Annual Survey of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Grantees' Program Implementation

Supporting Statement – Section A

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TABLE OF CONTENTS

1LIST OF ATTACHMENTS

Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354, **see Attachment A- Authorizing Legislation)** which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and to conduct program monitoring and evaluation activities. Currently, the NBCCEDP funds 67 grantees including all 50 states, the District of Columbia, 5 U.S. territories, and 11 American Indian/Alaska Native tribes or tribal organizations. Grantees provide screening services for breast and cervical cancer to low-income, uninsured, and underinsured women who otherwise would not have access to screening[1].

Since 1991, NBCCEDP-funded grantees have served more than 4.3 million women, provided more than 10.7 million breast and cervical cancer screening examinations, and diagnosed more than 56,662 breast cancers, 3,206 invasive cervical cancers, and 152,470 premalignant cervical lesions, of which 41% were high-grade (**see Attachment B – About the National Breast and Cervical Cancer Early Detection Program).**

As a comprehensive, organized screening program, the NBCCEDP supports activities including program management, partnership development, public education and targeted outreach, screening and diagnostic services, patient navigation, quality assurance and quality improvement, professional development, data management and utilization, and program monitoring and evaluation (**see Attachment C – NBCCEDP Framework**). For clinical service delivery, grantees fund health care providers in their state/territory/tribe to deliver breast and cervical cancer screening, diagnostic evaluation, and treatment referrals for women diagnosed with cancer.

CDC issued a new Funding Opportunity Announcement (FOA) to support a 5-year cooperative agreement for the NBCCEDP effective July 2012 (CDC-RFA-DP12-1205). This new FOA begins to shift the NBCCEDP from a focus on direct service provision to implementation of expanded evidence-based activities intended to increase rates of breast and cervical cancer screening at the population level. Though NBCCEDP grantees continue to provide breast and cervical cancer screening for un- and underinsured women, CDC is encouraging the implementation of strategies to increase screening rates beyond that of program-eligible women.

CDC plans to initiate an annual survey of NBCCEDP awardees in order to assess program implementation, particularly related to these expanded population-based efforts. A survey of NBCCEDP awardees was conducted in Fall/Winter 2013-2014 and approved by OMB under OMB No. 0920-0879 as "Assess Breast and Cervical Cancer Screening Program Activities to Expand Access to Screening." The survey was found to be useful by CDC and the awardees (which received feedback reports). For example, after analyzing findings from the 2013-2014 survey, CDC was able to tailor sessions at the subsequent Program Director's meeting to grantees based on the needs

[1] Lee, NC, Wong, FL, Jamison, PM, Jones, SF, Galaska, L, Brady, KT, Wethers, B, Stokes-Townsend, GA, Implementation of the National Breast and Cervical Cancer Early Detection Program: The beginning.", Cancer. 2014 120 Suppl 16:2540-8

they expressed during the initial information collection. DCPC has decided to continue the data collection as an annual survey to document needs and trends over time **(see Attachment D1 -Data Collection Instrument: MS Word version and D2 - Data Collection Instrument: Screen Shot version).** The annual survey instrument is based on the survey instrument that was initially fielded in 2013-2014, but a number of changes will be made reflecting experience with the instrument, CDC's interaction with awardees, and CDC's current priorities. A crosswalk of changes to content is provided in **Attachment F**.

2. Purpose and Use of the Information Collection

The purpose of this data collection is to assess state, tribal and territorial health departments' implementation of programs to increase breast and cervical cancer screening within an expanded target population and an evolving health care context. This data collection will enable CDC to identify implementation activities and assess alignment with NBCCEDP goals and objectives, monitor program transition to efforts aimed at impacting population-based screening, identify technical assistance needs of state, tribe and territorial health department cancer control programs, and identify implementation models with potential to expand and transition to new settings to increase program impact and reach. The proposed data collection activity will allow CDC to gauge its progress in meeting NBCCEDP program goals as outlined in Attachment C. The survey will provide insight into areas that need improvement and identify successful activities that should be maintained, replicated, or expanded. Specifically, the activities to be assessed include (1) program activities (2) clinical service delivery (3) non-screening partnerships (4) data use (5) training and technical assistance and (6) program management.

The proposed data collection activities will contribute to a more effective NBCCEDP and strengthen CDC's ability to demonstrate program results. The scope of data collection is limited to the activities and experiences of NBCCEDP grantees acting in their official capacity. Collection of these data will not yield data that can be generalized. CDC expects to use these findings to better understand the variability of experiences among state, tribal and territorial governmental grantees and as one of many inputs into decision-making and/or program management or assessment. In addition, the findings will be reported so that grantees may identify successful implementation models and focus networking for shared experiences, lessons learned, and best practices.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via a web-based questionnaire allowing respondents to complete and submit their responses electronically. This method was chosen to reduce the overall burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed annual survey will provide information about the NBCCEDP that is not available from other sources. For example, under the terms of the cooperative agreement, NBCCEDP awardees are required to submit semi-annual reports to CDC's Procurement and Grants Office (PGO). Grantees

are responsible for submitting programmatic information including a list of staff, a delineation of program objectives, a progress report on performance measures, a program work plan, and a listing of accomplishments. While information collected through these reports identifies program activities, it does not provide any systematic information specific to the implementation of these activities or describe the relationship with implementation partners.

CDC also collects de-identified, client-level information from NBCCEDP awardees (see OMB No. 0920-0571, Minimum Data Elements Reporting for the NBCCEDP, exp. 10/31/2015). This information collection describes the demographic characteristics of clients served through the NBCCEDP, the screening and diagnostic services provided through the NBCCEDP, diagnostic outcomes, and treatment information. This information collection does not address strategies for program implementation.

Thus, this proposed annual survey will fill a gap in allowing CDC to systematically assess program implementation across all NBCCEDP grantees. The effectiveness of the implementation activities can then be assessed based on analysis of the MDE data.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The purpose of this request is to ensure collection of data that is not otherwise available in a current, time sensitive, or standardized format to specific or emergent priorities of HHS and CDC. Specifically, without this data there would be:

- No systematic collection regarding the implementation of years 2-4 program activities as specified in the CDC-RFA-DP12-1205.
- No systematic assessment of training and technical assistance needs.
- Less effective and less timely assessment of implementation partners of program activities.
- Fewer resources from which to make data-driven decisions that are often required of CDC and state, tribal, and territorial governmental health agencies.

This request is for an annual data collection over a three year period. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

Notice of this study was published in the Federal Register on Thursday, November 7, 2013, Vol. 78, No. 216, pages 66935-66936 (**See Attachment E – 60-day FRN 11 07 2013**). No public comments have been received.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

1. Overview of the data collection system

Information will be collected annually from 67 health departments in states, tribal organizations, and territories that receive cooperative agreement funding to implement breast and cervical cancer early detection programs (BCCEDP) in their jurisdictions. The program director or manager for each cooperative agreement will serve as the survey respondent; however, names or other identifying information for respondents will not be collected as part of the annual survey. The survey will be made available to respondents on a secure, open source, Web-based platform called Lime Survey (limesurvey.org). A contractor will manage primary data collection and send respondents a link directing them to the online instrument only (i.e., not a website). There is no website content directed at children < 13 years of age. After receiving responses to the survey, the contractor will prepare and submit a validated analysis file to CDC and assist in interpreting the findings. CDC will then prepare and distribute an individualized feedback report and a summary report to each awardee.

2. Description of the information to be collected

The information to be collected is programmatic in nature and does not involve research with human subjects. IRB approval is not required.

The information collection instrument is designed to clarify how awardees are implementing BCCEDP in their jurisdictions and to assess the awardees' needs for training and technical assistance. The instrument currently consists of 133 questions, including: 3 questions on respondent background, 56 questions on program activities, 24 questions on clinical service delivery, 37 questions on non-screening partnerships, 3 questions on data use, 3 questions on training and technical assistance, and 7 questions on program management. Based on pre-programmed skip patterns, respondents will have to answer a subset of the total 133 questions. Questions are of various types including dichotomous and multiple response. To minimize burden, there are a limited number of questions requiring open-ended or narrative responses.

No individually identifiable information will be collected. Contact information for the awardee (used for distributing an introductory email and a reminder email encouraging participation) will be obtained from agency records associated with the cooperative agreement award and will not be collected as part of the annual survey.

3. Information sharing and dissemination plan

Each participating awardee will receive a customized feedback report relating to its own submission but will not have access to other awardees' submissions or individualized reports. Each awardee and CDC will use the customized feedback report(s) to identify opportunities for strengthening awardee performance. The contractor will also prepare an aggregate report for CDC's use in overall management of the BCCEDP. CDC does not plan to create a public use dataset.

4. Consent

Participation in this survey is voluntary, as stated in the introductory (invitation) email and the reminder email distributed to awardees. Respondents are informed that their information will be maintained in a secure manner and that they will receive individualized feedback reports for their use. There are no advisements that relate to data sharing since CDC has no plans to share information or develop a public-use data set. There is no impact on the respondent's privacy.

5. Information security

The data contractor will host the collection instrument and data using a secure submission web site. Respondents will be provided with a unique 'token' that will enable them to view and enter their data. Receipt and processing logs are maintained to document data receipt, file processing and report production. The contractor's server is housed in a secure facility with user ID and password restricted access. Networked systems are maintained in a locked room with access strictly limited to essential employees. The contractor will aggregate and validate the data for quality and completeness and prepare an analysis file for delivery to CDC via email.

Once the data have been delivered to CDC, data will be housed on CDC's secure LAN server where restricted access is controlled by the data manager. A CDC-issued identification badge (key card) is required for access to CDC facilities. Access to relevant data files is controlled by user ID and password. Both the contractor and CDC will retain the data collected for a period of 10 years.

Periodic review and update of security processes will be conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.

6. Privacy Act determination

The Privacy Act does not apply. Information to be collected is programmatic in nature. Employees of state, tribal, and territorial public health agencies will be speaking from their official roles and will not be asked, nor will they provide, individually identifiable information.

11. Justification for Sensitive Questions

No information of personal or sensitive nature will be collected.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the revised data collection instrument, completed by 2 public health professionals. In the pilot test, the average time to complete the

instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 40 minutes.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). Based on DOL data, an average hourly wage of $57.11 is estimated for all 67 respondents. Table A-12 shows estimated burden and cost information.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Breast and Cervical Cancer Program Directors	67	1	40/60	45	$57.11	$2550.91
TOTALS	**67**	**1**		**45**		$2550.91

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There will be no direct costs to the respondents other than their time to participate in each data collection.

14. Annualized Cost to the Government

There are no equipment or overhead costs. The only cost to the federal government will be the salary of CDC staff and funding for the data contractor, Information Management Services (IMS), to support the development of the web-based application, data collection, and associated tasks.

Questions have been prepared by CDC staff (FTE) and the web-based instrument has been programmed by data contractor staff. Two senior level FTEs will conduct all related activities. A senior FTE manager at CDC will oversee all related activities. A data contractor will program, field, and analyze the results of the web-based data collection. The estimated cost to the federal government is $47,642.40. Table A-14.1 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Health Scientist (GS-13) Overall lead for development of instrument, pilot testing, OMB package preparation, data collection, quality control, data analysis, report preparation	400	53.26	$21,304.00
Health Scientist (GS-13) Consultation with staff lead on instrument development, OMB package preparation, data collection, quality control, data analysis, report preparation	160	53.26	$8,521.10
Lead Health Scientist (GS-14) Management oversight for instrument development, pilot testing, OMB package preparation, data collection and analysis, report preparation	80	62.93	$5,034.40
Contractor Costs			
Annualized Cost of Contract with Data Contractor Responsible for building web-based application, data collection, data coding and entry, quality control, data analysis, report preparation (GS-13 equivalent)	240	53.26	$12,782.40
Estimated Total Cost of Information Collection			$47,642.40

15. Explanation for Program Changes or Adjustments

This is a revised data collection based on the experience of fielding a similar instrument in Fall/Winter 2013-2014. Changes were made to improve clarity, group similar topics together, increase the probability of consistent reporting and to reduce the burden of the respondents. We also anticipated having to make changes to include topics more relevant to program activities beginning after ACA implementation (i.e. facilitating enrollment of newly eligible women into insurance plans). Questions that were no longer relevant have been removed. When possible, we used responses from last year's survey to create common response categories and changed question structure from open-ended to multiple-choice. A crosswalk of changes details the revisions made to the original instrument (See **Attachment F – Crosswalk Question Tracking 2014**).

16. Plans for Tabulation and Publication and Project Time Schedule

The results of this data collection, individual and aggregate, will be published in the form of a grantee report. The results will be used to support individual grantees in the state, tribe and

territory health departments and to provide CDC management a snapshot of how the NBCCEDP is being implemented as a whole. Within 150 days following OMB approval, respondents will receive a report summarizing findings (**see Attachment G – Sample Grantee Report**). Reports which will be generated for internal CDC use will also be produced (**see Attachment H – Sample Management Report**) and will be completed within 150 days following OMB approval. A summary of this timeline is provided below:

Estimated Project Time Schedule

- ❑ Design questionnaire..... (COMPLETE)
- ❑ Pilot test questionnaire..... (COMPLETE)
- ❑ Enter questions into [Lime Survey]..... (COMPLETE)
- ❑ Prepare OMB package..... COMPLETE)
- ❑ Submit OMB package..... (COMPLETE)
- ❑ OMB approval..... (TBD)
- ❑ Conduct data collection (includes reminders)..... (Open 3 weeks)
- ❑ Collect, code, enter, quality control, and analyze data..... (6 weeks)
- ❑ Prepare report..... (3 weeks)
- ❑ Disseminate results/reports…….…… (Date TBD)

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.