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 healthcare research and healthcare 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: February 29, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–5574 Filed 3–8–12; 8:45 am]

BILLING CODE 4160–90–M

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: ''Demonstration of a Health Literacy Universal Precautions Toolkit.'' 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 May 8, 2012.

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

Demonstration of Health Literacy Universal Precautions Toolkit

A goal of Healthy People 2020 is to increase Americans' health literacy, defined as, ''the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.'' The effects of limited literacy are numerous and serious, including medication errors resulting from patients' inability to read labels; underuse of preventive measures such as Pap smears and vaccines; poor self-management of conditions such as asthma and diabetes; and higher rates of hospitalization and longer hospital stays.

According to the 2003 National Assessment of Adult Literacy (NAAL), more than one-third of Americans—77 million people—have limited health literacy. Although some adults are more likely than others to have difficulty understanding and acting upon health information (*e.g.,* minority Americans, elderly), providers cannot tell by looking which patients have limited health literacy. Experts recommend that providers assume all patients may have difficulty understanding health-related information. Known as adopting ''health literacy universal precautions,'' providers create an environment in which all patients benefit from clear communication.

AHRQ contracted with the University of North Carolina at Chapel Hill to develop the Health Literacy Universal Precautions Toolkit to help primary care practices ensure that systems are in place to promote better understanding of health-related information by all patients. As part of Toolkit development, testing of a ''prototype Toolkit'' was conducted in eight primary care practices over an eight-week period. Testing provided important information about implementation and resulted in refinement of the Toolkit, which AHRQ made publically available in Spring 2010. At this time, the Toolkit includes 20 tools to prepare practices for health literacy-related quality improvement activities and to guide them in improving their performance related to four domains: (1) Improving spoken communication with patients, (2) improving written communication with patients, (3) enhancing patient self-management and empowerment, and (4) linking patients to supportive systems in the community.

The tools included in the Health Literacy Universal Precautions Toolkit are listed below:

Tools To Start on the Path to Improvement

Tool 1: Form a Team
Tool 2: Assess Your Practice
Tool 3: Raise Awareness

Tools To Improve Spoken Communication

Tool 4: Tips for Communicating Clearly
Tool 5: The Teach-Back Method
Tool 6: Follow up with Patients
Tool 7: Telephone Considerations
Tool 8: Brown Bag Medication Review
Tool 9: How to Address Language Differences
Tool 10: Culture and Other Considerations

Tools To Improve Written Communication

Tool 11: Design Easy-to-Read Material
Tool 12: Use Health Education Material Effectively
Tool 13: Welcome Patients: Helpful Attitude, Signs, and More

Tools To Improve Self-Management and Empowerment

Tool 14: Encourage Questions
Tool 15: Make Action Plans
Tool 16: Improve Medication Adherence and Accuracy
Tool 17: Get Patient Feedback

Tools to Improve Supportive Systems

Tool 18: Link Patients to Non-Medical Support
Tool 19: Medication Resources
Tool 20: Use Health and Literacy Resources in the Community

AHRQ will now conduct a demonstration of the Health Literacy Universal Precautions Toolkit. The purpose of this demonstration project is to explore whether the Toolkit helps motivated practices to make changes intended to improve communication with and support for patients of all literacy levels. Twelve primary care practices will be recruited to implement at least four tools from the Health Literacy Universal Precautions Toolkit. The project team will provide participating practices with limited technical assistance throughout the implementation period. Data regarding the assistance provided will contribute

to the team's assessment of the ease with which specific tools can be implemented and will provide insight into additional resources and guidance that might be valuable to add to the Toolkit.

This study is being conducted by AHRQ through its contractors, the University of Colorado, the American Academy of Family Physicians National Research Network and Synovate, Inc., under its statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness, and value of health care services and with respect to quality measurement and improvement (42 U.S.C. 299a(a)(1) and (2)).

Method of Collection

To achieve the goals of this project the following activities and data collections will be implemented:

(1) Practice Screening Calls: To recruit practices into the project, the project team will conduct screening calls with all interested practices, typically with the lead physician or practice administrator. The introductory script presents an overview of the project. For those practices that agree to participate, some basic data about the practice will be collected, such as the type of practice, the number of full and part time clinicians, the number of patients seen in a typical week and the percentage of patients enrolled in Medicaid.

(2) Health Literacy Assessment Questions: In implementing Tool 2, which guides practices in conducting a self-assessment of their health literacy-related systems and procedures, practices will complete the Health Literacy Assessment Questions at the beginning of the project. We will request that they complete the same items again following implementation so that we may examine whether these items suggest change over time. Practices will collect responses from staff members representing different components of the practice (*e.g.,* clinicians, front desk staff). A member of the practice staff, who will be designated the project coordinator, will oversee collection of survey data.

(3) Implementation Tracking Form: The Implementation Tracking Form will be completed by the leader of the Health Literacy Team at the beginning of the project period and updated prior to each check-in phone call with project staff (see item 13 below). (As part of implementation of Tool 1, participating practices will establish a Health Literacy Team to oversee Toolkit implementation.) This form elicits information about the timing with which different steps in the implementation process were completed (*e.g.,* when was the first training conducted).

(4) Webinar/Orientation: Prior to beginning data collection, we will conduct a Webinar with all practices to review the pre-implementation data collection requirements and provide an overview of Tools 1 and 2, which practices are to complete prior to our conducting site visits. Up to four members of the Health Literacy Team or other practice members will attend.

(5) On-site Observation: At pre- and post-implementation, the project team will conduct an observational review of the practice environment to assess health literacy-related features, such as readability of patient materials in the waiting room and ease of patient navigation. This data collection activity involves no burden to participating practices and their patients and, therefore, is not included in the burden estimates in Section 12.

(6) Patient Survey: The Patient Survey will be collected at pre- and post-implementation and is designed to obtain patient input on health literacy-related performance of providers and staff (*e.g.,* ''did your provider use medical words you did not understand''). Each practice will recruit 50 patients at each time point to complete the survey. The survey will include the same items at the two time points. The on-site project coordinator will oversee recruitment and collection of survey data.

(7) Survey Using Items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS): In two of the participating practices, selected health literacy-related items from the CAHPS Clinician and Group Survey will be administered at pre- and post-implementation. Surveys will be sent by mail, with phone follow up. Across practices and the two time points (pre- and post-implementation), we will collect surveys for 1800 patients.

(8) Medication Review Form: Each practice that chooses to implement Tool 8 (Brown Bag Medication Review) will conduct medication reviews with 20 patients at pre-implementation and 20 at post-implementation, completing the Medication Review Form for each review (we estimate that 3 of the 12 participating practices will choose to implement Tool 8.) During these reviews, the Medication Review Form will be completed to record errors found in the medication regimen (*e.g.,* expired medications, incorrect dosing, patient misunderstanding of regimen). So that this data collection activity will be of value to practices and patients, reviews will be conducted with patients identified through routine clinical practice (*e.g.,* the prescription refill process, regular follow-up visits) to require a full review of current medications.

(9) Practice Staff Survey: We will request that all staff members of participating practices complete the Practice Staff Survey, which elicits staff perceptions regarding health literacy-related practices (*e.g.,* staff use of effective communication techniques and confirmation of patient comprehension). Surveys will be completed at pre-implementation and post-implementation, with items varying slightly at the two time points. The project coordinator for each practice will oversee collection of survey data.

(10) Health Literacy Team Leader Survey: The leader of the Health Literacy Team will complete this survey at pre- and post-implementation to provide data regarding health literacy-related policies and details regarding Toolkit implementation (*e.g.,* has the reading level of written patient materials been assessed, how does the practice remind patients to bring in medication bottles to facilitate medication reviews).

(11) Health Literacy Team Leader Interview: The leader of the Health Literacy Team will be interviewed in person at pre- and post-implementation. At the beginning of the project, this qualitative interview will focus on expectations regarding implementation (*e.g.,* expected barriers) and technical assistance needs. The post-implementation interview is designed to elicit detailed information about the implementation process, suggested revisions to the Toolkit, and an assessment of the technical assistance provided.

(12) Check-in Phone Calls: To ensure that practices stay on track, the project team will contact practices on a regular schedule to assess progress and provide facilitation that might be needed to help practices address barriers they may be experiencing. Calls will take place two weeks, one month, two months, and four months into implementation and will involve the leader of the Health Literacy Team.

(13) Health Literacy Team Member Interview: So that we may obtain information about the implementation process as well as functioning of the Health Literacy Team (*e.g.,* how difficult was it to reach decisions about which tools to implement), we also will interview a member of the Team other than the Team leader at post-

implementation. Interviews will be conducted on site at the practice.

(14) Practice Staff Member Interview: So that we can obtain input about Toolkit implementation and project participation from someone outside of the Health Literacy Team, we will conduct on-site interviews at post-implementation with one or two staff members who were not involved in the Health Literacy Team.

Data collected will be used for the following purposes:

- To explore whether/how the Toolkit assists motivated practices to take a systematic approach to reducing the complexity of health care and ensuring that patients can succeed in the health care environment. Based on the data collected, AHRQ will issue a Technical Assistance Guide for use by practice facilitators that work with Toolkit implementers and Case Studies that highlight lessons learned.
- To improve the Health Literacy Universal Precautions Toolkit, AHRQ will issue a new edition of the Toolkit based on insights from this study.
- To see whether items from the CAHPS Item Set for Addressing Health Literacy are sensitive to quality improvement activities. AHRQ will use the findings to modify the document entitled ''About the CAHPS Item Set for Addressing Health Literacy,'' which discusses use of the items for quality improvement.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this research.

- Practice Screening Calls will be conducted with one person from 20 different practices, with 12 practices expected to ''screen-in'' and be included in this project. The screening calls will take 20 minutes.
- The Health Literacy Assessment Questions will be completed twice; once at pre-implementation and again at post-implementation. We estimate that five staff members from each of the 12 practices will complete the questionnaire at each time point, for a total of 120 respondents, and will require 30 minutes to complete. (The same staff members will not be targeted to complete the survey at both time points.) A staff member will distribute and collect the survey, which we estimate will take approximately five minutes per survey.
- The Implementation Tracking Form will be completed at the beginning of the project and updated before each of the four Check-in Phone Calls and again at the end of the intervention. The form will be completed by the Leader of each practice's Health Literacy Team and will take approximately 5 minutes to complete each time.
- The Webinar/Orientation will take place at the beginning of the intervention and will include, on average, 4 staff members from each of the 12 practices and may take up to 2 hours.
- The Patient Survey will be completed at each of the 12 practices at pre-implementation and post-implementation. Fifty patients from each time period will be surveyed at each of the practices for a total of 1200 patients. The same patients will not be targeted to complete both surveys. The two surveys are identical and will take 20 minutes to complete. These will be administered by a practice staff member (recruiting patients, distributing surveys, collecting surveys). It is estimated that it will take 10 minutes of the staff member's time to administer each survey.
- The Survey Using Items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS) will be completed by mail or phone and will take approximately 12 minutes to complete. It will be completed by a total of about 1800 patients total at two of the participating practices; 900 will complete it at pre-implementation and 900 at post-implementation. The same patients will not be targeted to complete both surveys.
- The Medication Review Form will not be used by all of the participating practices. We estimate that 3 of the 12 practices will choose to implement Tool 8 from the Toolkit (Brown Bag Medication Review), and only practices implementing Tool 8 will collect these data. For practices that do complete the Medication Review Form, we expect that about four clinic staff per practice will complete this form and each will complete it approximately five times at each time point (pre-implementation and post-implementation). Therefore, a total of 12 clinical staff will complete a total of 120 Medication Review Forms and each form will take about 30 minutes to complete.
- The Practice Staff Survey will be completed twice by each staff member; about 18 staff at each of the 12 practices. The pre-implementation version of the survey will take 15 minutes to complete, whereas the post-implementation version of the survey will take 20 minutes to complete. The surveys will be disseminated and collected by a member of the practice, a role which we expect to take about five minutes for each survey.
- The Health Literacy Team Leader Survey is completed by the Team Leader at each of the practices at pre-implementation and post-implementation. The pre-implementation version of the survey will take 15 minutes to complete, whereas the post-implementation version of the survey will take 20 minutes to complete.
- During the course of the intervention, there will be four Check-in Phone Calls with the Health Literacy Team Leader at each practice. Each call will last approximately 30 minutes.
- The Health Literacy Team Leader from each practice will be interviewed at pre-implementation and post-implementation. The pre-implementation version of the interview will take about 30 minutes, whereas the post-implementation interview will take 90 minutes.
- The Health Literacy Team Member interview will target one member of the Health Literacy Team from each practice (other than the Team Leader) and will be conducted at the post-intervention time period. The interview is expected to last 90 minutes.
- For the Practice Staff Member Interview, two other staff members per practice (24 total) will be interviewed post-implementation and these will take 30 minutes to complete.

The total annualized burden hours are estimated to be 1,446 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Practice Screening Calls	20	1	20/60	7
Health Literacy Assessment Questions:				
Staff	120	1	30/60	60
Staff Administration	12	10	5/60	10

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Implementation Tracking Form	12	6	5/60	6
Webinar/Orientation	48	1	2	96
Patient Survey:				
Patients	1200	1	20/60	400
Staff Administration	12	100	10/60	200
Survey Using Items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS)	1800	1	12/60	360
Medication Review Form	12	10	30/60	60
Practice Staff Survey—Pre-implementation:				
Staff	216	1	15/60	54
Staff Administration	12	18	5/60	18
Practice Staff Survey—Post-implementation:				
Staff	216	1	20/60	72
Staff Administration	12	18	5/60	18
Health Literacy Team Leader Survey—Pre-implementation	12	1	15/60	3
Health Literacy Team Leader Survey—Post-implementation	12	1	20/60	4
Check-in Phone Calls	12	4	30/60	24
Health Literacy Team Leader Interview—pre-implementation	12	1	30/60	6
Health Literacy Team Leader Interview—post-implementation	12	1	1.5	18
Health Literacy Team Member Interview—post-implementation	12	1	1.5	18
Practice Staff Member Interview—post-implementation	24	1	30/60	12
Total	3,788	na	na	1,446

Exhibit 2 shows the estimated annual cost burden to respondents, based on their time to participate in this research. The annual cost burden is estimated to be $34,329.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate [a]	Total cost burden
Practice Screening Calls	20	7	[c] $18.52	$130
Health Literacy Assessment Questions:				
Staff	120	60	[d] 29.15	1,749
Staff Administration	12	10	[c] 18.52	185
Implementation Tracking Form	12	6	[c] 18.52	111
Webinar/Orientation	48	96	[d] 29.15	2,798
Patient Survey:				
Patients	1200	400	[b] 22.48	8,992
Staff Administration	12	200	[c] 18.52	3,704
Survey Using Items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS)	1800	360	[b] 22.48	8,093
Medication Review Form	12	60	[d] 29.15	1,749
Practice Staff Survey—Pre-implementation:				
Staff	216	54	[d] 29.15	1,574
Staff Administration	12	18	[c] 18.52	333
Practice Staff Survey—Post-implementation:				
Staff	216	72	[d] 29.15	2,099
Staff Administration	12	18	[c] 18.52	333
Health Literacy Team Leader Survey—Pre-implementation	12	3	[d] 29.15	87
Health Literacy Team Leader Survey—Post-implementation	12	4	[d] 29.15	117
Check-in Phone Calls	12	24	[d] 29.15	700
Health Literacy Team Leader Interview—pre-implementation	12	6	[d] 29.15	175
Health Literacy Team Leader Interview—post-implementation	12	18	[d] 29.15	525
Health Literacy Team Member Interview—post-implementation	12	18	[d] 29.15	525
Practice Staff Member Interview—post-implementation	24	12	[d] 29.15	350
Total	3,788	1,446	na	34,329

[a] Mean hourly and wage costs for Colorado were derived from the Bureau of Labor and Statistics National Compensation Survey for May 2010 (*http://www.bls.gov/oes/current/oesco.htm*).
[b] Hourly rate for all workers (occupation code 00–0000) estimates the cost of time for patients.
[c] Hourly rate for medical records and health information technician (29–2071).
[d] Hourly rate for Healthcare Practitioners and Technical Workers, All Other (29–9799).

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to the Federal Government for conducting this research. These estimates include the costs associated with the project such as the preparation of survey administration procedures, labor costs, administrative expenses, costs associated with copying, postage, and telephone expenses, data management and analysis, preparation of final reports, and dissemination of findings/results/products. The annualized and total costs are identical since the data collection period will last for one year. The total cost is estimated to be $784,910.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total	Annualized cost
Administration	$81,654	$81,654
Research Activities	446,201	446,201
Dissemination Activities	57,222	57,222
Final Report ..	57,864	57,864
Overhead	141,969	141,969
Total	784,910	784,910

Request for Comments

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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: February 29, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–5569 Filed 3–8–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee for Dose Reconstruction Reviews (SDRR), Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned subcommittee:

TIME AND DATE: 9 a.m.–5 p.m., March 30, 2012.

PLACE: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018. Telephone (859) 334–4611, Fax (859) 334–4619.

STATUS: Open to the public, but without a verbal public comment period. Written comment should be provided to the contact person below in advance of the meeting. To access by conference call dial the following information 1 (866) 659–0537, Participant Pass Code 9933701.

BACKGROUND: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2013.

PURPOSE: The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

MATTERS TO BE DISCUSSED: The agenda for the Subcommittee meeting includes: discussion of dose reconstruction cases under review (sets 7–10); DCAS dose reconstruction quality management and assurance activities; and dose reconstruction issues from NIOSH 10-year review.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

CONTACT PERSON FOR MORE INFORMATION: Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E–20, Atlanta GA 30333, Telephone (513) 533–6800, Toll Free 1 (800) CDC–INFO, *Email ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: March 5, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012–5792 Filed 3–8–12; 8:45 am]

BILLING CODE 4163–18–P