ET Date	Trans No.	ET req. status	Party name
		G	B&H Contracting, L.P.
		G	RHMB Capital, LLC.
	20110168	G	Blackstone Capital Partners (Cayman) V–NQ L.P.
		G	Mark Buster.
		G	RHMB Capital, LLC.
		G	B&H Contracting, L.P.
		G	SCS Materials, L.P.
		G	RK Hall Construction Limited.
		G	Hall Materials, LTD.
17–NOV–10	20101200	G	Laboratory Corporation of America Holdings.
		G	Genzyme Corporation.
		G	Genzyme Genetic Counseling, LLC.
	20110151	G	General Electric Company.
		G	Clarient, Inc.
		G	Clarient, Inc.
18–NOV–10	20110159	G	Carlyle Partners V, L.P.
		G	Syniverse Holdings, Inc.
		G	Syniverse Holdings, Inc.
	20110160	G	Lion Capital Fund III (USD), L.P.
		G	Bumble Bee Foods, L.P.
		G	Stinson Seafood (2001), Inc.
	20110164	G	Athene Group Ltd.
		G	Royal Bank of Canada.
		G	Liberty Life Insurance Company.

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, or Renee Chapman, Contact Representative, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2010–30806 Filed 12–8–10; 8:45 am]

BILLING CODE 6750–01–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.

DATES: Comments on this notice must be received by February 7, 2011.

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

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 4½ 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*	Total 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.bls.gov/oes/current/naics4_622100.htm, http://www.bls.gov/oes/current/oes273091.htm http://www.bls.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: November 30, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–30902 Filed 12–8–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–E–0047]

Determination of Regulatory Review Period for Purposes of Patent Extension; ILARIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ILARIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human biologic product ILARIS (canakinumab). ILARIS is indicated for the treatment of Cryopyrin Associated Periodic Syndromes in adults and children 4 years of age and older including Familial Cold Autoinflammatory Syndrome and Muckle-Wells Syndrome. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ILARIS (U.S. Patent No. 7,446,175) from Novartis AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 24, 2010, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of ILARIS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ILARIS is 1,072 days. Of this time, 889 days occurred during the testing phase of the regulatory review period, while 183 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 13, 2006. The applicant claims July 12, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 13, 2006, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262:* December 17, 2008. The applicant claims December 15, 2008, as the date the biologics license application (BLA) for ILARIS (BLA 125319) was initially submitted. However, FDA records indicate that BLA 125319 was submitted on December 17, 2008.

3. *The date the application was approved:* June 17, 2009. FDA has verified the applicant's claim that BLA 125319 was approved on June 17, 2009.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 177 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments and ask for a redetermination by February 7, 2011. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 7, 2011. To meet its burden, the petition must contain sufficient facts to merit an FDA