

**Supporting Justification for the Clearance of the Medicare Part C and Medicare Part D
Enrollment Form Interviews**

**Supporting Statement-A: Justification for the
Collection of the Data
(CMS-10816; OMB 0938-1440)**

Revised December 4, 2023

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Part C and D Enrollment Form Interviews

Supporting Statement – Part A

Background

Section 4001 of the Balanced Budget Act of 1997 (Public Law 105-33) enacted August 5, 1997, established Part C of the Medicare program, known as the Medicare + Choice program, (now referred to as Medicare Advantage (MA)). As required by 42 CFR 422.50(a)(5), an MA eligible individual who meets the eligibility requirements for enrollment into an MA or MA-PD plan may enroll during the enrollment periods specified in §422.62, by completing an enrollment form with the MA organization or enrolling through other mechanisms that the Centers for Medicare & Medicaid Services (CMS) determines are appropriate.

Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108-173) enacted December 8, 2003, established Part D of the Medicare program, known as the Voluntary Prescription Drug Benefit Program. As required by 42 CFR 423.32(a) and (b), a Part D-eligible individual who wishes to enroll in a Medicare prescription drug plan (PDP) may enroll during the enrollment periods specified in §423.38, by completing an enrollment form with the PDP, or enrolling through other mechanisms CMS determines are appropriate.

The collection of information as required by 42 CFR 422.50, 422.60, and 423.32 was originally approved under OMB Control No. 0938-1378 (CMS-10718) on July 17, 2020. It incorporated changes to the previous standard (“long”) model enrollment form (used by both MA and PDP sponsors) which yielded a new “shortened” model enrollment form.

The collection of information was further updated and approved on October 21, 2021 based on final rule CMS-4190-F, RIN 0938-AT97.

With the long-term goal of collecting race and ethnicity data from all Medicare enrollees, CMS requested and received OMB approval of the revised collection of information (CMS-10718) based on the inclusion of race and ethnicity data on the model MA and Part D enrollment form. CMS will initially focus efforts on individuals who newly elect or are already enrolled in an MA plan and change coverage starting January 1, 2023 during the Medicare Advantage Open Enrollment Period (MA-OEP).

The data collected through the updated enrollment form will be used to conduct interviews among non-responders to the race and ethnicity questions to understand how people who elect to not respond to the race and ethnicity questions perceive the addition of those questions on the form.

CMS' primary objective for the interviews is to identify the drivers of nonresponse to the race and ethnicity questions. Specifically, we aim to solicit detail on whether and what concerns drove individuals' nonresponse to these items, including (but not limited to) (a) concerns about confidentiality of their data, (b) concerns about how their race and ethnicity data would be used, including concerns about whether disclosing such information could in any way affect eligibility for Medicare benefits (which it would not), or (c) concerns about response options (e.g. missing response options for race or ethnicity groups in which they may identify). We also intend to explore whether it is possible to amend the race and ethnicity elements on Part C/D enrollment form to address any of those concerns, and if so, how. Additionally, we plan to ask whether there are other – beyond the Part C/D enrollment form – vehicles for collecting race and ethnicity information that would be more acceptable to non-responders, and if so, what those are.

Collecting complete race/ethnicity data is important to CMS because CMS has interest in identifying patterns of differences across many key process and care outcomes by sociodemographic characteristics, including race and ethnicity. To best characterize these differences, self-reported *and* granular data are needed. Improving how these data are collected will support efforts to continue to strengthen, for example, CMS OMH's [stratified reporting](#) efforts, which currently *do* consider quality indicators by race and ethnicity, but at present these data are *not* granular and *not* self-reported. In addition, better quality data will allow us to validate imputation methods CMS currently uses for race and ethnicity, to ensure that we do not rely on methodologies that unintentionally create or exacerbate disparities.

A. Justification

1. Need and Legal Basis

The general authority for requiring this data collection for MA plan enrollment is section 1851(c) – (2)(A) of the Act and implementing regulations at §§ 422.50 and 422.60.

The general authority for requiring this data collection for PDP enrollment is section 1860D1(b) (1)(A) of the Act, and implementing regulations at §§ 423.30 and 423.32.

Reliable race and ethnicity data are necessary as CMS moves towards stratified reporting of quality measures and strives to understand inequity in health outcomes associated with inequality of healthcare. CMS is beginning with exploring the quality of the race and ethnicity data collected through enrollment in the Medicare Part C and Part D plans. The recent Executive Orders (EO) 13985 on [Advancing Racial Equity and Support for Underserved Communities Through the Federal Government](#) and EO 14031 on [Advancing Equity, Justice, and Opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders](#), have focused attention on the need for CMS to improve the collection and quality of its enrollees' race and ethnicity data, especially at the disaggregated level.

The enrollment form is considered a “model” under Medicare regulations at §§ 422.2262 and 423.2262, for purposes of communication and marketing review and approval; therefore, MA and Part D plans are able to modify the language, content, format, or order of the enrollment form. Section 1 of the model enrollment form requests the minimal amount of information to process the enrollment for MA and PDP plans. Section 2 is comprised of questions that are optional for the prospective enrollee to complete. For the 2023 enrollment periods, CMS required that the sponsor include race and ethnicity data elements in Section 2 of their MA and PDP enrollment applications. All data elements in Section 2 are optional for the prospective enrollee to complete. Plan enrollment will not be affected if the person does not complete this additional information.

2. Purpose of Collection and Use of Information

The purpose of the cognitive interviewing for which clearance is requested is to understand why people do not supply the race and ethnicity data requested on the Part C and D enrollment forms. Examples of reasons for not providing one’s demographic information in other contexts include: concern about how the information might be used (e.g., it might be used to determine the level of services one receives or the level of reimbursement one receives for services); skepticism that the Federal government can or will protect the confidentiality of their data; general skepticism about the government which leads them not to provide information that is not necessary for enrollment.

If there are systematic reasons why enrollees are not providing the information, CMS may be able to use the results of the cognitive interviewing to design (and test) ways to increase item response to the optional race and ethnicity questions. Understanding reasons for non-response rates and reasons for non-response will help CMS decide whether to continue and even expand the use of yearly changes in enrollment (e.g., in the future for Parts C and D and/or expanding to changes in enrollment to supplemental insurance.)

In parallel with this cognitive testing, CMS will conduct statistical analysis of whether there may be non-response bias in who provides and does not provide race and ethnicity data (e.g., are those with certain healthcare usage patterns or health conditions more or less likely to provide such information).

The cognitive interviews will be conducted on a varied convenience sample of people who did not provide information on their race and ethnicity in completing their enrollment for a Part C or Part D plan in one of three contexts:

- a) 2023 Medicare Advantage Open Enrollment Period (MA-OEP),
- b) 2024 Medicare Open Enrollment Period (OEP) or
- c) individuals who qualify for a Special Enrollment Period (SEP).

As the new MA and PDP enrollment form requirements began on January 1, 2023, the first group of potential study participants are those who newly elect or are already enrolled in an MA plan and change coverage during the MA-OEP, January – March 2023. This group can participate in cognitive interviewing after March 31, 2023. Participants who enroll in an MA or PDP plan during the Medicare OEP, mid-October – early December 2023, can participate in

cognitive interviewing starting mid-December 2023. The third group of participants, the individuals who qualify for a SEP, will enroll in MA and PDP plans throughout 2023, but will be sampled with the other groups after the MA-OEP and annual Medicare OEP. The varied convenience sample will include participants in all three groups who did not complete the optional race and ethnicity questions on the MA and PDP enrollment form.

3. Use of Information Technology

Interviews will be conducted by phone and interviews with respondents who consent to be recorded will be audio recorded. This approach capitalizes on the use of improved information technology, allowing participants to verbally share their responses with an interviewer without time needed for the traveling and logistics of in-person interviews, thus minimizing reporting burden on the respondent and any ongoing concerns of safety due to the COVID-19 pandemic. There is no intention of making this data collection completely electronic as the data needs to be collected with an interviewer.

4. Duplication of Efforts

Data collection to understand reasons for electing to not respond to race and ethnicity questions among the Part C and D Medicare populations have not been conducted before, and thus this information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection is not expected to impact small businesses or other small entities.

6. Less Frequent Collection

Data will be collected from each respondent only one time. If reliable race/ethnicity data is not collected, CMS would not be able to accurately assess the effect of current policy as well as future program changes on racial and ethnic disparities. CMS must have the most reliable, valid, and standardized data on the race and ethnicity of program participants across all programs. This collection will help CMS educate enrollees about its efforts to improve the collection of race and ethnicity data by understanding the reasons why people choose to not answer the race and ethnicity questions.

7. Special Circumstances

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

- requiring respondents to report information to the agency more often than quarterly;
- requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- requiring respondents to submit more than an original and two copies of any document;
- requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- 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,
- requiring the use of a statistical data classification that has not been reviewed and approved by OMB;
- that includes 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; or
- requiring respondents to 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/Outside Consultation

The 60-day Federal Register notice published in the Federal Register on August 24, 2022 (87 FR 51675).

The 60-day public comment period (87 FR 51675), which was extended, closed on November 8, 2022 with a total of 2 comments. We received a general comment regarding potential drivers of nonresponses to the race and ethnicity question. Another commenter encouraged CMS to share the results of the cognitive interviews/study. We do not propose any program changes or adjustments.

The 30-day Federal Register notice published in the Federal Register on November 25, 2022 (87 FR 72485).

CMS OMH contracted with NORC at the University of Chicago (NORC) to assist with Reducing Health Disparities through Quality Improvement. NORC was tasked to use its expertise in the Medicare population and qualitative data collection to assess nonresponse on enrollment forms. NORC will conduct the interviews, analyze the results, and develop recommendations for CMS to consider for improving response to race/ethnicity questions on program enrollment forms.

9. Payments/Gifts to Respondents

Eligible respondents will receive a token of appreciation valued at \$40 in the form of a gift card for participating in a 30-minute interview about reasons they did not elect to provide their race and/or ethnicity information on the Part C/D enrollment form. The principal statistical agencies typically use \$40 incentives for one hour on-line cognitive interviews of this sort.

10. Confidentiality

This information collection will include personally identifiable information (PII) but will not involve protected health information and no Privacy Act records will result from this activity (no information will be retrieved by personal identifiers). The interview transcript will use unique identifiers so no names are tied to transcripts.

A number of procedures will be used to ensure confidentiality of respondents. NORC will be collecting limited personal identifiers (i.e., contact information, such as name and email address; race/ethnicity information) for the purposes of conducting the interview. Any PII collected will be accessible only to authorized NORC data collection staff. Interview transcripts will be stripped of any PII and will be assigned a unique participant identifier so that the name of the participant and other PII collected will not be connected to their answers. All data will reside on NORC's secure servers, which has highly secure internal network storage protocols that are used to prevent data loss, corruption, and unauthorized breach, as well as to administer least privilege, password-protected access rights. All NORC system environments meet or exceed FISMA, HIPAA, and NIST 800-53 Revision 4 moderate-level framework compliance standards. Further, all remote access to internal NORC computing resources requires two-factor authentication and encrypted channels. NORC will retain limited personal identifiers for the duration of the project and will destroy the transcripts and personal identifiers after the conclusion of the project. This will be kept private to the extent allowed by law.

The information collected from Medicare beneficiaries and contained in medical records, and other health and enrollment information, is disclosed as specified in the System of Records Notice (SORN) "Medicare Advantage Prescription Drug (MARx)", System No. 09-70-0588 (February 14, 2018; 83 FR 6591).

1 Kelly B, Margolis M, McCormack L, LeBaron PA, Chowdhury D. What Affects People's Willingness to Participate in Qualitative Research? An Experimental Comparison of Five Incentives. *Field Methods*. 2017;29(4):333-350. doi:10.1177/1525822X17698958

11. Sensitive Questions

This data collection includes matters that are commonly considered private by some people (i.e., their race and gender identity). At the beginning of the call, participants will be told that they may skip any questions that they do not wish to answer, including race/ethnicity.

12. Burden Estimates (Hours & Wages)

The total estimated respondent burden and costs are calculated below. The annualized burden was derived using 350 as the expected number of newly enrolled or switched Part C and D enrollees who elected not to complete the race/ethnicity questions on the enrollment form

contacted and screened and a 35% response rate for up to 130 completed interviews. The annualized burden cost will be \$2,660.95, which is based on the Bureau of Labor Statistics data May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at \$28.01/hr. since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Due to the wide range of individuals working and not working, fringe and overhead benefits are not required.

The estimates of individual annualized costs are based on the number of respondents interviewed and the amount of time required from individuals who were reached and completed the one-time interview. The invitation call and screener will take up to 5 minutes to read and the interview will take up to 30 minutes to complete, including verbal informed consent.

Exhibit 1: Annualized Burden Hour Table

Forms (If necessary)	Respondents (If necessary)	Number of Respondents	Number of Responses per Respondent	Average Burden per Response	Total Burden Hours
Invitation & Screening	Part C/D enrollees who elected to not respond to race/ethnicity questions	350	1	5/60 hours	30
Interview Guide	Part C/D enrollees who elected to not respond to race/ethnicity questions	130	1	0.50 hour	65
Total					<u>95 hours</u>

Exhibit 2: Estimated Annualized Respondent Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Part C/D enrollees who elected	95	\$28.01	\$2,660.95

to not respond to race/ethnicity questions			
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13. Capital Costs

There will be no cost to participants other than their time. No additional materials or equipment are needed to generate a report.

14. Cost to Federal Government

The overall annual cost to the Federal government for conducting interviews and compiling data for the interviews will be approximately \$122,904. This total includes time for contract staff to operationalize the interview guide, schedule and conduct the interviews, analyze the data, and share findings with CMS. Exhibit 3 presents total costs to the Federal government.

Exhibit 3: Costs to the Federal Government

Category	Cost
Contract labor	\$ 118,704
Total	\$ 118,704

*G&A and fee included in total.

15. Changes to Burden

We are updating this collection of information request to revise the cognitive interview protocol to accurately reflect the order of the response options for the race question on the updated Part C and D enrollment form. We are also adding prompts to questions 9 and 10 of the interview protocol for cognitive interview participants who do not recall the race and ethnicity questions on the enrollment form. After stating the question, e.g., “Are you Hispanic, Latino/a, or Spanish origin?” we will ask again if they recall the question and then list and ask about the response options. These changes do not impose additional burden on respondents.

CMS originally planned to complete 80 cognitive interviews during Wave 1 and 40 interviews during Wave 2. In Wave 1, interviews were completed with 90 participants including some Spanish-speaking members and PDP members. For Wave 2, CMS aims to complete a total of 40 interviews to ensure a sufficient number of Spanish-speaking and PDP members are represented in the interview data. CMS is therefore requesting to increase the number of interviews for the approved data collection from 120 to 130. This represents an increase in total burden hours from 90 to 95, which results in an increase in estimated total annualized respondent costs from \$2,520.90 to \$2,660.95.

16. Publication/Tabulation Dates

Invitation calls for interviews will begin April 2023 or following OMB approval, whichever is later. Interviews will be on an ongoing basis until saturation is reached or until June 2024.

Data will be analyzed once all interviews are completed and summarized in a report solely for CMS. CMS will not make the resulting report public.

17. Expiration Date

CMS would like to display the expiration date. The OMB number and expiration date can be displayed on the top right corner of the interview materials and instrument tool.

18. Certification Statement

This collection of information involves no exception to the Certification of Paperwork Reduction Act Submissions.