Violent deaths include all homicides, suicides, legal interventions, deaths from undetermined causes, and unintentional firearm deaths. The average state will experience approximately 1,000 such deaths each year.

There is no cost to respondents to participate other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)	Total burden (in hours)
State Health Departments	27	1,000	2.5	67,500

Dated: May 6, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–11128 Filed 5–12–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Conunent 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.

DATES: Comments on this notice must be received by July 13, 2009.

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

''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 (CAHPSR) 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 CAHPSR 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 CAHPSR 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 CAHPSR Hospital Survey.

This study will be conducted for AHRQ by its contactor, 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 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.

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 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 R 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 approximately 1200 patients will be sampled across all field sites with a response rate of 50%. This pretest will use a mixed mail-telephone mode of data collection which will include the following steps:

- Mailing an advanced notification letter
- Mailing of the questionnaire and cover letter
- Postcard reminder
- A second mailing of the questionnaire to non-respondents.
- Up to 10 telephone calls to every mail non-respondent approximately two weeks after the final mailing.

Every effort will be made to maximize the response rate, while retaining the voluntary nature of the effort. An advanced notice will be mailed prior to mailing the survey and will include a letter explaining what the survey is about, who is doing it and why, and providing contact information for questions. The second mailing and telephone follow-up are expected to result in significant increases in response. Every effort to maximize the response rate among Spanish-speaking respondents will be made. A Spanish version of the advance notice, the questionnaire, cover letters, and the reminder card, as well as a Spanish version of the telephone transcript have been developed. The cover letters in English include a note in Spanish instructing respondents to call a toll free number if they would like to receive a copy of the survey in Spanish. In addition, participating field sites will ask for information on language preference and/or race/ethnicity of sample patients so that the mailing of the survey can be tailored for Spanish-speakers.

Finally, phone follow-up to respondents who do not complete the survey by mail will be conducted by bilingual interviewers so that those who want to complete the survey by telephone in either English or Spanish can be accommodated.

Surveys generally do not yield complete responses from every individual sampled from the population. In this analysis, patterns of both unit and item nonresponse will be examined and modeled, and the potential impact of nonresponse bias assessed. A common set of administrative variables (e.g., age, gender, race/ethnicity) will be used to predict unit nonresponse. These variables and others collected on the survey itself will be used as predictors of item nonresponse. Case mix adjustment and nonresponse weights will be used to more accurately reflect consumer experiences with health care in the field test hospitals. Multivariate logistic regression models will be used to analyze the factors associated with unit nonresponse and item nonresponse.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this data collection. The CAHPS Hospital Survey Health Literacy Module will be completed by about 600 persons in total, or an annual average of 400 persons per year for the 18 months of the pretest. The estimated response time of 20 minutes is based on the written length of the survey and AHRQ's experience with previous CAHPS® surveys of comparable length that were fielded with similar samples. The total annualized burden hours are estimated to be 133 hours.

Exhibit 2 shows the respondents' cost burden associated with their time to participate in this data collection. The total annualized cost burden is estimated to be $2,601.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Mail survey with reminder card, mail and phone follow-up mail and phone follow-up	400	1	20/60	133
Total	400	1	na	133

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Mail survey with reminder card, mail and phone follow-up	400	133	$19.56	$2,601
Total	400	133	na	2,601

*Based upon 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

The total cost for the contracted service is approximately $245,000 and the cost for AHRQ staff to oversee the project is $50,000, including benefits. The project was initiated in October of 2008 and it is forecasted that it will be completed in 18 months. It is estimated that the total cost of the project is approximately $295,000. The annualized cost of the project is approximately $196,669.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annualized cost
Review of literature	$20,000	$13,334
Cognitive interviews	60,000	40,000
Field test	90,000	60,000
Data analyses	40,000	26,667
Finalize survey	35,000	23,334
AHRQ project management	50,000	33,334
Total	295,000	196,669

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: May 4, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–11012 Filed 5–12–09; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0122] (formerly Docket No. 2004D–0327)

Compliance Guidance for Small Business Entities on Labeling Over-the-Counter Human Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act. It is intended to help small businesses better understand and comply with the agency's over-the-counter (OTC) labeling requirements and to prepare new labeling. This compliance guidance finalizes the draft compliance guidance published on December 9, 2004.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this compliance guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the compliance guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the compliance guidance document.

FOR FURTHER INFORMATION CONTACT: Marina Y. Chang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5418, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' FDA has prepared this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act. This is one of several guidances the agency has developed to help manufacturers, packers, and distributors implement the final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format requirements for the labeling of OTC drug products (21 CFR 201.66). This regulation is intended to standardize labeling for all OTC drug products so consumers can easily read and understand OTC drug product labeling and use these products safely and effectively. The regulation requires manufacturers to present OTC drug labeling information in a prescribed order and format. The standardized format requires revision of all existing labeling and covers all OTC drug and drug-cosmetic products, whether marketed under a new drug application, abbreviated new drug application, or OTC drug monograph (or drug product not yet the subject of a final OTC drug monograph).

Following issuance of the final rule, the agency received a number of inquiries from manufacturers seeking guidance on how to present the labeling information for their OTC drug products using the standardized content and format requirements. To address these inquiries, FDA published a notice in the **Federal Register** of December 9, 2004 (69 FR 71420), announcing the availability of a draft compliance guidance for small business entities entitled ''Labeling OTC Human Drug Products; Small Entity Compliance Guide.'' The draft compliance guidance summarizes the new Drug Facts labeling requirements set forth in § 201.66. The