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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-15BDJ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Education and Awareness Requires Learning Young (EARLY) Act of 2009, which is outlined in section 10413 of the Patient Protection and Affordable Care Act, authorizes the CDC to fund research and initiatives that increase knowledge of breast health and breast cancer among women, particularly among those under the age of 40. The EARLY Act along with section 301 of the Public Health Service Act authorizes the CDC to conduct research that will inform the prevention of physical and mental diseases such as breast cancer, and serves as the main basis for this data collection activity.

Research indicates that young women diagnosed with breast cancer face many barriers accessing high-quality breast cancer care and treatment. Some research indicates that employment status, financial stability, and insurance coverage are variables that individually affect treatment compliance, access to quality care, and ultimately quality of life for young women with breast cancer. However, to date, no comprehensive assessment exists examining the impacts of these factors on young, female breast cancer patients' access to comprehensive high quality breast cancer treatment and care.

CDC propose to address this gap by answering the following two research questions: (1) What are young, female breast cancer survivors experiencing after their diagnosis in terms of (a) continuation of insurance coverage, access to care, and quality

of care; (b) changes in employment status after breast cancer diagnosis; and (c) out-of-pocket medical costs? (2) What factors affect young breast cancer survivors' access to comprehensive, high quality care?

To answer these research questions, CDC is sponsoring a study to collect information from two groups of breast cancer survivors. Sample 1 will be a population-based cohort of approximately 1,200 female breast cancer survivors recruited from four state cancer registries. These respondents will be asked to complete a mail-in or web-based questionnaire. Self-reported survey data from Sample 1 will be supplemented by data maintained by their state's cancer registry, including information about tumor characteristics, date of diagnosis, and stage. The linked survey and cancer registry data will be used to answer research question about the factors that affect young breast cancer survivors' access to comprehensive, high quality care?). CDC's data collection contractor will securely maintain identifiable information from respondents recruited from state registries (Sample 1). No identifiable information will be transmitted to CDC.

Sample 2 will include a national convenience sample of 2,000 female breast cancer survivors who were diagnosed between the ages of 18 and 49 and are associated with one of two breast cancer advocacy groups, Living Beyond Breast Cancer and Young

Survival Coalition. Respondents from Sample 2 will complete the web-based version of the survey. A set of screening questions will be included at the beginning of this web-based survey to confirm eligibility and so that women from the four states included in Sample 1 can be excluded. The survey data will not be linked to any other data source.

Since the study uses two distinct samples and employs the same instrument with minor modifications, survey responses from the two samples can answer the following additional research questions: (1) How generalizable are the results from the four cancer registries? (2) Are there differences in the variables of interest between young breast cancer survivors based on the length of time that has elapsed from cancer diagnosis? (3) Do the experiences and barriers faced by women diagnosed between 18 and 39 years of age differ from those of women diagnosed between 40 and 44 years of age and 45 and 49 years of age?

The results can help inform future survey data collection methodologies by showing whether drawing a convenience sample from survivorship groups can be a more feasible, less expensive, but generalizable method to recruit respondents for future breast cancer survivor surveys.

The target number of responses for the overall study is estimated to be 3,200 completed surveys. Sample 1 respondents will have the option of completing a hardcopy questionnaire or

an online questionnaire, both of which are be estimated to take about 22 minutes to complete. Sample 2 respondents will complete a screener and the questionnaire online. Due to the inclusion of additional screening questions for Sample 2, a completed survey by an eligible respondent is expected to take about 24 minutes. If a respondent completes the screening section and is found to be ineligible for the study, the estimated burden per response is 2 minutes. Demographic information will be collected from all patients who participate in the study.

Findings from this study will be used to identify interventions that can eliminate existing barriers to treatment so that young women have access to high quality breast cancer treatment and care. Results will also be used to improve care and services provided to young women diagnosed with breast cancer. Study findings will be disseminated through reports, presentations, and publications.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,241.

Estimated Total Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
Sample 1 - Breast cancer survivors recruited from state cancer registries	Breast Cancer in Young Women Survey (Mail-in or web-based questionnaire)	1,200	1	22/60
Sample 2 - Breast cancer survivors associated with advocacy groups (ineligibles)	Breast Cancer in Young Women Survey (Screener only)	25	1	2/60
Sample 2 - Breast cancer survivors associated with advocacy groups (eligible and complete)	Breast Cancer in Young Women Survey (Screener and Web-based questionnaire)	2,000	1	24/60

Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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