiary Survey. These questions will be used to group participants and controls into four levels of engagement: active, passive, complacent, and high effort; and to match them on these levels along with other matching variables described above.¹

To facilitate an examination of the differences between the participant group and the comparison group, the questions in the participant surveys about outcome measures will be similar to the questions answered by the comparison group in the national survey. Program impact will be measured by identifying whether positive change in outcome measures is significantly greater for the participant group than for the comparison group.

In-Depth Interviews with Wellness Program Staff

In-depth interviews will be conducted with the staff from the eight wellness programs that partner with the evaluation contractor and participate in the evaluation. The eight wellness programs included in the evaluation are: 1) CDSMP; 2) DSMP; 3) Enhance Fitness; 4) Enhance Wellness; 5) Fit & Strong!; 6) A Matter of Balance; 7) Stepping On; and 8) Walk with Ease. An unstructured interview guide will be used to gather information from key program staff about wellness program features, implementation and best practices, program fidelity to their respective evidence base, and operational costs of program implementation (Part A, Attachment 4). In-depth interviews will be undertaken during on-site visits and

¹ Williams (2007). Patient activation among Medicare beneficiaries: Segmentation to promote informed health care decision making. *Journal of Pharmaceutical and Healthcare Marketing*, Vol 1 (3): 199-213.

by telephone, depending on the organizational structure of each program, and will take place towards the end of the first year of program participation in the study. The information gathered through these in-depth interviews with program staff will provide context.

3. Use of Improved Information Technology

All surveys of the control group will be based on a self-administered paper survey. For beneficiaries for whom the project team has a telephone number, the survey team will use Interactive Voice Response (IVR) Notification telephone prompting for respondents who fail to complete and return the mailed questionnaire within the designated time period. During the phone prompt, the message will encourage participants to return the questionnaire by mail or fax and will provide a toll-free number that beneficiaries can call to complete the survey over the phone. Incoming surveys will be scanned using TeleForm; paperless data verification, using the scanned images of the questionnaires, will also be conducted. Nonrespondents to the mail survey will be contacted by telephone and asked to complete the survey via telephone interview.

In-depth on-site and telephone interviews with wellness program staff will follow established qualitative evaluation methodology based on an unstructured interview discussion guide. The interview discussion guide includes open-ended discussion topics to allow for in-depth exploration of issues; and as such, electronic submission of responses is not a viable option.

4. Efforts to Identify Duplication

Information on Medicare beneficiaries' readiness to engage in wellness programs has not been collected and is not available through any other sources.

There is no comprehensive data source which collects data on outcomes (e.g., health-related quality of life, physical activity, falls, confidence in balance, medication adherence) for Medicare beneficiaries participating in wellness programs focused on the six targeted wellness intervention areas specified by the ACA and a comparison group specifically matched on readiness to participate in wellness programs. Similarly, data do not exist on the reasons for wellness disenrollment or non-completion.

Comprehensive information on wellness program implementation, operations and costs is not available for wellness programs focused on the six targeted wellness intervention areas specified by the ACA. The information gathered through the in-depth interviews with program staff will provide context and inputs into the relationship between program costs and expected cost savings and program cost-effectiveness, which currently are not available from any data source.

5. Involvement of Small Businesses

Small businesses are not involved or significantly impacted by this data collection. Surveys will be completed by Medicare beneficiaries and in-depth interviews will be conducted with wellness program staffs who are affiliated with national wellness programs and/or non-profit organizations.

6. Consequences If Information Collected Less Frequently

Surveys for estimating Medicare beneficiary readiness to engage in wellness programs will only be collected one time in the baseline National Survey of Medicare Beneficiaries.

Self-reported health outcome measures will be collected on Medicare wellness program participants and a comparison group of Medicare beneficiaries not participating in any wellness program at baseline, six months, and twelve months in order to quantitatively measure the impact of wellness program participation. A study design for measuring wellness program impact based on two follow-up periods is stronger than one using a single follow-up period in that it enables CMS to reduce threats to internal validity. This research design will allow CMS to compare changes in outcome measures between the baseline period and the six-month follow-up period; and between the baseline period and the twelve-month follow-up of the participant group relative to those of the matched comparison group derived from the national survey.

The in-depth unstructured interviews with staff from the eight wellness programs will be conducted only once, towards the end of the first year of program participation in the study. In-depth interviews will be undertaken during on-site visits and by telephone, depending on the organizational structure of each program and focus on implementation challenges and best practices, and operational costs (e.g., information that may not be readily available from secondary data sources such as program descriptions, policies and procedures, marketing materials, or financial plans).

7. Special Circumstances

There are no special circumstances that would cause the collection of information to be inconsistent with 5 CFR 1320.6.

8. Consultation Outside the Agency

Federal Register Notice

The 60-day Federal Register notice was published on November 22, 2013 (78 FR 70059). No public comments were received.

Outside Consultations

CMS consulted with its evaluation contractors, Acumen LLC and Westat, as well as wellness program experts in designing the surveys and developing the data collection plan. Wellness program experts provided input on the topic areas included in the survey and reviewed draft surveys. Experts also provided advice and insight on survey operations (e.g., maximizing baseline survey response rates) based on prior evaluation experience with this study population. The following wellness program experts were consulted regarding the evaluation:

- Margaret Haynes, MPA, Director, Elder Care Services, Partnership for Healthy Aging, MaineHealth, A Matter of Balance
- Susan Hughes, PhD, Professor, University of Illinois at Chicago School of Public Health, Fit and Strong!
- Susan Jenkins, Ph.D., Social Science Analyst, Administration for Community Living, HHS
- Vilija Joyce, MS, Research Associate, VA Palo Alto Health Care System

- Kate Lorig, DrPH, Professor Emeritus, Stanford University School of Medicine, Chronic Disease Self-Management Programs
- June Simmons, MSW, CEO, Partners in Care Foundation, San Fernando, CA, Home Meds, Healthy Moves
- Susan Snyder, MS, Director, Project Enhance, Senior Services, Seattle, WA Enhance Wellness and Enhance Fitness

No other outside consultants contributed to the formation of the study design.

9. Payments/Gifts to Respondents

Medicare beneficiary survey respondents will not be receiving any gifts or payments to participate in the study or respond to any surveys. Similarly, wellness program staff will not be reimbursed for participation in the in-depth interviews.

The evaluation contractor will negotiate subcontract agreements with each wellness program to compensate the program for evaluation data collection and submission activities including: collecting, maintaining, and submitting evaluation data on program participants (e.g., participant attendance); complying with Institutional Review Board (IRB) requirements, if needed; any data use agreement policies; providing the Program Participant Baseline Survey to program participants at enrollment; collaborating on evaluation data collection training, and provision of secondary data (e.g., program implementation policies and procedures, aggregated financial and operational cost information). The subcontract will specify the anticipated schedule of payments for evaluation activities and emphasize that evaluation funds cannot be used to support program implementation, operational activities, or infrastructure costs. Subcontracts will be negotiated after wellness program selection and be in effect for 19 months during the evaluation data collection period.

10. Assurance of Confidentiality

Medicare beneficiaries and wellness program staff will be assured of the confidentiality of their responses under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be informed of the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose without their prior consent.

The surveys will gather information from respondents including their awareness of wellness programs, participation in wellness programs, barriers to participation in wellness programs, and health-related quality of life measures, along with other outcomes. The surveys will also collect demographic information (e.g., living arrangements, marital status, education attainment, income, health insurance) about the respondents. CMS plans to collect personally identifiable information (PII), including program participant names, addresses, and phone numbers, from the wellness programs for survey follow-up. The Wellness Program Participant Baseline Survey will also request PII, including the last four digits of their Social Security Number (SSN) and their Medicare Health Insurance Claim (HIC) number, from wellness

participants in order to link the survey responses to their Medicare administrative data.² Information gathered from the in-depth interviews refers to wellness program implementation and operational costs, and not to individuals. All information collected will be kept secure to the extent permitted by the Privacy Act of 1974. All electronic files will be stored on a secure, password-protected server. Hard copy records will be stored in a locked file drawer in a secure office when not in use. All study reports will contain only de-identified data, quotes, and observations.

11. Questions of a Sensitive Nature

There are no sensitive issues.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 2 presents the estimate of the response burden for the surveys. It shows the expected number of respondents, the hours per response, and the burden hours and cost burden for the two years of data collection.

Exhibit 2. Estimated annualized burden hours

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Burden hours for 1 st year of data collection (Sept. 2014-Aug. 2015)	Burden hours for 2 nd year of data collection (Sept. 2014-Aug. 2015)	Cost burden for 1 st year of data collection (Sept. 2014-Aug. 2015)	Cost burden for 2 nd year of data collection (Sept. 2014-Aug. 2015)	Total cost burden ¹
National Readiness Survey ²								
Baseline	8,333	1	0.5	4,167	0	\$91,716	\$0	\$91,716
6-month follow up	6,667	1	0.33	1,100	1,100	\$24,211	\$24,211	\$48,422
12-month follow up	3,000	1	0.33	0	2,162	\$0	\$21,790	\$21,790
Program Participant Survey								
Baseline	11,200	1	0.5	5,600	0	\$123,256	\$0	\$123,256
6-month follow up	8,372	1	0.37	1,483	1,483	\$32,647	\$32,647	\$65,295
12-month follow up	5,242	1	0.33	0	1,730	\$0	\$47,589	\$38,074

¹ The total cost burden for Medicare beneficiaries is based on \$22.01, the mean hourly wage for all occupations from the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm#00-0000).

² The annual burden calculation for the National Readiness Survey is based on the sample needed (n=3,000) for the 12-month follow up and expected response rates for each round to arrive at the number of respondents for the baseline National Readiness Survey (n=8,333).

² The question asking for the last four digits of the wellness participants’ SSN is modeled after a recent Administration on Aging (AOA) evaluation of the Aging and Disability Resource Center Grant (ADRC), which requests the last four digits of ADRC participants’ SSN in anticipation of a later study comparing the health care utilization and costs using Medicare records for members of the ADRC consumer and comparison group members (OMB Control Number: 0985-0035).

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no capital costs.

14. Estimates of Annualized Cost to the Government

The total estimated cost to CMS for conducting the surveys is \$2,576,296. This total includes the contractor's costs for developing the survey instrument, data collection, data analysis, and preparation of the data file. The contractor cost estimate includes salary costs; other direct costs for computer, telephone, postage, reproduction, fax, printing, and survey facilities; and indirect costs for fringe benefits, overhead, general and administrative costs, and fees.

The total estimated cost to CMS for completing the in-depth interview with program staff is \$219,508. This total includes the contractor's costs for developing the in-depth discussion guide; data collection, including time to prepare and participate in the interviews; and the analysis of data. The contractor cost estimate includes salary costs; direct travel; and indirect costs for fringe benefits, overhead, general and administrative costs, and fees. Given that wellness programs will be under subcontract with the evaluation team, the wellness program staff who participate in the interviews are considered part of the contractor team.

Federal FTE costs are projected to be minimal. CMS anticipates that approximately 10% of the one FTE that CMS has dedicated to overseeing this study will be spent managing the data collection effort. Assuming a GS-13 level Project Officer, CMS anticipates that the FTE costs will be between approximately \$9,000 and \$12,000.

15. Changes in Hour Burden

The 60-day Federal Register notice was published on November 22, 2013 (78 FR 70059). No public comments received. During recent discussions with potential wellness programs, CMS was advised by the wellness program experts that on-site delivery and collection of the baseline program participant survey would result in a higher response rate than surveys delivered by mail, which was originally planned. It was determined that the earlier response rate estimate for mailed surveys was lower than what will be achieved with on-site delivery. Thus, the response rate was increased, and therefore the total number of completed baseline surveys was also increased. The total estimated burden associated with completing the Participant survey has been increased based on the following:

- The number of completed Participant baseline surveys has been revised based on new information about expected response rate for on-site survey delivery. We originally assumed a baseline response rate of 62.5% with 12,500 completed surveys for surveys delivered by mail. We have revised this assumption to 70% response with 14,000 completed baseline surveys delivered on-site at the start of the wellness program.
- The number of completed Participant 6-month followup and Disenrollee surveys has been revised based on a change in the operational design. It was initially envisioned that the disenrollee survey would be a separate instrument and would be sent only to disenrollees as identified by the

Wellness programs. We learned that the process of identifying disenrollees is complicated for the Wellness programs and that this would not be a viable strategy. We therefore decided to use a single 6-month followup to query both program completers and disenrollees by mail.

In addition, results from the cognitive testing with less than nine Medicare beneficiaries suggested that clarification for several items would also be beneficial. Questions have been added and deleted from the surveys. These clarifications have been made throughout the surveys in response to this feedback and documented in Part A, Attachment 5.

16. Time Schedule, Publication and Analysis Plans

Schedule and Publication

The national survey of non-institutionalized Medicare beneficiaries will be conducted by mail with telephone follow-up for nonresponse during the enrollment year of the wellness programs. Conducting the national survey over the one-year enrollment period allows for control for possible seasonal effects in both the national estimates of readiness and the program outcomes evaluation. The national survey will also serve as the basis for selection of the comparison group after the wellness program participant group is identified. To obtain outcome measures comparable to those collected for the wellness program participants, the six-month follow-up survey with all national survey respondents and a 12-month follow-up with only those selected for the comparison group will be conducted. To evaluate program impact at six and twelve months post enrollment, baseline and follow-up data for the participant samples will be compared to that of the comparison sample for each of these time frames. Descriptive statistics on reasons for discontinuing the wellness programs will also be provided. Exhibit 3 shows the schedule for the national and participant surveys and associated follow-up surveys.

The baseline program participant survey will be self-administered on-site on the first day of the wellness program. Six- and 12- month followup surveys will be delivered by mail in monthly batches based on wellness program start date.

In-depth interviews with staff from each wellness program, including such staff as Executive Director, Outreach/Recruitment Coordinator, Program Coordinator, Instructor(s), and the Financial Officer will be conducted on-site and by telephone, depending on the organizational structure of each program and will take place towards the end of the first year of program participation in the study (01/01/15 – 06/01/15). These in-depth unstructured interviews will gather information about implementation challenges, and successes and lessons learned. We will work with each selected program to determine the appropriate approach for the site visits, particularly for those programs where the program is national in scope and implemented in several sites. The approach will therefore be tailored to each program. Annual reports will summarize the findings to date from each data collection effort.

Exhibit 3. Survey schedule

Survey	Time Frame	National Surveys of Medicare Beneficiaries (Method of delivery)	Wellness Program Participants Survey (Method of delivery)
--------	------------	---	---

Baseline Survey	09/01/14 – 08/31/15	12 replicates at 1-month Intervals (mail)	Administered at enrollment over the 1-year enrollment period (on-site)
6-month follow-up Survey	03/01/15 – 2/28/16	12 replicates at corresponding 1-month intervals to all completing the baseline survey (mail)	Administered to all program participants at corresponding 6-month point (mail)
12-month follow up Survey	09/01/15 – 08/31/16	12 replicates at corresponding 1-month intervals to matched comparison only (mail)	Administered monthly to all program participants at corresponding 12-month point, with the exception of those who identify themselves in the 6-month survey as having stopped participation in the wellness program (mail)
Data delivery to CMS	9/30/17		

Note: Assumes OMB clearance in August 2014.

Analysis Plan

This evaluation will address the following research questions:

- 1) What is the distribution of readiness to participate in a wellness program in the general beneficiary population?
- 2) What are the determinants/predictors of beneficiary readiness and are certain subgroups of beneficiaries more prepared to participate than others?
- 3) Did beneficiary participation in a wellness program lead to improvement in key health and disease self-management behaviors?
- 4) Did beneficiary characteristics influence these behavioral improvements?
- 5) Did beneficiary participation in a wellness program lead to improvements in self-reported health status, functioning, and other key health outcome measures?
- 6) Did participation in a wellness program improve beneficiary health-related quality of life?
- 7) Did any beneficiary characteristics influence or modify improvements in health outcomes?
- 8) What were the effects of beneficiary participation in multiple interventions under a wellness program on key health outcomes and behaviors?
- 9) Did beneficiary participation in a community-based wellness and prevention program lead to reductions in health service utilization and associated costs?
- 10) Were any beneficiary characteristics associated with the improvements in these cost and utilization outcomes?
- 11) Did beneficiary participation in a wellness lead to reduction in beneficiary out-of-pocket costs?
- 12) Did beneficiary characteristics influence out-of-pocket cost savings?
- 13) What were the effects of beneficiary participation in multiple interventions under a wellness program on key utilization and cost outcomes?

The first aim of the Phase III evaluation study is to describe the overall distribution (research question 1) and determinants of readiness to engage in wellness programs in the Medicare population (research question 2). Questions 22 to 27 of the Baseline National Survey are designed to collect data to measure

the degrees of readiness to engage in targeted wellness programs. The degrees of readiness are defined as the different stages of change of the transtheoretical model (TMM) of readiness (pre-contemplation, contemplation, preparation, action, maintenance, and relapse).³⁴ To address research question 2, the analyses will assess the level of contribution of demographic and socio-economic characteristics (e.g., age, gender, race/ethnicity, income, health insurance, and education); barriers (e.g., transportation barrier and English proficiency); health status (e.g., depression, body mass index); social support; self-efficacy; awareness of wellness programs; physician referral; health behavior (e.g. smoking status), and region (identified by zip code). These determinants are collected in the Baseline National Survey, and they will be used in a logistic regression to predict the likelihood to engage in each targeted wellness programs.

The second aim of the Phase III evaluation study is to better adjust for selection biases in the evaluation of individual programs and interventions. Propensity score algorithms will be applied to match each wellness participant with one or more comparison respondents from the Baseline National Survey. Demographic, patient activation, behavioral, diagnostic, self-efficacy, and functional characteristics will be used to estimate the propensity to engage in wellness programs. These determinants are collected in the Baseline National Survey and the Baseline Participant Survey. The propensity score is calculated for each individual in both comparison and participant groups, after which the propensity scores are stratified, and each participant is matched with one or more comparison respondents by the propensity score stratum. Once matched, statistical testing will be performed for all covariates used in the matching to ensure that the differences in means across treated and comparison observations within each stratum are not significantly different from zero. Participants without a matched comparison respondent will be dropped from the sample. With the matched case-comparison sample, the sample selection bias due to observable differences between the treatment and comparison groups is corrected, and the causal effect of enrollment into a program on outcome measures can be properly calculated via the difference-in-differences technique. Data to calculate this propensity will be drawn mostly from the Baseline National Survey and the Baseline Participant Survey. Medicare administrative data will be used to identify diagnostic and chronic conditions of Medicare beneficiaries selected in the study sample.

The third aim of the Phase III evaluation study (research questions 3 to 13) is to evaluate program impacts on health behaviors (measured by the Rapid Assessment of Physical Activity (RAPA) tool and the self-reported medication adherence items used in the National Chronic Diseases Self Management Program (CDSMP)), self-reported health outcomes (SF-36 and the Activities Specific Balance (ABC) self-assessment tool), and claims-based measures of utilization and costs. To measure program impacts, wellness program participants and the matched comparison beneficiaries will be surveyed at three points: at program enrollment (baseline period), 6 months post enrollment, and 12 months post enrollment. The baseline instruments will include outcome measures along with control measures, whereas the follow-up surveys for the program participants and the comparison Medicare beneficiaries will include similar outcome measures and screening questions for sampling purposes.

The self-reported outcome measures that will be assessed for program impact are based on a number of well-established and validated measures including:

³ Prochaska, J.O., DiClemente, C.C., 1983. Stage and processes of self change of smoking: toward and integrative model. *Journal of Consulting and Clinical Psychology* 51, 390–395.

⁴ Prochaska, J.O., Marcus, B.H., 1993. The transtheoretical model: applications to exercise. In: Dishman, R.K. (Ed.), *Advances in Exercise Adherence*. Human Kinetics, Champaign,IL, pp. 161–180.

- SF-36 measures which focus on several domains: physical functioning, role limitations-physical, role limitations-emotional, social functioning, bodily pain, general mental health, vitality, and general health
- Rapid Assessment of Physical Activity (RAPA) tool to assess the level of physical activities of older adults
- Medication adherence measures used in the National CDSMP (Chronic Diseases Self-Management Program) Survey to assess the level of adherence to medication
- Activities Specific Balance (ABC) self-assessment tool for rating an individual's confidence about balance and steadiness in performing daily activities

As described above, program impacts will be measured using the difference-in-differences estimator. This estimator will be calculated for each outcome measure by estimating the average change for the participant group and that of the matched comparison group in each time period. Then, the average change of the comparison group is subtracted from that of the participant group to measure the effectiveness of program enrollment on the outcome measure of interest. Outcome measures will be collected at baseline, 6-month follow-up, and 12-month follow-up periods for both groups. Control variables will be fixed at the baseline period values. By holding the control variables fixed at the baseline values, the analysis will determine whether the difference in average change in outcome measures between the two groups is attributed to program participation. There will be three types of program impact comparisons. The first comparison will be between all program enrollees (regardless of whether or not the enrollees completed the program) and the matched comparison group. The second comparison will be between the program completers and the matched comparison group. The third comparison will be between program completers and potential compliers (defined as a control population that resembles participants who stop participating in the program in demographics, comorbidities, and levels of engagement). Survey data will be linked to Medicare administrative data for an analysis of Medicare costs and utilization. Data from the Chronic Conditions Warehouse will be used to define baseline comorbidities of Medicare beneficiaries in the sample. Baseline comorbidities will then be used as a matching variable to link wellness program participants with Medicare beneficiaries from the comparison group and as a control variable in the regression analyses. Medicare claims data will be used to measure the impact of program participation on Medicare costs and utilization.

The fourth aim of the Phase III evaluation study is to better describe program operations and cost in relation to the expected benefits. Information collected from the SF-36 will be used to map with the SF-6D for quality-adjusted life year (QALY) estimation in the cost-benefit and cost effectiveness analyses. Content analyses will be conducted of the in-depth interviews with the staff from the eight wellness programs that partner with the evaluation contractor and participate in the evaluation. Interviews with wellness program staff, using an unstructured discussion guide, will focus on the following topics:

- Overview and background of the wellness program
- Program features, including the key goals and components of the program
- Program outreach efforts and participant enrollment procedures
- Program implementation, including the timeline and processes
- Program staffing, including training of instructors
- Program outcomes that are tracked
- Program fixed and variable operational costs, including staff salaries, equipment, licensing or franchise fees, marketing and outreach materials, facility/rental costs and other administrative

costs

- Challenges and barriers to implementation, including lessons learned and best practices
- Sustainability and growth strategies

Detailed summaries of each program will be prepared and analyzed for common themes and synthesized across all programs by topic area. Where appropriate, analyses will also stratify common themes by focus of the six ACA intervention areas (i.e., chronic disease self-management, physical activity, obesity, diet and nutrition, falls reduction, and mental health management). In addition, operational and administrative costs obtained from secondary program data and clarified during the in-depth interviews will be used to estimate a per-beneficiary cost for the program. The project team will work with each program to ensure that the cost information is comparable across programs, both in terms of definition and timeframe for use in calculating per-beneficiary operational costs.

17. Exemption for Display of Expiration Date

CMS does not seek this exemption; the OMB expiration date will be displayed on the mail surveys and letters to beneficiaries.

List of Attachments

- Part A, Attachment 1 – Legal Authority for Data Collection, Affordable Care Act, Section 4202(b)
- Part A, Attachment 2 – National Surveys of Medicare Beneficiaries
- Part A, Attachment 3 – Wellness Program Participant Surveys
- Part A, Attachment 4 – In-Depth Interview Discussion Guide with Wellness Program Staff
- Part A, Attachment 5 – Crosswalk Between Data Collection Instruments from 60-day to 30-day Notice