**Exhibits**

**Exhibit 1. Overview of Proposed Improvements**

| **Type** | **Elements Affected** | **Number of Elements** |
| --- | --- | --- |
| Deletions from Current MDE Requirements | MDE Version, second-hand smoke, quality of life, hip circumference, measurement dates, priority areas, stage of change, length of lifestyle program/health coaching, type of lifestyle program/health coaching setting of lifestyle program/health coaching, and completion of lifestyle program/health coaching | 20 |
| Modifications to Data Elements/Questions or Response Options | Disease diagnosis history, heart related conditions, medication history, medication adherence, dietary and exercise behavior, blood pressure screening date, blood pressure measurements, follow-up alert status, and follow-up alert dates | 25   * Combined elements: 16 reduced to 6 * Rephrased elements: 6 * Renamed elements: 3 |
| New Elements | Navigation status, aspirin/statin therapy, medication follow-up dates, alcohol consumption, and quality of life. | 5 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Number of Current MDEs** | **Delete** | **Combine** | **Add** | **Number of MDEs** |
| 84 | -20 | -10 | +5 | 59 |

**Exhibit 2: Deletions from Current MDE (20):**

CDC proposes to remove twenty MDEs that were determined not to be useful for analysis. The rationale for no longer requiring each one of the twenty is provided in the last column.

| **MDE Field Number** | *Current Information Collection Phrasing* | **Rationale** |
| --- | --- | --- |
| **Item 0a** | 0a. MDE Version   1. Version of MDE Manual | We propose to eliminate this MDE because it is no longer useful as the version number rarely changes. |
| **Item 9b** | 9b. About how many hours a day, on average, are you in the same room or vehicle with another person who is smoking?  \_\_\_ Number of hours   1. Less than one 2. None 3. Don’t want to answer 4. No answer recorded | We propose to eliminate this MDE because grantees report their participants found it difficult to quantify responses to this question, therefore rendering it statistically unreliable. |
| **Item 11d.** | 11d. Hip Circumference  \_\_\_ Hip circumference in inches   1. Unable to obtain 2. Client refused 3. No measurement recorded | We propose to delete hip measurement as it has no analytical utility. Newly published scientific findings suggest that *change* in waist circumference alone is a sufficient predictor of obesity. Change in circumference is MDE 11C. |
| **Item 12d.**  **Item 12e.** | 12d. Systolic Blood Pressure Measurement #2  Blood pressure (mmHg)  12e. Diastolic Blood Pressure Measurement #2  Blood pressure (mmHg) | We propose to remove these MDEs because Item 12b and 12c now allow up to four measurements (see Exhibit 3). Combining them in one place will facilitate questionnaire flow. |
| **Item 14a**  **Item 15a**  **Item 17a** | 14a. Cholesterol Measurement Date  MM/DD/CCYY Date  15a. Glucose/A1c Measurement Date  MM//DD/CC/YY Date  17a. Risk Reduction Counseling Date  MM/DD/CCYY Date | We propose to eliminate cholesterol, glucose, and risk-reduction measurement dates because they are redundant with the date of blood pressure screening, which occurs on the same day and is captured in MDE 12a. |
| **Item 16c**  **Item 16d** | 16c. If GLUCOSE ≤50 or GLUCOSE ≥250, what is the status of the workup?   1. Workup complete 2. Follow-up – workup by alternate provider 3. Not an alert reading 4. Client refused workup 5. Workup not completed, client lost to follow-up   16d. If GLUCOSE ≤50 or GLUCOSE ≥250 Workup Exam Date  MM/DD/CCYY Date | We propose to eliminate these questions because data for very high blood sugar levels are already collected by the provider during on-site blood sugar readings. Reflected in existing MDE 15B. |
| **Item 17c**  **Item 17d**  **Item 17e**  **Item 17f** | 17c. Participant Decided Nutrition is a Priority Area   1. Yes 2. No   7. Unknown  17d. Participant Decided Physical Activity is a Priority Area   1. Yes 2. No   7. Unknown  17e. Participant Decided Smoking Cessation is a Priority Area   1. Yes 2. No 3. Unknown   17f. Participant Decided Medication Adherence for Hypertension (high blood pressure) is a  Priority Area   1. Yes 2. No 3. Unknown | We propose to eliminate these questions as grantees report that these questions are not phrased clearly enough to yield accurate responses and some participants have difficulty answering them; therefore, they do not yield statistically reliable program-specific information. |
| **Item 18a** | 18a. *Readiness to Change* Assessment Date  MM/DD/CCYY Date | We propose to eliminate the *readiness to change* date. Regression analyses conducted since current OMB approval (0920-0612, exp. 12/31/2018) reveal that *readiness to change* does not predict participation in Lifestyle Program and Health Coaching. |
| **Item 18b** | 18b. Participant Stage-of-Change   1. Pre-contemplation 2. Contemplation 3. Preparation 4. Action 5. Maintenance 6. Refused 7. No answer recorded | We propose to eliminate the *Stage-of-change* MDE. Regression analyses conducted since current OMB approval (0920-0612, exp. 12/31/2018) reveal that *stage of change* does not predict participation in Lifestyle Program and Health Coaching; it is therefore no longer useful. |
| **Item 20d.** | 20d. Length of Lifestyle Program (LSP) /Health Coaching (HC) Session Received by the Participant  \_\_\_ Length of session | We propose to eliminate collecting the length of each lifestyle program or health coaching session because all of the standardized lifestyle programs have a known length of session, so it is not a useful data element. Although the length of each health coaching session is variable, statistically, the skill of each coach is more important than the length of time. |
| **Item 20e**  **Item 20f** | 20e Type of Lifestyle Program/Health Coaching Session   1. Face-to-face 2. Phone 3. Smart phone/tablet application 4. Evidence that mailed materials were opened and reviewed 5. Evidence that audiotape or DVD as opened and reviewed 6. Evidence that non-interactive computer-based session was completed 7. Evidence that interactive computer-based session was completed 8. Other   9. No answer recorded  20f. Setting of Lifestyle Program (LSP) / Health Coaching (HC) Session   1. Individual 2. Group 3. Combination 4. No answer recorded | We propose to eliminate the type and setting of each session because it can be derive from the ID which CDC assigns to the lifestyle program/health coaching session, which makes this redundant information to collect through MDEs. |
| **Item 20g** | 20g. Completion of Lifestyle Program (LSP)/ Health Coaching (HC)   1. Yes – Lifestyle Program/Health Coaching is Complete 2. Yes – Intensive Follow-Up 3. No – Lifestyle Program/Health Coaching is still in progress 4. No – Withdrawal/Discontinued 5. No answer recorded | We propose to eliminate the completion of lifestyle program/ health coaching of each session because it can be derive from the ID which CDC assigns to the lifestyle program/health coaching session, which makes this redundant information to collect through MDEs. |

**Exhibit 3. Modifications to Element Questions or Response Options (25):**

We propose to rename 3 elements (12a, 12b, and 12c) to increase data clarity; rephrase 6 elements (4d, 7c, 7d, 7e, 16a, and 16b) to increase analytical utility; and combine 16 elements into 6 (4a, 4b, 4c, 5a, 5b, 5c, 5d, 5e, 5f, 7a, 7b, 8a, 8b, 10a, 10b, and 10c) to streamline questionnaire flow and strengthen the analytical framework. The table below describes these elements in further detail:

| **MDE Field Number** | *Current Information Collection Phrasing* | *Proposed Changes* | **Rationale** |
| --- | --- | --- | --- |
| **Item 4a**  **Item 4b**  **Item 4c** | 4a. Do you have high cholesterol?   1. Yes 2. No 3. Don’t know/Not sure 4. Don’t want to answer 5. No answer recorded   4b. Do you have hypertension (high blood pressure)?   1. Yes 2. No 3. Don’t know/Not sure 4. Don’t want to answer 5. No answer recorded   4c. Do you have diabetes (Type 1 or Type 2)?   1. Yes 2. No 3. Don’t know/Not sure 4. Don’t want to answer 5. No answer recorded | \*4a. Which of the following conditions do you have? (1 for yes/2 for no):  \_\_\_ Hypertension (high blood pressure)  \_\_\_ High cholesterol  \_\_\_ Diabetes (Type 1or Type 2)   1. Don’t know/Not sure 2. Don’t want to answer 3. No answer recorded | Combining all three questions into just one question is based on input from grantees to enhance questionnaire flow. |
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| **Item 4d** | 4d. Have you been diagnosed by a healthcare provider as having any of these conditions: coronary heart disease/chest pain, heart attack, heart failure, stroke/transient ischemic attack (TIA), vascular disease, or congenital heart defects?   1. Yes 2. No 3. Don’t know/Not sure 4. Don’t want to answer 5. No answer recorded | \*4b. 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   1. Don’t know/Not sure 2. Don’t want to answer 3. No answer recorded | We propose to ask the participants to choose any of the following conditions because it will facilitate questionnaire flow and improve data quality. |
| **Item 5a**  **Item 5b**  **Item 5c** | 5a. Do you take medication to lower your high cholesterol?   1. Yes 2. No 3. No- could not obtain medication 4. Not applicable 5. Don’t know/Not sure 6. Don’t want to answer 7. No answer recorded   5b. Do you take medication to lower your blood pressure?   1. Yes 2. No 3. No- could not obtain medication 4. Not applicable 5. Don’t know/Not sure 6. Don’t want to answer 7. No answer recorded   5c. Do you take medication to lower your blood sugar?   1. Yes 2. No 3. No- could not obtain medication 4. Not applicable 5. Don’t know/Not sure 6. Don’t want to answer 7. No answer recorded | \*5a. Was medication prescribed to lower (1 for yes; 2 for no):  \_\_\_ Blood Pressure  \_\_\_ Cholesterol (Statin)  \_\_\_ Cholesterol  (Other Prescribed Medications)  \_\_\_ Blood Sugar   1. Not Applicable 2. Don’t know/Not sure 3. Don’t want to answer   9. No answer recorded | We propose to combine all three questions regarding medication into a rephrased question based on input received from grantees to facilitate questionnaire flow. |
| **Item 5d**  **Item 5e**  **Item 5f** | 5d. During the past 7 days, on how many days did you take prescribed medication to lower your cholesterol?  Number of days  0. None  55. Not applicable  77. Don’t know/Not sure  88. Don’t want to answer  99. No answer recorded  5e. During the past 7 days, on how many days did you take prescribed medication (including diuretics/water pills) to lower your blood pressure?  Number of days   1. None   55. Not applicable  77. Don’t know/Not sure  88. Don’t want to answer  99. No answer recorded  5f. During the past 7 days, on how many days did you take prescribed to lower your blood sugar (for diabetes)?  Number of days   1. None   55. Not applicable  77. Don’t know/Not sure  88. Don’t want to answer  99. No answer recorded | \*5c. During the past 7 days, how many days did you take prescribed medication for the following conditions:  (0-7) High Blood Pressure  (0-7) High Cholesterol  (0-7) High Blood sugar   1. Don’t want to answer 2. Not applicable | We propose to combine the participant’s medication adherence into a single question to streamline questionnaire flow. |
| **Item 7a**  **Item 7b** | 7a. How much fruit do you eat in an average day?  Number of cups  00. None   1. Don’t want to answer 2. No answer recorded   7b. How many vegetables do you eat in an average day?  Number of cups  00. None   1. Don’t want to answer 2. No answer recorded | \*7a. How many cups of fruits and vegetables do you eat in an average day?  \_\_ Number of cups  00. None  88. Don’t want to answer   1. No answer recorded | We propose to combine these into one question. Scientific studies demonstrate there is no analytical significance to separating the two measurements. |
| **Item 7c** | 7c. Do you eat two servings or more of fish weekly?   1. Yes 2. No 3. Don’t want to answer 4. No answer recorded | \*7c. Do you eat fish at least two times a week?   1. Yes 2. No 3. Don’t want to answer 4. No answer recorded | We propose to rephrase this question as grantees report that participants often are unable to quantify two servings. Simplifying the question to capture the behavior will result in more accurate responses. |
| **Item 7d** | 7d. Do you eat 3 ounces or more of whole grain daily?   1. Yes 2. No 3. Don’t want to answer 4. No answer recorded | \*7d. Thinking about all the servings of grain products you eat in a typical day, how many are whole grains?   1. Less than half 2. About half 3. More than half 4. Don’t want to answer 5. No answer recorded | We propose to rephrase this question as grantees report that participants often are unable to quantify three ounces of whole grain. Simplifying the question to capture the behavior will result in more accurate responses. |
| **Item 7e** | 7e. Do you drink less than 36 ounces (450 calories) of beverages with added sugars weekly?   1. Yes 2. No 3. Don’t want to answer 4. No answer recorded | \*7e. Do you drink less than 36 ounces (450 calories) of sugar sweetened beverages weekly?  1. Yes  2. No  8. Don’t want to answer  9. No answer recorded | We propose to rephrase this question to align with common language. Simplifying the question to capture the behavior will result in more accurate responses. |
| **Item 8a**  **Item 8b** | 8a. How much moderate physical activity do you get in a week?  Number of minutes  000. None  888. Don’t want to answer  999. No answer recorded  8b. How much vigorous physical activity do you get in a week?  Number of minutes  000.aNone  888. Don’t want to answer  999. No answer recorded | \*8a. How many minutes of physical activity (exercise) do you get in a week?  \_\_ Number of minutes  000. None  888. Don’t want to answer  999. No answer recorded | We propose to combine this question because it is statistically relevant to measure the combined minutes of physical activity, regardless of moderate or vigorous. |
|  |  |
| **Item 10a**  **Item 10b**  **Item 10c** | 10a. Thinking about your physical health, which includes physical illness and injury, on how many days during the past 30 days was your physical health not good?  \_\_\_ Number of days   1. Don’t know/Not sure 2. Don’t want to answer 3. No answer recorded   10b. Thinking about your mental health, which includes stress, depression, and problems with emotions, how many days during the past 30 days was your mental health not good?  \_\_\_ Number of days   1. Don’t know/Not sure 2. Don’t want to answer 3. No answer recorded   10c. During the past 30 days, on about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?  \_\_\_ Number of days   1. Don’t know/Not sure 2. Don’t want to answer 3. No answer recorded | \*10a. Over the past 2 weeks, how often have you been bothered by any of the following problems? (Check 0 ̶ not at all/1 ̶ several days/2 ̶ more than half/3 ̶ nearly every day)  \_\_\_ Little interest of pleasure in doing things  \_\_\_ Feeling down, depressed, or hopeless   1. Don’t want to answer   9. No answer recorded | Previously we utilized the 30-day mental screener that was part of a Quality of Life screening tool. The National Institute of Health suggested to use the Patient Health Questionnaire (PHQ-2), which is a mental health survey, will now accurately reflect stress-related hypertension. |
| **Item 12a.** | 12a. Blood Pressure Measurement Date (Office Visit Date)  MM/DD/CCYY Date | \* 12a Clinical Assessment Date (Office Visit Date)  MM/DD/CCYY Date | We propose to rename Blood Pressure Measurement Date to Clinical Assessment Date because it is at the clinical assessment that the blood pressure is measured. |
| **Item 12b.** | 12b. Systolic Blood Pressure Measurement #1  Blood pressure (mmHg) | \*12b. Systolic Blood Pressure Measurement    Blood pressure (mmHg) | We propose to rename Systolic Blood Pressure Measurement #1 to Systolic Blood Pressure Measurement. We will allow up to four entries under this MDE. The first entry will be mandatory; however, grantees have requested these optional fields so that they can enter up to three additional readings. |
| **Item 12c.** | 12c. Diastolic Blood Pressure Measurement #1  Blood pressure (mmHg) | \*12c. Diastolic Blood Pressure Measurement  Blood pressure (mmHg) | We propose to rename Diastolic Blood Pressure Measurement #1 to Diastolic Blood Pressure Measurement. We will now allow up to four entries under this MDE. The first entry will be mandatory; however, grantees have requested these optional fields so that they can enter up to three additional readings. |
| **Item 16a.** | 16a. If average SBP >180 or DBP >110, what is the status of the workup?   1. Workup complete 2. Follow-up – workup by alternate provider 3. Not an alert reading 4. Client refused workup   \_\_\_\_ Workup not completed, client lost to follow-up | \*16a. Is a medical follow-up for blood pressure reading necessary?   1. Medically necessary 2. Not medically needed 3. Medically necessary follow-Up appointment declined | We propose to modify this question as the current question and the response option are not capturing sufficient detail to assist with program monitoring. Grantees have requested more flexibility in the use of this field which will be accomplished by this new wording. |
| **Item 16b.** | 16b. If Average SBP >180 or DBP >110, Workup Date  MM/DD/CCYY Date | \*16b. What is the date of the medically necessary follow-up appointment?  MM/DD/CCYY date | We propose to modify the language of the question to enhance program monitoring. This will assure that all participants with potentially uncontrolled hypertension can be referred to a medically necessary follow-up appointment. This change will synchronize this MDE with questionnaire flow. |

**Exhibit 4. Supplemental Elements/Questions (5)**

We purpose to add five supplemental programmatic elements detailed in the table below.

| **MDE Field Name/Proposed Location** | *Proposed Supplemental MDEs* | **Rationale** |
| --- | --- | --- |
| **Navigation**  **Proposed Location:**  **2d.** | \*2d. Were the navigation services paid for by:   1. NBCCEDP funds 2. WISEWOMAN funds 3. Indian Health Service/Tribal funds 4. Other 5. Not Applicable | We propose to capture navigation status within the intake categories to accurately account for all women served through federally-funded WISEWOMAN, which is relevant due to the changing healthcare landscape. CDC is required to report this number annually. |
| **Aspirin**  **Proposed Location:**  **5b** | \*5b. Are you taking aspirin daily to help prevent a heart attack or stroke:     1. Yes 2. No 3. Don’t know/Not sure 4. Don’t want to answer 5. No answer recorded | We propose to supplement the medication questions because of its important use as a treatment for cardiovascular events. |
| **Monitored**  **Proposed Location:**  **5d** | \*5d. After being prescribed medication, on what date(s) did the participant have her blood pressure re-measured either by a healthcare provider, or with another community resource?  MM/DD/CCYY Date | We propose to have multiple date options included as an MDE because grantees have requested these optional fields so that they can enter up to four follow-up dates for participants who have been prescribed blood pressure medications, and better monitor participants |
| **AlcDay**  **Proposed Location:**  **7f** | \*7f. In the past 7 days, how often do you have a drink containing alcohol?  (0-7) days   1. Don’t want to answer 2. No answer Recorded | As a part of our nutrition evaluation we were not accurately accounting for significant source calories from alcohol consumption. This supplements our existing nutrition questions. |
| **AlcFreq**  **Proposed Location:**  **7g** | \*7g. How many alcoholic drinks, on average, do you consume during a day you drink?  (0-7) days   1. Don’t want to answer 2. No answer Recorded | As a part of our nutrition evaluation we were not accurately accounting for significant source calories from for an alcohol consumption. This supplements our existing nutrition questions. |