Colorectal Cancer Screening Program

OMB No. 0920-0745
Revision Request

Supporting Statement Part A

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Abstract

In 2005, the Centers for Disease Control and Prevention (CDC) established a three-year demonstration program, subsequently extended to four years, to screen low-income individuals 50 years of age and older who have no health insurance or inadequate health insurance for colorectal cancer (CRC) (OMB No. 0920-0745, exp. 7/31/2010). The five demonstration sites report information to CDC including de-identified, patient-level demographic, screening, diagnostic, treatment, outcome and cost reimbursement data. CDC is increasing the number of funded sites to 26. In this Revision, CDC requests OMB approval to continue collecting information from funded sites for three years, with changes. The term "Demonstration" will be deleted from the title of the information collection; the clinical data component will be simplified; and an activity-based economic data collection will replace the cost reimbursement data collection. The information collected from funded sites will be used to monitor and evaluate the CRC screening program. The overall estimated burden will increase due to the increase in the number of funded CRC screening sites.

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Division of Cancer Prevention and Control (DCPC) requests approval from the Office of Management and Budget (OMB) to revise the economic and clinical data collection used to evaluate the colorectal cancer (CRC) screening program during its demonstration phase (OMB No. 0920-0745, exp. 7/31/2010).

Colorectal cancer (CRC) is the second leading cause of cancer-related deaths in the United States following lung cancer (2). Ninety-one percent of new cases and 94% of deaths from CRC occur in persons over 50 years of age (2). Although strong scientific evidence has shown that regular screening can prevent colorectal cancer, and is effective in reducing CRC incidence and mortality (3-9), screening rates remain low (1, 10). Findings from the National Health Interview Survey (NHIS) (OMB No. 0920-0214, exp. 1/31/2013), administered by CDC, indicate that in

2000, barriers to screening include limited or lack of insurance coverage for CRC, lack of a regular health care provider, lack of organized systems where screening and follow-up may be conducted, and lack of doctor's visits within the preceding year (10). In the face of these low rates of use of colorectal cancer screening tests, CDC and other federal and non-federal organizations are actively working to increase screening for colorectal cancer.

Regular CRC screening is now recommended for average-risk persons, using one or a combination of the following tests: fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, colonoscopy, and/or double-contrast barium enema (DCBE) (11-13). These tests vary in their costs, availability, and associated risks, and current evidence does not clearly demonstrate which of these tests is most effective. However, as of 2004, only 57% of the U.S. population had been screened for colorectal cancer as recommended (1), and most of the colorectal cancer screening performed in the US currently is opportunistic, with limited screening occurring in self-contained screening programs across the country. Before considering a larger national effort, CDC established a demonstration program in 2005 and funded five grantee programs for four years to explore the feasibility of establishing a colorectal cancer screening program for the underserved U.S. population and to better understand which settings and program models may be most viable and cost-effective in reaching a population of low-income persons 50 and older who are inadequately insured for colorectal cancer screening services. The programs that applied to be part of the CRC screening program were given the choice of which screening test(s) to offer from the above list of recommended tests. CDC has collected information from the initial sites to monitor and evaluate the program.

In 2009, with the conclusion of the demonstration program and increased Congressional funding to continue support of a colorectal cancer screening program for the underserved, CDC established the Colorectal Cancer Control Program (CRCCP). The CRCCP funds twenty-six grantees to provide direct services to screen individuals age 50 and older with inadequate or no health insurance and to promote screening of all individuals age 50 and older within the grantee's jurisdiction. The goals of the expanded program are to increase population-based screening and to reduce health disparities in colorectal cancer screening, incidence and mortality.

This program addresses the "Healthy People 2010" Cancer focus area, specifically to increase the proportion of adults who receive a colorectal screening examination.

The purpose of this Revision request is to expand the data collection from 5 to 26 grantees, delete the term “Demonstration” from the title of the information collection, simplify the clinical data component of the collection, and revise the economic data collection component. For the clinical component, two of three reporting forms are discontinued and the number of data items significantly reduced. Revised cost data are proposed, using an instrument that is currently in use with two other cancer programs administered within the Division, to capture costs by programmatic activity-level versus patient-level reimbursement. These revisions reflect the logical evolution from a demonstration program. Economic and individual patient-level screening, diagnostic and treatment data will continue to be used to monitor and evaluate the CRC screening program and have been critical in guiding its expansion.

In order to monitor the quality, effectiveness, appropriateness, cost, and cost-effectiveness of the CRC screening and diagnostic services delivered by grantee programs, and to compare any differences among the unique program sites, CDC will receive standardized, individual, patient-level data related to CRC screening, diagnostic follow-up, and treatment services in these programs, that the grantees will collect and submit to CDC. The data will be entered into the grantee's electronic database, and formatted so that it can be exported to CDC on a semi-annual basis (March 15, and September 15). The first data submission is planned for the next semi-annual period following OMB approval. The data collected from each grantee will be used to provide immediate feedback to the program for quality improvement and to inform current and future organized CRC screening efforts.

Additionally, program-level activity-based cost information will be collected from all sites using a Cost Assessment Tool (CAT) currently in use for two other CDC-funded cancer programs: “Economic Analysis of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP),” (OMB No. 0920-0776, exp. 3/31/2011), and “Economic Analysis of the National Program of Cancer Registries (NPCR)” (OMB No. 0920-0812, exp. 6/30/2012). The proposed collection of comprehensive economic variables will provide the CDC and grantees with the

information necessary to assess the cost and cost-effectiveness of program operations. Performing an assessment of the resources expended on the entire program in relation to the value created will provide critical information for improving program efficiency within the various components of the program and potentially identifying economies of scale. The program-level cost information will be collected annually through a web-based application.

This program is authorized by Section 301 of the PHS Act (42 U.S.C. 241). A copy of the legislation is included as **Attachment 1**.

Privacy Impact Assessment

The colorectal cancer screening program 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

CRCCP-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 and administrative performance data collected by grantees is reported to CDC to describe the services provided through the program and associated costs. The clinical and cost data collections are supported through different procedures and will be described separately.

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 information collected on cancer cases, and the linkages are used by CRCCP 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 CRCCP, 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 CCDE 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 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 locked 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 CRCCP 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 2.5 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 (CCDEs). Information in Identifiable Form (IIF) is collected. All screening records include date of birth and medical information on colorectal cancer screening and diagnostic tests and results. If cancer is detected, IIF is collected on the date and characteristics (histology, behavior, stage) of the cancer diagnosed and when the client started treatment.

Related to the cost data collection, grantees maintain fiscal data to manage program resources. A subset of data on program resources and expenditures will be reported annually to CDC electronically using a web-based Cost Assessment Tool (CAT) system. The CAT will be based on the tool previously pilot tested with five grantee programs who participated in the demonstration program. All grantees will receive training on use of the web-based CAT. Automated data checks will be incorporated into the tool and this will allow the grantees to review and check data prior to transmission. The CAT will only be accessible to program staff who are assigned a userid and password to access the site.

The following cost data will be collected from each grantee (see Attachments 5a and 5b for specific data items):

- Funding received and sources
- In-kind contributions
- Labor activities and cost
- Consultant cost
- Cost of Screening and diagnostic tests
- Administrative cost
- Total number of individuals screened/insured by the program

Identification of Website(s) and Website Content Directed at Children Under 13 Years of Age

Clinical and cost data compiled at the grantee level are transmitted to the data management and cost evaluation contractors via a password-protected secure website 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.

A.2 Purpose and Use of Information Collection

These clinical and cost data will be used by CDC for the following:

- to assess the appropriate use of colorectal cancer screening and diagnostic tests, specifically under appropriate conditions, in the appropriate sequence, and within the appropriate time intervals,
- to assess grantee's ability to ensure timely follow-up diagnostic tests and treatment when required,
- to document complication rates associated with screening tests to compare outcomes across different screening programs and tests,
- to estimate costs and cost effectiveness associated with the different program activities, designs and selected screening tests, and where possible given the different program activities and designs, and

- to compare outcomes across the different grantee programs and tests.

Measuring the quality of the delivery of these services is critically important since data published in the peer-reviewed literature have shown that colorectal cancer screening services are not consistently delivered appropriately (15, 16). These data will be used for grantee program monitoring and evaluation including immediate quality improvement, to make an evaluation of the overall program and an assessment of the feasibility of a systematic approach to increasing population-based CRC screening in this priority population, and to describe successes and barriers to establishing CRC screening programs in a community setting. The information collection will also inform any future expansion to organized CRC screening efforts.

If these data are not collected and monitored, CDC would be unable to appropriately monitor and evaluate program implementation, effectiveness, and efficiencies including program quality, screening outcomes, and costs. In addition, CDC would be unable to achieve the overall aim of assessing the feasibility of a systematic approach increasing population-based CRC screening in this priority population. Based on what is learned from the collection and analysis of these data, CDC may recommend continued expansion to a larger national effort. CDC has been using a similar data collection and evaluation strategy as part of the administration of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (OMB No. 0920-0571, "Minimum Data Elements (MDEs) for the NBCCEDP," and OMB No. 0920-0776, "Economic Analysis of the NBCCEDP"). These data have been critical in monitoring program quality and effectiveness and responding to inquiries regarding the use of federal funds that support the NBCCEDP. The data we propose to collect for this colorectal cancer screening program will be used in much the same way.

Privacy Impact Assessment Information

The clinical data will be used by CDC to monitor and evaluate the CRCCP, 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. In the event that program expansion creates the potential for broader use of the data, CDC will establish a data sharing agreement that will include the following: Review and approval of all data sharing requests by a multidisciplinary CRCCP evaluation team at CDC; require CDC collaboration and written approval prior to presentation or publication of analyses, and well-defined restrictions for use and presentation of data.

The current activity-based cost data collection will allow CDC to perform an in-depth evaluation of the CRCCP. The economic evaluation will be performed to address key questions that will guide the future implementation of CRC screening programs. The following questions will be addressed:

1. How much funding is required annually by each program? What funding sources are used by each program (i.e., CDC, state funds, in-kind funds)? What is the level of in-kind contributions received by each program? What are the primary sources of in-kind contributions?

2. What are the start-up costs for each program (i.e., costs before key patient directed program activities including recruitment, direct service delivery and patient support are initiated)?
3. What is the distribution of costs among the key program components (e.g., recruitment, service delivery, patient support) for each program?
4. What is the average and incremental non-clinical cost per person screened for each program? Does average and incremental cost change across the years for each program? Are the programs cost-effective? What is the cost per cancer detected (or cancer prevented if are polyps removed)?
5. What is the average clinical cost (screening and diagnostic testing) for each program (includes only individuals who receive direct service delivery)? How do these costs differ by type of screening test selected?
6. What is the average cost per number of screens performed due to specific recruitment activities? What type of recruitment efforts are the most cost-effective (assessed separately for the insured and uninsured population if possible)?
7. What is the average cost of enrolling individuals in insurance programs (Medicaid)?

The collection of activity-based cost information for economic analysis is essential for ensuring that CDC meets its fiscal responsibility for appropriate use of funds as appropriated by Congress; assessing how well the CRCCP is performing nationally and in individual grantee programs; and informing future program planning and policy decisions. The data collected will be analyzed and used by CDC and individual programs to improve program operations to make more efficient use of funding received. CDC will publish relevant findings in the peer-reviewed literature to assist other cancer screening programs to design efficient programs. No IIF is being collected in the CAT.

A.3 Use of Improved Technology and Burden Reduction

CDC will require grantees to electronically report a standardized set of screening and follow-up data elements, the Colorectal Cancer Clinical Data Elements (CCDE) **(Attachment 3a)**. Grantee programs can choose to collect additional data elements beyond what is included in the CCDEs,

but are only required to submit the specified elements to CDC. The CCDE data elements were selected because they will provide the minimum amount of information necessary to accomplish project evaluation objectives.

Clinical data elements to be collected in the CCDEs will be entered into electronic data systems. The CDC developed and maintains a patient tracking data management system software package for optional use by grantees to manage local program data. The software can be used to capture enrollment of patients into the program, track clinical care and follow-up, and facilitate the extraction of the CCDEs. The system is a Windows-based desktop application developed originally for NBCCEDP grantees, and will be available to all CRC screening program grantees. CDC provides technical support to grantees that use the data management system.
Grantee program may optionally use funds awarded for the program to develop or modify a custom electronic data system. Grantees will report the data set as an electronic, fixed-length text file. The data definitions and record layouts for this file were designed by the Division of Cancer Prevention and Control (DCPC) at CDC in conjunction with the data management contractor and the grantee programs.

The web-based cost collection tool will include several features to specifically reduce burden and collect high-quality data. For example, the tool will include automated data checks so that it can be used by the programs to perform self-directed quality checks on the data as they input the information. In addition, the list of program activities will be provided in drop-down boxes to eliminate the time spent typing in text. The tool will also contain an interactive user's guide that will provide field definitions and instructions for providing the required data. The tool will be easily accessible through the web and all programs will be provided with detailed instructions and training to input the required data. Only the minimum information necessary for the purposes of this project will be collected. Efforts have been made to design the instrument to be brief, easy to use, and understandable. The study investigators have carefully considered the content, appropriateness, and phrasing of the questions. All respondents will be using the same web-based cost collection tool.

A.4 Efforts to Identify Duplication and Use of Similar Information

As this is the only federally funded program that currently exists which offers CRC screening in community settings to this identified population, there are no existing, comparable data sources available for the collection of this information.

The consistent reporting by the grantee programs to CDC of screening, final diagnosis, and treatment initiation data will promote assurances that grantee programs provide appropriate and timely clinical services to persons who utilize the CRC screening program, a critical requirement of the program. These evaluation data will be used to improve patient care by helping to increase the percent of abnormal tests receiving an appropriate follow-up test, the timeliness of the receipt of the appropriate follow-up test, and the timeliness of the initiation of treatment services, as outlined in **Attachment 4abc** (see sample feedback reports). This data collection will be used to monitor and evaluate the program in aggregate and for individual grantees, and to inform the management and potential growth of the program over time.

The National Program of Cancer Registries (NPCR) collects data on all persons diagnosed with cancer (OMB No. 0920-0469, exp. 11/30/2012). However, NPCR data do not include screening and tracking information nor do they allow for assurances that persons receive appropriate and timely care prior to and following final diagnosis. Additionally, they are collected and verified through medical record confirmation many months after a final diagnosis is made. Because it is imperative that CDC monitor the appropriate delivery of diagnostic and treatment services in a timely fashion, the data collected through the NPCR would not be sufficient for evaluating the CRC screening program activities.

A.5 Impact on Small Businesses or Other Small Entities

There will be no impact on small businesses.

A.6 Consequences of Collecting the Information Less Frequently

CDC will receive screening, diagnostic follow-up and treatment data from grantee programs

semi-annually. After collecting these data on a quarterly basis in the early years of the screening program, we propose to reduce collection frequency from quarterly to semi-annually. This will allow CDC to evaluate the overall performance of the CRC screening programs on a routine basis, to make adjustments toward improved effectiveness, and to identify new goals as part of on-going planning efforts. Through semi-annual review of the screening and follow-up data, CDC can identify any problems in a timely fashion. We feel that the collection and evaluation of these data less than twice per year would compromise CDC's ability to appropriately monitor program progress and be able to provide technical assistance as needed.

The cost data will be received annually, since these data will likely have less time-sensitive repercussions.

A.7 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.

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

A Notice of this data collection was published in the Federal Register on February 1, 2010, in Volume 75, No. 20: pp. 5086-5087. A copy of the Notice is included as **Attachment 2a**. One public comment was submitted to CDC and received a courtesy reply (**Attachment 2b**).

The Division of Cancer Prevention and Control (DCPC) has employed several methods of consultation with individuals outside of the agency regarding the proposed data collection. In August 2004, DCPC convened a meeting of domestic and international stakeholders currently engaged in planning or implementing cancer screening programs. Attendees at this meeting were both federal and non-federal, and included clinicians, health planners, and representatives from various health organizations, all experts in CRC screening. The objective of the meeting was to gain stakeholder input on the need for and utility of establishing a colorectal cancer screening demonstration program and the need for key data elements to be collected to track,

monitor and evaluate the demonstration program. There was strong consensus among all meeting attendees that the demonstration program was a critical next step in advancing colorectal cancer screening and that the collection of patient-level data elements would be required to perform a comprehensive evaluation of the demonstration project. A list of these meeting participants is included in **Attachment 6.**

Additionally, once the CCDEs were drafted, CDC consulted with two clinicians, a gastroenterologist who is a leader in CRC screening, and a pathologist from the National Cancer Institute who focuses on liver and GI pathology, about the variables and data definitions included in the CCDEs. Revisions and improvements were made to the CCDEs based on input from these two clinicians. Their names and contact information are also included in **Attachment 6**.

A similar domestic stakeholder meeting was held in September 2008 to inform planning and data collection in the successor CRC screening program. Based on feedback from the national experts, demonstration grantees, and using the data to evaluate early years of the screening program, CDC revised the content of the CCDEs to reduce the burden on grantees and subset the content to include data most relevant for CDC program management and evaluation.

The CDC also maintains an internal CRC Consultation Team that serves as a Policies/Data/Evaluation working group. The group meets weekly to review issues related to the project and make recommendations on data collection and usage. This work group includes CDC physicians, epidemiologists, economists, program staff, senior statisticians, and social scientists.

A.9 Explanation of Any Payment or Gift to Respondents

No payments or gifts will be provided to program participants.

A.10 Assurance of Confidentiality Provided to Respondents

Respondents are clinical care sites and state and local 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, respondents will collect personally identifying information on each patient served by the CRC (e.g., name, address, social security number, age, race/ethnicity) as well as information about the patient's screening history, screening and diagnostic procedures provided, results of those procedures, and if cancer is diagnosed, information about treatment initiation and stage of disease. The respondent will assign a unique, sequential patient identification code to each patient in the CRC database (i.e., patient #1, patient #2, etc.), and the respondent will remove personal identifiers from CRC data prior to its transmission to the data contractor or CDC. The patient-level demographic data provided will include only the unique patient ID code, county of residence, state of residence, race, date of birth, and ethnicity. Respondents will not provide additional, potentially identifying variables or demographic information. These procedures allow CDC to anonymously track each patient served throughout his or her involvement with the CRC screening program, and to conduct the planned evaluations of the CRC screening program.

Each respondent will maintain a secure, encrypted data file linking its assigned CRC ID codes to patient identifiers such as name and SSN. The encryption scheme will not be provided to the contractor, CDC, or any other entity. These provisions allow the respondent, and only the respondent, to re-link its CRC data with patient identifiers. The respondents are thus capable of following up on provider-initiated requests for information about specific patients, and to queries from CDC, as needed. All grantee sites will also maintain physical security measures. Hard copy data will be stored in locked file cabinets. All electronic data files will be password protected and access to the files will be limited to authorized project staff.

Formal reports will be developed for publication both biennially and periodically. These reports will present data in anonymized form only. Program grantees understand and agreed to comply with CDC's administrative requirements for data sharing and release policy as written into the funding agreements with the grantees. The reports will be disseminated to the public through the CDC internet, peer review journals, and publications.

The contractual agreements between CDC and both contractors include non-disclosure terms. This data collection is a program evaluation activity, not research. IRB approval is not required.

Information collection procedures have been reviewed by CDC's Information Systems Security Office.

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 CCDE clinical data are secured by technical, physical and administrative safeguards as outlined below.

   Technical

   - The CCDE 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 are allowed access to the data. All of the contractor's project staff are required to sign a confidentiality agreement before passwords and keys are assigned.
   - CCDE 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 clinical data are maintain 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 CCDE data will be 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 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 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 agreements between CDC and both contractors include 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, access to these datasets will be overseen by the CCDE data manager as appropriate.

C. The respondents for the CRCCP are CRCCP 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. CRCCP-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 CCDE 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.

The cost data collection (CAT) has no IIF.

A.11 Justification for Sensitive Questions

Questions about cancer diagnosis can be considered sensitive, since at least a portion of patients would view a cancer diagnosis as a sensitive issue (relates to health, potential social stigmatization, and insurability). However, the questions about cancer are fundamental to core purposes of the project. The specific goals of this project can not be accomplished without this information. In addition, Race/Ethnicity information, which may be considered sensitive, is collected for purposes of data analysis and in conformance with HHS policy.

Because the project includes both sensitive information and patient-level identifiers (although no direct personal identifiers), the project team has devoted particular attention to the data security, data de-identification procedures and protecting sensitive information.

A.12 Estimates of Annualized Burden Hours and Costs

A. The total estimated annual respondent burden across all 26 grantee sites is 3,010 hours. Data collection for the clinical and cost types of data [patient-level clinical data (CCDEs, see **Attachments 3a and 3b**)), and program-level activity-based costs (CAT, see **Attachments 5a and 5b**)] will continue through each year of the program. The estimated burden to respondents is based on prior years of experience collecting information from the colorectal screening programs and from similar data collection for the NBCCEDP. We estimate 15 minutes to enter each CCDE form, due to the reduced number of clinical data items collected in the revised form. We estimate that each

respondent will report a total of 375 CCDE forms annually (approximately half of the CCDE forms will be reported at each semi-annual transmission). The CAT collection is estimated at 22 hours based on similarities to a similar tool and estimates used in the NBCCEDP. The CAT information will be reported once per year.

Table A.12-A summarizes the number of respondents and estimated annualized burden hours. Estimates are rounded to the nearest hour.

Table A.12-A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Colorectal Cancer Screening Programs	Clinical Data Elements (CCDE)	26	375	15/60	2,438
	Cost Assessment Tool (CAT)	26	1	22	572
				Total	3,010

B. The estimated annualized cost to respondents for reporting clinical and cost data is based primarily on a mean, hourly wage for grantee Data Managers of $50.00 (17). The annualized cost for all twenty-six grantee program sites to report data, as summarized in Table A.12-B, is estimated as $150,475.

Table A.12.B Estimated Annualized Costs to Respondents						
Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Average Hourly Wage (in dollars)	Total Cost (in dollars)
Colorectal Cancer Screening Programs	Clinical Data Elements (CCDE)	26	375	15/60	$50	$121,875
	Cost Assessment Tool (CAT)	26	1	22	$50	$28,600
					Total	$150,475

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

This proposed data collection entails no additional cost to respondents or record keepers, since each grantee site used federal funds awarded for the screening program to collect and manage the data needed to administer the program and report to CDC.

A.14 Annualized Cost to the Federal Government

Total operation and maintenance costs include work performed by the data and economic evaluation contractors. The data management contractor (currently IMS) is funded at an annual cost of $417,195 for data management activities including data processing, analysis, systems development and provision of technical support. The economic evaluation contractor (RTI) is funded at an annual cost of $183,291. CDC personnel costs are estimated at $228,899 annually for 0.2 full time data manager, 0.6 medical officers, 0.6 epidemiologists, 0.2 health economist, and 0.4 public health analysts. The total estimated annualized cost to the Federal government is

$829,385. The following table summarizes the estimated Federal Government cost distribution.

Distribution of Estimated Annualized Cost to the Federal Government:

Cost Category	Annualized Cost
CDC Personnel	$228, 899
Data Mgmt. Contractor	$ 417,195
Evaluation Contractor	$183,291
Total	$829,385

A.15 Explanation for Program Changes or Adjustments

In the previous OMB approval period, the total annualized burden was estimated at 1,270 hours. With this revision, the annual burden estimate will increase, primarily due to expansion of the program which results in an increase in respondents. Other proposed revisions to the data collection, described in A15.A,B,C, minimize the increase. These revisions are based on lessons learned and feedback from grantees and stakeholders during the demonstration phase of the program.

A. Number of data forms. The data collection has been reduced by two clinical forms (Medical Complications and Clinically Ineligible Aggregate Form). The detailed Medical Complications form, which was reported at the time of occurrence, was discontinued and replaced with three data fields on the CCDE record to identify the occurrence and type of complication. The data lag allowed to report information in the semi-annual CCDEs provides the grantee programs time needed to confirm that a complication was associated with the colorectal screening procedure. Additionally, this change consolidates all clinical results in the CCDE record and allows grantees to report the information on a fixed schedule. The more concise data collected on each complication meets CDC's objectives to use the data for program monitoring, planning and evaluation. Additionally, collecting aggregate data on clients clinically ineligible for screening was determined not feasible to collect across all program settings and was discontinued in the demonstration program. The Cost Assessment Tool (CAT) collection

replaces the Reimbursement Data Form for use in the economic evaluation, to assess costs of all programmatic activities versus only reimbursement for clinical services..

B. Reduction in frequency of information collection. Based on results from the demonstration phase of the program, and prior years of experience with the NBCCEDP, we learned it that it would be reasonable to expect that similar data quality can be obtained by using only semi-annual CCDE collections. Therefore redundancy in data collection has been removed by decreasing the frequency. The semi-annual data submission provides additional time for CDC to evaluate and provide feedback to the grantee on the quality of the data and for grantees to investigate and correct any incomplete or discrepant data prior to the next data submission.

C. Reduction in burden per response. The revised CCDE instrument includes a significant reduction in detail and data items collected through the CCDEs, based on the experience of the demonstration program and recommendations by CDC, external experts, and grantees. See **Attachment 3c** for a summary of proposed changes to the CCDE record as compared to data items collected during the demonstration program. The number of data items per record was reduced by over one-half, primarily due to collecting summary rather than detailed data from endoscopic procedures. Through the demonstration program, we learned that the overall diagnostic outcomes reported were adequate to ensure service quality and evaluate the program. As a result, the burden per response has changed to 15 minutes (15/60) per response, regardless of primary test type provided by the grantee program.

D. Increase in number of respondents. An increase from five to twenty-six grantees funded through the current cooperative agreement results in an increase in total burden hours.

A.16 Plans for Tabulation and Publication and Project Time Schedule

Time Schedule

CDC requests a 3-year clearance for this revision and recurring data collection. During the 3-

year project period, patient level clinical data will be reported by grantees on a semi-annual basis. 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.

Table A16A. Time Schedule for Data Reporting, Analysis and Publication:

Publication Plan

CDC plans to use the patient-level data reported by grantees to produce three categories of publications: Primary Statistical Reports, Planned Publications, and Special Research Projects. The Primary Statistical Reports will be standardized, semi-annual reports that include anonymized basic statistics and outcome variables by race and age. These reports will include formal, anonymized reports for use by CDC staff and internet publications posted to the CDC web site for dissemination to the public.

Planned Publications will be formal reports that include multi-variate analyses of the minimum data set and an examination of test characteristics. These anonymized reports will be 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. CDC expects these publications will be produced every 18 months during and immediately following the completion of the demonstration program.

Special Projects may be developed as 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.17 Reason(s) Display of OMB Expiration Date is Inappropriate

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

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are requested.

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