

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 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	Number of respondents	Number 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announce the following meeting for the aforementioned committee:

Times and Dates: 9:00 a.m.–5:00 p.m., EDT, March 31, 2016; 9:00 a.m.–12:00 p.m., EDT, April 1, 2016.

Place: Centers for Disease Control and Prevention, Global Communications Center, Building 19, Auditorium B, 1600 Clifton Road NE., Atlanta, Georgia, 30333.

Status: Open to the public, limited only by the space available. Please register for the meeting at www.cdc.gov/hicpac.

Purpose: The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion, the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters for Discussion: The agenda will include updates on CDC's activities for prevention of healthcare associated infections (HAIs), updates on antimicrobial stewardship, an update on Draft Guideline for Prevention of Infections in Healthcare Personnel, chlorhexidine gluconate-impregnated dressings, and an update from the workgroup for considerations on endoscope reprocessing.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Erin Stone, M.S., HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road NE., Mailstop A-07, Atlanta, Georgia 30333. Telephone (404) 639-4045. Email: hicpac@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Claudette Grant,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, Announces the Following Meeting

Name: ICD-10 Coordination and Maintenance (C&M) Committee meeting.

Time and Date: 9:00 a.m.–5:00 p.m., EST, March 9–10, 2016.

Place: Centers for Medicare and Medicaid Services (CMS) Auditorium,

7500 Security Boulevard, Baltimore, Maryland 21244.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 240 people. We will be broadcasting the meeting live via Webcast at <http://www.cms.gov/live/>.

Security Considerations: Due to increased security requirements CMS has instituted stringent procedures for entrance into the building by non-government employees. Attendees will need to present valid government-issued picture identification, and sign-in at the security desk upon entering the building.

Attendees who wish to attend the March 9–10, 2016 ICD-10-CM C&M meeting must submit their name and organization by March 1, 2016 for inclusion on the visitor list. This visitor list will be maintained at the front desk of the CMS building and used by the guards to admit visitors to the meeting.

Participants who attended previous Coordination and Maintenance meetings will no longer be automatically added to the visitor list. You must request inclusion of your name prior to each meeting you wish attend.

Please register to attend the meeting on-line at: <http://www.cms.hhs.gov/apps/events/>. Please contact Mady Hue (410-786-4510 or Marilu.hue@cms.hhs.gov), for questions about the registration process.

Purpose: The ICD-10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification and ICD-10 Procedure Coding System.

Matters for Discussion: Agenda items include: March 9–10, 2016.