

three (3) years, beginning on July 9, 2014:

(1) That the administrative actions delineated in (2)–(4) below will be required for three (3) years after the effective date of the Agreement, beginning on the date of Respondent's employment in a research position in which he receives or applies for U.S. Public Health Service (PHS) support; however, if within three (3) years of the effective date of the Agreement, Respondent has not obtained employment in a research position in which he receives or applies for PHS support, the administrative actions in (2)–(4) will no longer apply;

(2) to have any PHS-supported research supervised; Respondent agrees that prior to the submission of an application for PHS support for a research project on which the Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research; Respondent agrees that he shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(3) that any institution employing him shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract; and

(4) to exclude himself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Acting Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Donald Wright,

Acting Director, Office of Research Integrity.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*Care Coordination Quality Measure for Patients in the Primary Care Setting.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by September 29, 2014.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Care Coordination Quality Measure for Patients in the Primary Care Setting

Proposed Project

“Care Coordination Measure Development—Phase III”

This project is Task Order #11 under the Agency for Healthcare Research and Quality (AHRQ) Prevention and Care Management Technical Assistance Center Indefinite Delivery Indefinite Quantity contract. The project, entitled “*Care Coordination Measure Development—Phase III*”, will develop a patient survey of the quality of care coordination for adults in primary care settings, i.e., the Care Coordination Quality Measure for Primary Care (CCQM–PC). The project will update the *Care Coordination Measures Atlas* (<http://www.ahrq.gov/professionals/systems/long-termcare/resources/coordination/atlas/index.html>). In combination with primary research, the

project will use the *Atlas* and prior work that identified gaps in the measurement of care coordination to develop and pilot test a rigorous and psychometrically sound patient assessment (from the perspective of patient and family) of the quality of care coordination for adults within primary care settings—the CCQM–PC. The survey will address key care coordination domains; be appropriate for research; will set the stage for the future development of measures for quality reporting, accountability, and payment purposes; and be consistent with Consumer Assessment of Healthcare Providers and Systems (CAHPS®) principles. The instrument is to be developed, cognitively tested, revised and pilot tested. A stakeholder panel will provide input throughout the phases of the project.

There are four explicit objectives for our analysis of the pilot-test data:

- Evaluate the quality of the responses to the CCQM–PC survey (through item functioning analysis).
- Determine how the items that ask for reports of patient experiences could be summarized into a smaller set of composite measures (through factor analysis).
- Evaluate the measurement properties of the composite scales (assessment of reliability, validity, and variability of the measure).

- Identify information (i.e., case mix adjusters) that should be used to adjust scores to ensure valid comparisons among primary care practices (PCPs).

- Determine how CCQM–PC scores vary among practices that self-report processes of care that are more or less aligned with a medical home model.

This study is being conducted by AHRQ through its contractor, American Institutes for Research (AIR), pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

Thirty primary care practices of different types and ownership configurations will be recruited to provide a patient sample to AHRQ's contractor, AIR for the purpose of establishing the psychometrics of the CCQM–PC and understanding the relation of its domains to a practice-level measure of processes of care, the Medical Home Index (Long Version, MHI–LV). The CCQM–PC will be conducted by mail with phone follow-up for nonrespondents. Survey

operations for the CCQM-PC will follow standard CAHPS practice:

- Mail the questionnaire package, including a personalized letter introducing the study and explaining the respondent's rights as a research participant. Include a postage-paid envelope to encourage participation.
- Send a postcard reminder to nonrespondents 10 days after sending the questionnaire.
- Send a second questionnaire with a reminder letter to those still not responding thirty days after the first mailing.
- Begin follow-up by telephone with nonrespondents three weeks after sending the second questionnaire. Interviewers will attempt to locate respondents who have not responded to the mailed survey.
- Verify telephone numbers for sample respondents prior to calling.
- Make a maximum of 9 attempts by phone.
- Include a toll-free number in the cards and letters for respondents to call if they have questions about the survey. The firm responsible for fielding the survey will establish a helpdesk that will start operating at the first mailing and that will remain open until close of fieldwork.
- Answer incoming calls live during business hours and a recording machine will capture after hours calls. The after-hours calls will be returned next business day.
- Ask two clinicians from each participating practice complete the MHI-LV by paper-and-pencil jointly and return the form to the AHRQ contractor.

The information collected in the pilot survey will be used to test and improve the draft survey. The pilot design will support the standard suite of psychometric analyses conducted to identify and develop composite scoring algorithms as well as to provide evidence of the reliability and construct validity of the composite scores and any scores based on individual items. Additionally, the variations in composite scores and total CCQM-PC scores will be examined for any differences that may be correlated with variations in the practice's self-assessment of its engagement in processes of care that are consistent with the medical home model. The analyses will include the following components:

- Item functioning analysis

- Confirmatory Factor Analysis
- Exploratory Factor Analysis
- Evaluation of the reliability, validity, and variability of composite and single-item scores
- Case mix adjustment (if the data indicate this is needed).

Because the survey items are being developed to measure specific aspects of care coordination in accordance with the domain framework developed through previous phases of AHRQ's Care Coordination Measure Development portfolio, the factor structure of the survey items will be evaluated through multilevel confirmatory factor analysis. On the basis of the data analyses, items or factors may be dropped. Exploratory factor analysis is also planned.

Data from the pilot survey will be used to make final adjustments to the CCQM-PC. The final survey instrument will be made publicly available, at no charge, to prospective users, for use in research projects that aim to assess care coordination as it relates to quality care and healthcare outcomes, thereby helping to expand the evidence base for the care coordination construct and its associated processes. There is value, given where the field is now, in developing a survey of reasonable length that can be used for research purposes, but also can serve as the "parent" survey from which a smaller subset of items appropriate for quality improvement could be drawn.

A well-developed, psychometrically-sound, practical survey of adult patients' experiences of care coordination in primary care settings, that covers key conceptual domains articulated through AHRQ's past work in this area, will help generate evidence that is needed to understand the relationship between care coordination processes and health outcomes, in addition to offering a way to explore other critical questions regarding care coordination.

The development of this research-focused survey is a critical step in moving toward the future development of measures of care coordination in primary care settings that can be used for accountability purposes, including those submitted for consideration of endorsement by the National Quality Forum. This will ensure that the measures or measure set is useful from a public reporting perspective to a variety of potential stakeholders, including patients seeking providers

that engage in care coordination practices supported by the evidence base. The key target audiences for the use of the survey are researchers and, ultimately, payers (including health insurance plans, employers, and entities such as the Centers for Medicare & Medicaid Services), although use by health systems and individual primary care practices is also envisioned.

Estimated Annual Respondent Burden

Exhibit 1 shows the total estimated annualized burden hours for the CCQM-PC pilot survey (2,022 hours), including burden for survey respondents (1,890 hours) and practice staff (132 hours). With respect to the burden on CCQM-PC survey respondents, thirty practices will be sampled, with the survey sent to 375 prospective respondents per sample. A 40% response rate (in keeping with response rates on other CAHPS® and CAHPS®-like surveys of similar length and mode) will yield 150 respondents per practice. Total respondents were calculated by multiplying the number of practices by the respondents per practice, for a total of 4,500 (i.e., $150 \times 30 = 4,500$). The survey has 102 items (79 assessment items, 4 items about healthcare services sought in the past 12 months, and 19 items that assess participant characteristics such as demographics), with an estimated completion time of 25 minutes (.42 hours) per survey response. This estimate is based on the length of previous CAHPS® surveys of comparable length that have been administered to similar populations.

Burden hours for participating practices are calculated based on the total burden to one physician/administrator and one other clinician to complete the MHI-LV. The measure author recommends that both physician and non-physician viewpoints are considered in the PCP's response, thus the estimate is based on an assumption that two clinicians per practice will complete the MHI-LV process of care items together, with only one of the clinicians (i.e., the physician/administrator) completing the items on practice characteristics. Contract staff from AIR will ensure that practices realize there is no burden to them on the MHI-LV other than the time required to fill out the MHI-LV tool (i.e., they can ignore the measure author's reference in the instructions to a companion patient tool associated with the MHI-LV).

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: ¹ Physician/administrator	30	1	2.33	70
MHI–LV: Non-physician clinician	30	1	2.08	62
Total				2,022

¹ 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	¹ \$22.33	\$42,204
Physician/Administrator	70	² 88.43	6,190
Non-physician Clinician	62	³ 45.71	2,834
Total Overall	2,022	n/a	51,228

¹ Average wage for civilian workers, <http://www.bls.gov/news.release/ocwage.htm>.
² Average wage for family and general practitioners, <http://www.bls.gov/news.release/ocwage.htm>.
³ 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.

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).