The Centers for Medicare and Medicaid Services (CMS) received comments on the Model Medicare Advantage and Medicare Prescription Drug Plan Individual Enrollment Request Form (CMS–10718, OMB 0938-1378), as outlined by the *Federal Register* notice dated January 12, 2022 from Medicare Advantage (MA) and Prescription Drug Plan (PDP) Organizations and other essential stakeholders. This is the reconciliation of the comments.

Comment: A number of commenters supported CMS's proposal to collect self-reported race and ethnicity data from Medicare beneficiaries through the Medicare Parts C and D enrollment form to provide granular information for plans and CMS to understand the diversity of the beneficiary population. Two commenters suggested CMS collects this information more broadly across additional programs, including Medicare Fee-for-Service (FFS) and Exchanges to enable comparisons between each program serving Medicare beneficiaries as well as to improve standardized data collection.

Response: We appreciate the comments and agree, as noted in the Supporting Statement, that CMS's long-term goal is to collect granular, self-reported race and ethnicity data from all Medicare beneficiaries. Currently, the enrollment form for the Health Insurance Exchanges through the HealthCare.gov eligibility and enrollment platform collects race and ethnicity data using these same, granular standards (i.e. the <u>2011 HHS Data Standards</u>); thus, collecting race and ethnicity on the Medicare Part C and D enrollment forms will allow for apples-to-apples comparisons across these populations where needed.

Comment: Several commenters, citing some stakeholder concerns regarding operationalizing the changes to the model enrollment form for the 2023 Annual Enrollment Period (AEP), requested that CMS provide plans the flexibility to adopt and use the revised form for the 2024 AEP. Another commenter stated that in order for MA and Part D sponsors to comply with the proposed changes to the model enrollment request form and submit the collected race and ethnicity data to CMS, updates would be required to add new fields to plan transmission files. In addition, CMS would need to provide an updated record layout and a technical changes memo to advise plans of the new submission requirements, should these changes to the model be adopted. The commenter estimates these changes to take at least six months and further requests that CMS provide plans with a timeline for these expected changes.

Another commenter recommended that CMS considers any refinements to be incorporated into the model enrollment form for use during the 2024 Annual Enrollment Period and beyond. A commenter queried if the MA and PDP enrollment and disenrollment chapters would be updated with the revised forms.

Response: Thank you for the comments. CMS appreciates the suggestions and concerns expressed by these commenters, and agrees that plans should be given adequate time to implement system updates. We plan to release the new model MA and Part D enrollment form, at least 6 months prior to the start of the data collection, which we believe will afford plans adequate time to make the changes necessary prior to the Medicare Advantage Open Enrollment Period (MA-OEP) which starts on January 1, 2023 – March 31, 2023. There will be no updates to the MA and PDP Enrollment guidance except to include the new model MA and Part D model enrollment form.

Comment: A commenter requested we identify any downstream impacts to the Online Enrollment Center (OEC), Transaction Reply Report (TRR), and the Monthly Membership Report (MMR) files to give plans time for systems changes. Another commenter asked that CMS details how the race and ethnicity data files will be reported back to CMS and any other reporting requirements that will incorporate the data. The commenter also suggested the data could be used for broader reporting and current plan initiatives to better understand and address barriers within the Medicare population, but also questioned CMS's expectations for how plans may use the data.

Response: CMS will strive to provide plans with the updated OEC, TRR, and MMR technical specifications as soon as possible to ensure sufficient time for implementation. We agree that the race and ethnicity data collected can be used for reporting – for example, for stratified reporting (i.e. reporting of key indicators across race and ethnicity groups for the identification of areas of difference, or disparity, across groups). Plans may use these data to understand racial/ethnic distribution of populations served, changes in those distributions over time, or to identify areas where there may be disparities in coverage, health and health-related outcomes. Additionally, plans can use the information for targeting quality improvement activities and resources, monitoring health and drug plan performance, and advancing the development of culturally and linguistically appropriate quality improvement interventions and strategies. CMS's Office of Minority Health (CMS OMH) has been publishing national-level stratified reporting information for Medicare Advantage plans since 2016; more granular data would strengthen these efforts.

<u>Comment:</u> Several commenters recommended CMS to consider combining the race and ethnicity question into one question. Several commenters mentioned research from the U.S Census Bureau that has shown that a "combined" method yields higher response rates and allows individuals to self-identify more accurately. A commenter suggested not separating Hispanic, Latino/a, and Spanish origin question from race. Some commenters advocated adding Arab, Middle Eastern and North African (MENA) categories as a separate race category on the enrollment form as this data has been lacking across federal agencies for years.

A commenter suggested the collection of ethnicity data that includes country of origin, notably for Black (e.g., Caribbean, African American); Asian (e.g., Japanese, Chinese, Vietnamese); and Hispanic (e.g., Mexican, Venezuelan, Cuban) Medicare beneficiaries, and currently used by the Census Bureau, allows plans to better identify health trends that affect these populations and build culturally competent interventions to address disparities.

A commenter requested that if possible, we remove the use of an "other" category and add a space where the enrollee can fill in the blank. This commenter suggested CMS includes instructions on the form and in the use of the form that enrollees may check or write in as many answers as is meaningful to them.

Another commenter noted that the benefits of adding more accurate ethnic and racial categories to encourage self-identification far outweigh any risk of deterring response.

Response: We appreciate the suggestions provided by the commenters. We intend to comply with the 2011 HHS implementation guidance on data collection standards for the collection of race and ethnicity; these standards were developed by the Department of Health and Human Services (HHS)'s Data Council as a result of Section 4302 of the Affordable Care Act. These guidelines are well-established and are used in other settings across CMS (e.g. Marketplace), which will allow for apples-to-apples comparisons of race and ethnicity distributions across programs. These guidelines offer subcategories for Asian and Native Hawaiian and Other Pacific Islander race, as well as subcategories for Hispanic or Latino ethnicity. At present, these guidelines do not include the suggestions the commenters provided, including the MENA subcategories; however, CMS is interested in exploring the opportunities for updating, and expanding, these guidelines in the future.

Comment: A commenter expressed support for CMS's use of the race and ethnicity categories, which are compliant with the 2011 HHS Data Collection standards on the MA and Part D enrollment form. The commenter, however, recommended that CMS aligns the enrollment form with the United States Core Data for Interoperability (USCDI) data standards, which includes race and ethnicity, among other patient demographics. The commenter further urges the HHS and OMB to implement a diverse multi-stakeholder process to not only improve data collection of race, ethnicity, and language data but also help to mitigate harmful bias and improve care.

Response: Thank you for this comment. We agree that it is important to mitigate harmful bias and further improve upon care quality, and believe that the collection of robust and granular race and ethnicity data will be a critical step toward that goal. While we intend to rely on the 2011 HHS Data Standards for the race and ethnicity elements on the Part C and D enrollment forms, we believe that the USCDI standards for race and ethnicity data elements will inform any future opportunities to improve and expand upon any standard for race and ethnicity data elements that CMS adopts. We appreciate the suggestion.

Comment: A commenter suggested that CMS maintains the 'do not enter a PO Box' on the enrollment form, and consider adding a check box or field for an individual to indicate if they are experiencing homelessness or do not have stable housing – a question that justifies listing a PO box and allows targeted outreach to those that truly need the assistance. The commenter also asked for a definition of homelessness as they have come across applicants that have a gap in their permanent residence due to selling or building a home.

Response: We appreciate the comment and will take the suggestion in to consideration. We, however, did not propose removing the 'do not enter a PO Box' field on the enrollment form. Consistent with longstanding policy regarding permanent residence, in the case of homeless individuals, a Post Office Box may be considered the place of permanent residence. Regarding the commenter's ask for a definition of homelessness, for the purpose of the MA and Part D enrollment form, we did not define homelessness but there are a number of definitions available that may be helpful, such as from the U.S. Department of Housing and Urban Development or for purposes of ICD-10-CM Z codes coding.

Comment: Several commenters expressed support for the use of focus groups to identify drivers of non-response and request that CMS share the outcomes of these focus groups to educate plans.

Response: We thank you for your comments. CMS agrees and will ensure that the updated CMS-10718 Paperwork Reduction Act (PRA) package and the stand-alone focus group testing PRA package details the methodology and results of the focus groups.

Comment: A few commenters suggested we clarify how race and ethnicity data would be used. A commenter recommended that CMS provides plans with resources to explain why demographic data is being collected, how enrollees' privacy will be protected, how and with whom the data will be shared, and how the data will be used. Another commenter asked for further clarity on how health equity data for beneficiaries who select multiple races or ethnicities would be counted and used.

Response: We appreciate the commenters' suggestions. We intend to comply with the 2011 HHS implementation guidance on data collection standards for the collection of race and ethnicity; these standards were developed by the Department of Health and Human Services (HHS)'s Data Council as a result of Section 4302 of the Affordable Care Act (ACA). These guidelines are well-established and are used in other settings across CMS (e.g. Marketplace), which will allow for apples-to-apples comparisons of race and ethnicity distributions across programs. These guidelines offer subcategories for Asian and Native Hawaiian and Other Pacific Islander race, as well as subcategories for Hispanic or Latino ethnicity. Plans may use these data to understand racial/ethnic distribution of populations served, changes in those distributions over time, or to identify areas where there may be disparities in coverage, health and health-related

outcomes. Additionally, plans can use the information for targeting quality improvement activities and resources, monitoring health and drug plan performance, and advancing the development of culturally and linguistically appropriate quality improvement interventions and strategies. CMS's Office of Minority Health (CMS OMH) has been publishing <u>national-level</u> <u>stratified reporting</u> information for Medicare Advantage plans since 2016; more granular data would strengthen these efforts. Additionally, we agree that it is important to allow individuals to make multiple race and ethnicity selections and will take this suggestion under consideration as we update the enrollment form to ensure that the collection aligns with the <u>2011 HHS Data Standards</u>.

Comment: A commenter expressed a lack of support for CMS's proposal to collect race and ethnicity data via the model MA and Part D enrollment form.

Response: We thank you for your comment. We believe it is important that we are able to collect this information. The recent Executive Orders (EOs) 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and 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. Plans may use these data to understand racial/ethnic distribution of populations served, changes in those distributions over time, or to identify areas where there may be disparities in coverage, health and health-related outcomes. Additionally, plans can use the information for targeting quality improvement activities and resources, monitoring health and drug plan performance, and advancing the development of culturally and linguistically appropriate quality improvement interventions and strategies. CMS's Office of Minority Health (CMS OMH) has been publishing national-level stratified reporting information for Medicare Advantage plans since 2016; more granular data would strengthen these efforts.

<u>Comment:</u> Several commenters proposed CMS expands data collection efforts to include sexual orientation, gender identity and sex characteristics (SOGISC) data via the model enrollment form. A commenter noted that the pursuit of health equity cannot overlook the importance of SOGISC data as research shows LBGTQ individuals experience varying forms of disparities in health care. This commenter further stated that knowledge of an individual's SOGI status through an enrollment form will allow providers to provide better person-centered care.

Response: We appreciate the commenters' suggestion and agree with the commenters. As part of a broader health equity effort, CMS is interested in identifying patterns of differences across many key process and care outcomes by sociodemographic characteristics, including race and ethnicity, and will be exploring future initiatives to include additional health equity data elements on the form.

Comment: Several commenters suggested revisions to the language preference(s) question. A commenter requested revisions to enable demographic identification of limited English-proficient (LEP) individuals. Two commenters stated that while the current forms seek information about an enrollee's language, the collection is limited to languages in which plans have to provide translated information only for languages spoken by at least 5% of the population served. Instead, commenters identify the benefits of CMS collecting primary language of all applicants as this information can be used for planning purposes by plans and providers and not merely identify which individuals are eligible to receive a translated document. The commenters further cited that capturing primary language at enrollment can help plans identify how to best to provide language services in its Call Center, identify individuals needing interpreter services when meeting with providers or at the pharmacy. In almost all cases, speakers of languages other than English or Spanish get no benefit from the current translation regulation.

Response: We thank the commenters for the feedback. We will take this information into consideration for any opportunities to update the language preference data element on the form.

Comment: A commenter stated that CMS should add validated disability questions that appropriately capture mental and functional status. This commenter expressed concern that Medicare does not currently routinely collect and report information about health care disparities for people with disabilities citing that a significant portion of Medicare enrollees have a disability. The commenter recommended that CMS add questions on the enrollment form, starting with the six-question series that is used on the American Community Survey, CAPHS, MCBS, and other national surveys. The commenter noted that capturing data about an enrollee's disabilities and functional status at the time of enrollment allows providers to plan for accommodations that can improve the enrollee's quality of care. Additionally, it allows plans to share utilization data across various disability categories, allowing CMS to better monitor quality of care.

Response: Thank you for this question. We agree that there is a need for robust disability information for Medicare enrollees and we are eager to explore future opportunities to collect this information. We appreciate the commenter's recommendation regarding specific, existing disability questions to add to this form – this information will be useful when, and if, we consider exploring this option.

Comment: A commenter encouraged CMS to ensure that the privacy protections applied to demographic data comply with the privacy and security standards set forth in ACA Section 3101, which built upon the privacy protections required by HIPAA. The commenter noted that strict standards must be adopted to ensure that data cannot be used for negative actions such as immigration or law enforcement, redlining or targeting of specific groups. The commenter further noted that enrollees should be made aware of their privacy protections and rights and

have a clear understanding of why demographic data is being collected and who will have access to which forms of information.

Response: Thank you for this comment. We understand the concerns regarding data privacy and will take all the necessary steps to ensure that enrollees' privacy is protected and safeguards are put in place for data sharing. The privacy and security of Medicare beneficiary information remains a top priority for CMS. We also maintain that other entities must adhere to the strict standards established by the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA). The model MA and Part D enrollment form includes a Privacy Act statement, located at the bottom of the form, that cites why and the how the information is used.