# **Change Request**

**Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Reporting System**

(OMB no. 0920-0612, exp. date 03/31/2025)

March 23, 2023

# **Background and Justification**

The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program is a direct service program that provides clinical screening and healthy behavior support services to uninsured and underinsured women aged 40 to 64. The goal of the WISEWOMAN program is to reduce risk factors for cardiovascular disease (CVD) in a vulnerable and under-served population. Women in lower income brackets, or without health insurance, have an increased risk of CVD morbidity and mortality because they have limited access to health services such as screenings, medications, and healthy behavior support services. Through CDC’s WISEWOMAN program, state governments and tribal organizations receive funding to provide these services, and report information to CDC through the funding recipient’s annual progress report and an electronic dataset on clients enrolled in the program. The current dataset consists of 59 minimum data elements (MDE) that address CVD risk factors such as elevated blood cholesterol, high blood pressure, obesity, diabetes, smoking, sedentary lifestyle, and client demographics and behaviors, which are incorporated into the client’s health department electronic health record. Information is collected by providers at the time of enrollment and at rescreening (a minimum of 11 months post-enrollment). The information reported to CDC is used to evaluate the effectiveness and outcomes of WISEWOMAN services and programs.

CDC requests OMB approval for 11 additional data elements that align with the current purpose and scope of existing WISEWOMAN data elements. The additional MDE will strengthen:

* Program fidelity: Proposed additional elements will involve ascertaining social needs and will help decipher ways to mitigate barriers that are preventing active participation in the WISEWOMAN program. These proposed changes will improve CDC’s ability to improve CVD risk analysis and program efficacy.
* Data Quality: Proposed changes to MDEs provide companion data to existing data elements to provide a more complete picture for underserved women in the WISEWOMAN Program.

This request is a refinement of our current data approach of continuously serving underserved populations and also in line with HHS’s current health equity goals. The additional data elements emanate from the Notice of Funding Opportunity announcement (CDC-RFA-DP-23-0003) that was published in late March. These additional MDEs will improve analytical utility, program fidelity, and data quality and will have a marginal effect on burden hours. Overall, if approved the total number of MDEs will be 70. No changes are being proposed to the Annual Progress Report.

This Change Request also includes:

* non-substantive changes to response option to 2 previously approved MDEs in order to improve data accuracy. Proposed response option changes involve including distinction of modality for a follow-up screening, and maternal related diseases as a part of previous medical history.
* one (1) minor change to the wording an approved MDE question that will allow for more contextual knowledge about the respondent’s primary spoken language and enhance the engagement of non-English speaking participants in the WISEWOMAN program.

An overview of the proposed change to the MDEs is provided in Exhibit 1. Details of how the updated MDEs will appear and their exact locations in the manual are provided in Exhibit 2 and Exhibit 3. The exhibits are attached.

**Attachments**

* Exhibits
	1. Overview of Change Request
	2. Additional Proposed Minimum Data Elements
	3. Modifications to Previously Approved Minimum Data Elements
* WISEWOMAN MDE Manual

 **Implementation Schedule**

CDC is submitting this change request to OMB to provide Minimum Data Elements implementation guidance to programs for the new program year, which begins September 2023.

**Effect on Burden Estimate**

Minor change in burden is projected. Addition of 11 MDEs and non-substantive changes to 3 previously approved MDEs results in a total of 14 MDEs. Please see current and projected change in Estimated Burden Hours:

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**Table 1: Number of Respondents and Current Estimated Burden Hours**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondents** | **Type of Collection** | **No. of Respondents** | **Annual Frequency per Response** | **Hours per Response** | **Total Hours** |
| WISEWOMAN Awardees | Screening and Assessment and Lifestyle Program MDEs | 35 | 2 | 24 | 1680 |
| Annual Progress Report | 35 | 1 | 16 | 560 |
|  | Total |  | 3 | 40 |       2,240 |

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| --- |
|  |

**Table 2: Number of Respondents and Change in Estimated Burden Hours**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of Respondents** | **Type of Collection** | **No. of Respondents** | **Annual Frequency per Response** | **Hours per Response** | **Total Hours** |
| WISEWOMAN Awardees | Screening and Assessment and Lifestyle Program MDEs | 35 | 2 | 25 | 1750 |
| Annual Progress Report | 35 | 1 | 16 | 560 |
|  | Total |  | 3 | 41 |       2,310 |

**Exhibit 1. Overview of Change Request**

| **Type**  | **Elements Affected** | **Number of Elements** |
| --- | --- | --- |
| Additions to Minimum Data Elements Question or Response Options | Internet Access, Food Insecurity, Transportation Barriers, Child-Care Barriers, Housing Insecurity, Domestic Partnerships, Medication Adherence, and Referral to Social Needs | 11 |
| Modifications to current Minimum Data Elements Question or Response Options | Type of Screening Visit, Primary Language, Medical History | 3 |

**Exhibit 2. Proposed Additions to Minimum Data Elements Question or Response Options**

We propose to add 11 new MDE questions.  Capturing these barriers will enhance program implementation through engaging women, reducing their hypertension, and addressing barriers by making referrals to specific social support services offered by partners.  This includes internet access, food, housing, transportation, childcare barriers, intimate partner violence and barriers to medication adherence.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **MDE Field Name and File Position Location** | **Reference Document*Current Information Collection*** | **Changes Document*****Proposed Changes*** | **Rationale*Brief description of* intent *of change*** |
| 1 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | Do you own or use any of the following types of computer? Desktop/LaptopSmartphoneTablet/Other portable wireless Computer1. Yes2. No. 7. Don’t know8. Don’t want to answer9. No answer recorded | American Community Survey |
| 2 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | Do you or any member of this household have access to the internet?Yes- by paying a cell phone company or internet service provider.Yes- without paying a cell phone company or internet service provider. No access to internet in this house, apartment, or mobile homeDon’t knowDon’t want to answerNo answer recorded | American Community Survey |
| 3 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | During the last 12 MONTHS, was there a time when you were worried you would run out of food because of a lack of money or other resources?1. Yes
2. No

Don’t knowDon’t want to answerNo answer recorded | Food insecurity question will capture barriers to program engagement. This question is adapted from [Food Insecurity Experience Scale | Voices of the Hungry | Food and Agriculture Organization of the United Nations (fao.org)](https://www.fao.org/in-action/voices-of-the-hungry/fies/en/) |
| 4 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | Have you ever missed a doctor’s appointment because of transportation problems?1. Yes
2. No

Don’t knowDon’t want to answerNo answer recorded | Transportation barrier question will capture barriers to program engagement. This question is adapted from [Measuring Health-related Transportation Barriers in Urban Settings – PMC (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5704937/) |
| 5 | **Item****Current Location:** New Question**Proposed Location:** | NO CURRENT QUESTION | If you are you currently using child care services please identify the type of services you use, if not select *Not Applicable*.1. Infant (Birth to 11 months)
2. Toddler (11 to 36 months)
3. Preschool (3 to 5 years)
4. After School Care (K-9th grade)
5. Not Applicable
6. Don’t know

Don’t want to answerNo answer recorded | Childcare barrier question will capture barriers to program engagement. This question is adapted from  [350-056(FCS-132P).pdf (vt.edu)](https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/350/350-056/350-056%28FCS-132P%29.pdf) |
| 6 | **Item****Current Location:** New Question**Proposed Location:** | NO CURRENT QUESTION | Have you had any of these child-care related problems during the past year? (Select all that apply)1. Cost
2. Availability
3. Location
4. Transportation
5. Hours of Operation
6. Other
7. Not Applicable
8. Don’t know
9. No answer recorded
 | Childcare barrier question will capture barriers to program engagement. This question is adapted from  [350-056(FCS-132P).pdf (vt.edu)](https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/350/350-056/350-056%28FCS-132P%29.pdf) |
| 7 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | What is your housing situation today?1. I have housing
2. I have housing, but I am worried about losing my housing
3. I do not have housing

Don’t knowDon’t want to answerNo answer recorded | Housing insecurity question will capture barriers to program engagement. This question is adapted from [*PRAPARE-English.pdf*](https://prapare.org/wp-content/uploads/2021/10/PRAPARE-English.pdf) |
| 8 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | The following will ask about how safe you feel: 1. How often does your partner physically hurt you?
2. How often does your partner insult or talk down to you?
3. Never
4. Rarely
5. Sometimes
6. Fairly Often
7. Frequently
8. Response not given
9. No answer Recorded
 | This copyrighted IPV question can capture a barrier to actively participating in the WISEWOMAN Program.Question is from the Hurt, Insult, Threaten, and Scream (HITS) Tool (page 42).Intimate Partner Violence and Sexual Violence Victimization Assessment Instruments for Use in Healthcare Settings 06\_105344\_IPV\_SVBooklet\_knuth.indd (cdc.gov) |
| 9 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENT QUESTION | These four items are related to medication-taking adherence:1. Do you ever forget to take your (name of health condition) medicine?
2. Are you careless at times about taking your (name of health condition) medicine?
3. When you feel better, do you sometimes stop taking your (name of health condition) medicine?
4. Sometimes if you feel worse when you take your (name of health condition) medicine, do you stop taking it?
5. Yes
6. No

8. Response not given9. No answer Recorded | This proposed question can enhance understanding of participants adherence to medication. These questions are adapted from the Medication Adherence Questionnaire (MAQ) [The Clinical Utility of the Medication Adherence Questionnaire (Maq) in an Alcohol Pharmacotherapy Trial (nih.gov)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5480370/) |
| 10 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | Social Service ID | Identify specific resources used to address social determinant of health and barriers that impede engagement with the WISEWOMAN Program. |
| 11 | **Item** **Current Location:**New question**Proposed Location:** | NO CURRENTQUESTION | Social Service Referral Date1. MM/DD/YYYY
 | Identify specific resources used to address social determinant of health and barriers that impede engagement with the WISEWOMAN Program. |

**Exhibit 3. Proposed Changes to MDE Questions or Response Options**

We propose to alter response options to existing MDEs 2c and 3i and add three response options to existing MDE 4B to increase analytical utility and strengthen the analytical framework of the minimum data elements. The table below describes this element in further detail:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **MDE Field Number** | *Current Information Collection Phrasing* | *Proposed Changes* | **Rationale** |
| 1 | **Item** **Current Location:**2c: Type**Proposed Location:**2c: Type | Type of Screening Visit 1. Screening
2. Rescreening
3. Follow-up screening LSP/HC complete
4. Follow-up screening LSP/HC incomplete
5. No answer recorded
 | Type of Screening Visit 1. *Baseline Assessment*
2. *Reassessment*
3. *Follow-up Assessment (in-person)*
4. *Follow-up Assessment (at-home)*
5. No answer recorded
 | These modified responses can increase analytical utility and distinction between in-person and at-home follow-up screening visits. |
| 2 | **Item** **Current Location:**Item 3i: Language**Proposed Location:**Item 3i: Language | What is the primary language spoken in your home?01 English02 Spanish03 Arabic04 Chinese05 French06 Italian07 Japanese08 Korean09 Polish10 Russian11 Tagalog12 Vietnamese13 Creole14 Portuguese15 Hmong16 Other Language88 Don’t want to answer99 No answer recorded | *What primary language do you speak?*

|  |
| --- |
| 01 English |
| 02 Spanish |
| 03 Arabic |
| 04 Chinese |
| 05 French |
| 06 Italian |
| 07 Japanese |
| 08 Korean |
| 09 Polish |
| 10 Russian |
| 11 Tagalog |
| 12 Vietnamese |
| 13 Creole |
| 14 Portuguese |
| 15 Hmong |
| 16 “\_\_\_\_” (write in) |
| 88 Don’t want to answer |
| 99 No answer recorded |

 | This modified question can enhance understanding of participants’ needs for appropriate translated materials where needed. |
| 3 | **Item** **Current Location:**4B: SRHA**Proposed Location:**4B: SRHA | Have you had any of the following? (1 for yes/2 for no):\_\_\_ Stroke/TIA\_\_\_ Heart attack\_\_\_ Coronary heart disease \_\_\_ Heart failure\_\_\_ Vascular disease (peripheral arterial disease)\_\_\_ Congenital heart disease and defects1. Don’t know/Not sure
2. Don’t want to answer
3. No answer recorded
 | Have you had any of the following? (1 for yes/2 for no):\_\_\_ Stroke/TIA\_\_\_ Heart attack\_\_\_ Coronary heart disease \_\_\_ Heart failure\_\_\_ Vascular disease (peripheral arterial disease)\_\_\_ Congenital heart disease and defects*\*\_\_\_Gestational hypertension**\*\_\_\_Gestational diabetes**\*\_\_\_Pre-eclampsia/eclampsia*1. Don’t know/Not sure
2. Don’t want to answer
3. No answer recorded
 | This modified response can increase analytical utility as maternal diseases increase risk of CVD later in life. [Gestational diabetes and the risk of cardiovascular disease in women: a systematic review and meta-analysis | SpringerLink](https://link.springer.com/article/10.1007/s00125-019-4840-2)[Future Cardiovascular Disease Risk for Women With Gestational Hypertension: A Systematic Review and Meta‐Analysis | Journal of the American Heart Association (ahajournals.org)](https://www.ahajournals.org/doi/full/10.1161/JAHA.119.013991)[Cardiovascular Disease-Related Morbidity and Mortality in Women With a History of Pregnancy Complications | Circulation (ahajournals.org)](https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.118.036748) |