Supporting Statement Part-A
Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form
(CMS-10718, OMB 0938-1378)

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 current 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 updated and approved on October 21, 2021 based on final rule CMS-4190-F, RIN 0938-AT97, to account for changes to the number of Medicare-eligible beneficiaries estimated to make a valid enrollment request for calendar year (CY) 2021 through 2023 for End Stage Renal Disease (ESRD) Beneficiaries (§§422.50, 422.52, and 422.110), the Contracting Standards for Dually-Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514), and the MLR Deductible Factor for MA Medical Savings Account (MSA) Contracts (§ 422.2440).

With the long-term goal of collecting race and ethnicity data from all Medicare beneficiaries, CMS is requesting OMB approval of the revised collection of information based on the inclusion of race and ethnicity data on the model MA and Part D enrollment form. CMS will initially focus efforts on beneficiaries who newly elect or change coverage in the Medicare Part C and D program.

The detailed race and ethnicity categories collected through the demographic pilot on the enrollment form will be compliant with the 2011 HHS Data Collection Standards to provide granular information for plans and CMS to understand the diversity of the beneficiary population. The data collected through this vehicle (i.e. enrollment form) will be used to: 1) Explore the response rate to race and ethnicity questions as a whole and how it intersects with beneficiary income and other demographics; 2) Conduct focus groups, to be approved in a

separate PRA package, 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; 3) Continue to test CMS' race and ethnicity imputation models by adding additional race and ethnicity data to the data CMS already has; and 4) Determine the data necessary for sufficient samples sizes to conduct analyses of disaggregated race and ethnicity categories. As part of a broader health equity effort, 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. Collecting these data 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, this 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. To assess readiness for analysis of collected data (particularly with regard to considering sample sizes, especially of small groups), continual assessment will be required – simultaneously as enrollment happens – because readiness will depend partly on distribution of responses to these items by enrollees.

These categories are of great interest to CMS and will improve the accuracy of current data sets. We acknowledge that it may take several years of data collection to conduct other meaningful studies CMS intends to pursue that are not listed above.

CMS' primary objective for the cognitive 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 will 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 the 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.

The methodological design of this proposed study using cognitive interviews is based on cognitive testing research. The purpose of cognitive testing is to obtain information about the processes people use to answer survey questions as well as to identify any potential problems in the questions. These interviews will focus on the process of responding and any individual concerns about the questions. Specifically, CMS will elicit information on how the form was completed and concerns about the new additional questions, such as how their race and ethnicity data would be used, the data's confidentiality, and whether this question affects eligibility for Medicare benefits. In addition, the interviews will explore whether and how the available response options influenced their decision not to respond. The analysis will be qualitative. CMS' contractor, NORC at the University of Chicago, will design and conduct the cognitive interviews for this information collection and will also submit the protocol to the NORC Institutional Review Board for its approval.

Interview Participants. Participants in the cognitive interviews are people enrolling in a Medicare Advantage or Prescription Drug plan during the 2023 Medicare OEP Open Enrollment Period, Medicare Advantage Open Enrollment Period (MA-OEP) or individuals who quality for a Special Enrollment Period 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 a new enrollment in a Medicare Advantage or Prescription Drug plan during the 2023 Medicare OEP. The second group is people who completed the enrollment form because they switched plans during the Medicare OEP or MA-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 Medicare OEP but can extend information collection to include people enrolling during the 2023 MA-OEP or throughout the benefit year.

Selection of Interview Participants. CMS proposes to complete interviews with a sample of 120 eligible participants, 60 people who enrolled in a Medicare Advantage Health plan and 60 people who enrolled in a Prescription Drug Plan. Once the Medicare OEP begins on October 7, 2022, and as soon as it is available, CMS will provide NORC with a list of enrollees who newly enrolled in or switched enrollment in a plan **AND** did not complete the first two optional enrollment questions: “Are you Hispanic, Latino/a, or Spanish origin?” or “What’s your race?”

Using CMS enrollment records, CMS will provide NORC with a list that includes the name, age, phone number, county and state, and plan for each eligible individual. If available, CMS will also provide select demographic variables. NORC will put in place a robust data security approach to handle the secure and confidential transfer of this information from CMS to NORC (via sFTP). Participant contact information that is received by NORC from CMS will be stored within a highly secure internal network system at NORC to prevent data loss, corruption, and unauthorized breach, and that administers least-privilege, password-protected access rights. This safeguards all participants’ personally identifiable information (PII) and ensures individuals’ privacy.

To achieve 60 interviews, NORC will generate two random samples of 70 participants each. To ensure representation by age, geography and select socio-demographic variables and across diverse health plans, NORC will compare the distribution of the samples with the overall Medicare Advantage and Prescription Drug populations. NORC may use census data to further assess the geographic and demographic distribution of the samples. Given the objective of understanding how different people perceive these questions on race and ethnicity, NORC may conduct additional interviews using purposive sampling if information gaps are identified during the analysis of the interview data.

Recruitment and Interviews. NORC will use the sample list to recruit participants by phone. During recruitment, NORC will review the details of the study and consent statement, including a discussion of confidentiality. Participants will be offered a $50 incentive for completing a cognitive interview. If the participant agrees to participate, the interview will be scheduled during the call. Participants will also have the option of receiving a copy of the materials discussed during the recruitment call by mail or email.

Interviews will be conducted by NORC project staff, one interviewer and one notetaker with experience collecting qualitative data. Interviews will be conducted by phone or virtually if the participant prefers. NORC will use the IRB-approved interview protocol to guide each discussion and each discussion will last up to 45 minutes. The video option will be used based on the participant's preference. Audio recordings will be retained for transcription. NORC will develop a thematic codebook for the analysis of the interview data. Using qualitative coding software NORC project will code each interview for pre-specified themes and highlight any potential emerging categories. NORC will prepare a report of the thematic results for CMS.

The MA and Part D enrollment form needs to be in use for the 2023 Medicare Advantage Open Enrollment Period (MA-OEP) which begins January 1, 2023 – March 31, 2023. CMS is aiming to have an approved form by June 30, 2022, to allow plans and third-party vendors at least 6 calendar months to implement systems changes.

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 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 beneficiary. 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 beneficiary'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 beneficiary to complete. Plan enrollment will not be affected if the beneficiary 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 beneficiary race and ethnicity data, especially at the disaggregated level.

2. Information Users

MA and PDP organizations, applicants to MA and PDP organizations, and CMS will use the information collected to comply with the eligibility and enrollment requirements for Medicare Part C and Part D plans. We estimate that of the 15 million enrollments processed by MA and PDPs (8,990,796 MA and MAPDs and 7,116,852 by stand-alone PDPs in 2020), which includes new enrollments, switchers, and plan and/or CMS initiated enrollments each year, at a minimum approximately 5.6 million beneficiaries would complete an enrollment form and would have the opportunity to voluntarily provide race and ethnicity data.

CMS expects MA and PDP organizations to ensure the enrollment form complies with CMS' instructions regarding content and format. New and current enrollees that utilize the enrollment form to elect an MA or Part D plan must acknowledge the requirement to: (1) maintain Medicare Part A and B to stay in MA or Part A or B to stay in Part D; (2) reside in the plan's service area; (3) make a valid request during a valid election period; (4) follow plan rules; (5) consent to the disclosure and exchange of information between the plan and CMS; and (6) enroll in only one Medicare health plan and that enrollment in the MA or Part D plan automatically dis-enrolls him/her from any other Medicare health plan and prescription drug plan.

CMS will use this information to: track beneficiary enrollment, including tracking patterns in enrollment by race and ethnicity over time; to identify, monitor, and develop effective and efficient strategies and incentives to reduce and eliminate health and health care inequities; to validate existing race and ethnicity imputation methods; and to ensure that clinically appropriate and equitable care (in terms of payment, access and quality) is consistently provided to all Medicare beneficiaries.

3. Use of Information Technology

MA organizations and Part D sponsors must have, at a minimum, a paper enrollment form process (approved through the CMS marketing material review process described in the *Medicare Communications and Marketing Guidelines*) available for potential enrollees to elect enrollment in a MA or PDP plan.

Where feasible, the collection of information involves the use of automated, electronic, telephonic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy.

To comply with the Government Paperwork Elimination Act (GPEA), the following information is provided:

Plans may develop and offer electronic enrollment mechanisms made available via an electronic device or through a secure internet website. Plans also have the option of obtaining technical support, (e.g. licensed software) and related services from downstream entities, such as a broker or third-party website, as a means of facilitating and capturing the electronic enrollment request.

CMS holds plans responsible for ensuring that:

(1) Enrollment policies outlined in *Chapter 2 - Medicare Advantage Enrollment and Disenrollment* and *Chapter 3 – Part D Eligibility, Enrollment and Disenrollment* are followed, and

(2) There is appropriate handling of any sensitive beneficiary information provided as part of the online enrollment.

4. Duplication of Similar Information

This collection does not contain duplication of similar information.

An enrollment request mechanism (i.e. paper, electronic) is required for the plan to identify a beneficiary's expressed interest to join a plan and consequently for the plan to know that an enrollment is requested.

CMS maintains Medicare administrative records for beneficiaries in the Enrollment Database (EDB). The beneficiary Medicare eligibility determination and all originating data associated with the beneficiary are provided to CMS by the Social Security Administration (SSA) and to a lesser extent the Railroad Retirement Board (RRB) and the Office of Personnel Management (OPM). CMS receives information on individuals entitled to social security benefits and automatically enrolled in Medicare Parts A and Parts B, Fee-for-Service (FFS); however, individuals not entitled to these benefits even if they are eligible for Medicare based on age, are not identified and accounted for in CMS systems.

The Centers for Medicare and Medicaid Services does not currently collect race and ethnicity data upon enrollment into the Medicare program. The limitations in receiving race and ethnicity data from SSA have translated into wide variations in accuracy and validity across different racial and ethnic categories within CMS's data records. CMS utilizes a variety of indirect estimation techniques to improve analyses of race and ethnicity differentials among Medicare beneficiaries which disproportionately misclassifies beneficiaries who are of racial and ethnic minorities.

5. Small Businesses

Some MA organizations and Part D sponsors are small businesses so they may be affected. They will have to comply with all the information requirements described in this supporting statement.

6. Less Frequent Collection

This collection does not set out any daily, weekly, monthly, or annual requirements; rather this information is collected as needed (upon plan enrollment) to support the administration of the Medicare Part C and Part D plan enrollment process.

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; or
- 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 notice published in the Federal Register on January 12, 2022(87 FR 1752). A total of nine (9) comments were submitted as the comment period concluded on March 14, 2022. Generally, commenters supported the collection of race and ethnicity data on the Medicare Part C and D enrollment form, acknowledging the benefits of standardized data elements. Several commenters expressed support for the use of focus groups to identify drivers of non-response and requested that CMS share the outcomes of these focus groups to educate plans.

Regarding the new data elements, several commenters recommended we consider combining the race and ethnicity questions into one question, citing higher response rates based on research conducted by the U.S. Census Bureau. Separately, commenters proposed we expand data collection efforts to include disability data, sexual orientation and gender identity (SOGI) as well as revise the language preferences question on the model enrollment form. Three commenters expressed concerns about the timing for MA and Part D sponsors to update their systems to implement this collection and reporting to CMS by this October's AEP. These commenters recommended the Agency provide a minimum of six (6) months, but prefer that implementation be delayed until October 2023 AEP.

No changes were made, at this time, to the Medicare Part C and D enrollment form based on suggestions to add other demographic data to this pilot. We will take these suggestions in to consideration at a later update. We plan to move the release date of the new model MA and Part D enrollment form to January 1, 2023 to allow plans adequate time to implement systems

changes. Please refer to the complete "Response to Comments" document for further information on this collection.

The 30-day notice published in the Federal Register on May 5, 2022 (87 FR 26759)

Outside Consultation

CMS has consulted with our contractor, NORC at the University of Chicago, to design and conduct the cognitive interviews for this information collection.

9. Payments/Gifts to Respondents

This enrollment form requests information to determine eligibility for, and enroll a beneficiary into a MA, MA-PD or PDP plan. There are no payments/gifts to respondents. (Requirements for plans offering nominal gifts to beneficiaries for marketing purposes, provided the gift is given regardless of whether they enroll, and without discrimination, are outlined in the *Medicare Communications and Marketing Guidelines.*)

10. Confidentiality

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). Sections 1851 and 1860D-1 of the Social Security Act (the Act) and 42 CFR §§ 422.50, 422.60, 423.30, and 423.32 authorize the collection of this information including all Federal and State laws regarding confidentiality and disclosure.

11. Sensitive Questions

The collection does not solicit questions, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. However, the collection solicits questions on a voluntary basis, such as race and ethnicity information, to understand the diverse populations served within the plans service area. The collection informs enrollees that a response to these questions is optional and health and prescription drug coverage would not be denied or affected if the individual responds or declines to respond.

CMS recognizes the need to embark on an educational campaign and activities with independent agents and brokers to assure Medicare beneficiaries understand: (1) the impetus for the voluntary collection of race and ethnicity information as part of the enrollment process, and (2) that a response or lack thereof, does not impact coverage or the cost of coverage.

12. Burden Estimates

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Occupation Title	Occupation Code	Mean Salary ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Wage ($/hr)
All Occupations	00-0000	27.07	n/a	n/a
Business operation specialists	13-1000	37.66	37.66	75.32
Office and Administrative Support Workers, All Other	43-9199	18.91	18.91	37.82

Wages for Individuals: To derive average costs for individuals, we used data from the May 2019 National Occupational Employment and Wage Estimates for our salary estimate. We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at $27.07/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.

Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Information Collection Requirements and Associated Burden Estimates

Subpart B – Eligibility, Election and Enrollment

Eligibility to elect an MA plan (§ 422.50)

Beneficiary Burden

To elect an MA plan an individual must complete and sign an election form or complete another CMS-approved election method offered by the MA organization and provide information required for enrollment.

The burden associated with this requirement is captured below in § 422.60.

Election process (§ 422.60)

The election form or another CMS approved election method offered by the MA organization must be completed by the MA eligible individual (or the individual who will soon become entitled to Medicare benefits) and include authorization for disclosure and exchange of necessary information between CMS and the MA organization. Individuals (i.e., authorized representatives) who assist beneficiaries in completing the enrollment form must sign the form and indicate their relationship to the beneficiary.

There are approximately 8,928,380 enrollments processed by MA and MA-PDs in 2020. For this revised submission, we are adding 62,416 enrollments to be processed annually for a total of **8,990,796**. As explained in section 15 of this supporting statement, this revised estimate consists of the estimated 59,000 beneficiaries to enroll in MA plans, 651 beneficiaries transitioned out of a D-SNP look-alike per year in 2021 through 2023, and 2,765 beneficiaries to enroll in MSA plans. Based on the information requested for completion by the applicant on the enrollment form, we estimate it takes an enrollee **0.333 hour(s)** to complete.

The first burden associated with this requirement is the time and effort necessary for an individual to complete/submit the enrollment request.

The burden for all beneficiaries is estimated as follows:

We estimate an annual burden of **2,996,932 hours** (8,990,796x 0.333 hours), with a consequent burden/cost of $81,126,949 (2,996,932 x $27.07) or $9.02 per beneficiary ($81,126,949/ 8,990,796 enrollments).

Plan Burden

Additional burden associated with this requirement are 1) the time and effort for the MA plan to determine eligibility for enrollment, 2) submit the enrollment to CMS, 3) generate and submit the enrollment decision to the beneficiary and 4) retain the enrollment request. The time and cost burdens for these actions are outlined below.

(1) We estimate it would take approximately 5 minutes at 75.32/hr for a business operations specialist to determine an enrollee's eligibility and effectuate changes for enrollment. The burden for all organizations is estimated at **749,233 hours** (8,990,796 beneficiaries x 5 min/60) at a cost of $56,432,230 (749,233 hours x $75.32/hour) or $89,860 per organization ($56,432,230 /628 MA/MA-PDs).

(2) The MA organization must submit each enrollment transaction to CMS promptly. We estimate it would take the plan 1 minute per enrollment processed. The burden associated with

electronic submission of enrollment information to CMS is estimated at **149,847 hours** (8,990,796 notices x 1 min/60) at a cost of $11,286,476 (149,847 hr x $75.32/hr business operations specialist) or $1.26 per notice ($11,286,476 / 8,990,796 notices) or $17,972 per organization ($11,286,476 / 628 MA/MA-PD contracts).

(3) Once the enrollment change is completed, CMS estimates it would take 1 minute at $75.32/hr for a business operations specialist to electronically generate and submit a notice to convey acceptance or denial of the enrollment request for each of the 8,990,796 beneficiaries. The burden associated with each organization providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1/60th of an hour (1 minute) per application processed. The annual total burden is estimated at 8,990,796 /60 = **149,847 hours**, resulting in an annual cost of 149,847 hours x $75.32 (hourly wage of a business operation specialist) = $11,286,476.

(4) Additionally, per 422.60(c)(2), MA organizations must file and retain MA plan election forms, as well as records of MA enrollment requests made by any other enrollment request mechanism, for the period specified in CMS instructions.

The burden associated with this requirement is the time required for each organization to perform record keeping on each new application filed. It is estimated that it will take each organization 1/12 of an hour (5 minutes) times 8,990,796, the number of enrollments processed by MA/MA-PDs in 2020, resulting in an annual burden of 8,990,796 x (5 min/60) = **749,233 hours**, and an annual cost of 749,233 hours x $37.82 (hourly wage of an administrative and support worker) = $28,335,992.

The total burden to MA and MA-PD plans of 422.60 is **1,798,160 hours** (749,233 + 149,847 + 149,847 + 749,233) at a total cost of $107,341,174 (56,432,230 + 11,286,476 + 11,286,476 + 28,335,992).

Subpart B – Eligibility and Enrollment

Enrollment process (§ 423.32)

To elect a Prescription Drug Plan (PDP) an individual must complete and sign an election form or complete another CMS-approved election method offered by the Part D sponsor and provide information required for enrollment.

The election form or another CMS approved election method offered by the stand-alone PDP sponsor must be completed by the Part D eligible individual (or the individual who will soon become entitled to Medicare drug benefits) and include authorization for disclosure and exchange of necessary information between CMS and the PDP sponsor. Individuals (i.e. authorized representative) who assist beneficiaries in completing the enrollment form must sign the form and indicate their relationship to the beneficiary.

There are approximately **7,116,852**, enrollments processed by stand-alone PDPs in 2020. Based on the information requested for completion by the applicant on the enrollment form, we estimate it takes an enrollee **0.333 hour**(s) to complete.

The first burden associated with this requirement is the time and effort necessary for an individual to complete/submit the enrollment request.

We estimate an annual burden of **2,372,284 hours** (7,116,852 x 0.333 hours), with a consequent burden/cost of $64,153,518 (2,372,284 hr x $27.07) or $9.02 per beneficiary ($64,217,727 / 7,116,852 enrollments).

Plan Burden

Additional burden associated with this requirement are 1) the time and effort for the Part D plan to determine eligibility for enrollment, 2) submit the enrollment to CMS, 3) generate and submit the enrollment decision to the beneficiary and 4) retain the enrollment request. The time and cost burdens for these actions are outlined below.

(1) We estimate it would take approximately 5 minutes at 75.32/hr for a business operations specialist to determine an enrollee's eligibility and effectuate changes for enrollment. The burden for all organizations is estimated at **593,071 hours** (7,116,852 beneficiaries x 5 min/60) at a cost of $44,670,108 (593,071 hours x $75.32/hr) or $676,820 per organization ($44,670,108 /66 PDPs).

(2) As noted in 423.32 (c), the Part D sponsor must submit each enrollment transaction to CMS promptly. We estimate it would take the plan 1 minute per enrollment processed. The burden associated with electronic submission of enrollment information to CMS is estimated at **118,614 hours** (7,116,852 notices x 1 min/60) at a cost of $8,934,006 (118,614 hr x $75.32/hr business operations specialist) or $1.25 per notice ($8,934,006 / 7,116,852 notices) or $135,364 per organization ($8,934,006 / 66 Part D contracts).

(3) Once the enrollment change is completed, CMS estimates it would take 1 minute at $75.32/hr for a business operations specialist to electronically generate and submit a notice to convey acceptance or denial of the enrollment request for each of the 7,116,852 beneficiaries. The burden associated with each sponsor providing the beneficiary prompt written notice, performed by an automated system, is estimated at 1/60th of an hour (1 minute) per application processed. The annual total burden is estimated at 7,116,852 /60 = **118,614 hours**, resulting in an annual cost of 118,614 hours x $75.32 (hourly wage of a business operation specialist) = $8,934,006.

(4) Additionally, PDP sponsors must file and retain Part D plan election forms, as well as records of PDP enrollment requests made by any other enrollment request mechanism, for the period specified in CMS instructions.

The burden associated with this requirement is the time required for each organization to perform record keeping on each new application filed. It is estimated that it will take each organization

1/12 of an hour (5 minutes) times 7,116,852, the number of enrollments processed by standalone PDPs in 2020, resulting in an annual burden of 7,116,852 x (5 min/60) = **593,071 hours,** and an annual cost of 593,071 hours x $37.82 (hourly wage of an administrative and support worker) = $22,429,945.

The total burden to stand-alone Part D plan sponsors of 432.32 is **1,423,370 hours** (593,071 + 118,614 + 118,614 + 593,071) at a total cost of $84,968,065 (44,670,108 + 8,934,006 + 8,934,006 + 22,429,945).

As established by 42 CFR 422.50 and 422.60, individuals who meet the eligibility criteria may enroll in an MA plan. Similarly, 42 CFR 423.30 and 423.32 affords individuals eligible for Part D to enroll in a PDP. Requests for enrollment must comply with CMS instructions and be approved by CMS. CMS permits multiple ways in which a beneficiary can submit an enrollment request to the MA or Part D organization of his or her choice, such as paper, telephonic and electronic. In all instances, the MA and Part D organization is required to determine eligibility for enrollment based on the required collection of information.

While each organization develops their own enrollment collection (or "form"), sub-regulatory guidance, Chapter 2 and Chapter 3 of the Medicare Managed Care Manual outlines the items required to be collected for each enrollment request. These items are required to determine if the beneficiary is eligible for plan enrollment per statutory and regulatory requirements, and to submit the enrollment transaction to CMS. The enrollment request may also include optional items, which aid the MA and Part D organization to efficiently process the request and set up beneficiary preferences for services.

Previously, the model enrollment form was not an OMB-approved form; however, the data elements required to be collected in order for the enrollment request to be considered valid were approved under OMB control number 0938-0753 (CMS-R-267) and 0938-0964 (CMS-10141). The previously approved model enrollment "form" (attachment 1a), limits data collection to what is lawfully required to process the enrollment, and, other limited information that the sponsor is required or chooses to provide to the beneficiary.[1]

The model form consists of the following parts: (1) cover page with instructions, (2) model enrollment request form which is divided into sections. Section 1 includes data elements required to process the beneficiary's enrollment. Section 2 includes data elements that CMS requires the plan to include on the application, even if those data elements are voluntary for a beneficiary to fill out. The race and ethnicity data, will be in Section 2 and will be **optional** for the beneficiary to complete. Plan enrollment will not be affected if the beneficiary completes or does not complete this additional information, and, (3) optional sponsor addendum which is not required to be completed by the beneficiary. This optional addendum can include items such as premium payment option or beneficiary's choice of primary care physician including beneficiary language or accessible format preference. Please see model enrollment form attached.

[1] Requests for enrollment must comply with all requirements outlined in §§ 422.2262 & 423.2262 and be approved by CMS.

Subpart V – Medicare Advantage Communication Requirements

Review and Distribution of Marketing Materials (§ 422.2262)

To customize and produce the enrollment forms will require two teams: one team for requirements and another team for implementation.

The team to produce requirements will consist of a chief executive, a marketing manager, a web developer and a compliance officer. The chief executive is needed to explain plan goals. The marketing manager is needed to explain what sells best. Similarly, the web developer is needed to explain how people use websites and what works well. Finally, the compliance officer will assure that all needed elements are present. This requirements team will have an hourly wage of $493.68as shown in Table 2.

Table 2: Implementation Team & Requirements

Occupation Title	Occupation Code	Mean Salary	Fringe Benefits and Overhead	Cost per hour
Chief Executives	11-1011	95.12	95.12	190.24
Marketing Managers	11-2021	74.27	74.27	148.54
Web Developers	15-1257	41.10	41.10	82.20
Compliance Officers	13-1041	36.35	36.35	72.70
Computer Programmer	15-1251	45.98	45.98	91.96
Computer Systems analyst	15-1211	47.61	47.61	95.22

We estimate that each of the **628 MA/MA-PD contracts** will spend four hours for the development at a per contract cost of $1,974.72 (4*493.68). Therefore, the 628 plans will spend **2,512 hours** (628*4 hr) at a cost of 1,240,124 (1,974.72*628).

To implement the requirements will require a team of two professionals, a computer programmer and a computer systems analyst. The systems analyst is needed because multiple systems are being used both enrollment systems and web systems and the software programmer is needed to write the code. The hourly wage for the implementation team is $187.18. This is presented in Table 2

We estimate that each of the 628 contracts will spend 2 hours for the software implementation at a cost of $374.36 (2*187.18). Therefore, all 628 contracts will spend a total of **1,256 hours** (628 contract * 2 hours) at a cost of $235,098 (628*374.36/contract).

The total burden for 628 contracts is **3,768 hours** (2,512 hours requirements + 1256 hours for implementation) at an aggregate cost of 1,475,222 (1,240,124 for requirements + $235,098for implementation).

Subpart V – Communication Requirements, Review and Distribution of Marketing Materials (§ 423.2262)

To customize and produce the enrollment forms will require two teams: one team for requirements and another team for implementation.

The team to produce requirements will consist of a chief executive, a marketing manager, a web developer and a compliance officer. The chief executive is needed to explain plan goals. The marketing manager is needed to explain what sells best. Similarly, the web developer is needed to explain how people use websites and what works well. Finally, the compliance officer will assure that all needed elements are present. This requirements team will have an hourly wage of $493.68 as shown in Table 2.

We estimate that each of the **66 PDP** contracts will spend four hours for the development at a per contract cost of $1,974.72 (4*493.68). Therefore, the 66 plans will spend **264 hours** (66*4 hr) at a cost of 118,483 (1,974.72 *66).

To implement the requirements will require a team of two professionals, a computer programmer and a computer systems analyst. The systems analyst is needed because multiple systems are being used both enrollment systems and web systems and the software programmer is needed to write the code. The hourly wage for the implementation team is $187.18. This is presented in Table 2.

We estimate that each of the 66 PDP contracts will spend 2 hours for the software implementation at a cost of $374.36 (2*187.18). Therefore, all 66 PDP contracts will spend a total of **132 hours** (66 contract * 2 hours) at a cost of $24,708 (66*374.36/contract).

The total burden for 66 contracts is **396 hours** (264 hours requirements + 132 hours for implementation) at an aggregate cost of 143,191 (118,483 for requirements + $24,708 for implementation).

Responses – 32,215,990

TOTAL BURDEN 8,594,910

13. Capital Costs

Potential implementation costs are discussed in Section 12 which includes the costs of producing software. No additional capital or IT equipment costs will result from this collection since the software upgrades are sufficient to accomplish the task. MA and Part D Sponsors IT systems are fully operational/equipped to accept plan enrollments and determine an individual's eligibility per statutory and regulatory requirements.

14. Cost to Federal Government

MA organizations and Part D sponsors are responsible for the information collection requirements in this package. Plans receive the enrollment, determine eligibility, make a determination if the enrollment is accepted, denied or incomplete and finally communicate the decision to the beneficiary within specified timeframes. CMS systems provide automated responses to plan submitted transactions on a transaction reply report, which includes no additional burden or cost to change or shorten the enrollment form. There is no change to the process CMS uses for plans to submit the enrollment and therefore there is no additional cost to the Federal Government.

15. Program/Burden Changes

The current 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 updated and approved on October 21, 2021 based on final rule CMS-4190-F, RIN 0938-AT97, to account for changes to the number of Medicare-eligible beneficiaries estimated to make a valid enrollment request for calendar year (CY) 2021 through 2023 for End Stage Renal Disease (ESRD) Beneficiaries (§§ 422.50, 422.52, and 422.110), the Contracting Standards for Dually-Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514), and the MLR Deductible Factor for MA MSA Contracts (§ 422.2440). As outlined in Section 12 of the Supporting Statement, with regard to the expanded enrollment options for individuals with ESRD, we estimated an aggregate annual increase of 19,647 hours for ESRD beneficiaries to enroll in MA plans per year in 2021 through 2023. For the contracting standards for dual eligible special needs plan (D-SNP) look-alikes, we estimated an aggregate annual enrollee burden increase of 218 hours. For the Medical Loss Ratio (MLR) deductible factor for MA Medical Savings Account (MSA) contracts, we estimated an aggregate annual increase of 922 hours for a beneficiary to complete an enrollment form. Overall, we projected an increase of 62,416 respondents, 62,416 responses, 20,787 hours, and $534,616.

We are updating this collection of information request to account for changes to our currently approved form to include the addition of race and ethnicity data categories. We also added general enrollment assistance information on the cover page for individuals experiencing homelessness that do not have a permanent residence address but are eligible to enroll in a Medicare Advantage or Medicare Prescription Drug Plan. This updated information collection request does not propose any program changes or adjustments.

16. Publication/Tabulation

Currently, there are no plans to publish or tabulate the information collected.

17. Expiration Date

CMS would like the MA and Part D enrollment forms to display the expiration date next to the OMB control number.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

This collection does not employ statistical methods.