# The Effect of Reducing Falls on Acute and Long-Term Care Expenses

Report to OMB:

Paperwork Reduction Act Extension Submission

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# Supporting Statement for "The Effect of Reducing Falls on Acute and Long-Term Care Expenses"

## A. Justification

### 1. Circumstances Making the Collection of Information Necessary

The Office of Assistant Secretary Program and Evaluation (ASPE) is requesting from the Office of Management and Budget an approval on a previously approved collection - 0990-0308 - The Effect of Reducing Falls on Act and Long-Term Care Expenses project. The purpose of this submission is to continue the study which will allow ASPE to determine whether the proposed fall prevention model is effective at reducing falls in a long-term care population. A number of circumstances have necessitated the extension of this project beyond the timeline initially proposed, including changes in government funding of the project that necessitated a phased approach and the addition of sample in order to ensure sufficient sample size. As a result, the study is projected to last into 2014. ASPE has the authority to collect this data through legal code in Section 301 of the Public Health Service Act (42.U.S. C 241).

### 2. Purpose and Use of Information Collection

The information collected here will assist policy-related activities designed to support cost-effective fall prevention activities and reduce both the financial and system delivery burden caused by the problem of falls in older Americans. We believe we have designed an intervention and data collection method that will accurately and effectively address the outstanding questions and gaps in existing fall prevention work that will enable policymakers to make informed decisions when considering the issue of falls. The goal of the "Effect of

Reducing Falls on Acute and Long-Term Care Expenses" project is to contribute to the knowledge base regarding fall prevention strategies that are cost effective, and to operationalize, implement and evaluate a comprehensive fall prevention program. This will be accomplished by obtaining a sample of individuals with private long-term care insurance who are age 75 and over and deploying an innovative fall prevention program; as well, we will employ a multi-tiered random experimental research design to evaluate the effectiveness of the proposed fall prevention intervention program.

Falls constitute one of the most significant and common causes of injury and disability for the elderly. It has been estimated that one in every three people age 65 and older living in the community fall in any given year and that the rate increases to one in two by age 80.[1] Fall-related injuries in older adults—fractures, joint dislocations and severe head injuries—affect mobility, independence and can even result in premature death.

Expenditures on health care in the United States are rising rapidly and in 2002, reached $1.6 trillion or $5,440 per person; spending rose 8.5 percent in 2001 and 9.3 percent in 2002, contributing to a spike of 1.6 percentage points in the health share of gross domestic product (GDP) since 2000.[2] Much of the increase in spending is fueled by growth in the use of hospital care but there is also significant use of long-term care services such as nursing home and home health care. While accounting for roughly 12 percent of the U.S. population, elders account for more than 30 percent of all health care costs. Therefore, when thinking about strategies to reduce health care costs through preventive care programs, a focus on elderly populations is particularly warranted.

Thus, fall prevention is crucial if we are to be successful in reducing one of the leading causes of excess morbidity and premature mortality in older adults and in avoiding the concomitant high costs. The major risk factors for falling are diverse, and many of them—such as balance impairment, muscle weakness, polypharmacy, and environmental hazards—are potentially modifiable. The interventions that are designed to address these various risk factors are diverse as well. However, the evidence for the effectiveness of an intervention in preventing falls has been inadequate. Even when interventions take into account the multi-factorial nature of fall risk, the results have been mixed, leading to uncertainty about which interventions are most effective for specific populations.

**3. Use of Improved Information Technology and Burden Reduction**

In order to reduce burden, the primary mode of data collection for this study is telephone interviews. All participants will receive an initial telephone screen. Only experimental group participants will be interviewed in their homes as part of the intervention and at the conclusion of the study period, necessitated by the need for data on the falls risks in the participants' home. Follow-up telephone interviews will be used to collect information recorded by individuals on their exercise regimen and fall experience during the quarter; from the administrative system of the participating Long-term care insurance company; and from the Centers for Medicare and Medicaid Services. For a number of reasons, these interviews, as well as the follow-up phone interviews, should not prove to be burdensome to respondents.

First, the individual interviewers are part of the Family Caring Network[3] and are all highly trained and experienced nurses and social workers with a minimum of two years of experience in geriatric assessment. All have previous experience in assessing the functional (e.g.

Activities of Daily Living (ADLS) and Instrumental Activities of Daily Living (IADLS)) and cognitive (e.g. TICS cognitive screen)) status of disabled elders. Many have also had experience administering survey instruments in previous national studies sponsored by ASPE and approved by OMB. They will receive training in the use of new elements of the survey instruments that they have not yet seen. Most of the questions used in the interviews are very straightforward and easy to answer and are standard to the geriatric assessment field.

Second, many of the questions have already been tested and have been used in the assessment process of about 1,500,000 elders applying for long-term care insurance or making claims on their policies. Therefore, the interviewers have substantial experience collecting information on medical, functional and cognitive abilities similar to that which they will be collecting in this study. Finally, in cases where a respondent cannot answer questions due to cognitive impairment, interviewers have been trained to identify and work with proxy respondents. This has worked well in the past (in insurance assessments and other ASPE sponsored studies) and should help to assure the collection of accurate and reliable information.

Third, the telephonic interviews will be conducted using a Computer Assisted Telephone Interview (CATI) system, which allows the interviewer to move quickly through questions and reduce the amount of time spent on the phone. The interview questionnaire is programmed into a computer in such a way that the questions being viewed by the interviewer are generated based on a respondent's previous answers. This will serve to reduce the burden on the respondent and increase the accuracy and efficiency of the interviewer each time a quarterly follow-up is conducted.

In addition to the initial phone interview and in-person interviews, follow-up phone interviews will be conducted on a quarterly basis as part of the evaluation of the demonstration. These quarterly calls are designed to obtain information on compliance with the exercise program and track falls and changes in health status. Individuals who have had extensive training in administering telephone interviews will conduct these phone interviews. They will also have had significant experience in interviewing elders. These interviews will also be conducted using a Computer Assisted Telephone Interview (CATI) system. We expect the quarterly follow-up phone calls to take between 10 to 15 minutes to complete. Each contact with participants is designed to be brief, yet effective and we believe it does not cause undue burden. We are not aware of any legal or technical obstacles to reducing burden for the proposed study.

**4. Efforts to Identify Duplication and Use of Similar Information**

To date, no other Federal agency, private consulting firm, or trade association has conducted a study or data collection effort comparable to what is proposed in this study. No program with a longitudinal study and data collection approach based on a sample of individuals age 75 and over who have had long-term care insurance policies for more than five years and therefore more closely resemble a general population in terms of health status and fall risk -- exists. The project's Technical Advisory Group is comprised of policymakers, practitioners, academics, and generally recognized national experts on falls prevention. These individuals have all verified that the proposed study does not duplicate other studies or efforts of which they are aware. We conducted an extensive review of fall related literature and currently operating

fall prevention programs around the country and every effort has been made to avoid unnecessary duplication and to ensure that the research team is abreast of any related studies on falls prevention and efforts to measure the cost-effectiveness of approaches.

**5. Impact on Small Businesses or Other Small Entities**

Not Applicable- No small businesses or other small entities will be contacted as part of this project.

**6. Consequences of Collecting the Information Less Frequently**

Under the current protocol, participants are contacted quarterly by telephone to determine if there has been any change in their health status, medication use or hospital use, and to record any falls they may have had and the circumstances surrounding them. Additionally, researchers collect information on any fall prevention activities they have been involved in and their compliance with the recommended action plan that they received as part of the fall prevention program.

Collecting this information less frequently would have a negative impact on the accuracy of the reports provided by the participants, and make impede the validation of their self-reported falls, changes health status, medication use or hospital use. In addition, among respondents in this age group (age 75 and older), significant life changes such as hospitalization, nursing home placement, and death occur relatively frequently. It is necessary to contact participants at this frequency in order to accurately follow these changes.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

The request for the extension of this project fully complies with the regulation.

**8. Comments in Response to the Federal Register Notice/Outside Consultation**

The 60-day Federal Register Notice was published on Thursday, December 27, 2012 (Register Volume 77, Number 248). No questions or comments were received.

There are a number of individuals outside of ASPE and their contractor (Center for Health and Long-Term Care Research) that have been consulted on the design of the study, as well as on the development of all of the survey instruments and clinical protocols. The most prominent include members of the Technical Advisory Group and individuals involved in implementing exemplary Fall Prevention Programs around the United States. Members of the TAG include:

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|---|---|---|
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| **3** | Laurence Rubenstein, MD<br>Director, Geriatric Research<br><br>Education and Clinical Center | Sepulveda VA Medical Center<br>16111 Plumber Street<br>Sepulveda, CA 91343<br>Attn: GRECC<br>Mail Code 11E<br>Laurence.rubenstein@med.va.gov<br>1-818-895-9311 x9066 |
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| **9** | Pauline Lapin, MHS<br>Director, Healthy Aging Project | DHHS/CMS/OA/CBC/QMHAG/DHPDP<br>South<br>S3-02-01<br>Baltimore, MD<br>PLapin@cms.hhs.gov<br>410-786-6883 |
| **10** | Susan Coronel<br>Long Term Care Director | America's Health Insurance Plans (AHIP)<br>601 Pennsylvania Avenue, NW<br>South Building<br>Suite 500<br>Washington, DC 20004<br>(202) 778-3202<br>Scoronel@HIAA.org |
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In July of 2004 we held a two-day meeting in Washington, D.C. with the TAG to review the findings of the comprehensive review of the literature and our recommendations for the key elements of an effective falls prevention program. At that time, we also discussed the evaluation strategy. Along with additional telephone consultations, these interactions addressed study objectives and design, research hypotheses, methods for sample recruitment and retention, and sources and methods of data collection. As a result of these meetings, the broad parameters of the prevention and evaluation strategy were delineated and agreed to by the Technical Advisory Group.

In July 2005, after the project team had developed a detailed work plan laying out how the program was to be operationalized and implemented, the TAG met again for a two-day meeting. At this time, clinical protocols were reviewed as well as all of the assessment instruments, communication documents to participants and their physicians, and the implementation plan and strategy. Based on the input of the TAG, we made additional revisions to the project plan and instruments and shortly thereafter conducted a pretest. We also utilized whenever possible survey questions that had been used in other national studies and had been verified for validity and reliability.

**9. Explanation of any Payment/Gift to Respondents**

Participants will receive a quarterly newsletter that serves as an incentive/reminder of the program and that is mailed to Active Control and Experimental Group participants two weeks before every quarterly follow-up call. Respondents will receive financial incentives for continued participation in the study after the 2nd, 4th, 6th and final (8th) follow-up interviews in the amounts of $10, $10, $10 and $20 respectively. The annualized incentive is therefore approximately $25.

**10. Assurance of Confidentiality Provided to Respondents**

All data will be collected in compliance with HIPAA regulations and will be kept private to the extent allowed by law. A signed consent to participate in the study will be obtained from each participant, as well as signed authorizations in order to collect medical information, claims information and Medicare data. All participants will be randomly assigned a unique identifier so that when data is coded and analyzed it can be stripped of identifying information. All data file transfers will be encrypted and paper data will be kept in locked file cabinets until it is scanned and entered into a database. At this point, the originals will be shredded.

**11. Justification for Sensitive Questions**

There may be certain questions that may be viewed as sensitive by respondents, particularly those related to cognitive ability, and certain activities of daily living. It is important to note that at the beginning of each assessment (both telephonic and in-person), the assessor gives a brief introduction to put the individual at ease and let them know that the interview focuses on general health history. In other parts of the questionnaire the nature of the

question is explained, as is the purpose for obtaining the information. For example, the introduction to the telephonic assessment reads as follows:

> "Hi, my name is _____ and I am calling on behalf of *(Name of Insurance Company)*, your long-term care insurance company. A few weeks ago, you agreed to participate in a national study about falls prevention that your LTC insurance company is participating in. First, we want to thank you for your willingness to contribute to helping us understand such an important issue. As part of the study, we need to ask you some questions related to your general health history. It will take about 20 minutes. Do you have time to do that now or would you like to schedule a time that is more convenient for you?"

Regarding cognitive ability, all participants will be asked to answer questions from the TICS, a widely used telephonic geriatric assessment test that has been shown to be an accurate and reliable measure of current cognitive ability. It asks questions about orientation and memory, as well as tests certain computational abilities. In some cases the answers seem so obvious that an individual may wonder why they are being asked to answer them. The interviewers, who have been trained to administer the test, preface it with the following statement:

> "For this next exercise I am gong to ask you some questions to test your memory. Some of these are likely to be easy for you, but some may be difficult. Please bear with me and try to answer all the questions as best you can. If you can't answer a question don't worry, just try your best. If there is a television, radio on, please turn it off so that you are not distracted for this part of the interview."

Our experience with insurance assessments suggests that respondents do answer these questions and that the test does not encumber completion of the entire survey.

Another sensitive area of the surveys may be the assessment questions related to certain functional abilities like toileting and continence. Again, these are standard questions derived from the Katz Activities of Daily Living (ADL) scale and have been used by geriatricians for

over 30 years, as well as in all national studies of functional status among the elderly. The information is necessary to characterize the elderly person and every effort is made to assure that the respondent is not made uncomfortable by the question. For example, this can include a conscious choice by the interviewer not to use the word "continence" but instead to speak to the level of understanding of the respondent her/himself.

Finally, the issue of falls can in and of itself be sensitive. Many people might feel a sense of embarrassment if they have experienced a fall. Therefore, the question is asked in a way that minimizes this. It has been used in other national surveys and reads as follows: "How many times in the past 6 months have you had an episode of fainting, falling or dropping to the ground or lost your balance, slipped or tripped over something that resulted in falling or dropping to the ground?"

Information from these and other questions will be used to characterize study participants over time and determine whether and how the intervention influences the incidence of falls among the control and experimental groups.

**12. Estimates of Annualized Hour and Cost Burden**

Based on the pre-test, we expect that the administration of the telephonic risk assessment will take about 15 to 20 minutes to complete. The pre-test of the in-person interview suggests

[1] Campbell, AJ et al. Examination by logistic regression modeling of the variables which increase the relative risk of elderly women falling compared to elderly men. Journal of Clinical Epidemiology. 1990. 43. 1415-1420.
[2] Levit, K, Smith, C, Cowan, C. Sensenig, A., and Catlin, A. Health Spending Rebound Continues in 2002. Health Affairs, Volume 23, Issue 1, 147-159, (2004).
[3] The Family Caring Network is a national network of nurses and care managers that conducts in-person assessments with elders who are applying for long-term care insurance or are applying for benefits under their long-term care insurance policies. In its 15th year of operation, the network of locally contracted individuals has provided services to more than 1,500,000 individuals, conducted a previous study for the federal government, and works with more than 45 insurance companies.

that it takes between 1.0 to 1.25 hours to complete. We estimate that the phone call necessary to "jump-start" the Action Plan will take roughly 30 minutes to complete.

There will be quarterly telephone calls that are not part of the intervention, but associated with the evaluation of the intervention. We estimate that these phone calls will vary in length from 5 minutes (for those with no falls, exercise or changes in their medical history) to 15 minutes for those who may have fallen or have medical changes to report. Given this potential variation, we estimate an average of 10 minutes per phone call for our burden estimate.

Table 4 summarizes the parameters used in making an estimate of total burden. Of the 435 participants in each group enrolled each year, we assume an 80% response rate over the two year collection period and roughly a 4% mortality rate per year. The estimated annual response burden will be approximately 1,861 hours per year.

**12A.** Table 4: Relationship between Survey Instrument and Estimated Total Response Burden for Survey Administration

Estimated Annualized Burden Hours

| Forms (If necessary) | Type of Respondent | Number of Respondents | Number of Responses per Respondent | Average Burden hours per Response | Total Burden Hours |
|---|---|---|---|---|---|
| Initial Telephone Screen | Active Control Group (ACG)/ Experimental Group (EG) | 835 | 1 | 20 minutes | 278 hours |
| In-person interview | EG | 435 | 1 | 1.25 hours | 544 hours |
| Jump start phone call | EG | 435 | 1 | 30 minutes | 218 hours |
| Quarterly phone calls | ACG/EG | 835 | 4 | 10 minutes | 556 hours |
| Final Telephone Screen | ACG/EG | 167 | 1 | 20 minutes | 56 hours |
| Final In-person interview | EG | 167 | 1 | 1.25 hours | 209 hours |

| | | | | | |
|---|---|---|---|---|---|
| Total | | | | | 1861 hours |

We anticipate that the cost to the interviewees will be minimal. The participants in the experimental group will spend approximately 4.5 hours participating in the study. The active control group will spend approximately 1.25 participating in the study. Few of these individuals will be employed (as they are over age 75) so we do not expect meaningful lost earnings. Based on the 2008 labor force participation rate of adults aged 75 and older (7.3%; http://www.bls.gov/emp/ep_table_303.pdf), we expect approximately 32 participants of the 435 in each group to be employed. The Estimated Annualized Burden Costs table below reflects the 144 total burden hours for 26 participants (32 participants x 4.5 hours = 144 total burden hours) in the experimental group who are expected to be employed and the 40 total burden hours for the 26 participants (32 participants x 1.25 hours= 40 total burden hours) in the active control group who are expected to be employed. The average hourly wage for an employee aged 65 or older is approximately $16 (http://www.bls.gov/cps/cpswom2008.pdf). We were unable to identify average hourly wages for the 75+ population.

Estimated Annualized Burden Costs

| **Type of Respondent** | **Total Burden Hours** | **Hourly Wage Rate** | **Total Respondent Costs** |
|---|---|---|---|
| Experimental Group | 144[a] | $16 | $2304.00 |
| Active Control Group | 40[b] | $16 | $640.00 |
| | | | $2944.00 |

a Reflects the annualized burden hours (270/60) for 32 participants.
b Reflects the annualized burden hours (80/60) for 32 participants.

**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

Not applicable to this study.

**14. Annualized Cost to Federal Government**

The costs of the project can be classified as those related to the program implementation (demonstration project), and those related to the evaluation. The total costs of the demonstration are estimated at $4,391,000 over a six year contract period. Thus, the annual costs are $732,000, although these costs will likely not be divided equally among the six years. This includes the costs associated with coordinating sample recruitment; operationalizing and computerizing all of the clinical protocols; implementing the intervention in all its phases (including assessment, action plan development and coordination and final assessment), preparing all data for the evaluation phase of the project, analysis, report writing, and public and private briefings.

The evaluation related phase of the project is expected to cost $500,000. This includes activities related to data collection, data cleaning, development of all analytic files, analysis plan, quantitative analysis, report-writing, and public and private briefings.

**15. Explanation for Program Changes or Adjustments**

The length of the project was adjusted from the original estimate because the sample size has been expanded. The sample size was expanded to ensure there was sufficient statistical power to detect impacts of the program. In order to expand the sample size, more time is needed to recruit and enroll participants in the project.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Table 5 provides an updated timeline for the implementation and evaluation of the fall prevention program. As shown, we now anticipate that the project will be completed by December 2014, given that it had to be carried out in a phased approach and additional sample was added. The key project tasks include (1) sample recruitment; (2) initial telephone interview and randomization into control and experimental groups; (3) in-person baseline assessments; (4) deployment of the prevention protocols and intervention strategy; (5) quarterly follow-ups; (6) final interviews; (7) completion of evaluation and final report on outcomes of demonstration. We anticipate that the major operational development work necessary to support the implementation (CATI programming, systems development, assessor training, etc.) will commence after receipt of OMB clearance and procurement of funding. We expect that we will be able to do all of the administrative development in about 5 months, at which time, we will begin sample recruitment.

For individuals in the experimental group, baseline interviews will commence shortly after the telephonic-assessment has been completed. We anticipate that all in-person interviews will be completed roughly 7 months after the completion of telephonic assessments. Individuals will be monitored quarterly for just under two years after their in-person assessment. Thus, we expect to complete all data collection, deployment of Action Plans, and monitoring by January 2010.

As information is returned, it will be entered into a database for use by the evaluation team. Analysis will begin immediately once the initial assessment data is collected. Every quarter additional data will be appended to each case so that we can track changes in health and

functional status, falls history, risk factors, and compliance with the Action Plan over time. We anticipate interim reports after the baseline interview has been completed and after one full year of follow-up interviews has been completed. The final report and briefings to policymakers and insurers will occur by August 2010.

Table 5: Projected Implementation and Evaluation Timeline and Project Milestones

| **Task** | **Originally Estimated Time Frame** | **Phase 1** | **Phase 2** | **Phase 3** | **Phase 4** | **Phase 5** |
|---|---|---|---|---|---|---|
| Sample recruitment | January 2007-March 2007 | June 2008-September 2008 | April 2009-September 2009 | September 2009-December 2009 | June 2010-September 2010 | August 2012-February 2013 |
| Initial telephone interview and randomization into control and experimental groups | February 2007-June 2007 | July 2008-February 2009 | April 2009-August 2009 | September 2009-December 2009 | June 2010-December 2010 | August 2012-March 2013 |
| In-person baseline assessments | June 2007-January 2008 | September 2008-March 2009 | April 2009-September 2009 | September 2009-February 2010 | July 2010-January 2011 | September 2012-March 2013 |
| Deployment of the prevention protocols and intervention strategy | June 2007-February 2008 | November 2008-March 2009 | May 2009-October 2009 | October 2009-March 2010 | August 2010-February 2011 | October 2012- April 2013 |
| Quarterly follow-ups | September 2007-October 2009 | January 2009-January 2011 | August 2009-October – July 2011 | January 2010-December 2011 | November 2010-November-2012 | December 2012-January 2014 |
| Final interviews | June 2009-January 2010 | September 2010-April 2011 | May 2011-October 2011 | October 2011-March 2012 | July 2012-December 2012 | January 2014-May 2014 |
| Completion of evaluation and final report on outcomes of demonstration. | (preliminary report) June 2010 | X | X | X | January 2013-June 2013 | X |
| Briefings to | (preliminary | X | X | X | July 2013 | X |

| | | | | | | |
|---|---|---|---|---|---|---|
| policymakers and participating insurers | report) August 2010 | | | | | |

Below we present more detail on the data analysis techniques employed by the evaluation team. As mentioned, we will employ a rigorous evaluation of the falls prevention intervention that focuses on these study questions:

- ***How did the intervention affect the risk of falling?*** The initial and final telephone surveys include information on a number of factors that have been identified in the literature as contributing to the risk of falling, including medications (new medications, discontinued medications, medication dosage), general home safety, safety-related home modifications, medications (number of medications, use of medications for anxiety, depression, stress, memory loss), and physical activity. It is clear that the nature of falling is multifactorial – that is, there is not typically a single "cause" of falls, but rather, a combination of multiple risk factors that put an elder at risk for falling. If the intervention is effective, we should see a decrease in the number of intervention group members at high-risk of falling relative to the baseline assessment and to the administrative control group.
- ***How did the intervention affect the incidence of falls?*** There are two potential sources of information on falls:
    - *Quarterly follow-up reports:* Information on falls will be collected from the intervention group and the ACG through the quarterly follow-up reports. The available data includes whether a fall occurred; for those with a fall, we also plan to

collect information on the location and time of the fall, whether it resulted in injury, and whether medical attention was required.

- *Medicare claims data:* We can use information on the primary and secondary diagnoses to identify potential fall-related encounters. Examples of potential fall-related diagnoses include fractures, head injuries, sprains, abrasions, concussions, and records in which "fall" was listed as a diagnosis. Because there are often multiple encounters associated with a given fall, we can measure whether there was a fall-related record in a given period, but not the number of falls that occurred. We can also examine the broader category of "accident and injury" outcomes that could capture spillover effects of the intervention on the incidence of injuries

If the intervention is effective, then we should see a lower incidence of falls for those in the intervention group.

- ***How did the intervention affect use of physicians and other health professionals?*** Since a core component of the intervention is risk assessment, we expect to see more ambulatory visits for screening and follow-up from treatment group members with risks that are identified as part of the in-home assessment. Medicare claims data will be used for this analysis.
- ***How did the intervention affect hospitalizations and emergency department admissions?*** If the intervention is effective in reducing falls, then this should contribute to less overall utilization, although the exercise program that is part of the intervention may lead to some non-fall, exercise-related encounters. Medicare claims data will be used for this analysis.

- ***How did the intervention affect medication use? How did it affect use of psychotropic medications?*** If the medication review component of the intervention is effective, then physicians for some treatment group members at risk will prescribe fewer medications and fewer psychotropic medications[4]. Note that, since no claims data are available for medications, our only data source for these outcomes are the patient telephone interviews. As a result, we expect there to be significant limitations associated with self-reported medication information.
- ***How did the intervention affect nursing home admissions?*** Falls are a major source of nursing home admissions. If the intervention leads to a reduction in falls, then those in the intervention group should have fewer admissions for post-acute skilled nursing rehabilitation or for long-term placement due to fall-related injuries. Data from long-term care insurers will be used for this analysis, given that Medicare claims data would capture only a small portion of overall nursing home utilization.
- ***How did the intervention affect total (acute and long-term care) costs?*** The question of cost effectiveness is a key one for the evaluation. We can measure costs using a combination of Medicare claims and long-term care insurer data. If the intervention achieves its goals, then reduced spending on "big ticket" items like hospital and nursing home admissions should outweigh increased spending for screening and prevention. Note that we expect that we will be somewhat limited in our ability to measure subject's out-of-pocket costs.

[4] Psychotropic medications, used to treat neurological, psychological and emotional illness, are medications are medications that affect the mind or mood or mental processes. These medications may contribute to falls (either alone or in combination with other medications) by causing dizziness, unsteadiness, or perception issues. A number of previous studies have found a relationship between falling and the use of psychotropic medications.

- ***How did the intervention affect rates of change in functional and cognitive status?*** Persons less likely to fall should also experience slower rates of physical and cognitive decline. We can measure the change in functional and cognitive status using the screening items on the baseline and follow-up survey.
- ***How did the intervention affect subject's fear of falling?*** Raising consciousness could have the unintended consequence of making some treatment group members more fearful and apprehensive. However, if the intervention is to be successful, persons in the treatment group will have to have gained an increased sense of self-efficacy in falls prevention to accompany their increased awareness. Our telephone surveys include information on whether subjects avoid certain activities because of a fear of falling.
- ***How did the intervention affect caregiver burden?*** For elderly persons living on their own, fewer falls should mean less need for both formal and family support. We expect to find lower average weekly hours required of informal caregivers, and less likelihood of caregivers quitting their paying jobs.

Properly implemented, random assignment of persons who are willing to join the study assures that the comparison group does not differ from the treatment group in any systematic way other than having access to the intervention. Thus, any subsequent differences in outcomes between the two groups that exceed the bounds of sampling error can confidently be attributed to the intervention. We estimate the effects of the intervention simply by comparing averages of the outcome measures between the treatment and comparison groups. With any non-random comparison group, there is always a chance that differences in outcomes are the result of pre-existing differences between the two groups, rather than the intervention itself, so we plan to use

multivariate models that adjust for differences between the intervention and comparison groups that were present at baseline.

***Statistical Models***

We plan to evaluate impacts based on the change relative to baseline and by comparing outcomes for intervention and comparison group members. Multivariate regression models will be used to evaluate differences between intervention and comparison group members adjusting for baseline medical conditions, medications and falls. Covariates in these models will likely include age, gender, race, measures of baseline health status/utilization, and other relevant measures. We propose to utilize available pre-intervention information that we have on both experimental and control groups to adjust effects estimates in a multivariate context using an equation such as:

$$y = \beta x + \theta d + \varepsilon$$

where y is an outcome measure, x stands for all the potential covariates we can measure and $\beta$ measures the effect of the x's on the y's, d is a categorical measure of study status (= 1 for intervention group, 0 for comparison group), $\varepsilon$ is a measure of error; $\theta$ is a measure of the intervention's effect on y, adjusted for all the x characteristics.

***Analyses Using the Silent Comparison Group***

We will sample an external "silent control group" (SCG) of Medicare beneficiaries, matched to study subjects on age, gender, eligibility status and area of residence. We will compare these silent controls to controls in the study sample on utilization and expenditure outcomes for which comparable data exist (from Medicare administrative eligibility and claims

data). The main purpose of these analyses will be to assess how our study population of long-term care insurance holders compares to the general Medicare population.

***Internal Validity***

If those in the comparison group stop participating in the study at a higher rate than those in the intervention group, then this selective, non-random attrition may threaten the intervention design. Attrition may also be higher among subjects with certain characteristics (for example, older individuals). We will compare persons who stop cooperating with the data collection effort between the groups, to suggest ways in which attrition might bias our estimates.

Additionally, there could be a "halo effect" of data collection on behavior of the ACG. Even though comparison group members will not receive the intervention, ACG participation in the study through responding to requests for data could heighten awareness and generate behavior changes in that group similar to those hypothesized for the treatment group. As described earlier, we will assess the extent of this threat by sampling an administrative comparison group (ADCG) from long term care insurance policy holders who 1) meet the general inclusion criteria for the study but who were not sampled for randomization and 2) who resemble the study sample in all measurable characteristics. If geographic strata are selected for the study sample, we will use these strata to sample the SCG. Only administrative data (long term care insurance claims and Medicare claims) will be collected for the ADCG.

***Reporting bias***

Several key outcome measures, including self-reported incidence of falls and information on medications, rely on self-reported information, there will inevitably be some error due to poor memory or inconsistencies in how subjects count what should count as a fall or an active

medication. There also may be bias in reporting (over-or under-reporting the actual falls subjects experience) that will be associated with being an intervention or comparison group member, but we cannot predict the direction of bias. For example, the sense of external scrutiny and heightened awareness that treatment subjects may feel could lead to more scrupulous reporting of falls (compared to the controls), or it could lead subjects to under-report falls in an effort to show that the intervention worked for them. We cannot audit subjects' falls histories, but we can use claims data to compare variations among in health services utilization associated with injury to variations in reported falls incidence.

***Statistical Power Analyses***

Our goal is to have a final sample of at least 2,440 individuals in the intervention and active comparison groups. If we achieve an 80 percent response rate to follow-up survey, we should have survey data for approximately 1950 individuals in both the intervention group and the ACG. We use baseline estimates from a recently completed study[5] that examined the impact of an intervention intended to reduce falls and inappropriate medication use in an elderly population at risk of falls because of their medication use. The findings from this study give a general indication as to the distribution of some of the key outcome measures that we will examine for this study.

We assessed the statistical power of the sample by examining the minimum detectable difference between the intervention and comparison groups that has an 80 percent chance of being statistically significant, using a one-tailed hypothesis test at the 10 percent level and given

[5] White A, Weber V. Utilizing the Electronic Medical Record and Case Management to Improve Patient Safety in the Rural Elderly, Final Report. Completed for the Agency for Healthcare Research and Quality, October 2004.

assumptions about the population distribution of outcome measures. In the study referenced above, 14 percent of respondents reported one or more falls during a six-month period; this rate is probably lower than what would be experienced given the population targeted by the current study – individuals age 75 and over. Even with this somewhat lower incidence rate, we can be reasonably confident of our ability to detect an impact on self-reported falls of 20 percent or more but less confident in our ability to measure smaller effects (at this level of incidence). For example, if the intervention reduces the proportion reporting a fall from 18 to 14.4 percent (a 20 percent reduction), assuming a 28% annual incidence rate, the sample is sufficient so that we have an 80 percent chance of detecting a statistically significant difference (at the 10 percent level) between the two groups. Unless the incidence rate for falls is indeed higher, say in the range of 35%, it is less likely that we will be able to measure whether the intervention has had smaller differential impacts on falls for population subgroups, for example, based on age or gender. For example, assuming that 63 percent of the sample are female, at a 28% incidence rate, the intervention would need to be associated with a 25 percent difference in fall rates between male and female intervention group members in order for us to detect it with the power and statistical significance calculations above.

Combining the ACG and ADCG to analyze nursing home utilization, we have adequate statistical power to detect intervention impacts of around 20 percent (assuming a baseline nursing home utilization rate of around 15 percent).

In 2011 we expanded the sample size to improve statistical power to detect significant differences in medical costs. Because there is often a large variance and skewed distribution of medical costs, it may be more difficult to detect small impacts of the intervention on costs. In

2007, the average healthcare cost was $6,937 with a standard deviation of $13,055 (http://www.meps.ahrq.gov/mepsweb/data_stats/MEPSnetHC.jsp). If these estimates are accurate, we would need at least 1,096 people in each group to have 0.80 power to detect a 20% reduction in costs (one-sided test). But if the reduction in healthcare costs is more modest (e.g., 15%), a sample of 1,200 is underpowered (power= 0.62). As a result, we increased the sample size in order to ensure we had at least 1,975 participants in each group to ensure 0.80 power to detect a difference of 15% in expenditures.

It is important to note that these power estimates are likely conservative since the analytic approach will not be limited to bi-variate comparisons but will also include multivariate regression models, which will enhance statistical power by eliminating variation that is attributable to potentially confounding covariates. Moreover, we anticipate a somewhat higher incidence rate for falls given the population targeted for the study; as mentioned, national data suggests that one-in-three individuals age 65 and over fall at least once a year, and we are sampling older adults 75 years and older.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**
Does Not Apply

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**18. Exceptions to Certification for Paperwork Reduction Act Submissions**
There are no exceptions to the certification.

**B. See attached**