

**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-New)*

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Submitted by:

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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**

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 1860D-1(b)(1)(A) of the Act, and implementing regulations at §§ 423.30 and 423.32.

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. The model enrollment form includes the minimal amount of information to process the enrollment, located in Section 1 of the MA/PDP enrollment form, and other limited information, in Section 2, that the sponsor is required (i.e., race and ethnicity data, accessible format preference) or chooses (i.e., premium payment information) to provide to the enrollee. The optional data elements, which aids the MA and Part D plan in processing the enrollment, is developed for efficiency for the plan. Plan sponsors can obtain information at the initial point of contact to help streamline the enrollee’s enrollment process. The optional questions include information, specific to the plan’s business needs that serves to reduce overall burden and allow for timely processing of an enrollment request. All data elements in Section 2 are optional for the person to complete. Plan enrollment will not be affected if the person does not complete this additional information.

As CMS moves towards stratified reporting of quality measures and addressing healthcare inequity, highlighted by the COVID-19 pandemic, the ability to analyze disparities across Medicare programs and policies depends on the ability to access and collect reliable race and ethnicity data consistently from 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.

## 2. Information Users

Participants in the cognitive interviews are people enrolling in a Medicare Advantage or Prescription Drug plan during the 2023 Medicare Advantage Open Enrollment Period (MA-OEP), 2024 Medicare Open Enrollment Period (OEP), or individuals who qualify for a Special Enrollment Period (SEP) and who chose not to respond, i.e., did not complete, the Section 2 voluntary questions on race and ethnicity. There are several different groups of participants by type of enrollment. There is a group of people who completed the enrollment form because they switched plans during the Medicare Advantage OEP or MA-OEP. The second group includes individuals who completed a new enrollment in a Medicare Advantage or Prescription Drug plan during the 2024 Medicare OEP. The third group is those with a qualifying event who become eligible for Medicare mid-year. CMS intends to focus participant recruitment and interviews on people enrolling during the 2023 MA-OEP but can extend information collection to include people enrolling during the 2024 Medicare OEP or throughout the benefit year.

Data collection through the interviews will be used by CMS staff to understand drivers of nonresponse to the race and ethnicity items and, where possible, make changes to strengthen the race and ethnicity data collected through the enrollment form, for example, including more response options.

## 3. Use of Information Technology

Interviews will be conducted either by phone or by using Zoom videoconferencing technology. All interviews will be audio recorded. This software capitalizes on the use of improved information technology, allowing participants to verbally share their responses to an interviewer without time needed for the traveling and logistics of in-person interviews, thus minimizing reporting burden on the respondent and concerns of safety due to the COVID-19 pandemic. Furthermore, this technology allows the interviewer to use the chat feature to provide definitions, contact information, and relevant resources to the interviewee throughout the interview. There is no intention of making this collection completed electronically as the data collection 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 INSERT, 2022 (87 FR INSERT).

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

Respondents will be provided a \$75 gift card for participating in a 45-minute interview about reasons they did not elect to provide their race and/or ethnicity information on the Part C/D enrollment form. Incentives have been shown to increase participation in qualitative research such as interviews.<sup>1</sup> In this study, the incentive will help facilitate a more complete understanding of nonresponse.

#### 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

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<sup>1</sup> 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

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.

#### 11. Sensitive Questions

This data collection will not solicit questions, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private, but will focus on reasons for not electing to answer race/ethnicity questions on the enrollment form. During the informed consent process, 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 a 35% response rate for up to 120 completed interviews. The annualized burden cost will be \$3193.14, 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](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 email or call and screener will take up to 5 minutes to read and the interview will take up to 45 minutes to complete, including verbal informed consent.

**Exhibit 1: Annualized Burden Hour Table**

<b>Forms (If necessary)</b>	<b>Respondents (If necessary)</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden per Response</b>	<b>Total Burden Hours</b>
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	120	1	0.75 hour	84

	elected to not respond to race/ethnicity questions				
Total					<u>114 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 to not respond to race/ethnicity questions	114	\$28.01	\$3193.14

### 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	\$ 122,904
<b>Total</b>	<b>\$ 122,904</b>

\*G&A and fee included in total.

### 15. Changes to Burden

This is a new information collection request.

### 16. Publication/Tabulation Dates



Invitation emails and/or 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.