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: November 12, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–27522 Filed 11–20–08; 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: ''Improving implementation of the U.S. Preventive Services Task Force recommendation for prophylactic aspirin use among adults at risk for cardiovascular disease.'' 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 January 20, 2009.

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

''Improving implementation of the U.S. Preventive Services Task Force recommendation for prophylactic aspirin use among adults at risk for cardiovascular disease.''

This proposed information collection aims to identify, test and disseminate methods to improve patient-physician communication about aspirin prophylaxis in health care systems. This project falls under AHRQ's Accelerating Change and Transformation in Organizations and Networks (ACTION) program and will be conducted for AHRQ by Abt Associates in collaboration with Geisinger Health Systems. ACTION promotes innovation in health care delivery by accelerating the development, implementation, diffusion, and uptake of demand-driven and evidence-based products, tools, strategies and findings. ACTION develops and diffuses scientific evidence about what does and does not work to improve health care delivery systems. The program emphasizes projects—that are broadly responsive to user needs and operational interests and which are expected to be generalizable across a number of settings.

In this project, a randomized controlled trial with two intervention arms and one control arm will be conducted to evaluate two interventions designed to improve physician-patient communication and decision-making regarding the use of prophylactic aspirin use among adults at risk for cardiovascular disease. Each of the three study arms will take place in one of three similar clinics.

The first intervention uses a paper ''pre-visit summary'' handout describing the benefits and possible harms of daily low-dose aspirin use to prevent heart attack in men and stroke in women. The handout is given to patients in the waiting room of non-emergency outpatient clinics. The content of the handout, including baseline cardiovascular event risk and the magnitude of potential benefits and harms of aspirin use, is generated specifically for each patient using data in his or her electronic health record. The purpose of the handout is to increase the patients' knowledge of their own cardiovascular risk and increase awareness of prophylactic aspirin regimens as a-treatment option. The study will assess whether the handout is effective in stimulating subsequent discussion with physicians about cardiovascular risk and aspirin.

The second intervention also uses the pre-visit summary handout, but adds a computer-based clinical decision support tool. During the patient's visit with the physician, the electronic health record software used by the physician will alert the physician of the patient's elevated cardiovascular risk and prompt the physician to discuss prophylactic aspirin use with the patient. If the physician chooses to do so, he or she can use a computer-based tool as a decision aid during the discussion with the patient. The tool displays the patient's risk of cardiovascular event (heart attack or stroke) and the potential risk-reducing effect of daily aspirin use. The tool also shows the likelihood of potential harms of aspirin use (*e.g.*, gastrointestinal bleeding). The tool is interactive and allows the patient and doctor to explore the expected effects of behavior change related to modifiable cardiovascular risk factors (*e.g.*, smoking cessation) as well as prophylactic aspirin use.

The proposed data collection supports the ACTION program mission by promoting health care quality improvement. The overall aim of the study is to explore the effectiveness of innovative health care delivery methods in improving patient health behaviors (*i.e.*, using aspirin prophylaxis). The study has been constructed to produce results that will be helpful in a broad range of clinic settings including those utilizing electronic health records and those that rely on paper-based record systems. The proposed data collection will assess the study's main outcome: initiating a discussion about prophylactic aspirin use between at-risk patients and their physicians in order to facilitate a shared decision-making process, and is therefore a necessary and integral element of the overall research study and of the ACTION program mission.

This project is being conducted pursuant to AHRQ's 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 42 U.S.C. 299a(a)(1). The parties involved in the study will comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR parts 160 and 164, and the study will be required to obtain approval of the institutional review boards of Geisinger Health Systems and Abt Associates.

Method of Collection

Data for this study will be collected directly from study participants (patients, doctors, and clinic staff) and indirectly from patients' electronic health records and observation of the intervention in clinic waiting rooms. The first phase of the direct data collection will occur after a patient gives his or her informed consent to participate in the study and written authorization for the use of his or her protected health information for this study. Patients will complete a 5-minute pre-visit questionnaire. Fourteen days after a patient's visit, he or she will be contacted to complete a one-time, 25-minute telephone follow-up questionnaire to assess aspirin use, knowledge, and the relevant patient/physician encounter. Data will be collected from participating physicians through 30-minute semi-structured interviews. Similarly, a 10-minute semi-structured interview of participating clinic staff will also be administered to gather information about the feasibility and perceived effectiveness of the intervention.

Estimated Annual Respondent Burden

Exhibit 1 presents an estimate of the annual reporting time burden on respondents participating in the data collection process. Time estimates are based on experience with similar instruments used with comparable respondents. A total of 1,000 patients are expected to participate in the study, distributed into approximately equal groups across the three arms of the study. The pre-visit questionnaire will be completed by 1,000 respondents and will take about 5 minutes. The telephone follow-up questionnaire will be completed by 1,000 respondents and will take about 25 minutes. Qualitative interviews will be conducted with 10 physicians and 8 staff members from each of the two intervention clinics; the physician interview will require about 30 minutes while the staff interview will last about 10 minutes. The total estimated burden hours for the respondents' time to participate in this data collection is 513 hours.

Exhibit 2 shows the estimated cost burden based on the respondents' time to participate in this project and their hourly wage. The estimated cost burden is $10,388.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Pre-Visit Questionnaire	1,000	1	5/60	83
Telephone Follow-up Questionnaire	1,000	1	25/60	417
Qualitative Interviews: Physicians	2	10	30/60	10
Qualitative Interviews: Clinic Staff	2	8	10/60	3
Total	2,004	na	na	513

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Pre-Visit Questionnaire	1,000	83	$19.29	$1,601
Telephone Follow-up Questionnaire	1,000	417	19.29	8,044
Qualitative Interviews: Physicians	2	10	66.11	661
Qualitative Interviews: Clinic Staff	2	3	27.44	82
Total	2,004	513	na	10,388

*National Compensation Survey: Occupational wages in the United States, June 2006, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

The total cost to the government of this two-year project is expected to be $300,000. Exhibit 3 details the costs associated with this project, which include $74,206 for project development, $42,760 for data collection activities, $29,510 for data processing and analysis, $31,165 for the publication of results, $27,136 for project management and $95,222 for overhead.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annualized cost
Project Development	$74,206	$37,103
Data Collection Activities	42,760	21,380
Data Processing and Analysis	29,510	14,755
Publication of Results	31,165	15,583
Project Management	27,136	13,568
Overhead	95,222	47,611
Total	300,000	150,000

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, 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: November 6, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–27523 Filed 11–20–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–416]

Agency Information Collection Activities: Proposed Collection; 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) 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 functions; (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:* Revision of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Report; *Use:* States are required to submit an annual report on the provision of EPSDT services pursuant to section 1902(a)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a State's results in achieving its participation goal and to respond to inquiries. This collection is being submitted as a revision based on minor changes made to the form and instructions. CMS has added three additional lines of data to the form (lines 12d, 12e and 12f). This information is currently being collected; however, CMS expanded the lines to obtain a better understanding for the utilization of dental services. CMS believes there will be no additional burden for the changes made to the form. The changes were necessary to accommodate a need for more specific dental data and to preliminary notify States of a change in CPT codes. A clarification was also made to line 14 of the instructions. *Form Number:* CMS–416 (OMB# 0938–0354); *Frequency:* Yearly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site 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.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *January 20, 2009*:

1. *Electronically.* You may submit 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) 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: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 14, 2008.

Michelle Shortt,

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

[FR Doc. E8–27711 Filed 11–20–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0029]

Determination That NUBAIN (Nalbuphine Hydrochloride) Injection, 10 and 20 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that NUBAIN (nalbuphine hydrochloride) injection, 10 and 20 milligrams/milliliter (mg/ml), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nalbuphine hydrochloride injection, 10 and 20 mg/ml, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of