Change Request

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

(OMB no. 0920-0612, exp. date 12/31/2018)

April 6, 2018

Summary

CDC requests OMB approval for a non-substantive change to the approved WISEWOMAN information collection, OMB approval, 0920-0612, exp. 12/31/2018. The request is to modify the WISEWOMAN program's reporting system, used to both screen and monitor participants, as well as to evaluate and improve program efficacy. The current WISEWOMAN information collection consists of two parts, a Progress Report and Minimum Data Elements

The proposed change is to the minimum data elements (MDE) part of system to improve data accuracy and analytical utility, as well as to streamline the questionnaire flow for respondents. This consists of clarifying language, harmonizing the language of the MDEs with national surveys, and better reflecting the current scientific knowledge. The update results in removing, combining, and supplementing elements from the current questionnaire of 84 MDEs, for a new total of 59 MDEs.

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, as well as specific justifications for each, are provided in Exhibits 2, 3, and 4. The exhibits are attached.

The current information collection scope, purpose, burden, protocol, methodology, and analytical approach remain unchanged. Likewise, no changes are proposed to the Progress Report.

Attachments

- Exhibits
    1. Overview of proposed improvements
    2. Deletions from current MDE
    3. Modifications to element questions or response options
    4. Supplemental elements/questions

- WISEWOMAN MDE Manual as currently approved by OMB

Background

CDC collects information from funded WISEWOMAN programs (currently 19 state governments and 2 tribal organizations). Programs submit this information via a CDC web portal. The information is used to monitor, evaluate, and report on funded programs. WISEWOMAN stands for Well-Integrated Screening and Evaluation for Women Across the Nation, and is a direct service program with clinical screening and behavioral change interventions. It is authorized by the U.S. Congress to reduce cardiovascular disease risk factors among at-risk, low-income, uninsured, and underinsured women aged 40 to 64.

The state or tribal health departments gather or collect responses to the MDEs from providers, who administer and/or record responses in their electronic health record or another format the state approves. Providers ask participants the MDEs during their initial enrollment in the WISEWOMAN program and at rescreening (minimum 12 months later). The MDEs address cardiovascular disease (CVD) risk factors such as elevated blood cholesterol, high blood pressure, obesity, diabetes, smoking, sedentary lifestyle. The WISEWOMAN program encourages awardees to use electronic health records and to auto-fill fields in their files.

Justification

The proposed change is to improve WISEWOMAN data quality and analytical utility, and to streamline the questionnaire flow for respondents.

Data quality: Several MDEs contain information that can be interpreted differently, leading to unreliability and analytical variability, as well as incomplete data sets when respondents do not respond to particular MDEs. Improved data quality will lead to more accurate responses by conveying existing concepts more clearly, which will increase efficiency.

Analytical utility: Proposed changes include deleting elements that no longer have analytical utility; supplementing MDEs with related questions to improve analytical utility; and harmonizing data elements across information collections. These proposed changes will improve CDC's ability to report on the program's efficacy, as well as make comparisons between the health of women nationally and WISEWOMAN's population.

Improved questionnaire flow: Several elements reveal the same data, therefore proposed changes remove the redundancy and streamline the flow of questions for provider and participant. Other elements draw from the same date or clinical data that are in different parts of the questionnaire; the redundancies interrupt questionnaire flow.

We identified a number of opportunities for improving WISEWOMAN data quality, analytical utility, and questionnaire flow reflected in this change request during a 2017 analysis. This analysis of the MDEs was performed by CDC scientists and public health specialists. Additionally, input from WISEWOMAN state and tribal program staff during monthly technical assistance conferencing was received.

CDC scientists examined national surveys and tools related to CVD and risk factors, including federal agency and academic surveys such as NHANES, BRFSS, the Patient Health

Questionnaire, and American Heart Association's Life's Simple 7. CDC also reviewed new scientific literature published since 2014, as well as *Community Guide* recommendations relevant to WISEWOMAN programmatic work. We found limited analytical utility from several MDEs and found that slight rephrasing and combinations of MDEs would improve data quality.

For example, the Community Guide subset on obesity recommends accounting for alcohol use as it can be a significant source of calories, therefore, the proposed changes supplement the current nutrition-related MDEs with elements to measure calories from alcohol intake. Another example is using the American Heart Association recommendation regarding heart disease and supplementing the medication MDEs with aspirin.

Further justification details are included in Exhibits 2-4.

Implementation Schedule

CDC is submitting this non-substantive change request to OMB to provide implementation guidance to programs for the new program year, which begins July 1, 2018.

Effect on Burden Estimate

No change in burden is projected. Combining MDEs together to improve clinical flow do not reduce the content, therefore the burden remains equivalent. Rephrasing, renaming and replacing MDEs have no impact on burden. Finally, removing redundant dates that are auto-populated for the majority of programs that use electronic health records will not reduce overall effort. The supplemental MDEs are minimal and therefore do not impact the burden.

Terms of Clearance:

	Inventory as of this Action	Requested	Previously Approved
Expiration Date	12/31/2018	24 Months From Approved	12/31/2016
Responses	63	63	63
Time Burden (Hours)	1,344	1,344	1,344
Cost Burden (Dollars)	0	0	0