Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for the 45 CME/CE/CEU modules (15 per year for 3 years). The total cost is estimated to be $3,963,150.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Development of CME/CE/CEU Module	$2,256,300	$752,100
Module Accreditation	900,000	300,000
Module Dissemination	450,000	150,000
Evaluation instrument development and dissemination, data collection, processing and analysis	356,850	118,950
Total	$3,963,150	$1,321,050

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 15, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–4130 Filed 2–25–11; 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 Patient Safety System Implementation for Patients with Limited English Proficiency." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on December 2010 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by March 30, 2011.

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

Improving Patient Safety System Implementation for Patients With Limited English Proficiency

According to the 2009 American Community Survey (U.S. Census Bureau), approximately 57 million people—20% of the U.S. population—speak a language other than English at home. Of that number, approximately 24 million (8.6% of the U.S. population) are defined as having Limited English Proficiency (LEP), meaning that they report speaking English less than "very well." Recent research suggests that adverse events affect LEP patients more severely than they affect English-speaking patients. In addition to linguistic barriers, LEP patients often face cultural barriers to care and low health literacy as well.

AHRQ proposes to develop a new training program to improve patient safety system implementation for patients with limited English proficiency. The new training program is designed as a continuing education module within the TeamSTEPPS system. TeamSTEPPS is an evidence-based framework to optimize team performance across the healthcare delivery system with the goal of improving patient safety. This system has been successfully implemented in numerous hospitals across the United States. The TeamSTEPPS curriculum is an easy-to-use comprehensive multimedia kit that includes modules in text and presentation format, video vignettes to illustrate key concepts, and workshop materials, including a supporting CD and DVD, on change management, coaching, and implementation. Portions of the training module may also be useful for hospitals that have not implemented TeamSTEPPS. The new training module will show how TeamSTEPPS principles can be better implemented to improve the safety of patients with LEP.

AHRQ proposes to field-test this module by conducting case studies of its implementation in three hospitals. The primary goals of this field test are to identify needed changes in the training module content or format to increase the feasibility of implementation and improve module outcomes including audience response, learning, adoption of recommended team behaviors, and improved outcomes for LEP patients. Patient outcome measures for this project include the patient's access to an interpreter and how well they

understood instructions from the hospital staff.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare 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 will be implemented:

(1) Readiness Assessment Survey of whether a hospital has the right policies in place to implement the training module. The readiness assessment will be completed by the key contact person (hospital champion) at each site. The assessment may be completed in consultation with other members of a "change team" that the hospital champion may form to support the initiative.

(2) Pre-work for Master-Training, including a survey, process map exercise, and a request to locate the hospital's or organization's policy on accessing language services. The pre-work will be completed by one of the hospital staff persons selected to be a Master-Trainer at each site.

(3) Master Training session in which two staff members from each of three participating hospitals will learn how to teach the training module. The TeamSTEPPS system requires at least two trainers for each hospital because its implementation is a team endeavor. Trainers will be selected either by the hospital champion, or by the "change team" formed by the hospital champion to support the intervention. Trainers will be selected from among natural leaders working within the hospital unit where the training will take place. Ideally the team will include a provider (*e.g.*, doctor, nurse) and an interpreter. Hospital staff selected to attend the training will be required to travel to Boston for the training session.

(4) Staff Training session using the training module developed for this project. Training participants will be drawn from the interprofessional care team in one or more hospital units (*e.g.,* ob/gyn, surgery, *etc.*). This team may include nurses, physicians, technicians, front desk staff, and interpreters. Since the training teaches team behaviors, the entire interprofessional care team in a given hospital unit will be asked to attend the training session together. The training will be conducted onsite by the hospital staff members who attended the Master Training.

(5) Training Participant Satisfaction Survey to assess trainee satisfaction with, and perceived adequacy of, the training module. This questionnaire will be administered at the end of the training module.

(6) Learning Outcomes Survey to assess staff knowledge about the best way to handle situations with LEP patients. To measure the change in staff knowledge resulting from the training module this questionnaire will be administered both before and after the training.

(7) Pre-training Behavior Survey to assess trainee behavior change resulting from the training. The behavior measured by this survey is the hospital staffs' use of interpreters when interacting with LEP patients. To measure the change in staff behavior resulting from the training module, questions from this survey are repeated in the post-training behavior survey. Interpreters are exempt from this questionnaire because the questions relate to interpreter use.

(8) Post-Training Behavior Survey to assess trainee use of interpreters when interacting with LEP patients (repeated from the Pre-Training Behavior Survey) and questions to assess the use of team communication tools demonstrated during the training.

(9) Patient Outcome Survey to measure change in patient communication and safety outcomes resulting from the training. This survey's target audience is all patients identified as LEP. The purpose of this survey is to measure intermediate outcomes related to LEP patients' access to language services, comprehension, and satisfaction with services.

(10) Semi-Structured Follow-Up Interview to assess hospitals' experiences implementing the training module. This semi-structured interview's target audience consists of up to two master-trainers or change team members in each hospital where the training module is implemented. These interviews will be conducted 3 times at the 2-week, 6-week and 10-week mark after the training.

(11) Semi-Structured Site Visit Interview to assess the hospitals' experiences implementing the training module. This semi-structured interview's target audience consists of up to 6 persons who may include master-trainers, change team members, frontline staff members, or other persons designated by the "hospital champion" as persons who might provide insight into module implementation and outcomes. These interviews will be conducted 3 months after the training.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for this one-year data collection process. Time estimates are based on experience with similar instruments used with comparable respondents. The Readiness Assessment Survey will be completed by the key contact/project champion at each of the 3 participating hospitals and will take about 5 minutes. The pre-work for the Master-Training will be completed by the two trainers selected for each site and will take about 30 minutes. The Master-Training will be conducted with 2 staff members from each hospital and will last 4.5 hours; the burden estimate of 12.5 hours includes 8 hours of travel time to and from the training site. Staff Training will include up to 30 staff members at each hospital (plus the 2 trainers who are staff members) and will last 1 hour. The Training Participant Satisfaction Survey will be completed by Staff Training participants at the end of the training and takes 5 minutes to complete. The Learning Outcomes Survey will be administered twice, before and after the training, and will require 10 minutes. The Pre-Training Behavior Survey will be administered to all staff invited to the training except for interpreters. It will require approximately 5 minutes. Interpreters do not complete this questionnaire because the questions relate to interpreter use. The Post-training Behavior survey will be administered two or more weeks after the training to all staff who were invited to the training, and will take approximately 7.5 minutes to complete. The Patient Outcome Survey will be administered twice, before and after the intervention, to a sample of approximately 90 patients (30 from each of the 3 participating hospitals) and requires about 10 minutes to complete. Semi-Structured Follow-up interviews will be conducted three times over a 12-week period with two master trainers or change team members from each hospital. Each semi-structured follow-up interview will last for about an hour. Semi-Structured Site visit interviews will be conducted with 6 staff members from each hospital and will take an hour to complete. The total annualized burden hours are estimated to be 295 hours.

Exhibit 2 presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be about $6,980.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Readiness Assessment Survey	3	1	5/60	0.25
Pre-Work for Master-Training	3	2	30/60	3
Train the Trainer Training	3	2	12.5	75
Staff Training	3	32	1	96
Training Participant Satisfaction Survey	3	30	5/60	8
Learning Outcomes Survey	3	60	10/60	30
Pre-Training Behavior Survey	3	25	5/60	6
Post-Training Behavior Survey	3	30	7.5/60	11
Patient Outcome Survey	90	2	10/60	30
Semi-Structured Follow-up interview	3	6	1	18
Semi-Structured Site visit interview	3	6	1	18
Totals	117	na	na	295

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method	Number of respondents	Total burden hours	Average hourly wage rate *	Totals cost burden
Readiness Assessment Survey	3	0.25	$26.50	$7
Pre-Work for Master-Training	3	3	26.50	80
Train the Trainer Training	3	75	26.50	1,988
Staff Training	3	96	22.02	2,114
Training Participant Satisfaction Survey	3	8	22.02	176
Learning Outcomes Survey	3	30	22.02	661
Pre-Training Behavior Survey	3	6	22.04	132
Post-Training Behavior Survey	3	11	$22.02	$242
Patient Outcome Survey	90	30	20.90	627
Semi-Structured Follow-up interview	3	18	26.50	477
Semi-Structured Site visit interview	3	18	26.50	477
Totals	117	295	na	6,980

* The average hourly wage rate for readiness assessments, train-the-trainer trainings, semi-structured site visit interviews, and semi-structured follow-up interviews was calculated based on the average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $31.02 and the average hourly wage rate for interpreters and translators, $21.97. The average hourly rate for staff receiving training was calculated based on the average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $31.02, mean hourly wage rate for interpreters and translators, $21.97, and mean hourly wage rate for healthcare support occupations, $13.06. The average hourly wage rate for respondents to the pre-training behavior survey was calculated based on the average of the mean hourly wage rate for healthcare practitioners and medical occupations (all professions), $31.02, and mean hourly wage rate for healthcare support occupations, $13.06. The average hourly wage rate for patients was calculated on the mean hourly wage rate for all occupations. Average hourly rate for unit staff, non-interpreter was calculated based on the average of the mean hourly rate for healthcare practitioners and medical occupations (all professions), $31.02, and occupations (all professions), $31.02, mean hourly wage rate for interpreters and translators, $21.97, and mean hourly wage rate for healthcare support occupations, $13.06. Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on "Occupational Employment and Wages, May 2009" found at the following urls: *http://www.hls.gov/oes/current/naics4_622100.htm, http://www.hls.gov/ocs/current/ocs273091.htm, http://www.hls.gov/oes/current/oes_nat.htm.*

Estimated Annual Costs to the Federal Government

The total cost of this contract to the government is $499,978. The project extends over 4 fiscal years, although data collection will take place over the course of a single year. Exhibit 3 shows a breakdown of the total cost as well as the annualized cost for the data collection, processing and analysis activity.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annual cost
Project Development	$301,664	$75,416
Data Collection Activities	52,629	13,157
Data Processing and Analysis	52,629	13,157
Publication of Results	51,658	12,915
Project Management	41,399	10,350
Total	499,978	124,995

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 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 15, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–4135 Filed 2–25–11; 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 (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b-21 to b-26, (Patient Safety Act), and its implementing regulation at 42 CFR part 3, provides for the formation of Patient Safety Organizations (PSO5), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. On December 30, 2010, HHS issued "Guidance Regarding Patient Safety Organizations' Reporting Obligations and the Patient Safety and Quality Improvement Act of 2005" (Guidance) which can be accessed electronically at: *http://www.PSO.AHRQ.gov/regulations/guidance.pdf*.

This notice announces the intention of AHRQ to request that the Office of Management and Budget (OMB) amend the approved clearance, OMB No. 0935–0143, that allows information collection related to implementation of the Patient Safety Act. This amendment includes a new attestation form related to the Guidance. In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. The purpose of this notice is to allow 30 days for public comment on the new attestation form related to the Guidance.

DATES: Comments on this notice must be received by March 30, 2011.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, AHRQ, Reports Clearance Officer, by fax at (301) 427–1000 (attention: AHRQ Reports Clearance Officer) or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov*. Copies of this proposed form and specific details on the estimated burden can be obtained from AHRQs Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427–1477.

SUPPLEMENTARY INFORMATION:

Proposed Form

This notice proposes the addition of a new attestation form, "Supplemental Attestations Regarding FDA Reporting Obligations Of PSOs," to the existing approved clearance, "Patient Safety Organization Certification for Initial Listing and Related Forms and a Patient Safety Confidentiality Complaint Form" (OMB No. 0935–0143).

In order to implement the Patient Safety Act, HHS issued the Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. Pursuant to the Patient Safety Rule, entities seeking to become and remain listed by the Secretary as PSOs submit certifications to the Secretary. These entities must certify that they meet or will meet specified statutory criteria and requirements for PSOs, as further explained in the Patient Safety Rule.

On December 30, 2010, HHS issued Guidance to address questions that have arisen regarding the obligations of PSOs where they or the organization of which they are a part are legally obligated under the Federal Food, Drug, and Cosmetic Act and its implementing regulations to report certain information to the FDA and to provide FDA with access to its records, including access during an inspection of its facilities. This proposed form will collect information from PSOs as described in the Guidance.

Methods of Collection

Existing PSOs will be required to complete this proposed form immediately; an entity seeking listing as a PSO will be required to complete this proposed form at the time it submits its certifications for initial listing. Every entity completing this proposed form will be required to attest whether it is subject to the Guidance. Entities that are subject to the Guidance will be required to make one to three additional attestations. To complete this form, a respondent will need to review each attestation, check the appropriate "yes' or "no" box that follows each applicable attestation, and complete and sign the form.

The burden estimate for completing this form is 15 minutes per respondent; fewer than 100 entities are expected to submit responses.

Estimated Annual Costs to the Federal Government

Under the Patient Safety Act and Patient Safety Rule, AHRQ collects and reviews certifications from entities that seek listing or continued listing as PSOs. Entities applying to be PSOs and existing PSOs may also be required to provide additional information to AHRQ. The cost to AHRQ of processing the information collected with the above-described form is minimal: An estimated equivalent of approximately 0.01 FTE or $1,500 and no new overhead costs.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on the above described attestation form are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's 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