TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
203.23(a) and (b)	31,676	5	158,380	.25	39,595
203.23(c)	31,676	5	158,380	.08	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	.50	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2,000	6	12,000
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	.50	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	.17	2,125
203.50(b)	125	100	12,500	.50	6,250
203.50(d)	691	1	691	2.0	1,382
Total					332,769

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 15, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–17394 Filed 7–21–09; 8:45 am]

BILLING CODE 4160–01–S

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: ''Study of Factors Influencing Consumer Choices Among Health Plans and Clinicians.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection. This proposed information collection was previously published in the **Federal Register** on September 3rd, 2008 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. This notice differs from the 60 day notice in the following ways: (1) The number of responses has been decreased from 6,000 to 4,950, (2) the burden hours are decreased from 838 to 709, and (3) the descriptions of each experimental arm in the sections: Clinician Choice Experimental Design and Health Plan Choice Experimental Design were removed.

DATES: Comments on this notice must be received by August 21, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

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 e-mail at *doris.lefkowitz@ahrq.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Study of Factors Influencing Consumer Choices Among Health Plans and Clinicians''

AHRQ proposes to use an experimental design to determine factors that influence consumers' understanding and use of performance information to select among health plans and clinicians. The experimental design will include two parallel experiments, one designed to assess factors influencing choice of health plans and one designed to assess factors influencing choice of individual doctors. For both the health plan and clinician choice experiments respondents will be randomly assigned to one of six experimental arms that vary according to the type and complexity of performance information

and the size of the choice set (number of plans or doctors) included in the Web-based report. Respondents will complete the experiment through a secure online connection from their homes. Data will be derived from pre and post-test questionnaires and from server logs that record the web pages visited and viewing times.

The results of this study will be used to develop recommendations for helping consumers to better understand and more effectively use complex information to select health plans and providers, with the aim of making performance information less burdensome and more accessible, useful, and transparent to the public. This study, funded through cooperative agreements with the RAND Corporation and Harvard University, is being conducted pursuant to AHRQ's statutory mandate to promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, 42 U.S.C. 299(b)(l), and to conduct research on health care and on systems for the delivery of such health care, 42 U.S.C. 299a.

Method of Collection

Participants in this study will be recruited through the Knowledge Networks national online panel of consumers. The experimental designs of the clinician choice experiment and of the health plan choice experiment are discussed separately below.

Clinician Choice Experimental Design

Participants will see a web page labeled ''Performance Overview'' that presents performance information for a set of primary care doctors in a way that allows them to compare doctor ratings. Performance is summarized by assigning one to five stars to show how each doctor compares with others in the same geographic area. Participants can click on hyperlinks or a tab to see more detailed results. The six experimental arms differ in the type and amount of performance information presented and the number of doctors listed.

The goals of the experiment are to assess the process of consumer choice and the extent to which the Consumer Assessment of Healthcare Providers and Systems (CAHPS)-type measures are consulted, and to examine how consumers respond to different types of information about doctor quality, including quantitative patient experience measures, anecdotal reports from individual patients, and clinical performance indicators. The post-test questionnaire will elicit participants' understanding and impressions of the material they saw on the Web site and inquire about how they made their choice. Therefore, the post-test questions will differ across experimental arms.

Health Plan Choice Experimental Design

The basic design of the health plan choice experiment is similar to that used for the clinician choice experiment. The key difference in the choice set is that as is true in real-world choices health plan choice is made complex in the experiment by introducing a larger number of measures of performance, compared to those available to inform clinician choice. Even the simplest experimental arm has twice as many component measures for health plans as for clinicians. Reports from consumers include both anecdotes and a count of aggregate complaints that have been filed against the plan.

Potentially offsetting the cognitive burdens caused by additional measures, health plan choices typically involve fewer options than do clinician choices; in this choice experiment participants will face choice sets involving either 4 or 8 health plans.

A second substantial difference exists between the health plan and clinician choice experiments: the former assesses in an explicit manner the ways in which emotionality affects how consumers make use of information. It will do so in two ways. First, the counts of complaints mentioned above as an additional measure of plan performance represent a quantitative score with a stronger emotional valence than the other measures. Second, two of the experimental arms will ''prime'' respondents to think about health outcomes in a more emotionally laden manner, to see if this alters the way in which they process this information.

The goals of the experiment are to assess the process of consumer choice and the extent to which CAHPS-type measures are consulted, and to examine how consumers respond to different types of information about health plan quality, including customer services and accessibility of care issues, selected Healthcare Effectiveness Data and Information Set (HEDIS) measures for preventive care and treatment of chronic conditions, and selected reports on enrollee complaint rates and other issues. The post-test questionnaire will elicit participants' understanding and impressions of the material they saw on the Web site and inquire about how they made their choice. Therefore, the post-test questions will differ across experimental arms.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this one year experiment. All participants will complete the pre-test, which is estimated to require 5 minutes. As explained above, the experimental website varies by experimental arm; however, based on preliminary testing, each participant will require an average of 10 minutes to review the information on the site. The post-test questionnaires will require between 7 to 14 minutes to complete, depending on the experimental arm. The total burden hours are estimated to be 709 hours.

Exhibit 2 shows the respondents' cost burden associated with their time to participate in this experiment. The total cost burden is estimated to be $13,887.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Experimental group	Number of responses	Number of responses per respondent	Hours per response	Total burden hours
Clinician Choice Experiment: Pretest	750	1	5/60	63
Experimental Web site	750	1	10/60	125
Baseline/Control Arm Post-test	125	1	7/60	15
Experimental Arm #1 Post-test	125	1	8/60	17
Experimental Arm #2 Post-test	125	1	8/60	17
Experimental Arm #3 Post-test	125	1	12/60	25
Experimental Arm #4 Post-test	125	1	12/60	25
Experimental Arm #5 Post-test	125	1	14/60	29
Health Plan Choice Experiment: Pretest	900	1	5/60	75
Experimental Web site	900	1	10/60	150

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Experimental group	Number of responses	Number of responses per respondent	Hours per response	Total burden hours
Baseline/Control Arm Post-test	150	1	7/60	18
Experimental Arm #1 Post-test	150	1	8/60	20
Experimental Arm #2 Post-test	150	1	12/60	30
Experimental Arm #3 Post-test	150	1	12/60	30
Experimental Arm #4 Post-test	150	1	14/60	35
Experimental Arm #5 Post-test	150	1	14/60	35
Total	4,950	na	na	709

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Experimental group	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Clinician Choice Experiment: Pretest	750	63	$19.56	$1,232
Experimental Web site	750	125	19.56	2,445
Baseline/Control Arm Post-test	125	15	19.56	293
Experimental Arm #1 Post-test	125	17	19.56	333
Experimental Arm #2 Post-test	125	17	19.56	333
Experimental Arm #3 Post-test	125	25	19.56	489
Experimental Arm #4 Post-test	125	25	19.56	489
Experimental Arm #5 Post-test	125	29	19.56	567
Health Plan Choice Experiment: Pretest	900	75	19.56	1,467
Experimental Web site	900	150	19.56	2,934
Baseline/Control Arm Post-test	150	18	19.56	352
Experimental Arm #1 Post-test	150	20	19.56	391
Experimental Arm #2 Post-test	150	30	19.56	587
Experimental Arm #3 Post-test	150	30	19.56	587
Experimental Arm #4 Post-test	150	35	19.56	685
Experimental Arm #5 Post-test	150	35	19.56	685
Total	4,950	709	na	13,887

*Based upon the mean of the average wages, ''National Compensation Survey: Occupational Wages in the United States, May 2007,'' U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for developing and conducting both the health plan and clinician choice components of this study, including the cost of designing the experiments, developing the simulated Web-based reports, conducting usability testing of the Web reports, pilot testing the experiment, collecting the data, analyzing the data, preparing reports and papers for journal submission, and the cost for AHRQ staff to oversee the project. The total and annual costs are identical since data collection will not exceed one year. The total cost is estimated to be $844,000.

EXHIBIT 3—TOTAL AND ANNUALIZED COSTS

Cost components	Total cost	Annual cost
Experimental design	$168,900	$168,900
Development of simulated Web-based reports	157,900	157,900
Pilot testing	56,000	56,000
Usability testing of Web-based reports	56,300	56,300
Data collection via Knowledge Networks	126,000	126,000
Data analysis	56,300	56,300
Preparation of reports and journal papers	112,600	112,600
AHRQ project management	110,000	110,000
Total	844,000	844,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, 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 8, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–17203 Filed 7–21–09; 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: ''Health Literacy Item Set Supplemental to CAHPS Hospital Survey—Pretest of Proposed Questions and Methodology.'' In accordance with the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on May 13th, 2009 and allowed 60 days for public comment. The purpose of this notice is to allow an additional 30 days for public comment. This notice differs from the 60 day notice in the following ways: (1) The burden hours are increased from 200 to 250, and (2) an incentive experiment has been added.

DATES: Comments on this notice must be received by August 21, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

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 e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

''Health Literacy Item Set Supplemental to CAHPS Hospital Survey—Pretest of Proposed Questions and Methodology''

AHRQ proposes to conduct a pretest of the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Hospital Survey health literacy module. The CAHPS program is a multi-year initiative of the Agency for Healthcare Research and Quality. AHRQ first launched the program in October 1995 in response to concerns about the lack of good information about the quality of health plans from the enrollees' perspective. Numerous public and private organizations collected information on enrollee and patient satisfaction, but the surveys varied from sponsor to sponsor and often changed from year to year. The CAHPS® program was designed to make it possible to compare survey results across sponsors and over time, and to generate tools and resources that sponsors can use to produce understandable and usable comparative information for consumers.

Over time, the program has expanded beyond its original focus on health plans to address a range of health care services to meet the various needs of health care consumers, purchasers, health plans, providers, and policymakers. Based on a literature review and an assessment of currently available questionnaires, AHRQ identified the need to develop a health literacy module for the CAHPS® Hospital Survey. The intent of the planned module is to examine patients' perspectives on how well health information is communicated to them by healthcare professionals in the hospital setting. The objective of the new module is to provide information to health plans, hospitals, clinicians, group practices, and other interested parties regarding the quality of health information delivered to patients. The set of questions about health literacy will be evaluated as a supplement to the CAHPS® Hospital Survey.

This study will be conducted for AHRQ by its contractor, RAND Corporation. It is being conducted pursuant to AHRQ's statutory authority to conduct research and evaluations on health care and systems for the delivery of such care, including activities with respect to (1) the quality, effectiveness, efficiency, appropriateness and value of health care services. See 42 U.S.C. 299a(a)(1).

This study is a one-time field test to be completed in the calendar years 2009 and 2010. The field test to be conducted under this request will be done for the following purposes:

a. Analysis of item wording—Assess candidate wordings for items.

b. Analysis of participation rate—Evaluate the overall response rate and the proportion of that obtained from mail versus telephone modes of data collection.

c. Case mix adjustment analysis—Evaluate variables that need to be considered for case mix adjustment of scores.

d. Psychometric analysis—Provide information for the revision of the health literacy item set based on the assessment of the reliability and validity.

e. Incentive experiment—Provide information on the effectiveness of a post-paid, $5 incentive as a mechanism to enhance response by randomizing half the sample at one site to an experiment in which a post-paid incentive of $5 is provided for completing the survey.

The end result will be collection of the data related to the assessment of patients' perspective on how well health information is communicated to them by health care professionals in a hospital setting. The field testing will ensure that future data collections yield high quality data and minimize respondent burden, increase agency efficiency, and improve responsiveness to the public. The survey items will be added to currently available CAHPS® surveys and will enhance the ability of hospitals to assess the quality of their services.

Method of Collection

The potential respondent universe is persons who had at least one overnight stay at a hospital within the previous five months. Excluded from the study will be those who were less than 18 years old at the time of their admission, had a psychiatric diagnosis, were discharged to a hospice facility or died during the hospitalization. Testing sites will be selected purposively based on several considerations, including ability to execute the activities necessary to participate in the pilot, number of beds, number of discharges for medical, surgical, and obstetric patients, average length of stay, location (urban versus rural), profit status, and academic medical center status.

The draw will be a sample large enough to yield approximately 600 completes. It is assumed that