



BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-16-16AWP]

[Docket No. CDC-2016-0075]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed study to examine the facilitators and barriers to receiving clinical preventive services among newly insured medically underserved women who had

previously been served by the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The purpose of this survey is to assess if newly insured women receive appropriate clinical preventive health services, what barriers and facilitators these women experience, and if they are able to maintain consistent health insurance coverage.

DATES: Written comments must be received on or before [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2016-0075 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Women's Preventive Health Services Study - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) provides free or low-cost breast and cervical cancer screening and diagnostic services to low-income, uninsured, and underserved women. The NBCCEDP is an organized screening program with a full complement of services including outreach and patient education, patient navigation, case management, professional development, and tracking and follow-up that contribute to the program's success. Compared to when the NBCCEDP was established, more women are eligible for insurance coverage but there are still many women who are not insured and many insured women not obtaining preventive services that they are eligible to receive. Currently, the NBCCEDP not only provides screening services to uninsured and underinsured, but has expanded its services to include population-based activities that prevent missed opportunities and ensure that all women receive appropriate breast and cervical cancer screening.

Previous research suggests that access to health care through insurance alone does not ensure adherence to cancer

screening, as many individual, cultural, and community factors serve as barriers to preventive service use. With recent increases in the numbers of women who are insured, there is a need to understand the experiences of women who had been served by the NBCCEDP and become newly insured. This project will inform the development of future activities of the NBCCEDP so that all women receive the information and support services needed for obtaining clinical preventive services.

The purpose of this project is to examine the facilitators and barriers to receiving clinical preventive services among newly insured medically underserved women who had previously been served by the NBCCEDP. The Women's Preventive Services Study aims to survey newly insured women about what clinical preventive health services they receive, what barriers and facilitators they experience, and their ability to maintain consistent health insurance coverage.

While having newly acquired health insurance will improve access to preventive services, insurance coverage alone would not result in improved clinical preventive services utilization for all women, especially among underserved populations. This project proposes to follow a group of women previously served by the NBCCEDP over 3 years by administering a yearly questionnaire.

This study will focus on the following research questions:

1. What are the insurance coverage patterns (e.g., public or private insurance) for a sample of medically underserved women previously screened through the NBCCEDP?
2. What barriers and facilitators do these women face in enrolling in new insurance coverage?
3. What preventive health services, including cancer screening, do these women receive?
4. What barriers and facilitators do these women face in accessing preventive health services through their new coverage?
5. What are the non-financial and financial costs to these women?

The respondents will be uninsured or underinsured women who previously had been screened through the NBCCEDP but now have health insurance coverage. To be potentially eligible for the study, women must be between the ages of 30-62 years, a U.S. Citizen or U.S. permanent resident, resident of the state where they received NBCCEDP services, and English or Spanish speaking. Additionally, women must meet one of the prior screening criteria: (1) having received a Pap test through a NBCCEDP state program not less than 1 year but not more than 4 years from the time of study implementation OR (2) received a Pap/HPV co-test

through a NBCCEDP grantee not less than 3 years but not more than 5 years from the time of study implementation OR (3) received a mammogram through a NBCCEDP grantee not less than 1 year but not more than 3 years from the time of study implementation.

NBCCEDP state programs will identify potentially eligible women and consent the women to have their contact information shared for the study. The women who agree will receive an invitation letter to participate in the study through an on-line survey. The first step of the on-line survey will be a set of screener questions to determine whether they have insurance coverage. Only those who currently have insurance will be eligible to continue with the main survey instrument. Women who complete the survey will be asked to repeat the survey annually the next 2 years.

The sample design proposes that 14,240 women be identified as eligible. We estimate that 80% will be contacted and agree to participate. Of that, we expect 9,683 completed on-line screenings to occur during year one, representing an annualized 3,288 respondents. With an 85% expected completion rate and annual attrition, we estimate that 3,292 surveys will be completed in Year 1; 2,222 completed surveys in Year 2; and 1,500 completed surveys in Year 3. This represents an annualized 2,338 respondents for the survey.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 1,243 hours.

Estimated Annualized Burden Hours

| Type of Respondents | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hrs.) | Total Burden (in hrs.) |
|--|-----------|--------------------|---------------------------------|------------------------------------|------------------------|
| Women aged 30-62 who previously received services in the NBCCEDP | Screeners | 3,228 | 1 | 5/60 | 269 |
| | Survey | 2,338 | 1 | 25/60 | 974 |
| | | | | Total | 1,243 |

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