National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities

Revision: OMB No. 0920-1046

Exp.11/30/2021

Supporting Statement A

Program Official/Contact
Dara Schlueter, MPH
Health Scientist
National Center for Chronic Disease Prevention and Health Promotion
Centers for Disease Control and Prevention
P: 770-498-1782
F: 770-488-4760
Sax9@cdc.gov

11/1/2021

TABLE OF CONTENTS

ATTACHMENTS

Attachment 1: Authorizing Legislation
Attachment 2: Breast and Cervical Cancer Mortality Prevention Act of 1990
Attachment 3: NBCCEDP Logic Model
Attachment 4: NBCCEDP Evaluation Question Matrix
Attachment 5: Annual NBCCEDP Survey
Attachment 5a: Annual NBCCEDP Survey (screenshots)
Attachment 5b: NBCCEDP Survey Introductory Email
Attachment 5c: NBCCEDP Survey Reminder Email
Attachment 6: NBCCEDP Clinic-Level Data Collection Instruments
Attachment 6a: NBCCEDP Clinic-Level Data Collection Instruments (screenshots)
Attachment 6b: NBCCEDP Clinic-Level Data Collection Introductory Email
Attachment 6c: NBCCEDP Clinic-Level Data Collection Reminder Email
Attachment 7: NBCCEDP Quarterly Program Update
Attachment 7a: NBCCEDP Quarterly Program Update (screenshots)
Attachment 7b: NBCCEDP Quarterly Program Update Pre-Administration Email
Attachment 7c: NBCCEDP Quarterly Program Update Administration Email
Attachment 7d: NBCCEDP Quarterly Program Update Reminder Email
Attachment 8: NBCCEDP Service Delivery Projection Worksheet
Attachment 8a: NBCCEDP Service Delivery Projection Worksheet (screenshots)
Attachment 9: MDE Data Definitions
Attachment 10: Institutional Review Board Approval
Attachment 11: 60-Day Federal Register Announcement
Attachment 11a: 60-Day FRN Public Comment and CDC Response

JUSTIFICATION SUMMARY

- **Goal of the project**: To systematically collect information about implementation, including delivery of screening and follow-up clinical services, and outcomes of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), which funds 70 recipients.
- **Intended use of the resulting data**: To monitor processes and outcomes associated with NBCCEDP activities.
- **Methods to be used to collect**: An annual survey from recipients; baseline and annual clinic-level information from recipients' partner health system clinics; quarterly program updates from recipients; annual service delivery projections from recipients; and semi-annual minimum data elements (MDEs) from recipients.
- **The subpopulation to be studied**: For the NBCCEDP survey, the quarterly program updates, and the service delivery projections the subpopulation is the 70 NBCCEDP program directors/program managers. Clinic-level information, including breast and cervical screening rates, represents clients ages 50-74 for breast cancer screenings and 21-65 for cervical cancer screenings within partner health systems. The subpopulation for the MDEs is the 70 NBCCEDP data managers.
- **How the data will be analyzed**: CDC will use descriptive statistics to produce reports for CDC program management and NBCCEDP recipients, with a particular focus on the primary outcomes of

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

CDC is requesting a revision to the information collection with OMB control number 0920-1046 (exp. 11/30/2021), entitled "National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Monitoring Activities." In anticipation of a new 5-year cooperative agreement to be issued in 2022, CDC proposes redesigned information collection including a revised Annual NBCCEDP Survey (previously "Annual Awardee Survey"), revised baseline and annual clinic-level data collection, a new Quarterly Program Update (QPU), a new Service Delivery Projection Worksheet, and the addition of existing minimum data elements (MDEs; currently approved under OMB control number 0920-0571, exp. 03/31/2022) to this approval package. The estimated burden will increase from 683 hours to 1,233 hours. OMB approval is requested for three years.

Breast and cervical cancers are prevalent among U.S. women. In 2018, the U.S. experienced 254,744 new cases and 42,465 deaths as a result of breast cancer,

as well as 12,733 new cases and 4,138 deaths as a result of cervical cancer.[i] Evidence shows that deaths from both breast and cervical cancers can be avoided by increasing screening services – mammography, pap, and human papillomavirus (HPV) tests – among women. However, screening is typically underutilized among women who are under- or uninsured, have no regular source of healthcare, or who recently immigrated to the U.S.[ii] As a longstanding priority within chronic disease prevention, CDC focuses on increasing access to these cancer screenings, particularly among women who may be at increased risk.

CDC is authorized to collect information by the Public Health Service Act **(see Attachment 1 – Authorizing Legislation)**.To improve access to cancer screening, Congress passed the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 106-354, **Attachment 2 - Breast and Cervical Cancer Mortality Prevention Act of 1990**), which directed CDC to create the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and currently funds 70 recipients under “Cancer Prevention and Control Programs for State, Territorial, and Tribal Organizations (DP17-1701).” Recipients partner with health systems and their clinics to deliver breast and cervical cancer screening, diagnostic follow-up, and treatment referrals for women diagnosed with cancer, and to implement evidence-based interventions (EBIs) to increase breast and cervical cancer screening among clinic populations ages 21-64.

In 2022, CDC will issue a new Notice of Funding Opportunity (DP22-2202) to continue this mission with a stronger focus on collaborating with other public health programs and community-based organizations to serve populations disproportionately burdened by breast and/or cervical cancer. Based on data collection conducted throughout DP17-1701 and consistent with programmatic changes, the information collection plan has also been revised to update existing and add new data collection instruments and integrate the previously approved MDEs into this single approval package to increase efficiency. DP22-2202 is expected to fund the same number of recipients (N=70).

A2. Purpose and Use of the Information Collection

CDC is required to monitor and evaluate processes and outcomes for the NBCCEDP. Recipients are required to report information to CDC to support these efforts. Based on the redesigned NBCCEDP under DP22-2202, CDC developed a logic model to illustrate the strategies and expected outcomes associated with the NBCCEDP over time (**Attachment 3** – **DP22-2202 NBCCEDP Logic Model**). In contrast to DP17-1701, DP22-2202 has a stronger focus on selecting and

engaging partners to support NBCCEDP implementation, including serving populations disproportionately burdened by breast and/or cervical cancer and tracking them through screening completion. As illustrated in the logic model, CDC anticipates that recipients' implementation of the five strategies and activities described will result in several desired short-, intermediate-, and long-term outcomes, including increased breast and cervical screening rates. The logic model guided development of CDC's NBCCEDP monitoring and evaluation plan, which includes evaluation questions and sub-questions that map to the proposed information collections (**Attachment 4 – NBCCEDP Evaluation Question Matrix**) to be addressed through systematic monitoring and evaluation of these key strategies and the primary outcome of screening rate changes over time.

Five forms of information collection – two revised, two new, and one previously approved to be integrated into the current approval - will be implemented to answer our evaluation questions regarding program activities and outcomes. These include the Annual NBCCEDP Survey, clinic-level data collection, the QPU, the Service Delivery Projection Worksheet, and MDEs.

Annual NBCCEDP Survey

This survey is administered annually and allows CDC to monitor recipient-level activities and identify technical assistance (TA) needs. Under DP17-1701, the annual survey focused on the following areas: (1) management, program, and evaluation challenges, (2) program resources, (3) partnerships, (4) screening delivery, (5) EBI implementation for health systems change, (6) other strategies for sustainable cancer control, and COVID-19 impact. For DP22-2202, CDC proposes use of a revised Annual NBCCEDP Survey (**see Attachments 5 – Annual NBCCEDP Survey**) that eliminates questions related to management, program, and evaluation challenges as well as strategies for sustainable cancer control. Based on experiences during DP17-1701, CDC found that these sections did not yield high quality, timely data that could be used by CDC staff to provide meaningful TA. In addition, CDC has made minor updates to some questions (e.g., reformatting, revised response options). Survey questions are of various types, including dichotomous, multiple response, and free text. CDC will conduct the survey among all 70 recipients following the end of each program year.

Clinic-Level Data Collection

This information collection is reported at baseline and annually and allows CDC to gather clinic-level data on health system, clinic, and patient population characteristics; monitoring and quality improvement activities; EBI implementation; baseline or annual screening rates; and the impact of COVID-19 on clinic activities **(Attachment 6 – NBCCEDP Clinic-Level Data Collection Instruments).** At baseline (i.e., when a partner clinic is recruited), recipients

report aggregate baseline data for each of their partner clinics (an average of six clinics per recipient). In program years 2-5, recipients report aggregate annual data for each partner clinic. NBCCEDP recipients will collect and report NBCCEDP clinic-level (not patient) data for all partner clinic sites. Information will be collected separately for breast and cervical cancer activities. Clinics typically already collect these data elements for ongoing monitoring of their own clinical activities. These data will help CDC to describe program reach, the clinic settings, characteristics of the population being served, program activities implemented at the clinic-level, and changes in breast and cervical cancer screening rates over time.

QPU

This new information collection will be reported quarterly to support rapid reporting of programmatic information to support CDC program consultants in providing tailored and meaningful TA. The QPU gathers data on (1) federal award spending, (2) current staff vacancies, (3) program successes and challenges, (4) TA needs, and (5) the effect of COVID-19 on NBCCEDP implementation at the recipient level (**Attachments 7 - Quarterly Program Update**. The QPU will be administered among all 70 recipients in the month following each program quarter (i.e., October, January, April, July).

Service Delivery Projection Worksheet

This information collection gathers annual program-level estimates of the number of women that will be served for breast and cervical cancer clinical services during that program year. Recipients are required to submit service delivery projections in their initial application as well as their annual continuing applications. Reported data will include proposed number of women to receive clinical services overall and by populations of focus defined by the recipient program (e.g., by rurality). Estimates will be reported overall as well as separately for patients who receive clinical services for breast cancer, cervical cancer, and patient navigation only (**Attachment 8 – NBCCEDP Service Delivery Projections Worksheet**).

MDEs

The MDEs allow CDC to collect patient-level data semiannually on patient demographics; breast and cervical cancer screening, diagnosis, and treatment; timeliness of services; and patient navigation (**Attachment 9 – MDE Data Definitions**). This information collection was previously approved (OMB No. 0920-0571, exp. 03/30/2022). CDC proposes integration of the MDEs into this single approval package to increase efficiency. There are no changes to the instrument for DP22-2202.

Together, the proposed information collection activities are expected to contribute

to a more effective NBCCEDP and strengthen CDC's ability to demonstrate program results. These monitoring activities will also help to identify successful implementation activities that need to be maintained, replicated, or expanded; provide insight into programmatic areas needing improvement; and identify program activities and management efforts requiring immediate CDC TA. Additionally, the information collection supports the national evaluation of the NBCCEDP, including assessing implementation and program outcomes.

The scope of information collected via the annual survey, clinic-level data collection, QPU, and service delivery projection worksheet is limited to monitoring the public health activities and experiences of NBCCEDP recipients acting in their official capacity and will not yield information that can be generalized. As such, these information collections will not require IRB review. However, information collected via the MDEs include patient-level data that is generalizable and has received approval from CDC's Institutional Review Board (**Attachment 10 – Institutional Review Board Approval**). CDC will use this information to better understand the range of experiences among recipients and as one of many inputs into decision-making and/or program management. In addition, the findings will be reported back to the recipients to help them identify areas for program improvement and successful implementation models and focus networking for shared experiences, lessons learned, and best practices.

A3. Use of Improved Information Technology and Burden Reduction

The Annual NBCCEDP survey, clinic-level data collection, QPU, and Service Delivery Projection Worksheet will be administered via online instruments to minimize burden to respondents (**Attachments 5a, 6a, 7a, and 8a**). The MDEs are collected via an existing management software package designed to facilitate the data entry, editing, quality assurance, and reporting of the MDE dataset (**Attachment 9 – MDE Data Definitions**). This system minimizes burden among recipients by providing a standardized reporting system and making the data submission process more efficient. The CDC provides TA to recipients using the data management system. Recipients report the dataset as an electronic, fixed-length text file to a secure, password-protected submission Web site where recipients post their text files once prepared (www.nbccedp.org). This submission Web site simplifies the process of reporting MDE data for recipients and organizes the receipt of recipient text files by the CDC.

A data contractor, Information Management Services, Inc. (IMS), is retained to assist with data management and analysis of all information collections, which includes generating standardized reports for the recipients and the CDC. All information collections use pre-existing web infrastructure or tools easily

accessible by NBCCEDP recipients to facilitate ease of reporting for respondents.

A4. Efforts to Identify Duplication and Use of Similar Information

The information to be collected from the NBCCEDP recipients is unique to the current program and, therefore, not duplicative of any other efforts.

The Annual NBCCEDP Survey, clinic-level data collection, and MDEs collect information with which previously funded recipient programs are familiar; these, along with new items, are essential for program monitoring and to answer CDC's evaluation questions. The MDEs were previously approved (OMB no: 0920-0571, exp 03/30/2022) and will be integrated (not duplicated) into this approval package for increased efficiency. Former approval will expire and not be renewed. The MDE dataset is a unique national dataset that assists the CDC in the ongoing development and management of a cancer screening program designed to provide underserved women with access to breast and cervical cancer screening and diagnostic services. All elements within the QPU and Service Delivery Projection Worksheet are new and there are no existing, comparable data sources available for the collection of this information.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

A6. Consequences of Collecting the Information Less Frequently

The purpose of this request is to ensure collection of information that is not otherwise available in a current, time sensitive, or standardized format to specific or emergent priorities of HHS and CDC. Information collection plans, including the frequency of collection, are informed by previous funding cycles, approved information collection for other DCPC screening programs (i.e., the Colorectal Cancer Control Program), and feedback from stakeholders (e.g., recipient programs, subject matter experts in the field). Without this information collection, there would be:

- No systematic information collection regarding the implementation of NBCCEDP program activities and outcomes, as required in the current NOFO.
- No systematic assessment of recipients' TA needs.
- No systematic assessment of monitoring and evaluation efforts at the recipient and clinic levels.

- Less effective and less timely assessment of clinic partners and their program activities.
- Fewer resources from which to make data-driven decisions that are often required of CDC as well as required of its recipients.

OMB approval is requested for three years. There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CRF 1320.5

There are no special circumstances with this information collection request. This request fully complies with the regulation 5 CFR 1320.5. Participation in the cooperative agreement program is voluntary. Participation in the information collection is required for funded recipients.

A8. Comments in Response to the FRN and Efforts to Consult Outside the Agency

Part A: PUBLIC NOTICE
A 60-day Federal Register Notice was published in the *Federal Register* on July 26, 2021, vol. 86 No. 140, pp. 40055-40057 (**Attachment 11 – 60-Day Federal Register Notice**). CDC received one non-substantive comment and replied with a standard CDC response **(Attachment 11a – 60-Day FRN Public Comment and CDC Response).**

Part B: CONSULTATION

CDC received expert consultation from CDC contractors, recipients, and external partner organizations who provided substantive feedback on data collection tools (e.g., MDE data variables, survey instruments) and information collection protocols. A list of those individuals is included in **Table 1.**

Consultant	Title	Affiliation	Email	Phone
Bill Helsel	Project Manager	Information Management	helselb@imsweb.com	301-680-9770
Bill Kammerer	Project Manager	Information Management Services, Inc. (IMS)	kammererb@imsweb.com	301-680-9770
Peggy Hannon	Director, Associate Professor	University of Washington School of Public Health	peggyh@uw.edu	206-616-7859
Heather Brandt	Associate Professor	University of South Carolina	hbrandt@sc.edu	803-576-5649

Christen Lara	Data Quality and Analytics Manager	University of Colorado	Christen.Lara@state.co.us	303-692-2531
Steven Leadbetter	Consultant	DB Consulting Group, Inc.	szl1@cdc.gov	727-623-0074
Emily Kinsella	Program Director	Colorado Department of Public Health and	Emily.Kinsella@state.co.us	303-692-2511
Cynthia Snyder	Data Manager	Kansas Department of Health and Environment	Cynthia.snyder@ks.gov	785-296-2923
Maryann Zaremba	Program Director	Maine Center for Disease Control and Prevention	Maryann.M.Zaremba@Maine.gov	207- 287-3262
Libby Bruggeman	Data Manager	New Mexico Department of	Libby.Bruggeman@state.nm.u	505-841-5835
John Veazey	Data Manager	Rhode Island Department of	john.veazey@health.ri.gov	401-222-5960
Michael Mosley	Data Manager	Southeast Alaska Regional Health Consortium (SEARHC)	mmosley@searhc.org	907-463-4000

A9. Explanation of Any Payment or Gift to Respondents

Respondents do not receive an incentive. Recipients are expected to participate in the collection to comply with their cooperative agreement.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondent

This submission has been reviewed by CDC's Information System Security Office, who determined that the Privacy Act does not apply for the annual survey, clinic-level data collection, QPU, and service delivery projection worksheet. Activities do not involve the collection of individually identifiable information, and all information is programmatic in nature.

For the MDEs, this submission has been reviewed by CDC's Information System Security Office, who determined that the Privacy Act does apply since personally identifiable information is collected within the MDEs, including patient demographics (i.e., date of birth; race/ethnicity; city, state, and zip code). The primary use of these data is to calculate patient age to allow CDC to stratify analyses by age.

Overview of the Information Collection

CDC proposes to collect information in five forms from all 70 NBCCEDP recipients. The information collection will support monitoring and evaluation of program implementation and outcomes of the NBCCEDP and timely delivery of TA from CDC to recipients. DP22-2202 and program policy require recipients to report all five forms of information to CDC.

Annual NBCCEDP Survey

This information collection consists of a web-based questionnaire designed to collect program-level information from all 70 NBCCEDP recipients. The Program Director or Manager for each cooperative agreement will serve as the survey respondent. Contact information for the recipient is obtained from program administrative systems and used to distribute survey introductory and reminder emails only **(Attachments 5b-c).** The CDC contactor will manage primary information collection and send respondents a unique link to an online instrument (not a website) that will enable recipients' access to view and enter their survey information. After receiving responses to the survey, the contractor will prepare a validated analysis file and set of reports for CDC to assist in interpreting results. CDC will prepare and distribute program-specific and NBCCEDP summary feedback reports. The online information collection instrument software will be developed using an open-source product called LimeSurvey (limesurvey.org). This effort will build on a pre-existing survey information collection currently in place for DP17-1701.

Clinic-level Data Collection

This information collection consists of aggregate data from each clinic site where NBCCEDP program interventions are implemented. Based on the NBCCEDP clinic-level data collection for DP22-2202, CDC estimates six partner clinics per recipient program. The data manager will serve as the respondent. Contact from program administrative systems will be used to distribute introductory and reminder emails to recipients **(Attachments 6b-c).** Information will be reported through an online information data entry instrument accessible to recipients on the pre-existing secure NBCCEDP program website (www.nbccedp.org) to simplify the reporting process with centralized information collection, validation, access control and technical support. These data will be used to generate program-specific and aggregate data reports to identify progress towards the main program outcome – increased breast and cervical screening rates.

QPU

The QPU is a web-based questionnaire that will be administered to all 70 NBCCEDP recipients. The Program Director or Manager will serve as the respondent. The CDC contactor will manage primary information collection and send respondents a unique link to an online instrument (not to a website) that will enable recipients' access to view and enter their program information. The online instrument will be developed using an open-source product called LimeSurvey (limesurvey.org). Contact information for the recipient is obtained from program administrative systems and used to distribute QPU pre-administration, administration, and reminder emails **(Attachments 7b-d).** After receiving responses to the QPU, the contractor will prepare an analysis file and set of reports for CDC to assist in interpreting results. CDC will use recipient-specific and aggregate information to inform ongoing CDC TA and guidance.

Service Delivery Projection Worksheet

This information collection is a web-based form that will be administered to all 70 NBCCEDP recipients. The Program Director or Manager will serve as the respondent. Recipients are required to submit service delivery projects with their applications and continuing applications each year. The contractor will prepare an analysis file and set of reports for CDC to assist in interpreting results. CDC will use recipient-specific and aggregate information to inform ongoing CDC TA and guidance.

MDEs

The MDEs consist of an electronic submission of patient-level data from all 70 NBCCEDP recipients. The data manager within each recipient program will serve as the respondent. Approximately half of all recipients use the CDC-developed Windows-based application for data collection; remaining recipients use their approved data management and reporting systems. All recipients submit their data electronically through a secure, password protected program web site. Recipients will continue to submit MDEs semi-annually in April and October of each program year, which runs from July-June. All MDE data submissions are reported via an electronic, fixed-length text file to a secure, password-protected submission Web site on nbccedp.org. The CDC contactor will manage, aggregate, and validate the MDE data for quality and completeness, and prepare an analysis file and reports for delivery to CDC.

<u>Opportunities to consent to sharing and submission of information</u>

Respondents are notified that their information will be maintained in a secure manner and that they will receive individualized feedback reports for their use. The data set is restricted and only available in cases where a data sharing agreement is established and a CDC staff member is an author on a related manuscript. There is no impact on the respondent's privacy.

How information is secured

Both information collections are secured by technical, physical, and administrative safeguards as outlined below.

Technical

- All data reside on a dedicated server on the contractor's local area network behind the contractor's firewall, and is password protected on its own security domain. Access to the server is limited to the contractor's authorized project staff. Non-project staff will not have access to the data. All of the contractor's project staff are required to sign a non-disclosure agreement before passwords and keys are assigned.
- Access to the NBCCEDP program website is restricted via a password-protected secure website. Access to recipient submissions and data entry systems are further restricted within the website. Each recipient has its own directory location, so no recipient has access to another recipient's information. The NBCCEDP website utilizes the Hypertext Transfer Protocol Secure (HTTPS) method to ensure secure connections. In addition, the website will enable Strict Transport Security (HSTS), which is in compliance with OMB memorandum M-15-13, Policy to Require Secure Connections across Federal Websites and Web Services.
- Once information has been compiled by the contractor and delivered to CDC via a secure website, all data are maintained with restricted access on CDC's secure LAN server with access permission granted by the CDC NBCCEDP data manager.

Physical

- The contractor's server is housed in a secure facility with restricted access.
- Receipt and processing logs are maintained to document data receipt, file processing and report production. All reports and electronic storage media containing recipient information are stored under lock and key when not in use and will be destroyed when no longer needed.
- Once data have been compiled by the contractor and delivered to CDC, all datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff are issued identification badges and access to the building is controlled by key cards.

Administrative

- CDC and contract staff have developed and implemented an information system security plan to ensure that the information is kept secure. Periodic review and update of the contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the

continued security of the information.

- The contractual agreement between CDC and the contractor includes non-disclosure terms. The contractor's project security team oversees operations to prevent unauthorized disclosure of the NBCCEDP data.
- Once the information have been delivered to CDC, data are housed on CDC's secure LAN server and restricted access is controlled by the NBCCEDP data manager.

A11. Institutional Review Board (IRB) and Justification for Sensitive Questions

For the Annual NBCCEDP Survey, clinic-level data collection, QPU, and Service Delivery Projection Worksheet, no information will be collected that are of personal or sensitive nature. IRB approval is not required. For the MDEs, datasets include sensitive information about cancer diagnosis and treatment initiation, which is central to the purposes of program evaluation and oversight. In addition, race and ethnicity data are collected per the Department of Health and Human Services guidelines and for use in data analyses. The MDEs received approval by CDC's Institutional Review Board (**Attachment 11 – Institutional Review Board Approval**)

A12. Estimates of Annualized Burden Hours and Costs

The NBCCEDP currently funds a total of 70 recipient programs. CDC anticipates that the new cooperative agreement DP22-2202 will fund the same number of recipients. Estimated burden hours are described below.

- The estimated burden hours for the Annual NBCCEDP Survey are based on a pilot by 5 public health professionals. In the pilot test, the average time to complete the instrument was approximately 45 minutes. The updated survey includes a 23% (n=7) increase in survey items of similar nature to the previous version. Therefore, the estimated time to complete the revised instrument is approximately 56 minutes. The overall estimated annualized burden is 65 hours.
- The estimated burden hours for clinic-level data collection are based on a pilot by 4 public health professionals. In the pilot test, the average time to complete the instrument was approximately 45 minutes. We estimate an average of 6 responses per recipient annually for breast cancer activities, and 6 responses per recipient annually for cervical cancer activities, to correspond with the number of health system partners. Only minor wording and formatting changes were made to the instrument; therefore, the estimated completion time remains the same. The overall estimated

annualized burden is 315 hours for breast cancer and 315 hours for cervical cancer.

- The estimated burden hours for the QPU are based on a pilot test of the information collection instrument by 3 public health professionals. In the pilot test, the average time to complete the instrument was approximately 32 minutes. The estimated annualized burden is 149 hours.
- The estimated burden hours for the Service Delivery Projection Worksheet are based on a pilot test of the instrument by 3 public health professionals. In the pilot test, the average time needed to complete the instrument, including reviewing the instructions and gathering information to complete the items was 29 minutes. The overall estimated annualized burden is 34 hours.
- The estimated burden hours for the MDE data collection are based on previous reporting experience, the specific features of the data management system developed and maintained by CDC to perform these exact functions, and voluntary consultation from six recipients' estimated time for completion. No changes were made to MDE variables or the process of generating the electronic data file. The burden estimate is 150 minutes per response for a total annualized burden of 350 hours. The total estimated annualized burden hours for this ICR is 1,228.

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden Hours
NBCCEDP Recipients	Annual NBCCEDP Survey	70	1	56/60	65
	NBCCEDP Clinic-level Information Collection Instrument - Breast	70	6	45/60	315
	NBCCEDP Clinic-level Information Collection Instrument – Cervical	70	6	45/60	315

	Quarterly Program Update	70	4	32/60	149
	Service Delivery Projection Worksheet	70	1	29/60	34
	MDEs	70	2	150/60	350
Total					1,228

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 respondents.

Type of Respondent	Form Name	Number of Respondents	Total Burden Hours	Average Hourly Wage	Total Cost
NBCCEDP Recipients	Annual NBCCEDP Survey	70	65	$57.11	$3,712
	NBCCEDP Clinic-level Information Collection Instrument - Breast	70	315	$57.11	$17,990

	NBCCEDP Clinic-level Information Collection Instrument - Cervical	70	315	$57.11	$17,990
	Quarterly Program Update	70	149	$57.11	$8,509
	Service Delivery Projection Worksheet	70	34	$57.11	$1,942
	MDEs	70	350	$57.11	$19,989
Total					$70,1322

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

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

A14. Annualized Cost to the Federal Government

Total operations and maintenance costs includes work performed by both the contractor and CDC personnel. Salary cost of CDC staff include two FTEs (GS-13) to prepare OMB documents and coordinate all related activities of each information collection including data management, analysis and report preparation, as well as two FTEs (GS-14) to provide subject matter expertise and reporting oversight. Nine hundred and sixty hours of staff time was estimated for each FTE annually for this information collection. Cost of the contractor represents an estimated 35% ($463,152) of total annual contract funds ($1,323,293) allocated for NBCCEDP data management activities. The estimated annualized cost to the federal government is $682,478. Table A.14-A describes how the cost estimate was calculated.

Table A14.-A. Estimated Annualized Federal Government Cost Distribution

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Health Scientist (GS-13) Health scientist to prepare OMB package; overall coordination; and consult on information collection, analysis, report preparation	960	$52.50	$50,400
Health Scientist (GS-13) Data management support, analysis, report preparation	960	$52.50	$50,400
Health Scientist (GS-14) Subject matter expertise, reporting oversight	960	$61.68	$59,213
Health Scientist (GS-14) Subject matter expertise, reporting oversight	960	$61.68	$59,213
Contractor Costs			
Annualized Cost of Contract with Information Management Services Responsible for building web-based application, information collection, coding and entry, quality control, analysis, report preparation			$463,152
Estimated Total Cost of Information Collection			$682,478

The majority of data collection and management tasks will be the responsibility of the CDC contractor, and will not require additional operational or maintenance costs to the Federal government. CDC personnel will oversee the project, and provide leadership and coordination which will not require additional costs beyond individual employees' salaries. Therefore, there are no additional operational or maintenance costs associated with this information collection.

Table A14-B. Total Cost to the Federal Government

Operational and Maintenance Costs	Estimated Annualized Federal Government Costs	Total Cost
$0.00	$682,478	$682,478

A15. Explanation for Program Changes or Adjustments

This is a request to revise OMB No. 0920-1046. To increase efficiency across information collections for the NBCCEDP, CDC proposes integration of the previously approved MDEs into the current package (OMB No. 0920-0571) which expires 03/30/22 and will not be renewed separately. No revisions were made to the MDEs. CDC made minor revisions to both the annual survey and the clinic-level data collection, including minor changes to wording and formatting of survey questions and response options, and removal of sections that did not yield high quality, timely data (survey only). These revisions were made to improve data quality. Because revisions increased the number of questions in the annual survey, burden hours increased from 56 to 65 burden hours. Revisions to the clinic-level data collection did not result in increased burden; therefore, the estimated burden remains the same. The QPU is new and involves four annual submissions for all 70 recipients for a net increase of 104 estimated burden hours. The service delivery projection worksheet is also new and involves an annual submission for all 70 recipients for a net increase of 34 estimated burden hours. There were no changes to the MDEs; therefore, the estimated burden remains the same.

	Previous Approval		**Proposed Changes for Current Revision**			
Information Collection Instrument	**No. Respondents**	**No. Burden Hrs.**	**No. Respondents**	**No. Burden Hrs.**	**Change in Respondents**	**Change in Burden Hrs.**
Annual NBCCEDP Survey	70	53	70	65	0	+12
NBCCEDP Clinic-level Data Collection Instrument - Breast	70	315	70	315	0	0
NBCCEDP Clinic-level Data Collection Instrument - Cervical	70	315	70	315	0	0
QPU	-	-	70	149	+70	+149
Service Delivery Projection	-	-	70	34	+70	+34

Worksheet						
MDEs	-	-	70	350	+70	+350
						+550

A16. Plans for Tabulation and Publication and Project Time Schedule

CDC proposes two revised, two new, and one previously approved instrument to be integrated into the current approval. As such, the time schedule for data reporting reflects all five information collections. Recipients are required to submit service delivery projections in their initial and continuing applications for funding and revised projections based on their approved budget 3 months after the program start date. The Annual NBCCEDP Survey and NBCCEDP Clinic-Level Data Collection Instrument will each be completed annually within 3 months after the end of each program year (July – September). The Quarterly Program Update will be completed the month following the end of each quarter (October, January, April, and July). Recipients will report MDEs semiannually during each program year (October, April). Data validation, analysis, and report preparation and dissemination will follow each information collection. A summary timeline is provided below:

Table A.16. Estimated Time Schedule for Project Activities

Activity	Timeline
Annual NBCCEDP Survey and Clinic-Level Data Collection	
Introductory emails for survey and clinic-level data collection sent to respondents with link to survey, information collection begins.	Begin 1-3 months after end of program year, information collection continued for up to 6 weeks
Reminder emails sent (non-responders only)	10 days after introductory emails sent
Data validation	Completed 1 month after end of information collection
Data analysis	Completed 4 months after end of information collection
Report preparation and dissemination	Completed 6-7 months after end of each information collection
QPU	

Pre-administration and administration emails sent to respondents with link to instrument, information collection begins	Quarterly beginning 3 months after start of program year (October, January, April, July), information collection continues for up to 4 weeks
Reminder emails sent (non-responders only)	Quarterly, 10 days after pre-administration email sent
Data analysis and dissemination for QPU (Recipients and CDC only)	Completed 1 month after end of information collection
Service Delivery Projection Worksheet	
Recipients submit projection worksheet	With initial and continuing application
Initial email sent to recipients with instructions to submit revised projection worksheet	Completed 1 month after program year start date
Reminder emails sent (non-responders only)	10 days before due date
Recipients submit revised worksheet	Completed 3 months after program start date (September)
Report preparation and dissemination	Completed 4 months after submission
MDEs	
Recipients submit MDE file and submission narrative on nbccedp.org	Semi-annual: April and October
Data validation, aggregation and analysis file creation for MDEs sent to CDC from data contractor	Completed within 2 months after submission
MDE recipient feedback report preparation and dissemination	Completed 3 months after submission
Data reviews held with recipient, CDC and data contractor for MDEs	Completed 4 months after submission
MDE action items generated for response in next submission (feedback loop informs the next submission)	Completed 5 months after submission

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submission

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

REFERENCES

[i] U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2020 submission data (1999-2018): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; www.cdc.gov/cancer/dataviz, released in June 2021.

[ii] Centers for Disease Control and Prevention. Cancer Screening Test Use—United States, 2015. **MMWR** 2017;66(8):201-206.