

Change Request
OMB No. 0920-0571, exp. 1/31/2010

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

Supporting Statement Part A and Part B

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LIST OF ATTACHMENTS

- Attachment 1: Public Law 101-354, The Breast and Cervical Cancer Mortality Prevention Act of 1990
- Attachment 2: Section 301 of the Public Health Service Act [42 U.S.C. 241]
- Attachment 3: MDE Data Items and Definitions Required for Reporting
- Attachment 4: Proposed Changes to the Currently-Approved MDE Data Set
- Attachment 5: Discontinued STAR Data Items and Definitions Required for Reporting
- Attachment 6: Announcement of the Discontinuation of STAR

A. JUSTIFICATION

A1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) is requesting approval of a change to the Minimum Data Elements (MDEs) and System for Technical Assistance Reporting (STAR) for the National Breast and Cervical Cancer Early Detection Program (NBCCEDP); OMB Number 0920-0571, Expiration date: 01/31/2010. The proposed change is to discontinue collection of infrastructure information through STAR and modify the content of the MDE data collection. The title of the information collection will also be modified to reflect the change.

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 1; also cited as 42 U.S.C. § 300k). This legislation authorized the 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 Act also authorizes the CDC to ensure that NBCCEDP grantees effectively implement and maintain the program management components for which they are funded such as the collection and maintenance of screening and follow-up data for women served; and the completeness, quality and timeliness of the data. The NBCCEDP currently funds 68 grantees including all 50 states, 5 U.S Territories, 12 American Indian/Alaska Native Organizations and the District of Columbia, through cooperative agreements awarded under Program Announcement DP07-703, National Cancer Prevention and Control Program.

The currently approved information collection is based on a program requirement that NBCCEDP-funded grantees must report clinical data on breast and cervical cancer screening services to the CDC in a minimum data elements format semiannually; and must also report program infrastructure data to the CDC via STAR annually. The CDC requires that grantees report these data for analysis to ensure an effective method of evaluating the grantees' performance, and to facilitate the continuing surveillance of a national screening and tracking program for the early detection of breast and cervical cancer. The data collection authority for this study is Section 301 of the Public Health Service Act [42 U.S.C. 241] (Attachment 2).

However, over the last few years, the CDC has relaxed the STAR program infrastructure reporting requirements and has now decided

to discontinue the reporting of infrastructure data by grantees. The infrastructure data were underutilized by the CDC and did not effectively serve the program monitoring and evaluation purposes for which they were intended. In addition, many of the infrastructure data elements were reported to the CDC as free text information and were difficult to standardize for analyses. Attachment 5 details the infrastructure data elements for which reporting by the grantees to the CDC have been discontinued. The discontinuation of infrastructure data reporting will greatly reduce the overall reporting burden for the application. The CDC has no plan to amend the application in the future to collect a revised set of infrastructure data from NBCCEDP grantees. The CDC informed the NBCCEDP grantees of its decision to waive the infrastructure data reporting requirement for the final two years of the previous program announcement in correspondence dated 06/30/2006 (Attachment 6). Also, STAR reporting was not included as a requirement in the current 5-year program announcement, effective fiscal year 2007.

The reporting of screening and follow-up clinical data by grantees to the CDC, however, remains critical for grantee oversight and program administration. It is also necessary for the CDC to continually reevaluate the effectiveness of the MDE data requirements to understand and describe the NBCCEDP, to reflect policy changes, and to capture meaningful data as clinical practice evolves. The MDE data set was last revised in October 2002. Therefore, the CDC is proposing a revised MDE data set in this application that the NBCCEDP grantees would begin reporting to the CDC, effective 01/01/2009 (Attachment 3).

The specific changes to the MDE data set and the rationale for the changes are outlined in Attachment 4. Several underutilized data elements were removed from the MDE data set. While the grantees should retain these data elements in their data systems if they are useful at the local level, these specific MDE data elements will no longer be reported to the CDC in the MDE data file. Also, several existing data elements were repositioned in the MDE file format to improve the logical flow of the record.

New data elements were added to the MDE data set to capture information about cervical screening and diagnostic procedures that are now utilized and reimbursed within the program due to evolving clinical standards and practice. These new data elements will allow the CDC to monitor clinical follow-up using these procedures, to capture costs associated with these procedures and to analyze outcomes.

New data elements were added to the MDE data set to better define the clinical indication, or intent, of a patient's visit. These new data elements will allow the CDC to distinguish between records in which patients receive screening services and those records in which patients are referred to the program for diagnostic services. These new elements will make NBCCEDP results and outcomes more comparable to other screening programs, allow the CDC to better interpret high rates of diagnostic follow-up occurring in the program, and add precision to edit checks, quality measures and analyses.

New data elements were added to the MDE data set to improve the consistency with which Assessment Incomplete mammogram results are reported and tracked. These new data elements will also standardize the MDE data set with the Breast Imaging Reporting and Data System (BI-RADS) which is a method of classification used by radiologists to interpret and report the results of imaging procedures used in breast cancer screening and diagnosis. In addition, the new data elements will provide important final imaging outcome data that are not currently reported in the MDE data set, and will enhance the CDC's oversight of clinical follow-up and associated costs.

The National Cancer Prevention and Control Program cooperative agreements require that NBCCEDP grantees routinely link with their State Central Cancer Registry (CCR) to identify missing cancer cases, confirm diagnoses, and to obtain stage and tumor size data about cancers diagnosed within their program. Therefore, the CDC has added new elements to the MDE data set for the reporting of data obtained through linkages with State CCRs. Cancer stage at diagnosis is an important outcome measure for the NBCCEDP, and the current stage data in the MDE data set are not standardized to one data source or classification. It is expected that data obtained from the CCRs will confirm diagnostic outcomes and provide standardized cancer stage data for CDC evaluation and research; and will improve the quality of data in both the MDE data set and the State CCRs.

A2. Purpose and Use of Information Collection

The NBCCEDP is authorized to ensure that breast and cervical cancer screening services are available for under-served, low income, and under-insured women through grantee programs. In support of that mission, the CDC aggregates data about grantee screening and tracking performance semiannually. Since receiving OMB approval in September 2002, the CDC has used the MDE data for grantee surveillance and program administration purposes. The

data collection methodology has been successful with no problems reported by the NBCCEDP grantees. As stated in Section A1 of the supporting statement, the CDC has decided to discontinue the collection of infrastructure data from grantees.

A data contractor, Information Management Services, Inc. (IMS), is retained to assist with data management and analysis of the semiannual MDE submissions, which includes generating standardized reports for the grantees and the CDC. These reports support regular data reviews for completeness, timeliness and quality as part of grantee monitoring and evaluation. The CDC provides regular feedback to grantees based upon a review of their data submissions and tailors technical assistance as necessary. The MDE data set also allows for analyses by Division of Cancer Prevention and Control epidemiologists for research purposes.

The CDC has developed a set of program performance indicators that are used to assess the grantees. Program and Fiscal Management indicators reflect the ability of grantees to plan and implement program management criteria. Service Delivery indicators reflect the ability of grantees to provide complete and timely screening and follow-up services to women in priority populations. Both sets of program performance indicators are produced using the MDE data reported by the NBCCEDP grantees.

The CDC also monitors the percentage of records with one or more errors in grantee data submissions. Data completeness, accuracy and management are critical to the proper tracking and follow-up of women served by the NBCCEDP grantees. In addition, the Division of Cancer Prevention and Control has developed specific measures for the Government Performance Results Act (GPRA) and the Program Assessment Rating Tool (PART). The DCPC is required by the Act to develop and assess performance measures for the NBCCEDP and to report them to the Office of Management and Budget (OMB). The continuation of the currently approved data collection with the proposed changes outlined in Attachment 4 is imperative for future monitoring and evaluation of the NBCCEDP. The data, whether MDE, GPRA and PART measures, or program performance indicators, are also used for reporting to CDC officials, Congress, and other national stakeholders.

A3. Use of Improved Information Technology and Burden Reduction

As stated in the currently approved information collection, the CDC developed and maintains a data management software package designed to facilitate the data entry, editing, quality

assurance, and reporting of the MDE data set. The system is a Windows-based application currently used by approximately one-half of the NBCCEDP grantees. The CDC provides any technical assistance required by grantees that use the data management system. Grantees report the data set as an electronic, fixed-length text file. The CDC has developed and supports a secure, password-protected submission Web page where grantees post their text files once prepared. This submission Web page simplifies the process of reporting screening and follow-up data for grantees, and organizes the receipt of grantee text files by the CDC; but it does not reduce the grantees' burden of reporting screening and follow-up data. NBCCEDP grantees previously reported infrastructure data using a secure, Web-based system developed and maintained by the CDC. For the reasons previously stated in Section A1, the CDC has discontinued the reporting of infrastructure data by grantees.

A4. Efforts to Identify Duplication and Use of Similar Information

As stated in the currently approved information collection, 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 who are specifically enrolled and screened in the NBCCEDP. The consistent reporting of these data to the CDC remains critical and promotes assurances that the grantees provide appropriate and timely clinical services to women who utilize the NBCCEDP, a requirement of the law establishing the program. The MDE data set is unique in providing a national data set that assists the CDC in the ongoing development and management of an early detection program designed to provide under-served women with access to breast and cervical cancer screening services. For the reasons previously stated in Section A1, the CDC has discontinued the reporting of infrastructure data by grantees.

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

As stated in the currently approved information collection request, the CDC aggregates screening and follow-up data from grantees semiannually. This allows for consistent program evaluation and planning by CDC and facilitates grantee oversight and guidance. The collection of these data less frequently would

compromise the ability of the CDC to perform the above 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. For the reasons previously stated in Section A1, the CDC has discontinued the reporting of infrastructure data by grantees.

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

The enclosed application is a request to change the MDE data reporting requirements. As stated in the currently approved information collection request, these data are collected in a manner that fully complies with the guidelines in 5 CFR 1320.5. No special circumstances are contained within this application.

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

- A. The enclosed application is a request to change the MDE data reporting requirements. Notice was not published in the Federal Register.
- B. The enclosed application is a request to change the MDE data reporting requirements. As stated in the currently approved information collection, the CDC employs several methods of consultation with individuals outside of the agency. These include a formally sanctioned advisory committee, regularly convening working groups and special working groups, semiannual national data conference calls, and an annual conference. The proposed changes to the MDE data collection were developed in collaboration with a workgroup representing the Executive Council of NBCCEDP Program Directors.

A9. Explanation of Any Payment or Gift to Respondents

Not Applicable.

A10. Assurance of Confidentiality Provided to Respondents

The CDC Privacy Act Officer previously reviewed the currently approved application and determined that the Privacy Act does not apply. The new questions added to the MDE data set were reviewed and found to be consistent with the previous ruling.

A11. Justification for Sensitive Questions

Both the currently approved and proposed MDE data sets include sensitive information about cancer diagnosis and treatment, which is central to the purposes of program evaluation and oversight. 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 CDC is discontinuing its request for STAR infrastructure data, for which the total estimated, annualized, respondent burden across all 68 grantees was 1,700 hours. As a result the total estimated burden in hours for the currently approved information collection has been greatly reduced.

The requested MDE screening and follow-up data are already collected and maintained by NBCCEDP grantees. Therefore, the additional burden for reporting these data 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 semiannually.

The estimated respondent burden of 544 hours for all grantees to generate and report the electronic MDE data file with screening and follow-up data is based upon use of the data management system developed and maintained by the CDC to perform these exact functions. While the data management system will be updated to accommodate the proposed reporting changes, the process of generating the electronic data file will not change. Prior to submitting the enclosed change application, the CDC also received voluntary consultation from not more than six respondents regarding the impact that the changes to the MDE data reporting requirements are estimated to have upon the average burden per response. Based upon this consultation it is estimated that the changes to the MDE data set, which include the removal of underused data elements, will neither increase nor decrease the average burden per response, currently estimated as four hours. Table A12A summarizes the number of respondents and estimated burden hours for MDEs.

Table A12A. Estimated Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Screening and Follow-up (MDE)	68	2	4	544

B. The CDC is discontinuing its request for STAR infrastructure data from grantees. As a result the estimated, total annualized cost to respondents for the currently approved information collection is greatly reduced. The estimated annualized cost to respondents for the hour burden of reporting screening and follow-up information 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 \$25.21 plus a 25% allowance of \$6.31 for benefits, for an estimated hourly wage plus benefits of \$31.52. The estimated annualized cost of 8 hours of effort for each Data Manager to report MDE screening and follow-up data is \$252.16. The total estimated annualized cost for all respondents is \$17,147, as summarized in Table A12B.

Table A12B. Estimated Annualized Cost to Respondents:

Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage	Total Cost
Screening and Follow-up (MDE)	68	2	4	\$31.52	\$17,147

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, Information Management Services, Inc. (IMS)

and CDC personnel. For NBCCEDP, IMS is funded at an annual cost of \$1,372,335 for a five-year total of \$6,861,673. IMS' MDE related activities, included in the table below, are estimated at \$850,848 annually for 6.5 full-time employees. MDE related activities include data processing, data analysis and data systems maintenance. IMS' NBCCEDP program administration activities are estimated at \$521,487 annually for 4.0 full-time employees. IMS NBCCEDP program administration activities include administration, technical support, training, and other direct costs. CDC personnel costs are estimated at \$222,592 annually for 1.8 full-time data managers and 0.2 public health advisor. The following table summarizes the estimated Federal Government cost distribution.

Estimated Annualized Federal Government Cost Distribution:

	Annualized Cost
CDC Personnel	\$222,592
Data Contractor	\$850,848
Total	\$1,073,440

A15. Explanation for Program Changes or Adjustments

The total annualized burden decreased from 2,244 hours to 544 hours due to the removal of the STAR infrastructure data reporting requirements. The total annualized burden for reporting screening and follow-up (MDE) data for 68 grantees is estimated to neither increase nor decrease despite the proposed changes to the reporting requirements, as stated in Section A12.

A16. Plans for Tabulation and Publication and Project Time Schedule

The enclosed application is a request to change the MDE data reporting requirements. There are no changes relating to the time schedule for data reporting, analysis and publication that is detailed in the currently approved information collection.

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

The enclosed application is a request to change the MDE data reporting requirements. As stated in the currently approved information collection, there is no request for an exemption from displaying the expiration date for OMB approval.

A18. Exceptions to Certification for Paperwork Reduction Act

Submissions

The enclosed application is a request to change the MDE data reporting requirements. As stated in the currently approved information collection, these data are collected in a manner consistent with the certification statement identified in Item 19 "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I. No exceptions are requested.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B1. Respondent Universe and Sampling Methods

The respondents are the 68 NBCCEDP grantees that currently receive CDC funds to develop and maintain comprehensive breast and cervical cancer screening and tracking programs. Sampling methods are not employed in the data collection, as previously stated in the currently approved information collection.

B2. Procedures for the Collection of Information

NBCCEDP grantees are funded by the CDC to aggregate screening and follow-up data for the breast and cervical services they provide. The collection and processing procedures for these data have not changed since approval of the current information collection. As stated in the current application, the CDC has discontinued its request for infrastructure data from grantees.

B3. Methods to Maximize Response Rates and Deal with Non-response

As stated in the currently approved information collection, the CDC requires that all NBCCEDP grantees report data as a stipulation of the Program Announcement and the cooperative agreement notice of grant award. The schedule for MDE data reporting remains consistent each year and is not expected to change.

Grantees collect and report screening and follow-up data by the continued use of a data management system developed and maintained by the CDC, or by alternate grantee-specific data management systems. In either method, the exported MDE data are transmitted to CDC electronically as an ASCII text file, which is a common format for data interchange. The data definitions for version 6.0 of the MDE data set are provided in Attachment 3. An updated Data User's Manual is being prepared for release with the

revised MDE data set that will provide comprehensive instructions for each data item to be reported. The manual will be accessible to the NBCCEDP grantees via a secure, password-protected Web site.

B4. Tests of Procedures or Methods to be Undertaken

As stated in the currently approved information collection, the data management reporting system and the submission Web page developed and maintained by the CDC have been internally tested by NBCCEDP staff and the data contractor, and have also been voluntarily tested by not more than six grantees. In addition, the processes of developing the master and analysis files, editing and formatting the reported data, and generating the standardized reports have been thoroughly tested by the CDC and the data contractor. It is expected that only minor changes will be required to the analysis files, formatting procedures and the standardized reports to address the proposed changes to the MDE data set.

B5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The data collection was designed by the Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-52, Atlanta, GA 30341-3717.

The CDC Project Officer for the data management contract is Janet Royalty, MS (770-488-3085), Data Manager at the Program Services Branch, Division of Cancer Prevention and Control, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mail Stop K-57, Atlanta, GA 30341-3717.

Data analysis is performed by Information Management Services, Inc. under the direction of Mr. David Roney, Corporate Officer (301-680-9770), 12501 Prosperity Drive, Suite 200, Silver Spring, MD 20904. NBCCEDP data collection and data quality standards are formulated and recommended by the Program Services Branch of the Division of Cancer Prevention and Control and the Division's NBCCEDP data working group.