DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BDJ]; [Docket No. CDC-2015-0070]

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 effort 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 the proposed information collection request entitled "Breast Cancer in Young Women Survey", which is designed to assess insurance coverage, employment status and out-of-pocket health care expenses among young women diagnosed with breast cancer and to look at the relationship between these variables and treatment decisions.

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

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0070 by any of the following methods:

Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, 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

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. These barriers are compounded by the multiple roles that these young women serve in society including parenting young children, developing a career, and completing their education. Treatment decisions can be complicated for young women with breast cancer. Some research indicates that employment status, financial stability, and insurance coverage are variables that affect treatment compliance, access to quality care, and ultimately quality of life for young women with breast cancer. However, to date, no comprehensive assessment has been conducted to examine breast cancer care and treatment for young women.

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: one randomly drawn from state-based cancer registries (Sample 1), the other a self-selected convenience sample drawn from two advocacy organizations (Sample 2).

Sample 1 will include up to 1,750 young (diagnosed between the ages of 18 and 39), female breast cancer survivors diagnosed for the first time with breast cancer 12 months before the survey is fielded. Respondents will be recruited through approximately four state-based central 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 #2 (What

factors affect young breast cancer survivors' access to comprehensive, high quality care?).

Sample 2 will include a nation-wide convenience sample of 2,000 female breast cancer survivors diagnosed between the ages of 18 and 49 who are associated with one of two breast cancer advocacy groups (Living Beyond Breast Cancer and Young Survival Coalition). This cohort will exclude individuals from Sample 1 and will not be linked to any other data source.

Comparing results between Sample 1 and Sample 2 will help us address these additional research questions: (1) How generalizable are the results from the convenience Sample 2? (2) Are there differences 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 (Samples 1 and 2) differ from those of women diagnosed between 40 and 44 years of age and 45 and 49 years of age (Sample 2)? This comparison will also help CDC explore whether drawing a convenience sample from survivorship groups will be a methodologically legitimate, less expensive method to recruit respondents for future breast cancer survivor surveys.

The target number of responses for the overall study will result in up to 3,750 completed surveys. Respondents will be asked to complete a questionnaire, which is estimated to take

about 22 minutes. Sample 1 respondents will have the option of completing a hardcopy questionnaire or an online questionnaire. Sample 2 respondents will complete the questionnaire online. Demographic information will be collected from all patients who participate in the study.

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

OMB approval is requested for three years and the burden table presents annuitized estimates. CDC's data collection contractor will securely maintain identifiable information from respondents recruited from state registries (Sample 1). No identifiable information will be collected by CDC. Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Sample 1 - Breast Cancer survivors included in one of as many as four state registries	Breast Cancer in Young Women Survey (Mail or web-based version questionnaire)	583	1	22/60	214
Sample 2 - Breast Cancer survivors associated with advocacy groups	Breast Cancer in Young Women Survey (Web-based questionnaire)	667	1	22/60	244
				Total	458

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