

## EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR CCQM-PC SURVEY PILOT TEST BY ENTITY

|                                                    |       |   |      |       |
|----------------------------------------------------|-------|---|------|-------|
| CCQM-PC survey .....                               | 4,500 | 1 | 0.42 | 1,890 |
| MHI-LV: <sup>1</sup> Physician/administrator ..... | 30    | 1 | 2.33 | 70    |
| MHI-LV: Non-physician clinician .....              | 30    | 1 | 2.08 | 62    |
| Total .....                                        |       |   |      | 2,022 |

<sup>1</sup> The instructions for completing the MHI-LV recommend that a physician/administrator and a non-physician clinician each fill out the index separately. So, even though it is one form as reproduced in Appendix B, we have two rows in the table to describe the burden of the two individuals. There are a series of questions on the first two pages of the index which simply require administrative information and would only need to be completed once. We assume that the administrator would complete these and so the time required for the administrator to complete the MHI-LV is longer than that required for the clinician.

Exhibit 2 shows the estimated annualized cost burden associated with the pilot survey administration. The total cost burden is estimated to be \$51,228 for the one-time survey pilot.

## EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR CCQM-PC SURVEY PILOT TEST BY ENTITY

|                               |       |                      |          |
|-------------------------------|-------|----------------------|----------|
| Survey Respondents .....      | 1,890 | <sup>1</sup> \$22.33 | \$42,204 |
| Physician/Administrator ..... | 70    | <sup>2</sup> 88.43   | 6,190    |
| Non-physician Clinician ..... | 62    | <sup>3</sup> 45.71   | 2,834    |
| Total Overall .....           | 2,022 | n/a                  | 51,228   |

<sup>1</sup> Average wage for civilian workers, <http://www.bls.gov/news.release/ocwage.htm>.

<sup>2</sup> Average wage for family and general practitioners, <http://www.bls.gov/news.release/ocwage.htm>.

<sup>3</sup> Average wage for nurse practitioners, <http://www.bls.gov/news.release/ocwage.htm>.

## Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 24, 2014.

**Richard Kronick,**  
AHRQ Director.

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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](mailto: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                       | Number of respondents | Number 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                      |

**Leroy Richardson,**

Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10433]

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Centers for Medicare &  
Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: The necessity and utility of the proposed information collection for the proper performance of the agency's functions; the accuracy of the estimated burden; ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed. We are seeking emergency approval for modifications to the information collection request (ICR) currently approved under Office of

Management and Budget (OMB) control number 0938-1187 to include account registration elements associated with submitting data through the Amazon Cloud EDGE Server or the On-Premise EDGE server. As a result of contractor changes and technical design changes to our distributed data collection (DDC) approach for implementing the risk adjustment and reinsurance programs, we must change the data elements that issuers will submit as part of the DDC information collection requirements. These modifications will permit us to register EDGE servers with the appropriate issuer accounts, permitting CMS to make risk adjustment and reinsurance payments to issuers.

**DATES:** Comments must be received by August 27, 2014.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS-10433/OMB Control Number 0938-1187, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

#### SUPPLEMENTARY INFORMATION:

##### Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement

and associated materials (see **ADDRESSES**).

### *CMS-10433 Initial Plan Data Collection To Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations*

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. This is necessary to ensure compliance with an initiative of the Administration. We are requesting an emergency review under 5 CFR Part 1320(a)(2)(i) because public harm is reasonably likely to result if the normal clearance procedures are followed.

#### Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the CMS-9989-F, Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange Establishment Rule), each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). In addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS-9975-F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium