Extension Request
OMB No. 0920-0571, exp. 11/30/2012

Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP)

Supporting Statement Part A

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ABSTRACT

CDC is currently approved to collect performance indicator data from state, tribal and territorial programs funded through the National Breast and Cervical Cancer Early Detection Program (NBCCEDP). The information collection allows CDC to provide routine feedback to grantees based on their data submissions, to tailor technical assistance as needed, and to support program planning, surveillance and secondary data analysis activities. A three-year extension was approved by OMB in November 2009. The current request is to extend OMB approval for three years. No additional changes to the information collection instrument are proposed. The total estimated burden estimate is reduced slightly due to a previously funded grantee no longer participating in the NBCCEDP. There is no change to the estimated burden per response.

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval of a three-year extension for the Minimum Data Elements (MDEs) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); OMB Control Number 0920-0571, Expiration date: 11/30/2012.

Breast cancer is a leading cause of cancer-related death among American women. The American Cancer Society (ACS) estimates that 226,870 new cases of invasive breast cancer will be diagnosed among women in 2012 and 39,510 women will die of breast disease. Mammography is extremely valuable as an early detection tool because it can detect breast cancer well before a lump is palpable, when the cancer is still in an early and more treatable stage. Women older than age 40 reduce their risk of breast cancer mortality and increase their treatment options when they receive annual mammography screening.

Papanicolaou (Pap) tests effectively detect both precancerous lesions and invasive cervical cancer. The detection and treatment of precancerous lesions can prevent nearly all cervical cancer-related deaths. Although the widespread use of Pap tests has contributed greatly to a decreased incidence of invasive cervical cancer in recent decades, the ACS estimates that 12,170 new cases will be diagnosed in 2012 and 4,220 women will die of this disease.

Congress established the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in 1991 by enacting the Breast and Cervical Cancer Mortality Prevention Act of 1990, Public Law 101-354 (Attachment 1a). This legislation authorized the Centers for Disease Control and Prevention (CDC) to provide funding to states for the development and maintenance of early detection programs designed to ensure that under-served, low income, and under-insured women receive access to breast and cervical cancer screening services. The NBCCEDP has operated for 22 years and currently funds 67 programs including all 50 states, five U.S. Territories, 11 American Indian/Alaska Native organizations and the District of Columbia. The present agreement between NBCCEDP grantees and the CDC is outlined in Program Announcement DP12-1205 effective 6/30/2012.

The Breast and Cervical Cancer Mortality Prevention Act of 1990 authorizes the CDC to ensure NBCCEDP grantees implement and maintain effective program components including screening, tracking, follow-up and case management, quality assurance and improvement, public education and outreach, provider education, partnership development, evaluation and surveillance. In addition, grantees are funded to collect and maintain screening and follow-up data and to assure the completeness, timeliness and quality of information about women served through the program. Twice per year, grantees submit a de-identified subset of these data to CDC. These datasets, called the Minimum Data Elements (MDEs), contain patient demographic, screening and outcome data (Attachment 3a). No changes to the MDE dataset are proposed in this extension request.

The data collection authority for this study is Section 301 of the Public Health Service Act [42 U.S.C. 241] (Attachment 1b). A data contractor has been retained to assist with data management and analysis.

Privacy Impact Assessment

The NBCCEDP data collection has not been previously assessed. An overview of the data collection system and a listing of the items of information to be collected are provided in the subsequent sections.

Overview of the Data Collection System

NBCCEDP-funded grantees, which are state, territorial and tribal governments or bona-fide agents, collect data to manage their screening programs and retain primary responsibility for information collection procedures. A subset of clinical data collected by grantees is reported to CDC to describe the services provided through the program.

Grantee programs establish a provider network for cancer screening and diagnostic services and collect clinical data from these providers on each client screened through the program. Each grantee program is responsible for developing an appropriate consent form, and for implementing assurances that all sensitive and/or personally identifiable information collected is properly maintained and secured. Grantees maintain data in local data management systems used to administer their programs, reimburse providers for services, ensure quality of services, and track patients for appointments and follow-up. Grantees can use any software system that meets their needs. They have the option to use a software application provided by CDC, a state health department based data system, or a data system customized to meet local needs. The optional software provided by CDC is a Windows-based desktop application that supports patient tracking and facilitates the extraction of data to report to CDC. CDC provides any necessary technical support to grantees that use this data management system.

Grantees are required to establish a Memorandum of Agreement with their corresponding state Central Cancer Registry (CCR) and link records of cancer cases diagnosed through their screening programs for case reporting and quality assurance. State CCRs are the primary source of end result information collected on cancer cases, and the linkages are used by NBCCEDP grantees to confirm diagnostic outcomes and collect a discreet set of standardized registry data on cancer stage at diagnosis, a measure of the extent/spread of disease and a critical indicator to evaluate the effectiveness of a cancer screening program.

Twice a year, grantees aggregate and report a subset of their patient-level clinical data to CDC to monitor and evaluate the program. Prior to electronic data transfer to the data contractor, each grantee will remove all direct personal identifiers (such as name) and assign a unique code for each client in the data base. The CDC will not accept a method of record identification, such as social security number, that may be linked to other databases. The development of a unique method of record encryption and identification by each grantee program will permit the CDC to anonymously track each client served throughout their association with the NBCCEDP, without the use of names. The grantees will maintain the encryption information between their unique codes and the personal identifiers in their database. Neither the encryption scheme nor identifying information on the client, other than the fields noted, will ever be provided to the CDC or the data contractor.

Grantees submit the MDE data as an electronic fixed-length text file using a secure submission web site (Attachment 3b), which simplifies the data reporting process for grantees and organizes the receipt of grantee text files by the CDC. The data provided to the contractor will be archived on secure network servers with user ID and password restricted access at the location of the data contractor and at the CDC. Access rights and restrictions to network resources are determined by user ID. Networked systems are maintained in a secure room with access strictly limited to essential employees. Information will be archived indefinitely. The contractor aggregates and validates the data for quality and completeness and prepares a SAS analysis file and a set of feedback reports to CDC and grantees within 60 days of the submission. The analysis file contains the same patient ID code that is submitted by the grantees and the day of birth is recoded to equal ‘15’ prior to submission to CDC. Once data have been compiled by the contractor and delivered by courier service to CDC, all NBCCEDP datasets are maintained for restricted access on CDC’s secure LAN server.

Items of information to be collected

Twice a year, grantees aggregate and report a subset of their patient-level clinical data to CDC to monitor and evaluate the program. The data submission will include cumulative records since the inception of the grantee screening program through a cutoff-period that allows a minimum of 3.5 months to collect, validate and prepare the data for submission. These data include coded

patient identifiers, screening history, demographic data, screening and diagnostic tests provided and results, diagnostic outcomes, and treatment initiation information if cancer is diagnosed. The list of specific data items is provided in Attachment 3a (MDEs). Information in Identifiable Form (IIF) is collected. All screening records include date of birth and medical information on cervical and breast cancer screening and diagnostic tests and results. If cancer is detected, IIF is collected on the characteristics (histology, behavior, stage) of the cancer diagnosed and the dates the client was diagnosed and started treatment.

Identification of Websites and Website Content Directed at Children under 13 Years of Age

MDE data compiled at the grantee level are transmitted to the data management contractor via a password-protected secure website (Attachment 3b) and are encrypted during transmission. The encryption is accomplished via Secure Sockets Layer (SSL) strong encryption, the same level of protection used by e-commerce sites to protect financial transactions.

The clinical and cost data reporting websites do not have content directed at children under 13 years of age.

A2. Purpose and Use of Information Collection

The CDC uses standardized reports generated from each semi-annual MDE submission to assess performance of the national program and grantees. The CDC provides routine feedback to grantees based on their data submissions and tailors technical assistance as needed. The data are also used by the CDC for national program surveillance, planning and improvement, reporting program results to Congress and other legislative authorities, and secondary analyses by CDC's Division of Cancer Prevention and Control (DCPC) scientific staff for research purposes.

The CDC reviews the quality of MDE data in each submission to ensure data are appropriate to monitor and evaluate the program. Data accuracy and management are critical to the proper tracking and follow-up of women served by the grantee programs. Edits identify incomplete information as well as improper skip patterns between data fields and patient records. The CDC expects that less than five percent of records reported in grantee data sets contain edits.

The CDC has defined a set of core program performance indicators that use MDE data to

evaluate grantee performance in meeting NBCCEDP guidelines and expectations for service delivery, to target technical assistance needs, and to influence performance-based funding decisions. Core indicators evaluate two critical categories of performance — Screening Priority and Service Delivery.

Screening Priority Indicators assess performance in directing resources to priority populations as defined by CDC evidence-based policy. For example, the CDC expects that a minimum of 75 percent of all mammography screenings funded by the NBCCEDP be provided to women age 50 and older, where mammography is proven most effective as a screening tool. For cervical screening, the CDC prioritizes screening women who have not had a Pap test in the past five years, where the majority of cervical cancers occur. The allocation of screening resources to under-served and priority populations is essential to the NBCCEDP's mission to reduce breast and cervical cancer morbidity and mortality.

Service Delivery Indicators help to ensure that women receive high quality clinical services through the program. Grantees must meet expected standards for providing appropriate and timely patient follow-up when diagnostic evaluation and treatment services are needed. The CDC monitors the percentage of records with either an abnormal screening result or a planned diagnostic procedure that indicate complete follow-up. The amount of time that passes between abnormal screening results and diagnoses is monitored, as well as the amount of time between diagnoses and the initiation of clinically recommended treatment.

The following table summarizes the core program performance indicators and standards. Program indicators may change over time to reflect program priorities and areas of concern.

Core Performance Indicators and Standards for Service Delivery Evaluation:

Screening Priority Indicators	Initial Program Pap tests; Never or Rarely Screened	A minimum of 20% of all women receiving a first funded Pap test within the NBCCEDP should either have never had a previous Pap test, or not had a previous Pap test within the last five years.
	Screening Mammograms Provided to Women ≥ 50 Years of Age	A minimum of 75% of all mammogram screenings funded by the NBCCEDP should be provided to women ≥ 50 years of age.
Cervical Cancer Service Delivery Indicators	Abnormal Screening Results with Complete Follow-up	A minimum of 90% of records with either an abnormal screening result or a diagnostic procedure planned should indicate that diagnostic evaluation has been completed.
	Abnormal Screening Results; Time from Screening to Diagnosis > 90 Days	No more than 25% of records with a diagnostic procedure planned should exceed 90 days between the screening procedure and the final diagnosis.
	Treatment Started for Diagnosis of HSIL, CIN II, CIN III, CIS, Invasive	A minimum of 90% of records with a final diagnosis of HSIL, CIN II, CIN III, CIS or invasive carcinoma should indicate that treatment has been initiated.
	HSIL, CIN II, CIN III, CIS; Time from Diagnosis to Treatment > 90 Days	No more than 20% of records with a complete final diagnosis of HSIL, CIN II, or CIN III/CIS should exceed 90 days between final diagnosis and treatment initiation.
	Invasive Carcinoma; Time from Diagnosis to Treatment > 60 Days	No more than 20% of records with a complete final diagnosis of invasive cervical carcinoma should exceed 60 days between final diagnosis and treatment initiation.

Breast Cancer Service Delivery Indicators	Abnormal Screening Results with Complete Follow-up	A minimum of 90% of records with either an abnormal screening result or a diagnostic procedure planned should indicate that diagnostic evaluation has been completed.
	Abnormal Screening Results; Time from Screening to Diagnosis > 60 Days	No more than 25% of records with a diagnostic procedure planned should exceed 60 days between the screening procedure and the final diagnosis.
	Treatment Started for Breast Cancer	A minimum of 90% of records with a final diagnosis of invasive breast cancer should indicate that treatment has been initiated.
	Breast Cancer; Time from Diagnosis to Treatment > 60 Days	No more than 20% of records with a complete final diagnosis of invasive breast cancer should exceed 60 days between final diagnosis and treatment initiation.

The CDC also uses the MDE data to monitor grantee performance in meeting projected screening volume, to assess fiscal management and realistic goals for service delivery.

MDE data are used to report results to CDC officials, Congress, and the Office of Management and Budget. CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) has developed performance measures for the Program Rating Assessment Tool (PART) that use MDE data to evaluate NBCCEDP program outcomes in annual reports to the Office of Management and Budget (OMB). PART measures require credible data sources. The NBCCEDP PART measure evaluates trends in cervical cancer incidence among women receiving Pap tests through the program. In 2008, MDE data were also used to report program performance and outcome data to a comprehensive Government Accounting Office (GAO) study of the Medicaid Treatment Act and the NBCCEDP.

The data collection methodology has been successful with no problems reported by the NBCCEDP grantees. The continuation of data collection is imperative for future monitoring and evaluation of the NBCCEDP. Finally, subsets of MDE data are available to internal and external investigators, on a limited basis and with appropriate security controls, for research purposes.

Privacy Impact Assessment Information

The clinical data will be used by CDC to monitor and evaluate the NBCCEDP, ensure the quality of clinical services, provide feedback to grantees and Congress on program outcomes, evaluate the costs and effectiveness of the program, and inform future efforts for program planning and policy decisions for organized colorectal cancer screening programs.

There are no plans for a public-use clinical dataset. DCPC investigators will have restricted access to an analytical dataset of program results to use for analysis and publication in peer-review journals and presentations to cancer control organizations. Program participation and results will be reported in aggregate to describe client demographics, volume of screening, cancer detection rates by screening test type, diagnostic outcomes by age, race/ethnicity, and geographic region, complication rates, and quality assurance of patient follow-up and adherence to cancer screening guidelines. Any data published in program reports, either in printed copy or on the Internet, will be scrutinized to assure that small cell counts are masked and the privacy of the individual is protected.

The analysis dataset at CDC will not contain direct personal identifiers as this information is not available to CDC. As such, the data collection will have little or no effect on the respondent's privacy. However, it may contain information that is potentially identifiable especially when linked with other datasets, such as in the occurrence of a cancer in a person of a certain combination of age, race, ethnicity and geographical information. CDC has established a data sharing for special use agreement that includes the following: review and approval of all data sharing requests by a multidisciplinary NBCCEDP evaluation team at CDC, well-defined restrictions for use and presentation of data, and a CDC collaborator for external investigators.

A3. Use of Improved Information Technology and Burden Reduction

The CDC requires grantees to electronically report a minimum set of screening and follow-up

data. The data definitions and record layouts for this file were designed by the Program Services Branch of the Division of Cancer Prevention and Control and are detailed in Attachment 3a. Grantees submit the MDE data as an electronic fixed-length text file using a secure submission web site, which simplifies the data reporting process for grantees and organizes the receipt of grantee text files by the CDC. The CDC developed and maintains a patient tracking data management software package for optional use by grantees to manage local program data and facilitate the extraction of the minimum data set. The system is a Windows-based desktop application currently used by approximately one-half of the NBCCEDP grantee programs. CDC provides any necessary technical support to grantees that use the data management system.

A4. Efforts to Identify Duplication and Use of Similar Information

There are no existing, comparable data sources available for the collection of this information. The reported screening and follow-up data provide information about women specifically enrolled and screened in the NBCCEDP and are available exclusively from NBCCEDP grantees. The consistent reporting of screening, final diagnosis, and treatment initiation data to the CDC promotes assurances that grantee programs provide appropriate and timely clinical services to women who utilize the NBCCEDP, a requirement of the law establishing the program.

The Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (OMB No. 0920-0776, exp. 3/31/2011) collected activity-based cost information from NBCCEDP grantees to support analysis of the costs and cost-effectiveness of the NBCCEDP. The information will be used to assess the costs of various program components, identify factors that impact average cost, perform cost-effectiveness analysis, and to develop a resource allocation tool for ensuring the most appropriate use of limited program resources. The MDE data complement the cost data collection by providing the effectiveness measure for the cost-effectiveness analyses of the program. This collection has been discontinued and the economic analysis is in progress.

The National Program of Cancer Registries (NPCR; OMB No. 0920-0469, exp. 11/30/2012) collects data on all women diagnosed with cancer. However, NPCR data are collected and verified through medical record confirmation several months after a final diagnosis is made. The data aggregated by the NPCR do not include screening and tracking information nor do they

allow for assurances that women receive appropriate and timely care prior to and following final diagnosis. The NPCR data complement the NBCCEDP by providing national population-based rates of disease for which to compare and evaluate the outcomes of a cancer screening program. The NBCCEDP data collection is unique in providing a national data set that assists the CDC in the ongoing development and maintenance of an early detection program designed to ensure access to breast and cervical cancer screening services for under-served women.

A5. Impact on Small Businesses or Other Small Entities

No small businesses are involved in this study.

A6. Consequences of Collecting the Information Less Frequently

The CDC aggregates screening and follow-up data from grantees semi-annually. This allows the CDC to regularly evaluate the overall performance of the NBCCEDP, to make adjustments toward improved effectiveness and to identify new goals as part of on-going planning efforts. It also allows the CDC to effectively monitor grantee performance and provide constructive guidance to them on a consistent basis. In addition, the semi-annual review of the screening and follow-up data enables the CDC to identify problems with timely and complete follow-up for women with abnormal screening results or diagnoses of cancer or pre-cancer. The collection of these data less frequently would compromise the ability of the CDC to perform this surveillance. The CDC is also obligated to provide annual status reports on the NBCCEDP to Congress and other CDC officials. There are no legal obstacles to reduce the burden.

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

These data are collected in a manner consistent with the guidelines in 5 CFR 1320.5. There are no special circumstances contained within this application.

A8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Notice of this study was published in the Federal Register on June 6, 2012, Vol. 77, No. 109, pages 33467-33468 (Attachment 2a). One public comment was received and acknowledged (Attachment 2b).

B. The Division of Cancer Prevention and Control has employed several methods of consultation with individuals outside of the agency regarding the proposed data

collection. The NBCCEDP has a formal advisory committee, the Breast and Cervical Cancer Early Detection and Control Advisory Committee, which is comprised of 22 members. This committee is formally sanctioned by the CDC and meets annually to review relevant issues, including data issues. The formal advisory committee last convened on June 16-17, 2011, and the next meeting is scheduled for November 15-16, 2012. A list of the Committee members and their contact information is provided in Attachment 4.

In addition to the formal advisory committee, Program Directors, Data Managers, Quality Assurance Coordinators, and other key employees within each NBCCEDP grantee program participate in an annual conference, quarterly calls, and periodic webinars and trainings. These contacts provide an extended forum for the direct discussion of data issues between the CDC and grantee programs and an opportunity for the CDC to solicit consultation from grantee staff members. These forums also provide excellent networking opportunities for grantee staff to share their data management experiences and ideas among associates.

The CDC maintains an internal working group to review and discuss data issues as needed. This working group includes program staff, epidemiologists, medical professionals, and social scientists. Based on the issues reviewed, the work group makes related recommendations for data changes, data analyses, and other program improvements.

Finally, when specific NBCCEDP data issues and concerns arise, the CDC typically convenes a special workgroup that includes representatives from outside of the agency to discuss the issues and develop recommendations. For example, in 2010-2011 a study to estimate the impact of implementing digital vs. film mammography in the NBCCEDP and make recommendations for changes to program policies was conducted through a collaborative modeling analysis using two Cancer Intervention and Surveillance Modeling Network (CISNET) breast cancer models from Georgetown University and Erasmus Medical Center in the Netherlands. In 2011, the CDC and the American Cancer

Society sponsored a study by George Washington University to analyze the effects of the Patient Protection and Affordable Care Act on breast, cervical and colorectal cancer screening and treatment services to understand the potential impact of the law on the population and identify gaps and barriers remaining after implementation of the new law. In both studies, MDE data were used in part to model impact.

A9. Explanation of Any Payment or Gift to Respondents

Not Applicable.

A10. Assurance of Confidentiality Provided to Respondents

Confidentiality is of the utmost importance to the CDC. Respondents are NBCCEDP grantees from state, tribe and territorial health departments that have routine access to identifiable medical information for conducting patient care and public health activities. In order to provide clinical and screening services, the NBCCEDP grantees collect personally identifiable information on each woman served (e.g., name, address, social security number, age, race/ethnicity) along with information about each woman's screening history, the screening and diagnostic procedures provided, and the results of those procedures. If cancer or pre-cancer is diagnosed, then information about treatment initiation and stage of disease is also collected. Although the variables and data collection instruments vary among grantees, the grantees standardize the data format before reporting them. Grantees remove most personal identifiers and assign a unique code for each woman in the database prior to the electronic transfer of a data file to the data contractor. The unique patient ID number is created by each grantee and most use a sequential number so that patients are identified as patient #1, #2, etc. Each grantee maintains the linkage information between the unique codes and the personal identifiers in their local database in order to respond to and follow-up with specific providers about an individual woman or to respond to data queries from the CDC. The unique method of record identification allows the CDC to anonymously track each woman served throughout her involvement with the NBCCEDP. The identifying data provided to the data contractor include patient ID number, county of residence, state of residence, zip code of residence, race, date of birth, and Hispanic origin. The linkage information is never provided to the data contractor or the CDC, nor is identifying information on women beyond the variables noted above. The study protocol for the collection of this information, CDC Protocol #1976, received approval of continuation from the CDC Institutional

Review Board (IRB) through May 17, 2013, (Attachment 5).

The grantee programs also maintain the encryption scheme between their unique codes in the MDE data and the personal identifiers in their database. Neither the encryption scheme nor identifying information on women, other than the variables noted, will ever be provided to the CDC or the data contractor.

The CDC does not anticipate the development of a public-use data set using the NBCCEDP data. Formal reports will be developed for publication both semi-annually and periodically. These reports will present results from the program based upon demographic information such as age and race, and reported as national aggregate data rather than grantee-specific. A limited set of grantee-specific data reported in a five-year aggregate are available to the public on the CDC web site. Reports do not include record identifiers. Reports are disseminated to the public through the CDC public web site, peer review journals, and publications. Secondary analysis of data for the purposes of research is conducted to address specific research questions concerning breast and cervical cancer screening.

Investigators outside of the agency are permitted to submit a proposal to the CDC requesting use of the national data set. Each proposal is reviewed internally by a committee comprised of designated representatives from each Branch in the DCPC who are knowledgeable about the data set, its uses, and limitations. Upon review by the committee, each proposal is approved, denied, or the investigator is asked to provide additional information. Investigators who submit successful proposals to the CDC are required to sign a Data Sharing Agreement for Special Use Form (Attachment 6) indicating they agree to comply with the provisions outlined for data use. Successful applicants do not gain access to the entire data set. The CDC develops and provides to each successful applicant a custom data set that meets the minimum needs of their proposal. The CDC replaces all encrypted identifiers in custom data sets with randomly generated record identifiers that cannot be linked back to the CDC database or to any of the identifying information maintained in the grantee databases.

Privacy Impact Assessment Information

A. This submission has been reviewed by CDC's Information Collection Review Office, who determined that the Privacy Act does not apply. Although grantees have access to personally identifiable information in order to deliver services, only de-identified records are transmitted to CDC and the data management and evaluation contractors.

B. The MDE data are secured by technical, physical and administrative safeguards as outlined below.

Technical

- The MDE data reside on a dedicated server that resides 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. No non-project staff is allowed access to the data. All of the contractor's project staff is required to sign a confidentiality agreement before passwords and keys are assigned.
- MDE data that are submitted electronically are encrypted during transmission from the grantees and arrive on a server behind the data collection contractor's firewall. Each grantee has its own directory location so no grantee has access to another grantee's data.
- Once data have been compiled by the contractor and delivered to CDC via courier, all MDE data are maintained for restricted access on CDC's secure LAN server.

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 MDE data 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 data contractor and delivered to CDC, all CCDE datasets are maintained for restricted access on a secure LAN server, which is housed in a secure facility. All CDC staff is 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 data are kept secure. Periodic review and update of the data contractor's security processes is conducted to adjust for needed changes and will be amended as needed to maintain the continued security of the data.
- 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 CCDE data.
- Once the data have been delivered to CDC, data are housed on CDC's secure LAN server and restricted access is controlled by the MDE data manager. .

C. The respondents for the NBCCEDP are NBCCEDP grantees, not individuals. Each grantee is responsible for implementing patient consent forms and procedures applicable within their jurisdiction to inform patients about the intended use of the information collection and any plans for sharing the information.

D. NBCCEDP-funded grantees are required to report patient-level information to CDC semi-annually. Each grantee program is responsible for developing an appropriate consent form from clients before enrolling them in the program to receive screening services. Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

The risk of direct identification of an individual in the MDE is remote because personally identifying information (name, SSN, address) data will not be reported to CDC. However, a unique identifier assigned by the grantee to each client screened will be reported to CDC. While each record constitutes a single screening test cycle, it is necessary to identify multiple screenings provided to the client to track appropriate re-screening over time and to track the number of unique individuals served by the program. The grantees maintain the linkage information between the identification codes and the personal identifiers in their database in order to respond and follow-up on quality assurance data queries from the CDC.

A11. Justification for Sensitive Questions

This data collection includes sensitive information about cancer diagnosis and treatment, which is central to the purposes of the program evaluation and oversight and to ensure timely and adequate clinical follow-up of women screened through the program. In addition, race and ethnicity data are collected per HHS guidelines and for use in epidemiologic analyses.

A12. Estimates of Annualized Burden Hours and Costs

A. The requested screening and follow-up data are already collected and maintained by NBCCEDP grantee programs. Therefore, the additional burden for data reporting is small and only entails the time needed to generate and submit an electronic data file. Grantees report the screening and follow-up data to the CDC on a semi-annual basis. The estimated respondent burden of 536 hours across all 67 grantees for generating and reporting this information is based upon use of the data management system and submission web site developed and maintained by the CDC to perform these exact functions. The CDC also received voluntary consultation from not more than six respondents regarding the estimated burden of reporting these data. The total estimated annualized burden hours are 536.

Table A12A. Number of Respondents and Estimated Burden Hours:

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
NBCCEDP Grantees	67	2	4	536

B. The estimated annualized cost to respondents is based upon the mean hourly wage plus benefits of grantee Data Managers as reported in NBCCEDP cooperative agreement awards. Grantee Data Managers are estimated to earn a mean hourly wage of $25.97 plus a 25 percent allowance of $6.49 for benefits, for an estimated hourly wage plus benefits of $32.46. The estimated annualized cost for each grantee Data Manager to report the MDE data is estimated as $259.68. The total estimated annualized cost to respondents is $17,398.

Table A12B. Estimated Annualized Cost to Respondents:

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Cost
NBCCEDP Grantees	67	2	4	$32.46	$17,398

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

None.

A14. Annualized Cost to the Federal Government

Total operation and maintenance costs include work performed by the data contractor and CDC personnel. The data contractor is funded at an annual cost of $1,187,106 for a five-year total of $5,935,531. Data contractor MDE-related activities, included in the table below, are estimated at $771,619 annually for 4.5 full time employees. MDE activities include data processing, data analysis and data systems maintenance. Data contractor NBCCEDP program administration activities are estimated at $415,487 annually for 2.4 full time employees. Data contractor NBCCEDP program administration activities include administration, technical support, training, and other direct costs. CDC personnel costs are estimated at $220,897 annually for 1.3 full time data managers and 0.5 program analyst. The following table summarizes the estimated Federal Government cost distribution.

Estimated Annualized Federal Government Cost Distribution:

	Annualized Cost
CDC Personnel Subtotal	$220,897
Data Contractor Subtotal	$771,619
Total	$992,516

A15. Explanation for Program Changes or Adjustments

The total estimated annualized burden hours is slightly reduced due to a decrease of one respondent grantee program that no longer participates in the NBCCEDP. There is no change to the average burden per response since the previous extension request was approved by OMB in November 2009.

A16. Plans for Tabulation and Publication and Project Time Schedule

The CDC requests a 3-year extension for this recurring data collection. The screening and tracking data sets are reported by grantees in April and October of each year. The data files include cumulative data from the beginning date of each grantee's funded screening services up to the current reporting date. The data are formatted and analyzed within 40 working days of reporting, and analysis reports are developed within 60 working days of the reporting date. The following table summarizes the time schedule for data reporting, analysis and publication.

Time Schedule for Data Reporting, Analysis and Publication:

Tasks	Schedule
Screening and tracking data reported	April 15 and October 15 of each year
Raw data reviewed	30 working days after each data submission
Data analysis file created	40 working days after each data submission
Standardized surveillance reports generated	60 working days after each data submission
Primary Statistical Reports	Produced semi-annually for publication
Planned Publications	Produced every 2-3 years for publication
Special Research Projects	Produced periodically for publication

The CDC uses the screening and tracking data reported by grantees to produce three categories of publications: Primary Statistical Reports, Planned Publications, and Special Research Projects.

The Primary Statistical Reports are standardized, semi-annual reports that include basic statistics and outcome variables by race and age. These are formal reports for use by CDC staff. In addition, the program maintains a web-based report on the CDC public website to report grantee-specific and national aggregate program performance to the public.

Planned Publications are formal reports that include multi-variate analyses of the minimum data set and an examination of test characteristics. These reports are reserved for inclusion in publications such as Morbidity and Mortality Weekly Report (MMWR) and presentations at conferences. These publications will also be posted to the CDC web site and included in peer review journals. The CDC expects these publications to be produced every 2-3 years. Significant publications include the 2003-2010 National Report scheduled for publication in 2012 as a supplement to the 1991–2002 National Report, summarizing the first 12 years of the National Breast and Cervical Cancer Early Detection Program. This report provides information on the program's framework, history, and future direction in addition to data on breast and cervical cancer screening outcomes for women served through the program. A monograph is also scheduled for 2012 publication in *CANCER* providing a 20 year retrospective of NBCCEDP services and impact.

Special Research Projects will be reports on topics of interest to CDC researchers that are for publication in peer reviewed journals. The CDC expects these projects to be developed periodically. A 2011 publication led by a CDC health economist examined the effectiveness of breast cancer screening in the NBCCEDP in reducing mortality among medically uninsured and underinsured low-income women: *Estimated Effects of the National Breast and Cervical Cancer Early Detection Program on Breast Cancer Mortality, Hoerger T et al.* A similar study of effectiveness of cervical cancer screening is in progress. Two publications led by CDC scientists examine the timeliness of service provision in the NBCCEDP: Published in 2009, *Time to Breast Cancer Diagnosis and Treatment in the National Breast and Cervical Cancer Early Detection Program, Richardson L, et al,* and in 2012, *Timeliness of Cervical Cancer Diagnosis and Initiation of Treatment in the National Breast and Cervical Cancer Early Detection Program, 1996-2009, Benard V, et al.*

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

There is no request for an exemption from displaying the expiration date for OMB approval.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

These data are collected in a manner consistent with the certification statement. No exceptions are requested.