

Supporting Statement A

Patient-Reported Indicator Survey (PaRIS)
(CMS-10792; OMB 0938-New)

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List of Attachments

Attachment 1: 60-day Federal Register Notice

Attachment 2: PaRIS Questionnaire and Showcards

Attachment 3: PaRIS Advance Letter – English

PaRIS Frequently Asked Questions (FAQs)

PaRIS Reminder Postcard – English

Attachment 4: PaRIS Cognitive Testing Report

A1. Circumstances Making the Collection of Information Necessary

The purpose of this new collection request is to seek approval for CMS to conduct the International Survey of People Living with Chronic Conditions (hereafter referred to as the PaRIS Survey). This survey has been developed by a collaborative workgroup under the auspices of the Organization for Economic Cooperation and Development (OECD), an international organization that works with governments, policy makers, and citizens to shape policies that foster prosperity, equality, opportunity, and well-being for all.

The OECD provides leadership on measuring how health systems respond to patients' needs. Health care delivery systems across OECD member countries vary widely, with member countries spending between 3.1% (Indonesia) to 16.8% (United States) of their gross domestic product (GDP) on health care¹. While health systems in OECD member countries collect data on certain aspects of health care delivery, such as spending and services provided, there is a significant gap in data on health care outcomes. In particular, very little is known about whether health systems are truly delivering the services that people need. The outcomes achieved for patients and how they experience care are rarely measured in a systematic and rigorous way.

When available, health outcome measures typically focus on mortality, and incidence and prevalence of disease, as reported by health care professionals or public health surveillance systems. Particularly on an international level, little information is available about user experiences with health care services. As populations age, and the prevalence of chronic conditions increases, it will be critical for policy makers to support health care providers, especially in primary, community, and ambulatory health care settings, who often serve as a patient's first point of contact with the health care system. These providers manage and treat people with chronic conditions, support self-management of their health and advise on health care plans. Because patients with chronic conditions often receive fragmented care from multiple health care providers, they are at risk of complications and incomplete care, which can add to the cost of caring for this population. While primary health care providers are asked to address rising needs of patients with chronic conditions, many countries struggle to respond due to a dearth of information and data available on outcomes for patients and performance of health systems².

To address this gap, the OECD launched the PaRIS initiative in 2017. OECD member countries, including the U.S., are working together to develop, standardize, and implement indicators that measure outcomes and experiences of health care that matter most to people. The PaRIS Survey will provide a common set of measures that support policy makers across participating countries to improve health care delivery.

Development of the survey has been a collaborative effort overseen by the OECD Health Committee and the Working Party for PaRIS. Survey development is also guided by advisory bodies including health care providers, patients, and technical experts to ensure that the instrument and indicators are relevant to all policy makers, patients, and health care providers. Developing the PaRIS Survey on an international level provides consistency and comparability across countries, offering opportunities for international learning about effective strategies for supporting people-centered care and measuring progress. It brings efficiencies and cost-savings by sharing the costs of developing, testing and validating the tools to measure patient-reported outcomes and experiences.

On behalf of the Department of Health and Human Services (DHHS) Assistant Secretary for Planning and Evaluation (ASPE), the Office of Enterprise Data and Analytics (OEDA) in the Centers for Medicare &

¹ <https://www.statista.com/statistics/268826/health-expenditure-as-gdp-percentage-in-oecd-countries/>

² <https://www.oecd.org/health/health-systems/PaRIS-survey-Patients-with-Chronic-Conditions-June-2019.pdf>

Medicaid Services (CMS) has been designated as the lead participant for the U.S. Staff from ASPE and CMS have been a part of the PaRIS working group that has developed a three-phase approach:

- **Development Phase** (Phase 1, Feb 2020-Jan 2021): A consortium of survey experts from participating countries developed the draft PaRIS Survey via a comprehensive review of existing, validated sources.
- **Field Trial Phase** (Phase 2, anticipated February 2021-July 2022): Cognitive testing of the draft PaRIS Survey; Pilot test of draft survey in European Union countries.
- **Main Survey Phase** (Phase 3, anticipated August 2022-December 2023): Full implementation of finalized PaRIS Survey in all participating countries, including collection and dissemination of data.

A2. Purpose and Use of Information Collection

The PaRIS Survey will help to close critical policy gaps by focusing on: (1) Patient Reported Experience Measures (PREMS) which measure how patients experience health care, and (2) Patient Reported Outcome Measures (PROMS) which measure how patients assess the results of the care they receive. The PaRIS Survey includes both PREMS and PROMS items and aims to collect vital information about primary health care, by asking about topics such as the respondent's health, health behaviors, patient activation and confidence in managing their health care, experiences with health care and health providers including access to health care, quality of life, physical functioning, and psychological well-being.

OECD and its member countries will use data collected by the PaRIS Survey to shed light on key questions about how well care in each country is organized around the needs of patients. Results from the survey will show how key outcomes and experiences vary across and within countries. This will allow countries to benchmark and learn from each other's approaches. The survey will also help policy makers in OECD member countries understand how health systems are addressing the needs of persons with chronic health conditions. Findings will foster a dialogue with service providers about how to further improve the performance and people-centeredness of primary health care services.

To facilitate U.S. participation in this important initiative, CMS, with financial support from ASPE, will leverage the existing sample for the Medicare Current Beneficiary Survey (MCBS). The MCBS is a continuous, multi-purpose survey of a representative national sample of the Medicare population, including the population of beneficiaries aged 65 and over and beneficiaries aged 64 and below with certain disabling conditions, residing in the U.S.; it is conducted under OMB clearance number 0938-0568. The MCBS is sponsored by OEDA of CMS and is conducted through a contract with NORC at the University of Chicago (NORC); therefore, the PaRIS Survey will also be conducted by NORC on behalf of CMS.

Given the age and health characteristics of Medicare beneficiaries, the MCBS sample will provide a comparable population to survey respondents selected in other participating OECD countries. Further, by fielding the PaRIS Survey to the MCBS sample, CMS realizes two key efficiencies. First, costs are reduced by having a sample already selected. And second, respondent burden is reduced by leveraging existing socio-demographic and health data already collected by the MCBS. Sampled MCBS beneficiaries will be sent an advance letter and frequently asked questions prior to data collection to explain the purpose of the study (Attachment 3). Interviewers will telephone beneficiaries and administer the PaRIS Survey by phone as a one-time survey during January 2023 through April 2023. Non-response follow-up will be conducted by telephone and in-person as needed.

To the extent possible, the exact same survey items will be fielded in each participating OECD country so that the metrics collected will be as comparable as possible. The PaRIS Survey (Attachment 2) was drafted by OECD using items from existing, validated sources such as the Patient-Reported Outcomes

Measurement Information System (PROMIS®) Global Health Scale, Porter-Novelli Scale, and European Health Interview Survey.

In addition to actively participating in the OECD working group, CMS also conducted a small number of cognitive interviews (nine) of the PaRIS instrument to assess the understanding of key healthcare related concepts among Medicare beneficiaries in the U.S. As a result of that testing, CMS has made minor changes to the U.S. instance of the PaRIS instrument so that terms are better understood when administered to a U.S. based audience. Results from this cognitive testing effort were shared with the OECD working group and can be found in Attachment 4. The OECD working group allows participating countries to adjust survey questions in minor ways for contextual understanding within their country.

A3. Use of Improved Information Technology and Burden Reduction

The PaRIS Survey will be programmed using Voxco, a software platform well-suited for computer assisted web interviewing (CAWI) and computer assisted telephone (CATI) surveys. Even though the PaRIS Survey will be programmed as a web survey, the questions will be administered by trained interviewers using Android tablets during telephone and in-person interviews. Key technology benefits of using Voxco includes programming that fully utilizes sophisticated logic checks, skip patterns, and text fills to ease question administration and reduce respondent burden by shortening the interview.

By leveraging the MCBS sample, the PaRIS Survey can benefit from using the rich contact information already collected by the MCBS that would otherwise be unavailable. This reduces the amount of contact attempts needed to schedule an interview. In addition, the PaRIS Survey will be able to leverage socio-demographics data already collected by the MCBS instead of having to ask this information again as part of the PaRIS Survey, thereby shortening the PaRIS Survey and reducing respondent burden.

A4. Efforts to Identify Duplication and Use of Similar Information

The PaRIS Survey was drafted by the OECD working group using items from existing, validated sources such as the Patient-Reported Outcomes Measurement Information System (PROMIS®) Global Health Scale, Porter-Novelli Scale, and European Health Interview Survey. CMS has conducted a comprehensive review of the PaRIS items and determined that there is minimal overlap with other similar surveys conducted in the U.S. While the PaRIS Survey covers some topics that are conceptually similar to the MCBS, such as respondent health, physical functioning, and experiences with care, there is no overlap of survey items. Items that do cover similar topics diverge in their question wording, reference period, or response options. Administering the PaRIS Survey as a stand-alone survey to MCBS respondents will be consistent with participating countries and will facilitate cross-country comparison.

A5. Impact on Small Businesses and Other Small Entities

The PaRIS Survey will only be for individuals in households.

A6. Consequences of Collecting the Information Less Frequently

The PaRIS Survey will be a one-time data collection during January through April 2023.

A7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

None of the special circumstances listed by OMB apply to the PaRIS Survey.

A8. *Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies*

The 60-day Federal Register notice was published on 11/9/2021 (86 FR 62173). One comment was received, which requested modifications to collect additional information about respondents' dietary habits, nomenclature used for nutrition professionals, and barriers to dietary changes. Several changes were made to the U.S. version of the PaRIS Survey as a result of this request, including clearer response options for capturing chronic conditions and clarifying text for measuring fruit and vegetable consumption. All other requested changes were excluded in an effort to maintain consistency in items administered across participating countries. The 30-day Federal Register notice was published on XX, XX, 2020 (XX FR XXXX).

CMS participated in extensive collaborations with member countries participating in the OECD working group. In addition, CMS consulted with staff from the Division of Health Care Financing Policy in the DHHS ASPE Office of Health Policy. CMS will be obtaining financial support from ASPE to conduct PaRIS.

CMS also conducted a small number of cognitive interviews (nine) of the PaRIS instrument to assess the understanding of key healthcare related concepts among Medicare beneficiaries in the U.S. As a result of that testing, and with permission from the OECD working group, CMS has made minor changes to the U.S. instance of the PaRIS instrument so that terms are better understood when administered to a U.S. based audience. Results from this cognitive testing effort were shared with the OECD working group and can be found in Attachment 4.

In general, CMS also regularly solicits input on MCBS questionnaire content from a large listserv as well as notification of opportunities to comment on the website ([CMS.gov/MCBS](https://www.cms.gov/MCBS) and [Research Statistics Data and Systems MCBS](#)). Also, CMS participates in interagency working groups as well as research conferences to consult with a wide variety of data users and policy officials interested in MCBS data.

A9. *Explanation of Any Payment or Gift to Respondents*

The PaRIS Survey will not provide payments or gifts as incentives to respond.

A10. *Assurances of Confidentiality Provided to Respondents*

On February 14, 2018, CMS published in the Federal Register a notice of a modified or altered System of Record (SOR) (System No. 09-70-0519). The notice was published in 83 Federal Register 6591.

The Advance Letter (Attachment 3) to the respondent includes the following statement regarding confidentiality of data:

Your participation in this special survey is your choice. Your Medicare benefits cannot be affected in any way by your decision to participate or the answers you provide, and your information will be kept private to the extent permitted by law, as prescribed by the Federal Privacy Act of 1974.

Interviewer training stresses the importance of maintaining confidentiality and project protocols are documented within the Field Interviewer manual. Field outreach and contacting procedures have been established to maintain and ensure confidentiality. These include the utilization of standard computer security procedures (dual authentication password protection) and prohibitions on submitting personally identifiable information through electronic mail submission.

Any PaRIS data published or shared with OECD will exclude information that might lead to the identification of specific individuals (e.g., ID number, and location codes) and follow strict CMS non-

disclosure standards. The collected data will be provided to OECD as a public use file (PUF) or summary statistics only. CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to the individual privacy or other personal or property rights of the individual.

All PaRIS Survey staff directly involved in data collection and/or analysis activities are required to sign a Non-Disclosure Agreement as well as a NORC confidentiality agreement.

A11. Justification for Sensitive Questions

CMS does not deem any content to be of a sensitive nature.

A12. Estimates of Annualized Burden Hours and Costs

To estimate the burden for the PaRIS survey, nine cognitive interviewers were conducted. We estimate a burden of about 40 minutes for each PaRIS survey interview.

The PaRIS Survey will use the MCBS sample of respondents aged 65 and over who live in the Community, have seen a medical provider in the last six months, and are eligible for the Winter 2023 MCBS interview. The initial sample selected is estimated to be 10,498 Medicare beneficiaries. From this sample, 7,348 will be administered a 3-minute screener. From this group, we expect 5,144 to have seen a medical provider in the last six months and therefore, to be administered the 40-minute PaRIS survey. This reflects both an estimated response rate of 70% and an eligibility rate of 70% (i.e., 70% of screened respondents aged 65 and over have seen a medical provider in the last 6 months and of this group, 70% will complete the survey)³.

Projects	Number of Participants	Number of Responses/ Participant	Average hours per response	Response Burden
PaRIS Eligibility Screener	7,348	1	0.05	367
PaRIS Survey	5,144	1	0.67	3,447
Total Burden				3,814

In order to provide an estimate of the cost of participating in this survey, we must select an hourly rate to use which is then multiplied by the burden hours of the respondent. We selected the U.S. minimum wage (\$7.25 for 2022⁴) and multiplied it to the Total Annual Hours for the PaRIS Survey (3,814), for a Total Annual Cost Burden in terms of dollars of roughly \$27,651.50.

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

We do not expect respondents to incur any costs other than that of their time to respond. All costs associated with this effort are reported in Items 12 and 14.

A14. Annualized Costs to the Federal Government

The estimated cost to the government for collecting these data by NORC is \$1,432,251. NORC has a contract with CMS to conduct the MCBS; the contract will also include conducting the PaRIS Survey. Funding for the PaRIS Survey is being provided by ASPE to CMS under an HHS Interagency Agreement.

³ This eligibility rate is based on medical provider utilization data from the Medicare Current Beneficiary Survey (MCBS).

⁴ <https://www.dol.gov/general/topic/wages/minimumwage>

NORC's costs cover data collection, data processing and data delivery for the PaRIS survey. CMS personnel involved in the MCBS include about approximately 12 FTEs at a cost of \$1,541,421 which is documented in the main MCBS clearance (0938-0568). As part of this cost, CMS will provide oversight and guidance to NORC for the PaRIS Survey.

A15. Explanation for Burden Changes (Program Adjustments)

This is a new request. There are no changes or adjustments to an existing program.

A16. Plans for Tabulation and Publication and Project Time Schedule

The PaRIS Survey will be in the field from January through April 2023. CMS plans to release a disclosure protected public use file with accompanying methodological documentation via CMS' website. This public use file will also be made available to OECD for analysis and released with data from other participating countries.

A17. Display of OMB Expiration Date

The OMB expiration date will be displayed on the hardcopy respondent materials, including the advance letter, frequently asked questions, and reminder postcard (Attachment 3). When conducting in-person interviews, the OMB expiration date will be displayed in the Voxco instrument on the first screen (introductory script and consent) and on the last screen (thank you script).

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to this certification statement.