

Supporting Statement for Evaluation and Development of Outcome Measures for Quality Assessment in Medicare Advantage and Special Needs Plans

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I. SUPPORTING STATEMENT OUTCOME MEASURES FOR QUALITY ASSESSMENT IN MEDICARE ADVANTAGE AND SPECIAL NEEDS PLANS

Supporting Statement--Part A

Supporting Statement for Paperwork Reduction Act Submissions

A. Background

The Centers for Medicare & Medicaid Services (CMS) request a one year clearance from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 for evaluation and development of outcome measures for quality assessment in Medicare Advantage and Special Needs Plans.

Quality improvement is a major initiative for the Centers for Medicare and Medicaid Services (CMS). With the passing of the Patient Protection and Affordable Care Act in March 2010, there is a focused interest in providing quality and value-based healthcare for Medicare beneficiaries. In addition, it is critical to develop criteria not only for quality improvement but also as a means for beneficiaries to compare healthcare plans to make the choice that is right for them.

It is critical to the CMS mission to expand its quality improvement efforts from collection of structure and process measures to include outcome measures. However, the development of outcome measures appropriate for the programs serving older and/or disabled patients has been somewhat limited. The development and subsequent implementation of outcome measures as part of the overall quality improvement program for CMS is crucial to ensuring that beneficiaries obtain high quality healthcare. In addition, process of care measures are needed that focus on the care needs of Medicare beneficiaries, such as factors affecting continuity of care and transitions.

This request is for data collection to test the use of new tools available to CMS to measure care pertinent to vulnerable beneficiaries where quality of care provided by Medicare Advantage Organizations (MAOs) should be closely monitored. The measures to be evaluated and developed upon approval of this request relate to (1) continuity of information and care from hospital discharge to the outpatient setting, (2) continuity between mental health provider and primary care provider (PCP), and (3) items that may be added to the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey addressing language-centered care, cultural competence, physical activity, healthy eating, and caregiver strain. Background regarding each group of measures is provided below.

(1) Continuity of information and care from hospital discharge to the outpatient setting: The importance of care transitions between clinical care venues, particularly between the hospital and outpatient setting, has rapidly gained recognition as a key element of quality of care. Inadequate care transitions can be a source of medical errors that can compromise beneficiaries' health. In previous work, CMS and the RAND Corporation collaborated with a MAO to develop and test a medical record abstraction tool to measure the quality of the care transition from hospital discharge to the outpatient setting. In this

pilot work, medical record data were collected on nine Medicare beneficiaries. The medical record abstraction form checked for transfer of key patient information -- such as medication changes, laboratory tests, and follow-up appointments -- from the inpatient to outpatient setting. The medical record abstraction process functioned well, however it was streamlined in response to the pilot testing and it now requires further testing in a larger sample of records to ensure that the data collection for the transition in care set of measures is robust enough for routine use. For this reason we are including these measures in the PRA package. If the medical record abstraction process remains feasible after testing in a larger sample and by multiple MAOs, CMS may choose to incorporate the medical record abstraction into a routine quality measurement approach such as the Medicare Healthcare Effectiveness Data and Information Set (HEDIS) data collection process, or another mechanism in order to measure care that can reduce the need for hospital readmission. The care transition measures may be particularly appropriate for Special Needs Plans (SNPs).

(2) Continuity between mental health provider and PCP:

Previous work has shown considerable unmet need in mental health care, particularly in the integration of mental health treatment with the other aspects of medical care provided to the patient. The need to be aware of potential drug-drug interactions and disease-drug interactions, as well as the potential to monitor adherence and condition severity across providers, argues for a close relationship between mental health and primary care. As part of a pilot effort, CMS and the RAND Corporation collaborated with a MAO to develop and test a medical record abstraction tool focused on continuity of information between mental health providers and PCPs in treating newly identified mental health conditions. The abstraction tool was tested on records from four Medicare beneficiaries. The focus of the medical record abstraction was on determining the level of continuity provided between primary care and mental health providers for individuals with mental illness. This pilot work revealed that evaluation of mental health care coordination via medical record abstraction appears to be feasible, but requires further testing in a larger sample. Hence this set of measures is included in the current PRA package for review. If the medical record abstraction process remains feasible after testing in a larger sample and by multiple MAOs, CMS may choose to incorporate the medical record abstraction into a routine quality measurement process such as HEDIS or another data collection process in order to improve mental health outcomes.

(3) Items to be added to the CAHPS survey:

The purpose of the proposed new items to be tested within the CAHPS survey is to determine unmet needs of beneficiaries that are under the purview of MAOs. These new items are specifically designed to measure health plan activities in the areas of language-centered care, cultural competence, provision of materials with regard to physical activity and healthy eating, and caregiver strain. Prior to the current PRA application, nine survey items (new items and existing survey items from the CAHPS Cultural Competence item set) underwent cognitive testing with nine older adults to establish whether items were understood by older adults and/or whether the items needed to be reworded. Cognitive testing demonstrated that several of the survey items would need to be reworded to be understandable to a cohort of frail older adults; in the current PRA package, we propose

these reworded items to be tested more thoroughly as part of the CAHPS survey. In addition, as part of a pilot effort, CMS and the RAND Corporation collaborated with a MAO to implement a set of items to identify caregivers and to assess level of caregiver strain. The survey was administered to nine Medicare beneficiaries. This pilot work revealed great interest in identifying the level of caregiver strain and suggested that a smaller set of items aimed at the beneficiary as caregiver should be tested. These items were developed and are proposed to be tested as part of the CAHPS survey alongside a previously validated set of items in order to evaluate convergent validity. Depending on results of field testing, measures could be incorporated into a CMS CAHPS survey as part of the regular administration of the CAHPS in order to identify unmet need in each of these areas.

B. Justification

1. Need and Legal Basis

MAOs are mandated to collect and report data that permit the measurement of Medicare beneficiary health outcomes and quality indices under section 1852 (e) (3) of the Social Security Act. To comply with the statute, MAOs are required to collect and report data from the Healthcare Effectiveness Data and Information Set (HEDIS), the Health Outcomes Survey (HOS) and the CAHPS.

2. Information Users

The primary purpose of this action is to support CMS in the development of outcome measures to assess healthcare quality for the MAOs including SNPs. Once developed and tested, these measures may be incorporated into the CMS quality improvement program or into reporting requirements.

3. Use of Information Technology

A variety of modes will be used as part of a data collection strategy, all of them employing some form of information technology (IT) to a degree. For all measures, IT will be used to help identify the patient population of interest. For measures related to continuity of information and care from hospital discharge to the outpatient setting and continuity between mental health provider and PCP, medical records will be reviewed, and information collected according to an abstraction form and guide. While the review itself will be conducted by hand, collection instruments are formatted for data entry and data from all abstractions will be entered into an electronic file for analysis. For the items that may be added to the CAHPS, the protocol specifies a mailed survey to respondents with follow-up telephone survey for non-responders.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. Panels of technical experts were consulted to help identify and narrow a list of measures for quality assessment in MAOs and SNPs. This information collection request is to develop novel measures prioritized by these panels. The measures for which information collection is being requested have already undergone limited pilot testing. The purpose of this data collection is to test implementation of these measures for future use by CMS.

5. Small Businesses

This data collection should not impact small businesses or other small entities. None of the health plans involved in the data collection for measures requiring medical record abstraction (continuity of information and care from hospital discharge to outpatient setting and continuity between mental health provider and PCP) will be small businesses. Survey respondents for the additional CAHPS items will be Medicare beneficiaries.

6. Less Frequent Collection

The current data collection is scheduled to occur only once. The consequence of not collecting these data amounts to delay in better understanding of health plan activities related to delivering high quality health care to Medicare beneficiaries, including vulnerable elders, pursuant to CMS' overall quality improvement program.

7. Special Circumstances

While we anticipate that many participants in this data collection will respond within 30 days of our requests, responding in fewer than 30 days is not a requirement. Our timeline allows for the possibility that some participants exceed this timeframe. No other special circumstances apply to this information collection request.

8. Federal Register/Outside Consultation

As described above, panels of technical experts were consulted to help narrow a list of measures for quality assessment in MAOs and SNPs. This information collection request is to implement select measures prioritized by these panels.

9. Payments/Gifts to Respondents

This data collection will not include respondent incentive payments or gifts.

10. Confidentiality

Individuals and organizations contacted are assured of the confidentiality of their replies under 42 U.S.C. 1306, 20 CFR 401 and 422, 5 U.S.C.552 (Freedom of Information Act), 5 U.S.C.552a (Privacy Act of 1974), and OMB Circular No.A-130. In instances where respondent identity is needed, the information collection fully complies with all aspects of the Privacy Act.

11. Sensitive Questions

This collection does not include questions that are sensitive in nature.

12. Burden Estimates (Hours & Wages)

Measures of transitions of care and continuity between mental health provider and PCP require medical record abstraction by Registered Nurses. Exhibit 1 shows the estimated annualized burden to abstract information for each of these two measures. Two Registered Nurses will be required for each measure, and each will abstract 30 patient cases (25 abstractions, 5 re-abstractions) from each of six plans. Based on piloting experience with plans, the transitions of care measure will require one hour per patient case to abstract. The continuity between mental health provider and PCP medical record abstraction will require 30 minutes per patient case. Thus the total burden for Registered Nurses to abstract medical records for these two measures for six plans is 540.0 hours, as indicated in Exhibit 1 below.

Exhibit 1. Estimated annualized burden hours to abstract information from medical records

Medical record abstraction	Number of Abstractors	Number of records per abstractor*	Hours per abstraction	Total Burden hours
Transitions of care	12	30	1.0	360.0
Mental health and PCP continuity	12	30	0.5	180.0
Total	24			540.0

*Includes a 20% re-abstraction rate to assess inter-rater reliability.

Exhibit 2 shows the cost burden for Registered Nurses abstracting information from medical records for the two measures requiring medical record abstraction for up to six plans. We estimate this cost to be \$17,506.80.

Exhibit 2. Estimated annualized cost burden to abstract information from medical records

Medical record abstraction	Total Burden hours	Hourly Wage Rate*	Total Cost Burden
Transitions of care	360.0	\$32.42	\$11,671.20
Mental health and PCP continuity	180.0	\$32.42	\$5,835.60
Total			\$17,506.80

*Based upon the wages for Registered Nurses published in “National Compensation Survey: Occupational Earnings in the United States, 2010, Table 3,” U.S. Department of Labor, Bureau of Labor Statistics.

Exhibit 3 shows the estimated annualized burden for enrollees completing a Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey with additional test items addressing language-centered care, cultural competence, physical activity, healthy eating, and caregiver strain. This survey will be collected from an estimated 100 English-speaking and 100 Spanish-speaking enrollees in each of 10 MAO contracts, for 2000 completed surveys in all. We estimate that it takes 30 minutes to complete the amended CAHPS survey. Thus, the total time that 2000 enrollees spend completing these surveys is 1000 hours.

Exhibit 3. Estimated annualized burden hours to complete amended CAHPS survey

	Number of Respondents	Hours per response	Total Burden hours
Amended CAHPS survey	2000	0.5	1000.0
Total	--	--	1000.0

Exhibit 4 shows the cost burden associated with enrollees responding to the amended CAHPS survey. We estimate this cost to be \$22,770.00.

Exhibit 4. Estimated annualized cost burden to complete amended CAHPS survey

	Number of Respondents	Total Burden hours	Hourly Wage Rate*	Total Cost Burden
Additional CAHPS items	2000	1000.0	\$22.77	\$22,770.00
Total	--	--	--	\$22,770.00

*Based upon the average wages published in “National Compensation Survey: Occupational Earnings in the United States, 2010, Table 3,” U.S. Department of Labor, Bureau of Labor Statistics.

13. Capital Costs

This collection has no capital costs.

14. Cost to the Federal Government

In addition to the burden hours and costs described above, there are additional burden hours and costs associated with this data collection. For the cost estimates provided below, wages are assumed to follow figures published in “National Compensation Survey: Occupational Wages Earnings in the United States, 2010,” Table 3, U.S. Department of Labor, Bureau of Labor Statistics.

- (1) For the medical record abstraction of transitions of care measure, we estimate that a Health Services Manager at each of six plans will require 10 hours to work out confidentiality issues and complete a resource and time survey. A Computer Programmer at each plan will require 15 hours to identify the discharge patient population from administrative data. The Health Services Manager will require 5 additional hours to identify 50 inpatient to outpatient transitions at clinical sites and an Administrative Assistant will require 2 hours to assign patient Study IDs to them. The Administrative Assistant also will need 4 hours per case to acquire medical records (2 hours each for the inpatient and outpatient record, or 200 hours for 50 patient cases), including requesting permission, filing of requests, recording received records and following-up on not-received records. Two Registered Nurses who will carry out the abstraction will require 8 hours each for orientation and training. The Administrative Assistant will require 2 additional hours to reproduce the medical record abstraction form and guide and 10 hours to track the study materials. Thus, we estimate that Health Services Managers, Administrative Assistants, Computer Programmers, and Registered Nurses will spend 15, 214, 15, and 16 hours, respectively, at each of six plans on efforts related to data collection for this measure (in addition to the medical record abstraction). Assuming \$42.28, \$19.60, \$33.65, and \$32.42, respectively, for the above labor categories, the additional cost to collect information for this measure is \$5,852.07 per plan, or \$35,112.42 for six plans. In combination with the cost shown in Exhibit 2, the total cost to prepare for and abstract medical record information for the transitions of care measure is estimated to be \$46,783.62, as indicated in Exhibit 5.
- (2) For the medical record abstraction of mental health professional/PCP continuity, a Health Services Manager at each of six plans will require 10 hours to work out confidentiality issues and to complete a resource and time survey. Administrative data will be used to identify 50 new mental health cases that have both mental health and PCP visits. A Computer Programmer will require 10 hours and a Health Services Manager will require 5 hours to identify these patients. An Administrative Assistant will require 2 hours to assign patient Study IDs to these patients. The Administrative Assistant will also require 4 hours per patient (each patient will have 2 records) to complete the medical record acquisition process, including requesting permission, filing of requests, recording received records and following-up on not-received records. Two Registered Nurses who will carry out the abstraction will require 8 hours each for orientation and training. The Administrative Assistant will require 2 additional hours to reproduce the medical record abstraction form and guide and 10 hours to track the study materials. Thus, we estimate that Health Services Managers, Administrative Assistants, Computer Programmers, and Registered Nurses will spend 15, 214, 10, and 16 hours, respectively, at each of six plans

on additional efforts related to data collection for this measure. Assuming \$42.28, \$19.60, \$33.65, and \$32.42, respectively, for the above labor categories, the additional cost to collect information for this measure is \$5,683.82 per plan, or \$34,102.92 for six plans. In combination with the cost shown in Exhibit 2 for this measure, the total cost to prepare for and abstract medical record information for the transitions of care measure is estimated to be \$39,938.52, as indicated in Exhibit 5.

- (3) There will be no additional costs to the federal government to administer the amended CAHPS survey for this data collection.

The total cost for collecting information for all outcome measures described in this request is \$109,492.14, as shown in Exhibit 5 below.

Exhibit 5. Summary of Burden for this Information Collection Request

Cost Burden Element (Measure)	Burden Hours	Annualized Cost
Transitions of care inpatient to community		
Medical record abstraction	360.0	\$11,671.20
Additional costs	1,560.0	\$35,112.42
Subtotal	1,920.0	\$46,783.62
Continuity between mental health provider and PCP		
Medical record abstraction	180.0	\$5,835.60
Additional costs	1,530.0	\$34,102.92
Subtotal	1,710.0	\$39,938.52
Items added to the CAHPS survey addressing language centered care, cultural competence, physical activity, healthy eating, and caregiver strain		
Responding to survey items	1,000.0	\$22,770.00
Additional costs	--	--
Subtotal	1,000.0	\$22,770.00
Total	4,630.0	\$109,492.14

15. Changes to Burden

This request seeks approval of 4,630.0 additional hours of burden to test the use of new tools to measure care pertinent to vulnerable beneficiaries where quality of care provided by MAOs should be closely monitored.

16. Publication/Tabulation Dates

Exhibit 6 describes the timeline for activities related to this collection, including health plan recruitment and preparation, data collection, data analysis, and delivery of the analytic report delivered to CMS.

Exhibit 6. Timeline

Task	Planned Start Date	Planned End Date
Plan recruitment and preparation	OMB approval	30 days after OMB approval
Data collection	30 days after OMB approval	120 days after OMB approval
Data analysis	120 days after OMB approval	150 days after OMB approval
Prepare and submit data analysis report	150 days after OMB approval	180 days after OMB approval

The data analysis plan is outlined below.

- (1) For the transitions of care measure, scores for as many as two National Quality Forum endorsed measures and five Assessing Care of Vulnerable Elders (ACOVE) measures will be computed using information from the medical record abstraction. Percentage of patients for whom complete records were obtained and abstracted, and reliability of abstraction also will be computed. Results will be used to evaluate: (a) adequacy of patient discharge information; (b) information transfer into the outpatient setting (for non-integrated electronic health records); (c) follow up on pending tests and treatments; and (d) comparison among plans. Personnel effort and other costs associated with this data collection also will be summarized.
- (2) For the measure of continuity between mental health provider and PCP, scores for one new measure and two ACOVE measures will be computed using information from the medical record abstraction. Percentage of patients for whom complete records were obtained and abstracted, and reliability of abstraction will also be computed. Results of the medical record abstraction will be used to evaluate: (a) continuity of information and communication between mental health provider and primary care provider and (b) comparison among plans. Personnel effort and other costs associated with this data collection also will be summarized.
- (3) For measures informed by responses to the amended CAHPS survey, we anticipate that survey results will be used to determine which items are ultimately included in a subsequent version of the CAHPS survey for MAOs. Concerning caregiver strain items, each beneficiary who reports being a caregiver will complete the proposed items to evaluate strain and also the Caregiver Strain Index survey. The statistical relationship between the proposed items and the Caregiver Strain Index will be used to evaluate the validity of the proposed items.

Publication of Results: CMS may present general results in a publicly available report format. RAND will work with CMS to develop peer-reviewed publications to extend the impact of this work.

17. Expiration Date

This is a one-time only data collection. CMS would like to display an expiration date one year after OMB approval of this collection.

18. Certification Statement

There are no exceptions to the certification statement identified in item 19 of OMB Form 83-I associated with this data collection effort.