REQUEST FOR OMB REVIEW AND
REINSTATEMENT WITH CHANGES

ESTIMATING THE CAPACITY FOR NATIONAL AND STATE-LEVEL COLORECTAL CANCER SCREENING THROUGH A SURVEY OF ENDOSCOPIC CAPACITY (SECAP II)

Previous Title: "National Survey of Endoscopic Capacity"

OMB No. 0920-0539

SUPPORTING STATEMENT

PART A: JUSTIFICATION

May 2010

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Abstract

The Centers for Disease Control and Prevention (CDC) requests OMB approval to reinstate a previously approved information collection, the National Survey of Endoscopic Capacity (SECAP), which was conducted in 2002-2003 (OMB #0920-0539, exp. 3/31/2003). The reinstatement request includes descriptions of the updated sampling frame for the next national survey in 2010-2011 as well as minor changes to the survey instrument.

CDC also seeks OMB approval to conduct a number of state-specific surveys of endoscopic capacity from 2010-2013. A previous series of state-specific surveys was conducted from 2003-2006 (OMB #0920-0590, exp. 6/30/2006). The data collection instrument for state-specific surveys is similar to the data collection instrument for the national survey.

The current request for reinstatement will allow CDC to obtain updated information on endoscopic capacity at both the national level and in selected states, and presents the national and state-specific surveys in a common framework. To reflect the change in scope to reflect the consolidated data collection effort, we are requesting that the study title be changed to "Estimating the Capacity for National and State-level Colorectal Cancer Screening through a Survey of Endoscopic Capacity (SECAP II). Approval is requested for three years.

A.1. Circumstances Making the Collection of Information Necessary

Background

This Information Collection Request (ICR) is submitted as a reinstatement with changes—to obtain OMB approval for a consolidated data collection effort drawing on experience gained from two previous data collection efforts. The proposed data collection will update the data from the *National Survey of Endoscopic Capacity* (OMB No. 0920-0539, exp. 3/31/2003) and the *State Survey of Endoscopic Capacity* (OMB No. 0920-0590, exp. 6/30/2006). In 2002, CDC conducted the *National Survey of Endoscopic Capacity (SECAP)* to obtain an estimate of the number of colorectal cancer screening and follow-up tests currently being performed, as well as the maximum number of screening and follow-up tests that could be performed in the event of widespread screening. In 2003–2005, CDC conducted the *State Survey of Endoscopic Capacity*, in which similar surveys were administered in 15 selected states to provide estimates of endoscopic capacity at the state and sub-state levels. These capacity estimates provided critical information that helped in the planning of national and state colorectal cancer screening efforts.

In light of recent trends in colorectal cancer screening (e.g., increases in the percentage of public and private insurers that reimburse for screening colonoscopy, increased use of colonoscopy and declining use of flexible sigmoidoscopy, availability of other colorectal cancer screening procedures), there is a need to update estimates of endoscopic capacity to guide continued screening initiatives. To provide updated estimates of endoscopic capacity, CDC is requesting OMB approval for a three-year study to conduct a national survey of endoscopic capacity in 2010, and to conduct additional state-level surveys. The proposed national-level information collection will involve administering a survey to a random sample of facilities, stratified by

region and urban/rural location. The proposed state-level information collection will include a census survey of up to 18 selected states, based on methodology employed with the previously fielded state-based survey. Fourteen of the potential 18 states, tribes, and territories have been selected, and are listed in Attachment K.

The same data collection instrument will be used in both the national and state surveys. The questions for the new national and state data collection instruments are identical, except for the cover pages, which will be state-specific. The new instrument is similar to the instruments used in the previous national and state surveys. Minor changes to the data collection instrument are proposed in response to recommendations by a consultant panel and our experience in implementing the previous national and state SECAP surveys.

Colorectal cancer is the second leading cause of cancer-related deaths in the United States. Removal of precancerous polyps before they transform into cancer can prevent colorectal cancer from developing. Additionally, early asymptomatic cancers found through screening respond better to treatment and are associated with reduced morbidity and reduced costs than more advanced cancers that are detected once they become symptomatic. As a result, colorectal cancer is ideally suited for prevention and early detection through regular screening. Flexible sigmoidoscopy and colonoscopy, two lower gastrointestinal (GI) endoscopic procedures currently recommended as colorectal cancer screening tests, provide direct visualization of the colon, and allow qualified medical professionals to identify and remove polyps as well as to detect early cancers. Both of these tests require specialized training. Flexible sigmoidoscopy provides a view of only the lower half of the colon, but is still used for CRC screening and is associated with reduced mortality from colorectal cancer (Selby, Friedman, Quesenberry, & Weiss, 1992). Colonoscopy, which provides a view of the entire colon, is both a primary screening test and the recommended follow-up procedure for any other positive colorectal cancer screening test.

Since periodic screening is both effective in reducing mortality from colorectal cancer and cost-effective, major medical and public health organizations (US Preventive Services Task Force, American College of Gastroenterology, US Multi-Society Task Force) recommend periodic screening for colorectal cancer and have issued colorectal cancer screening guidelines (U.S. Preventive Services Task Force, October 2008; Levin, et al., 2008) However, despite strong evidence and screening recommendations, current screening rates remain low. Approximately one-half of adults 50 years of age and older have not been screened according to guidelines (Shapiro JA, 2008). Thus efforts to promote widespread screening for colorectal cancer are intensifying nationwide among local, state, and federal health agencies and professional organizations. These efforts have included CDC's long-standing Screen for Life: National Colorectal Cancer Action Campaign, CDC's Colorectal Cancer Screening Demonstration Program, a number of state-level programs, and CDC's new Colorectal Cancer Control Program, which is establishing state and tribal wide programs in 22 US states and 4 tribal organizations.

With national and state screening efforts intensifying, updated capacity estimates are needed for planning and implementation purposes. Recent data suggest a change in colorectal cancer screening test use patterns, including increases in colonoscopy use and declining flexible sigmoidoscopy use, and certainly will affect capacity (Klabunde, Lanier, Nadel, McLeod, Yuan, & Vernon, 2009). Further influencing the colorectal cancer screening landscape is the

availability of newer colorectal cancer screening procedures, such as CT colonography ("virtual" colonoscopy) and stool DNA test, which may either increase or decrease demand on endoscopic tests (Levin, et al., 2008). Even with the potential that health care and health care insurance may be reformed, estimating the capacity for wide-spread screening is still a critical step needed for planning widespread screening.

This study is authorized by Section 301 of the PHS Act (42 U.S.C. 241). A copy of the legislation is included as Attachment A. Data will be collected by a contractor, Battelle Centers for Public Health Research and Evaluation.

Privacy Impact Assessment

The proposed study will involve data collection from facilities that perform lower GI endoscopy to screen for colorectal cancer in adults. Screening telephone calls will be made to receptionists to determine eligibility and to identify the respondent for the mail survey. Surveys will then be mailed to the person identified in the screening call, most likely a nurse manager or physician in charge of endoscopy at the facility.

The respondent to the proposed SECAP II survey is a medical facility, not an individual. Respondents are acting in their capacity as an employee of the medical facility and they are not requested to provide any personal information. The only individually identifiable information collected is the name and contact information of the person to whom the survey will be mailed. This is collected so that Battelle can mail the surveys and follow up with non-respondents. All identifying information will be deleted upon completion of data collection.

Overview of the Data Collection System

Using the National SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent (Attachment E2) or the State SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent (Attachment F2), Battelle survey staff will make a screening telephone call to the facility in order to (1) confirm that the facility is eligible for inclusion in the study and (2) obtain the name and address of the physician or nurse manager who is in charge of endoscopy, or the person who knows the most about the numbers of flexible sigmoidoscopies or colonoscopies being performed at the facility. Following the screening call, the individual identified during the call will be sent the CDC National Survey of Endoscopic Capacity (Attachment E1) or the CDC State Survey of Endoscopic Capacity (Attachment E2) by Federal Express. Respondents will be asked to return completed questionnaires in a postage-paid, return envelope. The national and state SECAP II reminder postcard (Attachment GI) will be sent two weeks after the initial mailing. Using the reminder call script (Attachment G2), Battelle staff will make up to 3 telephone calls to follow-up with non-respondents.

Items of Information to be Collected

The survey instruments for the proposed national SECAP II (Attachment E1) and the state SECAP II surveys (Attachment F1) are similar to the survey instruments used in the previous national and state SECAP surveys. These surveys will obtain information regarding: (1) the

numbers of flexible sigmoidoscopies and colonoscopies currently being performed; (2) the types of providers performing the procedures (including the numbers of procedures performed by non-physician endoscopists); (3) the maximum numbers of flexible sigmoidoscopies and colonoscopies that could be performed with no other investment of resources; (4) factors limiting the ability of the facility to increase the number of flexible sigmoidoscopies and colonoscopies performed; (5) steps that would be taken if the demand for screening flexible sigmoidoscopy and colonoscopy were to exceed their current capacity to perform these procedures; (6) number and type of endoscopes owned by the facility; (7) percentage of procedures that are for screening, surveillance, and diagnosis; (8) percentage of procedures that are incomplete; (9) room time for flexible sigmoidoscopies and colonoscopies; and (10) waiting times for various procedures.

Minor changes to the data collection instrument are proposed in response to recommendations by a consultant panel and our experience in implementing the previous national and state SECAP surveys. Proposed changes to the data collection instruments are summarized in Attachment D.

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

The study does not involve web-based data collection methods, nor are respondents referred to websites.

A.2 Purpose and Use of Information Collection

The proposed project will obtain updated national estimates of current endoscopic capacity by surveying a random sample of facilities in the U.S. that have purchased or leased lower GI endoscopic equipment during the period 2004-2009. In addition, in up to 18 states to be selected by CDC, all facilities that have purchased or leased lower GI endoscopic equipment will be surveyed to estimate each state's capacity to provide screening and follow-up procedures. This study will use the same methodology used in the previous national and state-level studies, and the same—but updated—sampling frame. The objectives of the survey are to provide: (1) current estimates of the number of colorectal cancer screening and follow-up procedures being performed; (2) current estimates of the maximum number of procedures that could be performed in the event of widespread screening; and (3) information regarding the types of facilities and providers that perform the procedures.

Without this research, the CDC and state public health departments have little information regarding the number of colorectal cancer screening and follow-up procedures currently being performed, or that could be performed in response to an increased demand for screening. CDC is working in partnership with states, public health and academic institutions, as well as appropriate private sector organizations, to promote broader use of colorectal screening tests. In the face of these efforts, it is necessary to determine that there are sufficient equipment and trained staff available to meet the potential increased demand for both colorectal cancer screening and follow-up examinations.

With clear evidence that screening is effective in decreasing morbidity and mortality from colorectal cancer, it would be unacceptable if these screening services were not available to

persons for whom screening is appropriate. To the extent that sufficient equipment and/or trained staff are not available for colorectal cancer screening examinations, individuals would face unacceptably long waiting times to obtain an appointment for the procedure. This is a particular concern for rural areas where endoscopic services are in short supply to meet current demand. Even more seriously, if sufficient equipment and trained staff are not available to meet the increased demand for follow-up examinations, patients with cancerous and pre-cancerous polyps could potentially have to wait a long time for a follow-up colonoscopy. Along with causing stress for patients and their families, this long waiting time could negatively impact the outcome of the disease for which the patient is being screened. Therefore, obtaining information regarding the capacity of the current healthcare system to handle a sudden increase in the demand for colorectal cancer screening and follow-up examinations is essential as CDC and its partners continue intensively promoting CRC screening to all eligible individuals.

Data analysis will lead to several scientific reports for use in federal and state planning to increase colorectal cancer screening. These reports will identify potential deficits in the current medical infrastructure and will help guide the development of training initiatives and educational programs for health care providers. The results of the study will also be disseminated to various stakeholders through the publication of manuscripts in a peer-reviewed journal, and through presentations at medical meetings.

The data that were collected by the previous national and state-level SECAP surveys were disseminated widely and provided critical data informing the planning for national and state level colorectal cancer screening. Study results were published in companion articles in *Gastroenterology* (see Attachments C1 and C2), and have been widely presented by invitation at national meetings, including an Institute of Medicine Workshop entitled "Economic Models of Colorectal Cancer Screening in Average-Risk Adults"; the annual National Colorectal Cancer Roundtable meetings in 2003, 2004 and 2005; an invited CRC screening symposium at *Digestive Disease Week*; the annual New York State Department of Health Cancer Services Program; the Society for Gastro Nurses annual meeting; and as part of the Comprehensive Cancer Control Phase III Leadership Institutes. In follow up to the national study, CDC assisted 15 states from 2003-2005 in performing state-specific CRC screening capacity assessments, using both the SECAP survey and state-specific forecasting models. These assessments have shown that state-level capacity varies tremendously, with some states more able to implement widespread screening using endoscopic tests than others. The assessments were used by many states to design their own state-funded colorectal cancer screening programs, or to prepare to respond to announcements for federally funded programs.

Because the colorectal cancer screening landscape has evolved substantially since both the national and original state-level surveys were conducted, there is a timely need to update these assessments. Test use patterns have changed, and the number of local, state and federal screening programs has dramatically increased. CDC too has expanded its screening efforts. Based in part on the successes of CDC's Colorectal Cancer Screening Demonstration Program (OMB #0920-0745, exp. 7/31/2010) and on the utility of the planning data for CRC screening, CDC received a substantial increase of $25 million in 2009 to expand its screening efforts, which are now active in 22 US states and 4 tribal organizations. By providing current estimates of endoscopic capacity, the proposed state SECAP II surveys will allow the CDC to assist the states, tribes, and

territories that have received CDC funding to establish CRC screening programs to make real-time adjustments in on-going programs—as well as to assist those states, tribes, and territories that are planning to establish CRC screening efforts, in measuring their capacity to do so.

Privacy Impact Assessment Information

The SECAP II study will involve data collection from facilities that perform lower GI endoscopy to screen for colorectal cancer in adults. Screening telephone calls will be made to receptionists at approximately 4,500 facilities to determine eligibility and to identify the most appropriate survey respondent for the SECAP II survey. The SECAP II survey will then be sent to the person identified in the screening call. The survey data will be used to provide: (1) current estimates of the number of colorectal cancer screening and follow-up procedures being performed; (2) current estimates of the maximum number of procedures that could be performed in the event of widespread screening; and (3) information regarding the types of facilities and providers that perform the procedures.

The respondent to the SECAP II survey is a medical facility, not an individual. Respondents are acting in their capacity as an employee of the medical facility and they are not requested to provide any personal information. The only individually identifiable information collected is the name and contact information of the person to whom the survey will be mailed. This is collected so that Battelle can mail the surveys and follow up with non-respondents. All identifying information will be deleted upon completion of data collection.

A.3. Use of Information Technology and Burden Reduction

As per the original SECAP survey, data collection will involve administering the SECAP II survey to health care facilities that are known to own flexible endoscopic equipment, based on information provided by the endoscopic manufacturers. A screening telephone call will be made to confirm that the facility is eligible for inclusion in the study and to obtain the name and address of the individual who is most knowledgeable about the use of the endoscopic equipment. The SECAP II survey was designed to minimize respondent burden. Every effort has been made to collect only that information which is necessary to achieve the objectives of the proposed study.

Prior to administering the SECAP II survey, we will make a screening call to each facility that was selected for the national and state SECAP II surveys. The purpose of this call is two-fold. First, the call will identify facilities that do not perform lower GI endoscopic procedures for colorectal cancer screening in adults, so that we do not mail surveys to ineligible facilities. Second, the call will be used to identify the best person to receive the survey, so that we will be able to personally address cover letters to the respondents. We will program the screening telephone call as a computer assisted telephone interview (CATI). Programming the screening call as a CATI survey will allow the interviewer to directly input the information provided during the call (e.g., whether or not the facility is eligible for the survey, reason for ineligibility, and contact information for the survey respondent). The CATI programming will also help the telephone interviewer to quickly identify the appropriate wording to use when calling facilities

that are surveyed as part of the national survey versus those that are surveyed in the various state surveys.

In designing the study, consideration was given to providing survey respondents with the option of completing the survey over the Internet. There are several advantages to providing respondents with the option of electronic submission, including ease of response for the survey respondent, which might increase the response rate, and ease of data entry for the staff persons responsible for data entry. There are, however, disadvantages to submitting the surveys electronically. Unlike a paper survey, for example, respondents would not be able to write clarifying comments in the margins of the survey, which can often be quite useful in understanding responses to survey questions. Furthermore, in studies that have provided the option of electronic submission (such as the NCI Survey of Colorectal Cancer Screening Practices in Health Care Organizations, OMB #0925-0468, exp. 8/31/2002), very few respondents chose to submit the survey electronically. Lastly, a high response rate was achieved in CDC's previous national and state SECAP surveys, which were administered only as mail surveys. For the reasons listed above, it was felt that the advantages of administering the survey electronically did not outweigh the disadvantages, and it was decided to administer the SECAP II surveys solely as a mail survey.

A computerized tracking database will be used to monitor data collection activities. The tracking database will store all background data known about each facility (including the name and contact information for the person to whom the survey is to be mailed). In addition, the database will contain the dates of screening and follow-up telephone calls, the dates that questionnaires and other survey materials are mailed, and the dates that completed questionnaires (or refusals) are received. Mailing labels and personalized letters will be generated from this system. The tracking database will be interfaced with the CATI software, so that interviewers are provided information about facilities to call, and information obtained by the interviewers will be stored in the tracking database. This will allow for the results of screening telephone calls to automatically provide data to generate a cover letter and survey mailing. Results of the reminder telephone calls will also automatically trigger the mailing of a second survey (if requested), and if appropriate, schedule another reminder call in 2 weeks. The survey tracking database will record the mailing and receipt of surveys. If a survey is returned, then the scheduled reminder call will be cancelled automatically. The tracking database will also be used to generate weekly reports summarizing the status of the data collection activity throughout the data collection period. This system will reduce respondent burden by ensuring that respondents are contacted at appropriate times and are not sent mailings or telephoned if a completed survey (or refusal) has been received.

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

CDC investigators have conducted a thorough review of existing databases, as well as the published literature, and consulted with representatives from other federal government agencies (e.g., NCI and CMS) in order to identify possible sources of information that could be used in determining the current capacity of the U.S. health care system to provide endoscopic colorectal cancer screening and follow-up examinations.

Population surveys, such as the National Health Interview Survey (OMB #0920-0214, exp. 12/31/2009), routinely collect information on a variety of health behaviors, including the use of colorectal cancer screening tests. While the results of these survey efforts provide valuable information regarding the percentage of the population 50 years of age and older that have been screened for colorectal cancer, the surveys do not collect any information regarding the types of facilities or the types of providers that perform the procedures. In addition, the surveys do not provide information regarding other key study questions, such as the maximum number of procedures that could be performed in the event of a sudden increase in the demand for the procedures.

The Centers for Medicare and Medicaid Services (CMS) collects Medicare and Medicaid claims data for endoscopic procedures. However, the usefulness of the CMS data for estimating the current capacity for colorectal cancer screening and follow-up examinations is limited in several respects. First, CMS data only include information on procedures performed for Medicare and Medicaid enrollees. Therefore, information regarding procedures performed in adults between the ages of 50 and 65 would not be available. Second, CMS does not define the types of medical practices in which endoscopy is performed. Third, certain important aspects of defining the current capacity to perform endoscopic screening and follow-up examinations (e.g. the use of non-physician endoscopists) are not included in the CMS data. Finally, other key questions to be addressed by the proposed study (e.g. maximum number of procedures that could be performed in the event of widespread screening, steps that would be taken to meet a sudden increase in the demand for screening and follow-up procedures) cannot be addressed using CMS data.

In 1999 to 2000 the National Cancer Institute (NCI) conducted a Survey of Colorectal Cancer Screening Practices in Health Care Organizations (OMB #0925-0468, exp. 8/31/2002), in collaboration with the Centers for Disease Control and Prevention (CDC) and the Health Care Financing Administration (HCFA) (Brown, Klabunde, & Mysliwiec, 2003). The NCI study surveyed a national random sample of physicians (1,235 primary care physicians, 349 gastroenterologists, and 316 general surgeons) and health plan medical directors (n= 323) regarding physician and health system factors which may influence the use of screening and diagnostic tests for the early detection of colorectal cancer. The results of the NCI survey do not provide adequate information for estimating the total number of sigmoidoscopies and colonoscopies performed in the U.S. Because the survey was designed to elucidate knowledge, attitudes and behaviors regarding colorectal cancer screening among a sample of providers and to explore barriers to screening among providers who are not currently conducting colorectal cancer screening, the sample for the NCI study included a large proportion of providers who do not currently conduct colorectal cancer screening. In addition, the NCI data obtained limited information regarding the role of the non-physician endoscopists in performing colorectal cancer screening. Non-physician endoscopists represent a large workforce with the potential to participate in widespread colorectal cancer screening. Finally, the NCI survey data cannot be used to provide estimates of the number of procedures which are currently being performed because the NCI survey collected information regarding the number of procedures performed by specialists and primary care physicians in a typical month as a categorical variable (e.g., none, 1-5, 6-10, 11-20, more than 20).

Other physician and health system surveys have collected information regarding the use of colorectal screening in various health care practices. For example, the American Academy of Family Physicians administers a biennial survey to its members to estimate the proportion of family physicians performing flexible sigmoidoscopy or colonoscopy in their offices or in their hospital practices (American Academy of Family Physicians, May 2000). The results of this survey are limited in two respects. First, the survey focuses on family practice providers and does not provide information on procedures performed by specialists (who perform the vast majority of endoscopies). Second, the survey provides information regarding the proportion of family practitioners that perform endoscopy, but it does not provide information on the numbers of procedures performed by family practitioners.

Two other health surveys — the National Center for Health Statistics (NCHS) Hospital Discharge Survey (OMB #0920-0212, exp. 10/31/2011) and the National Survey of Ambulatory Surgery (OMB #0920-0334, exp. 11/31/2008)— provide national estimates of the frequency of sigmoidoscopies and colonoscopies performed in hospitals and ambulatory surgery centers. However, neither survey provides information on the numbers of procedures performed in settings other than hospitals or ambulatory surgery centers. Furthermore, the surveys do not provide data on the type of provider performing the examinations, nor the maximum number of procedures that could be performed in the event of a sudden increase in demand for the procedures.

A recent literature review identified three state studies and one New York City study that have been conducted to estimate colonoscopy screening capacity (Ballew, Lloyd, & Miller, 2009; Butterly, Olenec, Goodrich, Carney, & Dietrich, 2007; Hoffman, et al., 2005; Leng, Thorpe, Feldman, Thomas, & Frieden, 2005). However, there have been no additional national studies of endoscopic capacity for colorectal cancer screening.

The previous national and state SECAP surveys were conducted to provide an estimate of endoscopic capacity at the national level and for 15 selected states. This information regarding the capacity of the health care system to provide lower GI endoscopic procedures is critical to planning widespread colorectal cancer screening programs. The estimates of endoscopic capacity from the previous national SECAP study, which reflect the capacity in 2002, are now out-dated (Seeff, et al., 2004; Seeff, et al., 2004). Similarly, the state SECAP survey was limited to 15 selected states. Since then, a number of other states have requested CDC's assistance in assessing colorectal cancer screening capacity at the state and sub-state level. In light of recent trends in colorectal cancer screening (e.g. , increases in the percentage of public and private insurers that reimburse for screening colonoscopy, increased use of colonoscopy and decreased use of flexible sigmoidoscopy, availability of other colorectal cancer screening procedures), there is a need to update estimates of endoscopic capacity to guide continued screening initiatives.

A.5. Impact on Small Businesses or Other Small Entities

The study population will include all health care facilities in the U.S. that use lower GI flexible endoscopic equipment (sigmoidoscopes and colonoscopes) for the detection of colorectal cancer in adults. This will include single-specialty and multi-specialty physician practices, ambulatory

surgery or ambulatory endoscopy centers, hospitals, medical clinics, and managed care organizations.

A small proportion of the sample will consist of small physician practices. Every effort has been made to minimize the burden of the survey on small businesses. First, the survey will be completed only one time. Second, in designing the survey instrument, the number of questions has been held to the minimum necessary for addressing the objectives of the proposed study. Finally, to the extent that small physician practices may be more likely to perform fewer procedures (e.g., only sigmoidoscopies and not both sigmoidoscopies and colonoscopies), small businesses may be more likely to skip portions of the questionnaire than larger practices such as hospitals and endoscopy centers.

A.6. Consequences of Collecting the Information Less Frequently

This data collection effort is essential for providing information to federal and state public health planners and policymakers regarding the ability of the current health care system to respond to an increased demand for colorectal cancer screening and follow-up. In the face of CDC efforts with its partners to promote broader use of colorectal screening tests, it is imperative to evaluate the current resources for providing CRC screening and follow-up examinations so that steps can be taken to address deficits, if deficits are identified. This data collection effort will be instrumental in determining how CDC funds should be divided between continued efforts to promote screening and efforts to address potential deficits in screening services. It will also provide a means for states to identify potential deficits and plan accordingly to address those potential deficits.

Survey respondents will be asked to complete the survey only one time. There are no legal obstacles to reduce burden.

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

This request fully complies with the regulations 5 CFR 1320.5.

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

A. Comments in Response to the Federal Register Notice

The Federal Register Notice (Attachment B) for the proposed data collection was posted in the *Federal Register* on January 29, 2010, Volume 75, No. 19, pages 4823-4824. No comments were received.

B. Efforts to Consult Outside the Agency

Input regarding the questions to be included in the SECAP II survey instrument was sought from a variety of individuals who perform colorectal cancer screening. The study consultants included

a primary care physician, three gastroenterologists, a surgeon, and a nurse endoscopist. Information regarding these study consultants is provided in Table A.8-1.

The study consultants were asked to review the survey instrument that was used in the previous national and state SECAP studies and, if necessary, to make recommendations for survey revision. The study consultants suggested that a few new questions be added to the survey instrument to measure colorectal cancer screening capacity (e.g., information about the number of procedures rooms, use of anesthesiologists), and recommended some minor wording changes and additional response categories. The SECAP II survey instrument was revised to incorporate the recommendations of the study consultants.

A.8-1 Study Consultants

Year	Consultant	Agency/Organization
2009	T.R. Levin, MD Associate Chief of Gastroenterology Phone: 925-295-6548 Theodore.Levin@kp.org	Kaiser Permanente Medical Center Walnut Creek, CA
2009	David Lieberman, MD Chief, Division of Gastroenterology Phone: 503 494-4373 lieberma@ohsu.edu	Oregon Health and Science University Portland, OR
2009	Richard Wender, MD Chairman, Department of Family Medicine Phone: 215-955-2356 richard.wender@jefferson.edu	Thomas Jefferson University Philadelphia, PA
2009	Paul Schroy, MD Director of Clinical Research Section of Gastroenterology Phone: 617-638-7440 Paul.Schroy@bmc.org	Boston University School of Medicine
2009	Alan Thorson, MD Clinical Associate Professor of Surgery Phone: 402-343-1122 agthorson@msn.com	University of Nebraska ,College of Medicine Omaha, NE
2009	Nancy Schlossberg, RN Senior Clinical Specialist Phone: 408-242-0439 nancy.schlossberg@cox.net	Avantis Medical Systems Sunnyvale, CA

A.9. Explanation of Any Payment or Gift to Respondents

As was done in the previous national and state SECAP studies, a payment of $40 will be included with the first mailing of the SECAP II surveys. There is clear and consistent evidence that monetary remuneration significantly increases response rates in most surveys, and experts on survey methods such as Dillman and Sudman recommend their use (Dillman, Mail and Telephone Surveys, 1978; Sudman, 1985; Dillman, Mail and Internet Surveys: The Tailored Design, 2000). A number of studies have compared the response rates of mailed surveys with

and without monetary incentives. These studies have clearly shown that even a nominal gratuity increases response rates by 10-20%, and that the amount of the incentive is positively correlated with response rate. Repeated contacts in the form of mail and telephone follow-up, and the inclusion of postage-paid, self-addressed return envelopes, are also effective in increasing response rates. Combining other measures to increase response with monetary payments has been shown to produce higher response rates than payments alone or other types of incentives without payments. The methods used in the previous national and State SECAP studies, including the $40 respondent payment, yielded response rates of 75% and 82%, respectively.

Achieving a response rate of 80% or higher to the proposed survey is critical to avoid selection bias and to ensure unbiased estimates of the current capacity to perform endoscopic colorectal cancer screening and follow-up examinations. The monetary incentive alone is not sufficient to ensure that the study achieves a response rate of 80%. As described in section B.3 (Methods to Maximize Response Rates and Deal with Nonresponse), other measures such as sending the surveys by Federal Express, thank you/reminder postcards, and follow-up telephone calls to non-respondents will also be used to maximize the response rate to the mail survey. If all of these measures are implemented, as they were in the previous national and state SECAP surveys, the SECAP II surveys are likely to achieve an 80% response rate.

A.10. Assurance of Confidentiality Provided to Respondents

In administering the national and state SECAP II surveys, Battelle must maintain the link between the facility names and their respective ID numbers. This link will be used for tracking survey mailings, and making follow-up telephone calls. The links between respondent contact information and ID numbers will be stored securely and separately. The links between survey ID numbers and facility identifying information, including the respondent's contact information, will be destroyed upon completion of data collection.

Data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. Neither the names of respondents nor the institutions they represent will be identified in published reports or publicly available data. Completed paper surveys will be stored in locked file cabinets in Battelle offices. All electronic files will be password protected and accessible only to authorized project staff. Measures to safeguard data will be emphasized in written and verbal training procedures for project personnel.

Privacy Impact Assessment Information

A. **Privacy Act Determination.** This submission has been reviewed by staff in the CDC Information Collection Request Office, who have determined that the Privacy Act is not applicable. The respondent to the SECAP II survey is a medical facility, not an individual. The contact person completes the survey on behalf of the facility and is answering as an employee of the facility. No personal information is requested. The name of the contact person will not be maintained in study data files.

B. Safeguards. The survey will be administered by the Battelle Centers for Public Health Research and Evaluation. Battelle will use security controls to protect against unauthorized

access, modification, destruction or disclosure of data through access control and authentication. Security controls will protect privacy and confidentiality of the survey data through technical controls, administrative controls and physical controls.

Technical Controls. The national and state SECAP II survey data will be stored in Battelle's SQL Server databases on Local Area Networks (LANs) behind firewalls. Each facility will be assigned a unique study ID number that is the unique identifier on all analytic and survey data records, assuring that analysts are blinded to the facility's identity. The link between the facility name and the assigned ID is stored in a separate secured database table with controlled access. Analytical data sets may be stored on analysts' PCs when they are working with the data. All Battelle PCs are currently Windows XP Professional, Service Pack 2 and access is controlled.

Physical Controls. All servers are located in secure controlled access areas. Physical access to Battelle offices during non-office hours requires possession of an electronic card. During office hours all visitors can only enter through a staffed reception area where they are logged in and must be escorted at all times while on the premises. Within each Battelle office are additional secure areas that have secured access at all times. All server rooms require 24-hours electronic card access. Each electronic card is programmed for a specific user and provides that user with access to all areas to which they are authorized. Authorized users have individual access codes and all access, including invalid attempts, are logged. In addition to these general security measures, sensitive material is stored in locked file cabinets when not in use. Only office administrators and staff authorized to work with these materials have keys to these file cabinets. Battelle staff are trained in these policies and periodically reminded of their importance. Battelle staff members are required to lock their computers when away from their desk using Windows XP Task Manager. Password-protected auto-locking is configured to activate after 10 minutes of inactivity.

Administrative Controls. Battelle's IT division maintains an intranet site on Cybersecurity Policies and Procedures that is accessible by all employees. This site includes staff responsibilities for protecting data and security requirements for protection of the network, PCs, mobile devices and the data residing on them. In addition, the IT division frequently sends emails to all staff reminding them of specific security issues (e.g., use of the internet, remote access, email safety). Battelle is in the process of developing its own IT Security Awareness training.

Differential backups of SQL Server databases are performed every hour. Full backups of SQL Server databases are performed nightly. These full and differential backups are made to a folder on the server's hard drive and integrity is verified upon completion. The folder containing these full database backups is then backed up to tape as part of our network backup plan. The network backups provide nightly incremental backups and full backups on weekends for all data stored on Battelle LANs and WANs. Tapes are stored offsite at secure contracted facilities. Permissions to access project databases are limited to staff members assigned to work on the project. Non-technical project staff can only access the data indirectly through applications and are authenticated by username and password when logging into the application. All PC-based files, folders, and applications are backed up

nightly to a secure server in encrypted format using Connected DataProtector software. Laptops are backed up using this software when staff reconnects to the Battelle network. Files remain encrypted while stored and only the owner of the files and the IT administrator has the encryption key. Staff can elect to backup or restore files at any time in addition to the automatic backup. A Battelle technical staff member is responsible for transferring data to CDC in a secure manner. Records will be retained and destroyed in accordance with the applicable CDC Records Control Schedule.

Battelle is not subject to a non-disclosure agreement.

C. <u>Consent</u>. The respondent to the national and state SECAP II surveys, as described above, is a medical facility and not a person. Informed consent for the survey will be explained in the cover letter that accompanies each survey request. The survey cover letters will inform respondents that participation in the study is voluntary. The letters will also assure respondents that we will protect the confidentiality of the data provided. Respondents will be told that their name will not be associated with the answers they provide, that only aggregated data will be reported, and that all identifiers will be destroyed after data collection has been completed. Respondents will be told that the data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. The cover letters will include the names and telephone numbers of individuals to call with technical questions regarding the survey or with concerns regarding their rights as a human subject. The voluntary nature of participation in the study and the confidential nature of the data provided will also be discussed on the cover of the questionnaire. Completing the survey and returning it in the envelope provided will be taken as indication of consent. These procedures have been reviewed and approved by Battelle's Institutional Review Board (see Attachment J).

D. <u>Voluntary Nature of Response</u>. Respondents to the SECAP II survey are organizations and not individuals. The surveys will be completed on a voluntary basis. Respondents are informed of this in writing in the survey cover letter.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include criminal behavior, sexual behavior and attitudes, alcohol or drug use, and religious beliefs. No questions regarding these topics or any other topic of a sensitive nature (i.e., organizational policies, performance data) will be asked in this survey.

A.12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden to Respondents

The estimated respondent burden for the national and state SECAP II surveys includes two components: (1) time for the screening telephone call to the facility to identify eligible facilities and identify the appropriate respondent for the mail survey and (2) time for the survey respondent to review the instructions, search existing data sources, gather the data requested and complete the mail survey. The previous national SECAP survey contained 52 questions, and the previous state SECAP survey contained 51 questions. The SECAP II survey contains 58 questions. Changes that were made for the SECAP II survey are summarized in Attachment D. A few questions were no longer needed and were deleted. The SECAP II survey also contains a few new questions that were added based on the recommendation of the consultants, and has minor wording and question-order changes which reflect the research team's experience with the previous national and state SECAP surveys. Based upon the results of a pre-test, we estimate that the screening telephone call will take approximately 5 minutes or less to complete and that the SECAP II survey will take 30-40 minutes to complete, with an average burden of 35 minutes per response.

National survey. A total of 2,100 facilities will be selected for the national SECAP II survey (see Attachment E1). Screening calls (see Attachment E2) will be made to determine whether or not the facilities are eligible for inclusion in the study and to identify the appropriate survey respondent. Based on data from the previous national and state capacity studies, we estimate that approximately 15% of the facilities selected will be lost to follow-up or will be ineligible because they do not perform lower GI endoscopic procedures in adults. Therefore, of the 2,100 facilities that are screened, we expect that approximately 1,800 national SECAP II surveys will be mailed. Assuming an estimated response rate of 80%, this will result in a total of 1,440 completed surveys, or an average of 480 surveys per year over the three-year period of this clearance request.

State surveys. All facilities that perform lower GI endoscopy to screen for colorectal cancer in adults—with the exception of those that are sampled as part of the national SECAP II survey—will be selected for the state SECAP II surveys (see Attachment F1), i.e., approximately 135 facilities in each of the 18 selected states. Screening calls (see Attachment F2) will be made to determine whether or not the facilities are eligible for inclusion in the study. Assuming that approximately 15% of the facilities selected will be lost to follow-up or will be ineligible because they do not perform lower GI endoscopic procedures in adults, we estimate that approximately 2,400 screening calls will be made and approximately 2,100 state SECAP II surveys will be mailed. Assuming an 80% response rate, this will result in 1,680 completed surveys, or an average of 560 surveys per year over the three-year period of this clearance request.

The total estimated annualized burden hours for respondents participating in national and state SECAP II surveys are 732, as summarized in Table A.12-1.

A.12-1 Estimated Annualized Burden to Respondents

Type of Respondent	Form Name	No. Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Medical facilities that perform colorectal cancer screening	National SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent	700	1	5/60	58
	CDC National Survey of Endoscopic Capacity	480	1	35/60	280
	State SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent	800	1	5/60	67
	CDC State Survey of Endoscopic Capacity	560	1	35/60	327
				Total	732

Estimated Annualized Cost to Respondents

The estimated annualized cost to respondents for the study is shown in Table A.12–2. There are no costs to respondents other than their time to participate. Respondents to the recruitment interviews and SECAP surveys are likely to vary, depending upon the type of facility surveyed. Respondents to the recruitment interviews are likely to include medical receptionists and hospital switchboard operators ($11.76 per hour) and registered nurses ($30.04 per hour). Respondents to the SECAP surveys are likely to include family and general practitioners ($73.86 per hour), general internists ($80.42), surgeons ($92.03 per hour) and medical and health services manager ($40.86 per hour). These wage rates were obtained from the Department of Labor, Bureau of Labor Statistics (**http://www.bls.gov/oes/current/oes_il.htm#b29-0000**).

For the purposes of estimating the cost to respondents, we utilized an average rate of $20 per hour for respondents to the recruitment script and $75 per hour for respondents to the SECAP surveys. Using these estimates, the total estimated annualized cost to respondents is $48,025.

A.12-2 Annualized Cost to Respondents

Type of Respondent	Form Name	Total Burden Hours	Average Hourly Wage Rate	Respondent Cost
Receptionists, hospital operators, and nurses	National SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent	58	$20	$1,160
	State SECAP II Screening Telephone Call to Identify the Appropriate Survey Respondent	67	$20	$1,340
Physicians and medical managers	CDC National Survey of Endoscopic Capacity	280	$75	$21,000
	CDC State Survey of Endoscopic Capacity	327	$75	$24,525
			Total	$48,025

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

The data collection entails no additional costs to respondents or record keepers.

A.14. Annualized Cost to the Federal Government

Data collection for the SECAP II study will take three years to complete. The estimated annualized project costs are shown in Table A.14-1. These total costs include (1) contract costs for Battelle for data collection, and (2) the cost of CDC staff to provide oversight to the study. The total estimated annualized cost to the government will be $311,450.

The contractual costs to Battelle include costs for scientific staff who have responsibilities for project management, study design and data analysis, and the personnel costs associated with recruiting respondent facilities through the CATI interviews, distributing and tracking surveys, and managing data. Other contractual costs include costs for survey production and distribution, the cost of computing equipment, study incentives, and other administrative costs. The total estimated cost of the contract is $840,000, with an estimated annualized cost of $280,000. The CDC oversight costs include personnel costs of Federal employees involved in oversight, estimated at $31,450 annually. This estimate includes a project director at the GS-14 level, a consulting medical officer and a consulting health economist at the GS-13 level, and a fellow.

A.14-1 Annualized Cost to the Federal Government

Type of Cost	Total Cost	Annualized Cost
Battelle Contract Costs		
Personnel	$440,000	$147,000
Data collection services/materials	$399,000	$133,000
Total Contract Costs	$840,000	$280,000
CDC Oversight Costs		
GS-14, $115,000/year @5%		$5,750
2 GS-13, $96,000/year $10%		$19,200
1 Fellow, $65,000/year @10%		$6,500
Total CDC Oversight Costs		$31,450
Cost to Federal Government		$311,450

A.15. Explanation for Program Changes or Adjustments

The changes proposed in this reinstatement request result in an overall increase in the burden estimate. Although the study there is a reduction in the number of respondents for the national survey, and a reduction in the number of responses for the state-based surveys, the consolidation of these data collections into a unified information collection request results in a net increase in estimated burden for 0920-0539. The estimated burden per response has not changed.

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

Tabulation Plan

Calculation of sampling weights. Weighting of the national SECAP II survey data will be performed to reduce bias by adjusting for patterns of non-response. The base weight for each survey respondent will be the inverse of the respondent's probability of selection. To adjust for non-response we will use sample weighting class adjustments. The variables that are the best candidates for the formation of weighting classes are those variables that are: (1) available for respondents as well as non-respondents; (2) highly correlated with the survey variables; and (3) highly correlated with the likelihood of non-response. Variables available for the non-response analysis will be limited to region and urban/rural location, and those variables obtained during the screening telephone interview (e.g., type of facility).

In the state SECAP II surveys, because we will survey a census of facilities purchasing endoscopic equipment in each of the selected states, weighting of the survey data need only be performed to reduce bias due to patterns of non-response. (Note: Facilities in selected states that are surveyed in the National SECAP II will not be surveyed again. However, the data obtained for those facilities will be merged with data for their states in order for all facilities in the state to be represented).

These sampling weights will be applied to all analyses described below. By using sampling weights we will obtain estimates that will be unbiased and generalizable to the population of all health care practices that use lower GI flexible endoscopic equipment for the detection of colorectal cancer in adults.

Data analysis. The objective of the proposed study is to determine the current capacity of the health care system in the U.S. and in up to thirteen selected states to provide endoscopic colorectal cancer screening and follow-up procedures. First, univariate analysis will be conducted on all items in the survey. As described above, survey weights will be computed and used to produce estimates that are representative of all facilities currently providing colorectal cancer screening and follow-up examinations nationally (as well as in each of the selected states). The data will be analyzed using Stata 6.0 (StataCorp, 1999)—a software package that adjusts standard errors to reflect sampling weights. Data analysis will focus on the following issues:

- ***Facility characteristics***. Facilities performing lower GI endoscopy will be described in terms of whether they are a hospital, ambulatory surgery center or physician practice; the number of physicians performing lower GI endoscopy (by specialty); the number of procedure rooms, video monitors, flexible sigmoidoscopes, colonoscopes and other lower GI endoscopes; use of non-physician endoscopists; use of conscious sedation or anesthesia; and average room time scheduled for the procedures.
- ***Characteristics of the individuals performing screening and follow-up examinations***. The data will be analyzed to estimate the percentage of sigmoidoscopies and colonoscopies being performed by type of provider (e.g., primary care physicians, gastroenterologists, general and colorectal surgeons). Examples of other variables to be examined include: (1) the number of non-physician endoscopists performing lower GI endoscopic procedures, by type of non-physician endoscopist; and (2) the level of supervision that is required when non-physician providers perform lower GI endoscopic procedures.
- ***Screening and follow-up tests currently being performed***. The data will be analyzed to provide an estimate of the number of sigmoidoscopies and colonoscopies currently being performed. Other variables to be examined will include: the percentage of lower endoscopies performed for colorectal cancer screening; frequency with which procedures are incomplete; and the typical waiting time for an appointment for colorectal cancer screening and follow-up procedures.
- ***Maximum number of screening and follow-up examinations with widespread screening***. In addition to estimating the total number of lower GI endoscopic procedures currently being performed, data analysis will provide estimates of the maximum number of screening procedures that could be performed if demand increased substantially. Factors that limit the maximum number of procedures that could be performed and steps that would be taken to meet an increased demand for procedures will also be examined.

Following this univariate analysis, we will conduct bivariate analyses to examine differences among various subsets of respondents. For example, in analyzing the national survey data, survey results will be shown separately by U.S. Census region, by urban/rural facility location,

and/or by type of facility (ASC, hospital, physician practice). State survey results will be shown by sub-state regions, and by facility type (ASC, hospital, physician practice). The number of sub-state regions will vary, depending upon the geography and population of the state and the number of facilities.

Attachments H1 and H2 contain table shells to present the national and state SECAP II survey results from the above analyses. Each table shell has a national and state-level version. These table shells include:

- ***Facility characteristics***
    - Number of eligible facilities by region (Table 1).
    - Response rate by region (Table 2).
    - Number of endoscopists by physician specialty, by facility type (Table 3).
    - Number of procedure rooms, video monitors, sigmoidoscopes, colonoscopes by region (Table 4) and by facility type (Table 5)
    - Average room time typically scheduled for flexible sigmoidoscopy and colonoscopy by facility type (Table 6).
    - Percentage of facilities typically using conscious sedation or propofol for colonoscopies by facility type (Table 7)

- ***Characteristics of the individuals performing screening and follow-up examinations***.
    - Percentage of flexible sigmoidoscopies and colonoscopies performed by physician specialty, by facility type (Table 8)
    - Percentage of facilities by facility type that authorize non-physician endoscopists to perform flexible sigmoidoscopies and colonoscopies with varying levels of supervision (Table 9)

- ***Screening and follow-up tests currently being performed***.
    - Number of procedures currently being performed, the percent of procedures for screening, and the percent of incomplete procedures. Table 10 shows these results for the state compared to the nation, and Table 11 breaks these results down by facility type.
    - Typical waiting times for various endoscopic procedures for the state compared to the nation (Table 12)

- ***Maximum number of screening and follow-up examinations with widespread screening***
    - Limiting factors to increasing the number of procedures. Table 13 presents the percentage of facilities selecting any of the limiting factors, and Table 14 presents the percentage of facilities selecting a limiting factor as the primary reason more procedures cannot be performed at the facility.
    - Steps that facilities would take to meet an increase in demand that exceeds their capacity (Table 15) and by facility type (Table 16)

- Estimated number of facilities that provide flexible sigmoidoscopies and colonoscopies by region, the mean number of weekly procedures that are possible with no other investment of resources, and the annual volume that is possible with no other investment of resources. The annual volume will be calculated for each facility by multiplying the weekly procedures that are possible by the number of weeks in the year that the facility has normal operations. The annual volume will then be summed across all facilities within a region (Table 17)
- Potential annual volume, the current annual volume, and the unused capacity to perform flexible sigmoidoscopies and colonoscopies by region (Table 18).

Survey weights (i.e., weights that will adjust for non-response) will be computed and used to produce estimates that are representative of all providers currently performing colorectal cancer screening and follow-up examinations nationally, as well in each of the 18 selected states. Appropriate statistical tests (e.g., Chi-square tests, t-tests) will be used to compare differences in frequencies and means by type of facility. P-values of .05 will be reported as an indication of statistical significance.

Publication Plan

Upon completion of the data analysis, a technical report will be prepared to summarize project activities and the results of the national SECAP survey data analysis. In addition, following the SECAP II state surveys, separate technical reports will be prepared for each of the 18 states in which census surveys were conducted. Each report will describe the objectives of the study, methods of survey administration (including the response rates to the survey), and analysis results. As sample state report for Colorado, which was prepared for the previous state SECAP study, is provided as Attachment I.

The results of the study will also be disseminated to various stakeholders through the publication of manuscripts in medical journals and through presentations at professional meetings.

Project Time Schedule

Data collection, analysis and reporting will be conducted over a 3-year period of time. The surveys will be administered in Waves—beginning with the national survey. The time schedule for remaining project activities is shown in Table A.16-1.

A.16-1 Time Schedule

Activity	Schedule (months after OMB clearance)
National SECAP II Survey	
Sample selection	Month 1
Screening telephone calls	Months 2-3
Conduct mail survey	Months 2-6
Data coding, entry, and cleaning	Months 4-7
Data analysis	Months 8-9
Prepare final national report	Months 9-10
State SECAP II Surveys—Wave 1	
Identify facilities to be surveyed	Month 7
Screening telephone calls	Months 8-9
Conduct mail survey	Months 8-12
Data coding, entry, and cleaning	Months 10-13
Data analysis	Months 14-19
Prepare final state reports	Months 18-23
State SECAP II Surveys—Wave 2	
Identify facilities to be surveyed	Month 13
Screening telephone calls	Month 14-15
Conduct mail survey	Months 14-18
Data coding, entry, and cleaning	Months 16-19
Data analysis	Months 20-25
Prepare final state reports	Months 25-30
State SECAP II Surveys—Wave 3	
Identify facilities to be surveyed	Month 19
Screening telephone calls	Month 20-21
Conduct mail survey	Months 20-24
Data coding, entry, and cleaning	Months 22-25
Data analysis	Months 26-31
Prepare final state reports	Months 31-36

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

No exemption from display of expiration date is requested.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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