and the intended use(s) of survey data. Individuals and organizations contacted will be assured of the confidentiality of their replies under 42 U.S.C. 924(c).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the medical offices' time to participate in this one-time data collection. It is anticipated that an average of 20 persons (about 6 physicians and 14 staff) in each of the 350 medical offices will respond to the survey, resulting in 7000 responses (approximately 2,000 physicians and 5,000 staff). The Survey on Patient Safety and the Post-Survey Evaluation will be completed by both physicians and staff, while the Office Characteristics Survey will be completed by the office manager at each of the 350 participating medical offices. Each survey will require approximately 15 minutes to complete. The total annualized burden for the medical offices to participate in this project is estimated to be 3,588 hours.

Exhibit 2 shows the estimated cost burden to participate in this project. The total annualized cost burden, based on the burden hours and hourly rates of the physicians and staff, is estimated at $99,368.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Survey name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Survey on Patient Safety (SOPS)	350	20	15/60	1,750
Office Characteristics Survey	350	1	15/60	88
Post-Survey Evaluation	350	20	15/60	1,750
Total	1,050	na	na	3,588

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Survey name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Survey on Patient Safety (SOPS)	350	1,750	$27.44	$48,020
Office Characteristics Survey	350	88	37.82	3,328
Post-Survey Evaluation	350	1,750	27.44	48,020
Total	1,050	3,588	na	99,368

* For the SOPS and Post-Survey Evaluation the wage rate is the national average wage for ''healthcare practitioner and technical occupations.'' For the Office Characteristics Survey the hourly wage is the national average wage for ''medical and health services managers.'' National Compensation Survey: Occupational Wages in the United States 2006, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

The total cost to the Government for conducting this research will be approximately $340,000. This estimate includes the costs of medical office identification and recruitment; data collection and aggregation; shipping, inputting and cleaning of data; analysis and report writing.

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: September 9, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–21822 Filed 9–18–08; 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: ''Conducting Measurement Activities in Support of the AHRQ Health IT Initiative.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by November 18, 2008.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail 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 e-mail at *doris.lefkowitz@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Conducting Measurement Activities in Support of the AHRQ Health IT Initiative

Over the past 35 years, AHRQ and its predecessor agencies have made adoption of health information technology (IT) an agency priority. In addition, AHRQ-supported research has helped to demonstrate the potential of health IT to enhance health care quality and patient safety. As the lead federal research agency on the quality, safety, efficiency, and effectiveness of health care in America, AHRQ plays a central role in efforts to increase the adoption of health IT.

Consistent with its mission, AHRQ proposes to develop measures of four indicators of performance of its health IT portfolio, namely:

1. Reduction in medication errors due to adoption of electronic prescribing systems;
2. The number of persons who can access their medication information online;
3. The number of clinicians who can electronically access evidence-based prevention or treatment information; and
4. The number of clinician organizations who have adopted evidence-based decision support technologies.

While secondary data are available to calculate measures 1, 3 and 4 described above, no national data exist for measure #2. Thus, this proposed information collection relates to measure #2: The number of persons who can access their medication information online.

This project is being conducted pursuant to AHRQ's statutory mandates to conduct and support research, evaluations and initiatives to advance information systems for health care improvement (42 U.S.C. 299b–3) and to promote innovations in evidence-based health care practices and technologies by conducting and supporting research on the development, diffusion, and use of health care technology (42 U.S.C. 299b–5(a)(1)).

Method of Collection

The data will be collected using a random-digit-dial (RDD) telephone survey of the U.S. adult population. To ensure a representative geographic distribution of the sample, the total sample will be allocated to each Census region in proportion to the total number of adults in each region. The survey will be administered in both English and Spanish.

Estimated Annual Respondent Burden

Exhibit 1 presents the estimated annualized burden hours for the respondents' time to participate in this project. The telephone survey will be completed by 1,000 respondents and is expected to require 12 minutes to complete. The cognitive pretest interviews, which are used to refine and validate the survey instrument, will be completed by 18 respondents (9 English-speaking and 9 Spanish-speaking) and are expected to last one hour. The total burden hours are estimated to be 218 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to participate in this project. The total cost burden is estimated to be $4,205.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Telephone Survey	1000	1	12/60	200
Cognitive Pretest Interview	18	1	1	18
Total	1018	na	na	218

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Telephone Survey	1000	200	$19.29	$3,858
Cognitive Pretest Interview	18	18	19.29	347
Total	1018	218	na	4,205

* Based upon the mean of the average wages, National Compensation Survey: Occupational Wages in the United States 2006, "U.S. Department of Labor, Bureau of Labor Statistics."

Estimated Annual Costs to the Federal Government

We are requesting approval for a one-time, one year, data collection effort. The estimated cost of this data collection is $310,067, which includes the cost of developing, administering and analyzing the survey. Exhibit 3 details labor hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expenses that would not have been incurred without this collection of information.

EXHIBIT 3. ANNUAL COSTS FOR THE ESTIMATE OF THE NUMBER OF PERSONS WHO CAN ACCESS THEIR MEDICATION INFORMATION ONLINE

	Annual cost
Labor:	
1,514 hours plus 42% fringe	$123,998
Data collection:	

EXHIBIT 3. ANNUAL COSTS FOR THE ESTIMATE OF THE NUMBER OF PERSONS WHO CAN ACCESS THEIR MEDICATION INFORMATION ONLINE—Continued

	Annual cost
Interviewer training, sample purchase, survey administration, data entry, toll calls	30,274
Other direct costs:	
Computer charge, telephone/fax/teleconference, printing and duplication, travel	28,418
Indirect costs:	
Regular overhead, 46.5%; G&A	101,775
Contract Fee	25,602
Total	$310,067

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, quality improvement and 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: September 9, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–21824 Filed 9–18–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–8003]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Home and Community Based Waiver Requests and Supporting Regulations in 42 CFR 440.180 and 441.300–310; *Use*: Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost and utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements. *Form Number*: CMS–8003 (OMB# 0938–0449); *Frequency:* Occasionally; *Affected Public*: State, Local or Tribal Governments; *Number of Respondents*: 50; *Total Annual Responses*: 136; *Total Annual Hours*: 8,010.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *October 20, 2008*.

OMB, Office of Information and Regulatory Affairs, *Attention*: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, *Fax Number*: (202) 395–6974.

Dated: September 11, 2008.

Michelle Shortt,

Director, Regulations Development Group. Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–21906 Filed 9–18–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Structured Product Labeling Content of Labeling and Electronic Drug Establishment Registration and Drug Listing for the Biologics Industry; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Structured Product Labeling (SPL) Content of Labeling and Electronic Drug Establishment Registration and Drug Listing for the Biologics Industry.'' The purpose of the public workshop is to provide the biologics industry with guidance on submitting to FDA content of labeling in SPL format, present an overview of FDA's voluntary pilot program for electronic submission of drug establishment registration and drug