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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-14-0963]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404-639-7570 or send comments to Leroy Richardson, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Colorectal Cancer Control Program Indirect/Non-Medical Cost Study (OMB No. 0920-0963, exp. 4/30/2014) — Reinstatement with Change — National Center for Chronic Disease Prevention and

Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2013 the Centers for Disease Control and Prevention (CDC) received Office of Management and Budget (OMB) approval to conduct a study to measure the time and costs incurred by patients screened for colorectal cancer (CRC) with colonoscopy or fecal immunochemical test (FIT)(OMB No. 0920-0963, exp. 4/30/2014). Information has been collected from patients screened through the Colorectal Cancer Control Program (CRCCP), however, the target number of respondents was not achieved during the initial approval period. CDC requests OMB approval to reinstate the information collection for one year in order to meet recruitment goals and complete the data analysis as outlined in the original approval.

Changes described in this Reinstatement request include a reduction in the number of respondents and a corresponding reduction in the total estimated burden hours. There are minor modifications to the data collection instruments to clarify intent but these modifications do not change the estimated burden per response.

Colorectal Cancer (CRC) is the second leading cause of cancer-related deaths in the United States, following lung

cancer. Based on scientific evidence which indicates that regular screening is effective in reducing CRC incidence and mortality, regular CRC screening is now recommended for average-risk persons. Screening tests that may be used alone or in combination include fecal occult blood testing (FOBT), fecal immunochemical testing (FIT), flexible sigmoidoscopy, and/or colonoscopy.

While screening rates have increased over the past decade, screening prevalence is still lower than desirable, particularly among individuals with low socioeconomic status. The indirect and non-medical costs associated with CRC screening, such as travel costs, may act as barriers to screening. Understanding these costs may provide insights that can be used to reduce such barriers and increase participation.

In 2005, CDC established a four-year demonstration program at five sites to screen low-income individuals aged 50–64 years who had no health insurance or inadequate health insurance for CRC. In 2009, by applying lessons learned from the demonstration program, CDC designed and initiated the larger population-based Colorectal Cancer Control Program (CRCCP) at 29 sites. The goals of the expanded program are to reduce health disparities in CRC screening, incidence and mortality by promoting CRC screening for the eligible population and providing CRC screening to low-

income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

To date there has been no comprehensive assessment of all the costs associated with CRC screening, especially indirect and non-medical costs, incurred by the low-income population served by the CRCCP. CDC proposes to address this gap by collecting information from a subset of patients enrolled in the program. Those who undergo screening by FIT or colonoscopy will be asked to complete a specialized questionnaire about the time and personal expense associated with their screening. Patients who undergo fecal immunochemical testing will be asked to complete the FIT questionnaire, which is estimated to take about 10 minutes. Patients who undergo colonoscopy will be asked to complete the Colonoscopy questionnaire, which includes additional questions about the preparation and recovery associated with this procedure. The estimated burden per response for the Colonoscopy questionnaire is 25 minutes. Demographic information will be collected from all patients who participate in the study.

CDC plans to conduct the information collection in partnership with providers in four states (Alabama, Arizona, Georgia, and Pennsylvania). Each participating provider will make patient navigators available to assist patients with coordinating the screening process and completing the

questionnaires. Providers will be reimbursed for patient navigator time and administrative expense associated with data collection. The target number of responses for the overall study will result in 300 completed Colonoscopy Questionnaires and 290 completed FIT Questionnaires. During the initial approval period CDC collected approximately 50% of the target number of completed questionnaires. To complete the study CDC plans to collect an additional 150 Colonoscopy Questionnaires and an additional 177 FIT Questionnaires.

This information collection will be used to produce estimates of the personal costs incurred by patients who undergo CRC screening by FIT or colonoscopy, and to improve understanding of these costs as potential barriers to participation. Study findings will be disseminated through reports, presentations, and publications. Results will also be used by participating sites, CDC, and other federal agencies to improve delivery of CRC screening services and to increase screening rates among low-income adults over 50 years of age who have no health insurance or inadequate health insurance for CRC screening.

OMB approval is requested for one year. Each respondent will have the option of completing a hardcopy questionnaire or an on-line questionnaire. No identifiable information will be collected by CDC or CDC's data collection contractor.

Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Type	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Patients Served by the Colorectal Cancer Control Program	FIT questionnaire	177	1	10/60	30
	Colonoscopy questionnaire	150	1	25/60	63
				Total	93

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Office of Scientific Integrity
Office of the Associate Director for Science
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