Medicare Health Outcomes Survey Field Test
CMS-10861; OMB 0938-New)

Supporting Statement-A

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Background

The Centers for Medicaid & Medicare Services (CMS) has authority to collect data on health outcomes and other health plan quality and performance indicators under section 1851(e) of the Social Security Act ("the Act"). CMS uses these data to develop and publicly post a 5Star Rating system for Medicare Advantage (MA) plans (i.e., the Medicare Part C Star Ratings) based on its authority to disseminate comparative information to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act. As codified at § 422.152(b)(3)(iii), MA plans are required to report health outcomes and quality measures that enable beneficiaries to compare health coverage options and select among the plans available to them. Based on requirements in the 1997 Balanced Budget Act, and later, the 2003 Medicare Prescription Drug Improvement and Modernization Act, CMS has collected information from beneficiaries enrolled in Medicare managed care plans through the annual implementation of the Medicare Health Outcomes Survey (HOS) since 1998.

The HOS includes both longitudinal patient-reported outcome measures (PROM) and cross-sectional measures. These measures assess self-reported beneficiary quality of life, functioning, and other key health indicators, including clinical processes, that allow CMS to measure physical and mental health outcomes and health plan performance. The HOS is unique among health status measures used in the Medicare Part C Star Ratings in that it assesses health status by asking beneficiaries themselves about their physical and mental health. As a PROM, the HOS measures outcomes and the impact of services provided by MA plans over time, but the HOS cross-sectional process and patient experience measures also provide a snapshot of activities or experiences at a specific point in time.[1] PROM and cross-sectional data collected by the HOS allow CMS to continuously assess the health of the MA population, a population at increased risk of adverse health outcomes, including chronic diseases and functional impairments that may significantly hamper quality of life.[2] The HOS supports CMS's commitment to improve health outcomes for beneficiaries while reducing burden on providers. Consistent collection of HOS data has allowed CMS, MA plans, and researchers to understand

1 Martha Hostetter and Sarah Klein, "Using Patient-Reported Outcomes to Improve Health Care Quality," The Commonwealth Fund, Accessed May 11, 2020, https://www.commonwealthfund.org/publications/newsletterarticle/using-patient-reportedoutcomes-improve- health-care-quality.

2 Office of Disease Prevention and Health Promotion, "Older Adults", Healthy People 2020, May 20, 2020, https://www.healthypeople.gov/2020/topics-objectives/topic/older-adults.

trends in the MA population's health outcomes over time, as well as beneficiary perspectives on their own health status. The longitudinal component of the HOS provides contract-level data on change in functional health status and health-related quality of life that CMS is unable to access in any other way, but is exploring potential new cross-sectional measures and potential new PROMs.

The sampling protocol for the HOS is unique among CMS surveys and allows for reliable estimates of MA plan performance at the contract level. Each year, the HOS is administered (baseline) to a random sample of beneficiaries from participating MA plans with a minimum of 500 enrollees. Two years later, the baseline respondents are surveyed again (follow-up). For each beneficiary who completes the follow-up survey, a two-year change score is calculated with risk-adjustment factors and the member's physical and mental health statuses are categorized as "better than expected," "the same as expected," or "worse than expected." Contract-level summary scores are calculated for each MA contract based on aggregated beneficiary outcomes. Multiple HOS measures are included in the Medicare Part C Star Ratings to help consumers choose health plans.[3]

Currently, the HOS is administered using a mixed mode data collection protocol that includes two survey mailings and telephone follow up for mail non-respondents. Prior CMS research demonstrated the potential to improve response rates using a multi-mode protocol with a web-based survey as the initial mode of administration, followed by mail, telephone, or both for web non-respondents.[4,5] Based on this research, CMS believes adding a web-based survey mode to the existing mixed mode protocol for HOS has the potential to improve response rates, particularly among younger enrollees.

This request is to conduct a field test with the goal of evaluating the measurement properties of new survey items, and the effects of new content and a web-based mode on response patterns and measure scores as compared to existing HOS survey items and protocols.

3 Centers for Medicaid & Medicare Services, "Fact Sheet – 2021 Part C and D Star Ratings," Part C and D Performance Data, Accessed December 7, 2021, https://www.cms.gov/files/document/2021starratingsfactsheet10-13-2020.pdf.

4 Parast L, Mathews M, Elliott MN, Tolpadi A, Flow-Delwiche E, Lehrman WG, Stark D, Becker K "Effects of Push-To-Web Mixed Mode Approaches on Survey Response Rates: Evidence from a Randomized Experiment in Emergency Departments" *Survey Practice* 12(1): 1-26. DOI:10.29115/SP-2019-0008. https://doi.org/10.29115/SP-2019-0008.

5 Mathews M, Parast L, Tolpadi A, Elliott MN, Flow-Delwiche E, Becker K. (2019) "Methods for Improving Response Rates in an Emergency Department Setting – A Randomized Feasibility Study" *Survey Practice* 12(1): 1-14. DOI: https://doi.org/10.29115/SP-2019-0007.

Within each of the proposed field test protocol arms, there will be two versions of the questionnaire (see Attachments A and B) that will be identical except for slight differences in selected items where empirical data are needed to ascertain which of the two versions produces the best results (see Attachment C). The two versions of the questionnaire will test alternatives for selected new survey content that will potentially enhance and refine existing measures, allow CMS to develop new and methodologically simpler cross-sectional and longitudinal measures, expand on CMS's measurement of physical functioning and mental health, and add to CMS's efforts to measure and address health equity.

Justification

1. Collection Necessity and Legal Requirements

CMS is required to collect and report quality and performance of Medicare health plans under provisions of the Social Security Act. Specifically, Section 1851(d) of the Act (Providing Information to Promote Informed Choice) requires CMS to collect data for MA plan comparison, including data on enrollee satisfaction and health outcomes, and report this information and other plan quality and performance indicators to Medicare beneficiaries prior to the annual enrollment period.[6] The HOS meets the requirement for collecting and publicly reporting quality and other performance indicators, as HOS survey measures are incorporated into the Medicare Part C Star Ratings that are published each fall for consumers on the Medicare website (www.medicare.gov).

The Medicare Part C and D Star Ratings, which are the basis for Quality Bonus Payments (QBP) for MA contracts, currently include five contract-level HOS measures: three cross-sectional Healthcare Effectiveness Data and Information Set (HEDIS®[7]) HOS Effectiveness of Care measures (*Monitoring Physical Activity*, *Improving Bladder Control*, and *Reducing the Risk of Falling*) and two longitudinal HOS outcome measures which have been temporarily moved to display[8] (*Improving or Maintaining Physical Health* and *Improving or*

6 United States Congress, "Medicare Prescription Drug Improvement Act," Congress.gov, December 8, 2003, https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf.

7 HEDIS is a registered trademark of the National Committee for Quality Assurance.

8 In the CY 2022 Medicare Advantage and Part D Final Rule, CMS finalized measure specification changes, simplifying the case-mix adjustment methodology and increasing the required denominator size from 30 to 100 for the *Improving or Maintaining Physical Health* and *Improving or Maintaining Mental Health* measures for measurement year 2022. In doing so, the two outcomes measures were moved to display for the 2024 and 2025 Star Ratings because the case-mix specification change is substantive, as described at § 422.164(d)(2). Both measures are scheduled to return to the Star Ratings program for the 2026 Star Ratings.

Maintaining Mental Health). A third longitudinal measure (*Physical Functioning Activities of Daily Living [PFADL]*) is currently under development and has been on display since 2021. Display measures are publicly available for informational purposes but are not used in the Star Ratings calculations or used for QBPs. The current HOS data collection is covered under OMB control number 0938-0701.

2. Information Users

The data collected in this field test will be used by CMS to inform decisions on possible changes to HOS content and survey administration procedures. The items in the questionnaire reflect current health priorities and would provide CMS with data to study new longitudinal PROMs, cross-sectional measures, and enhancements to existing HOS measures for MA plans to use as a focus of their quality improvement efforts. Potential new measures derived from new HOS items will go through the Measures Under Consideration (MUC) process and rulemaking before they are added to Star Ratings.

The new survey content includes the following three key items:

(1) Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function Items: These survey questions, taken from the PROMIS Physical Function and Mobility v2.0 item banks,[9,10] evaluate a wider range of functional impairment among MA enrollees than existing HOS items and may potentially enhance the PFADL measure (Questions 9-13).

(2) Generalized Anxiety Disorder 2 (GAD-2) Items: These survey questions use the GAD-2 scale[11] to measure anxiety, a significant mental health concern among both older adults[12] and MA enrollees with disabilities.[13] The addition of anxiety

9 HealthMeasures, "Search & View Measures." Available at https://staging.healthmeasures.net/search-view-measures. Accessed on March 10, 2023.

10 Schalet, B.D., Hays, R.D., Jensen, S.E., Beaumont, J.L., Fries, J.F., & Cella, D. (2016). Validity of PROMIS® Physical Function Measures in Diverse Clinical Samples. Journal of Clinical Epidemiology, 73, 112-118.

11 Wild, B., Eckl, A., Herzog, W., Niehoff, D., Lechner, S., Maatouk, I., ... & Löwe, B. (2014). Assessing generalized anxiety disorder in elderly people using the GAD-7 and GAD-2 scales: results of a validation study. *The American journal of geriatric psychiatry*, 22(10), 1029-1038.

12 Koma, W., True, S., Fuglesten Biniek, J., Cubanski, J., Orgera, K., & Garfield, R. (2020). One in four older adults report anxiety or depression amid the COVID-19 pandemic. KFF-Medicare. Available at https://www.kff.org/medicare/issuebrief/one-in-four-older-adults-report-anxiety-or-depression-amid-the-covid-19-pandemic/. Accessed on March 15, 2023.

13 Friedman, C. (2022). The mental health of Medicare beneficiaries with disabilities during the COVID-19 pandemic. *Rehabilitation Psychology*, *67*(1), 20.

measurement offers a broader assessment of mental health than measuring depression alone (Question 27a and Question 27b).

(3) Health-Related Social Needs (HRSN) Items: These survey questions focus on social determinants of health, such as transportation availability, food insecurity, and housing instability, underscoring CMS's commitment to measuring and addressing health equity (Questions 42-53).[14]

CMS will also test alternative wording for the following selected Veteran's RAND 12Item (VR-12) Survey questions, for the Activities of Daily Living question, and for selected HRSN questions:

- Physical Functioning: The alternative question will test a revised example of moderate activities in the item stem (Question 2a).
- Vitality and Mental Health: The alternative question will test revised response options (Question 6a-c).
- Activities of Daily Living: The alternative question will test a revision to the item stem (Question 8).
- Physical Functioning: The alternative question will test a wording variation in the item stem (Question 12).
- HRSN Needs: The alternative questions will test wording variations in the item stem (Questions 42, 46, and 50).

A total of 20 existing HOS questions will be removed and may be replaced with new content in the questionnaire. The criterion for removing questions includes reduced utility (e.g., no longer used for research, quality improvement, or public reporting) and changes in clinical measurement or standards. The field test will collect quantitative data on new content for potential addition to the HOS, and based on analysis of these data, not all questions in the questionnaire will be recommended for future inclusion in the HOS.

Multiple stakeholders use HOS data. Beneficiaries use information from the HOS survey to make informed choices among the health plans available to them. HOS survey results are reported by CMS on the Medicare Plan Finder website (www.medicare.gov/find-a-plan),

14 CMS conducted a limited number of cognitive interviews in March 2023 to inform the wording of the Health-Related Social Needs items. Online interviews with nine or fewer respondents were conducted for the three item sets (housing, food, and transportation).

where people can compare plan performance when making enrollment decisions. CMS also utilizes the HOS as an avenue for quality oversight and MA accountability. HOS data are included in the Medicare Part C Star Ratings and are used to calculate QBPs. MA plans use HOS results to support quality improvement (QI) activities,[15] as well as using HOS data and Part C and D Star Ratings scores to identify areas to improve the care they provide to Medicare beneficiaries. Additionally, HOS data are used extensively by researchers and other Federal partners to advance the science of health outcomes, cancer research, care for older adults, and end-of-life care.

3. Use of Improved Information Technology

The proposed field test will allow CMS to be responsive to requests for web-based survey administration. There are no barriers that prohibit the use of improved technology for this information collection. CMS will provide its contractor with the sample of enrollees in each MA contract. The data collection protocol is mixed mode and includes an experimental arm (i.e., the updated HOS questionnaires with web, mail, and telephone modes) and a control arm (i.e., the updated HOS questionnaires with mail and telephone modes). Within each arm, there will be two versions of the questionnaire (Attachments A and B) that will be identical with the exception of slight variations in nine items (see Attachment C).

Survey content from each version of the questionnaire will be compared with data collected using the existing HOS version 3.0 questionnaire with mail and telephone modes authorized under OMB control number 0938-0701.

4. Duplication of Efforts

The Medicare HOS is administered annually to MA enrollees. CMS's contractor will use the remaining unused sample frame from the annual HOS administration to draw samples for this field test. Thus, there will be no duplication of effort with the existing HOS administration. The sampling strategy for the HOS is unique among CMS surveys and allows for reliable estimates of plan performance at the contract level. Other surveys, such as the Medicare Current Beneficiary Survey (MCBS), cannot be used to evaluate performance of MA plans, because the sampling strategy would not allow reliable estimates at the contract level.

15 Quality improvement: *the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge (cited in* Crossing the Quality Chasm: A New Health System for the 21st Century. National Academy of Medicine. Washington, D.C.: National Academy, 2001. Print).

5. Small Businesses

Survey respondents are MA enrollees. MA contracts that participate in field testing will not pay anything to participate in the field test. The questionnaires and their associated completion procedures are designed to minimize burden on all respondents and will not have a significant impact on small businesses or other small entities.

6. Less Frequent Data Collection

This data collection effort will be conducted only once. If these data are not collected, CMS will not have data to inform decisions on possible changes to HOS content and survey administration procedures. We would be unable to evaluate the measurement properties of new survey items or the effects of new content and a web-based mode on response patterns and measure scores prior to implementation of the changes being considered.

7. Special Circumstances

There are no special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly.
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it.
- Submit more than an original and two copies of any document.
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years.
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study.
- Use a statistical data classification that has not been reviewed and approved by OMB.
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use.

- Submit proprietary trade secret or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register

The 60-day Federal Register Notice was published in the *Federal Register (88 FR 41404)* on 06/23/2023.

CMS received eight comments related to CMS-10861 (OMB control number 0938-New) for the Medicare Health Outcomes Survey Field Test during the 60-day comment period. A summary of the comments and CMS's responses can be found in the document "CMS Response to Public Comments Received for CMS-10861."

The 30-day Federal Register Notice was published in the Federal Register (88 FR 73858) on 10/27/2023.

9. Payments or Gifts to Respondents

Respondents do not receive any payments or gifts for their participation. Data collected through HOS provides all Medicare beneficiaries with information to help them make more informed choices among health plans available to them.

10. Confidentiality

Individuals contacted are assured confidentiality 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. The Systems of Records is the Health Plan Management System (HPMS) (SORN 09-70-0500) and the Medicare Integrated Data Repository (IDR) (SORN 0970-0571).

11. Sensitive Questions

There are no sensitive questions associated with this collection activity. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private. It is possible that some beneficiaries may feel that certain questions are sensitive, such as those about urinary incontinence or race and ethnicity. However, participation is voluntary, and respondents may skip any question they prefer not to answer.

12. Burden Estimates (Hours & Wages)

The proposed field test will be conducted one time. The average time to complete the HOS questionnaire is about 20 minutes. Table 1 shows the estimated annualized burden for respondents' time to participate in this data collection.

Table 1. Estimated Annualized Burden (Hours and Cost)

HOS Survey	Number of Participating Contracts[a]	No. of Respondents per Contract[b]	No. of Responses	Average Burden per Response (hours)	Hourly Wage Rate[c]	Total Annual Burden (hours)	Total Annual Respondent Cost[d]
HOS	50	136	6,800	0.33	$29.76	2,266.667	$67,456.00

[a] The field test will sample eligible enrollees from 50 contracts.

[b] The number of respondents per contract is calculated as follows: The number of members sampled per contract (340) multiplied by an expected 40% response rate (136).

[c] The hourly wage rate is based on national wage data for all occupations.[16]

[d] The total annual respondent cost = the hourly wage rate multiplied by the total annual burden hours ($29.76 x 2,266.667 = $67,456.00).

13. Capital Costs

There are no capital costs associated with HOS administration.

14. Costs to Federal Government

The estimated total cost to the Federal government for the HOS field test is $500,000.00. This total includes CMS management and preparation for the field test, all data collection activities, and data analysis.

15. Burden Changes and Adjustments

This is a new data collection effort and not a revision to an existing survey. However, we have updated the burden estimates in the 30-day submission as follows. The average time to complete the HOS field test instrument was increased from 15 to 20 minutes in Form 83 Part II and Supporting Statement A, Section 12. The lesser time stated in the documents in the initial 60-day package was an error; as noted in the draft questionnaires (Attachments A and B), the estimated completion time for the HOS field test instrument is approximately 20 minutes. This change increased the annual burden from 1,700 hours to 2,266.67 hours, an increase of 566.67

16 *Occupational Employment and Wage Statistics* [Review of *Occupational Employment and Wage Statistics*]. United States Bureau of Labor Statistics. Retrieved October 11, 23 C.E., from https://www.bls.gov/oes/current/oes_nat.htm#00-0000.

annual hours. The hourly wage rate was also updated from $28.01 to $29.76 to reflect the current mean hourly wage for all occupations as of October 2023.[16] These changes increase the annual burden from $47,617 to $67,456, for a net increase of $19,839.

16. Publication and Tabulation Dates

Dissemination of findings will commence once data collection and analysis are completed.

17. Expiration Date

A three-year expiration date is being requested. The assigned expiration date and disclosure would be placed on the instruction page of the Medicare Health Outcomes Survey (HOS) Field Test Questionnaires, Versions A and B.

18. Exceptions to Certification Statement

There are no exceptions to Item 19 of OMB Form 83-1 associated with the HOS field test data collection.

List of Attachments

Attachment A: HOS Field Test Questionnaire Version A

Attachment B: HOS Field Test Questionnaire Version B

Attachment C: HOS Field Test Item Differences by Questionnaire Version