At each of the five sites, up to 100 pharmacy staff members will be sampled, with an expected response rate of 75 percent, yielding 75 respondents per site.

Estimated Annual Respondent Burden

Exhibit 1 show the estimated annualized burden hours for the respondents' time to participate in this evaluation. The on-site interviews will require about 1 hour to complete for a total of 30 burden hours. The pre-interview questionnaire is expected to take 15 minutes to complete for a total of 9 burden hours. The phannacy staff survey will take about 30 minutes to complete for a total of 188 burden hours. The total burden hours for all data collections is estimated to be 227 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this project. The cost burden is estimated to be $10,800.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of sites	Number of responses per site	Hours per response	Total burden hours
On-Site Interviews	5	6	1.00	30
Pre-Interview Questionnaire for Demonstration Project Leaders	5	1	15/60	1
Pre-Interview Questionnaire for All Interview Participants	5	6	15/60	8
Survey of Pharmacy Staff	5	75	30/60	188
Total	20			227

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of sites	Total burden hours	Average hourly wage rate*	Total cost burden
On-Site Interviews	5	30	$47.58	$1,427
Pre-Interview Questionnaire for Demonstration Project Leaders	5	1	47.58	48
Pre-Interview Questionnaire for All Interview Participants	5	8	47.58	380
Survey of Pharmacy Staff	5	188	47.58	8,945
Total	20	227		$10,800

*Based on the national average wage for pharmacists (29–1051), 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 estimated total cost to the Federal government for this one year evaluation is $208,874. Exhibit 3 shows a breakdown of the costs.

EXHIBIT 3—ESTIMATED ANNUAL COSTS TO THE FEDERAL GOVERNMENT

Component	Total
Developing the interview guide and survey instrument	$33,905
Preparing OMB clearance submission	6,704
Site visits to each demonstration	73,368
Analyzing the data from each demonstration site	54,835
Preparing a final report	40,062
Total	208,874

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: February 2, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–2679 Filed 2–9–09; 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: ''Reducing Waste and Inefficiency through Process Redesign: Lean/Toyota Production System (TPS) Implementation.'' 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.

This proposed information collection was previously published in the **Federal Register** on November 21, 2008 and allowed 60 days for public comment. No comments were 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 12, 2009.

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

''*Reducing Waste and Inefficiency through Process Redesign:* Lean/Toyota Production System (TPS) Implementation''

AHRQ proposes to investigate the contribution of Lean/TPS to reducing waste in health care delivery systems. Lean/TPS is a process-redesign methodology adopted from Toyota Production Systems. The goal of Lean/TPS is to empower front-line staff to apply continuous quality improvement methods to reduce waste and enhance value in workflows and operations (Spear, S., Fixing healthcare from the inside, today. Harvard Business Rev., 2005 83(9), 78–91).

AHRQ is interested in assessing and disseminating promising techniques and methodologies for redesigning health care processes to reduce waste and enhance efficiency. Using a purposive sample of health care organizations and projects, AHRQ will describe and assess the ways in which Lean/TPS has been implemented and the related challenges and solutions experienced. The sampled organizations will vary in community and market characteristics, type of service (*e.g.*, inpatient/outpatient), and delivery system characteristics (*e.g.*, relationship between physicians and hospitals, ownership). AHRQ plans to disseminate the lessons learned from this project on the implementation of Lean/TPS to health care delivery systems. AHRQ will work with a contractor to complete this work, including all activities mentioned above. This project is being performed pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on healthcare delivery systems, including activities with respect to: The quality, effectiveness, efficiency, appropriateness and value of health care services; quality measurement and improvement; and health care costs, productivity, organization, and market forces. 42 U.S.C. 299a(a)(1), (2), and (6).

Method of Collection

Four or five research locations (*i.e.*, hospitals or other heath settings) will be selected to create nine case study reports. Four of the studies will employ a retrospective analytics perspective, while five will employ a prospective analytics perspective, including one study focused on the construction of a hospital. For the other eight case studies, the department will be unit of analysis for the case study. At each research location, implementation of Lean/TPS in two departments will be studied: One department with an essentially linear process (clinical laboratory, radiology, or ED) and one department with an essentially non-linear process (cardiology, GI, or med/surg unit). A linear department is one in which the process is essentially uniform and predictable for most or all services delivered. A non-linear department is one in which the process is much less uniform and predictable.

Qualitative data will be collected directly from the departments selected for this study. The collection will be accomplished using interviews (telephone and in-person), collection of documentation, and digital diaries for the five prospective case studies. The ''digital diary'' is a data collection method using a diary entry guide and a digital recorder to describe key aspects of the implementation process. The number of digital diary submissions will depend on the number and duration of the Lean/TPS projects within in each department. The in-person interviews will be conducted through a multi-day visit to each site. Only the in-person interviews and collection of documentation methods will be employed for the retrospective case studies.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours. The table includes burden for both the retrospective and prospective case studies in separate sections. As this project will collect data from establishments, we have defined each establishment as the medical or administrative department that is implementing the Lean/TPS project to be studied.

In Exhibit 1, the total burden hours in each row (Column F) is calculated as the product of the values in the other columns (Columns B–E). Thus, for each of the 5 prospective case studies, we will conduct in-person interviews with 15 administrative and clinical personnel. Each person will be interviewed twice during the 36 week data collection period. The estimated time per response is 1.0 hour for a total of 150 burden hours for in-person interviews. Using the same calculation approach, we project 23 burden hours for telephone interviews, 53 burden hours for digital diaries, and 20 burden hours for assembling documents for a subtotal of 246 burden hours for the 5 prospective case studies. For each retrospective case study, we have defined establishment as the department from which we will collect data. A total of 15 in-person interviews will be conducted with the administrative and clinical personnel during a site visit. The estimated time per response is 1.0 hour. For all 4 retrospective case studies, we estimate a total of 60 burden hours. Similar to the prospective case studies, administrative staff from each site will be asked to provide training materials, reports on Lean/TPS implementation, and/or any other documentation or existing data from previous or current Lean/TPS projects implemented and will take 4 hours. The total estimated burden for the retrospective case studies is 76 hours. The total burden hours for all 9 case studies is 322 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to provide the requested data. The hourly rate of $35.07 is an average of the administrative personnel hourly wage of $14.53 and the clinical personnel hourly wage of $62.52 for physicians and $28.15 for registered nurses. The average hourly wage of administrative and clinical personnel is used to estimate the cost of in-person interviews, telephone interviews, and digital diaries, because all kinds of staff may be asked to participate in these three activities. The average hourly wage for administrative personnel—$14.53—is used to estimate the cost of assembling documentation, because administrative support staff will perform this task. The total estimated cost burden is about $10,554.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of establishments	Number of respondents per establishment	Number of responses per respondent	Hours per response	Total burden hours
A	B	C	D	E	F
Prospective Case Studies & Hospital Case Study					
In-person interviews	5	15	2	1	150
Telephone interviews	5	3	3	30/60	23
Digital Diaries	5	2	32	10/60	53
Collection of documentation	5	1	1	4	20
Prospective Subtotal	20	n/a	n/a	n/a	246
Retrospective Case Studies					
In-person interviews	4	15	1	1	60
Collection of documentation	4	1	1	4	60
Retrospective Subtotal	8	n/a	n/a	n/a	76
Grand Total	28	n/a	n/a	n/a	322

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of establishments	Total burden hours	Average hourly wage rate*	Total cost burden
Prospective, Retrospective, & Hospital Case Studies				
In-person interviews	9	210	$35.07	$7,365
Telephone interviews	5	23	35.07	807
Digital Diaries	5	53	35.07	1,859
Collection of documentation	9	36	14.53	523
Total	28	322	n/a	10,554

*Based upon the average hourly wages of administrative support personnel, physicians, and registered nurses, National Compensation Survey: Occupational Wages in the United States 2005, U.S. Department of Labor, Bureau of Labor Statistics.

Estimated Annual Costs to the Federal Government

The total cost to the Federal Government for this project is $494,999, with an average annual cost of $247,500. This figure includes the cost of data collection, data analysis, reporting, and contract oversight by the government. Exhibit 3 shows the individual cost components.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annualized cost
Project Development	$19,885	$9,942
Data Collection Activities	231,339	115,670
Data Processing and Analysis	62,621	31,310
Publication of Results	67,087	33,544
Project Management	21,349	10,675
Overhead	77,532	38,766
Government Oversight	15,186	7,593
Total	494,999	247,500

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQs 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's 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: February 2, 2009.

Carolyn M. Clancy,

Director.

[FR Doc. E9–2680 Filed 2–9–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the CDC announces the following meeting of the aforementioned committee:

Time and Date: 3 p.m.–4:30 p.m., February 24, 2009.

Place: The teleconference call will originate at the CDC. For details on accessing the teleconference is located in the supplementary information.

Status: Open to the public, teleconference access limited only by availability of telephone ports.

Purpose: The committee will provide advice to the CDC Director on strategic and other broad issues facing CDC.

Matters to be Discussed: The Advisory Committee to the Director will discuss and decide on recommendations from its Ethics Subcommittee, National Biosurveillance Advisory Subcommittee, and Budget Workgroup. The Ethics Subcommittee will make recommendations on using travel restrictions for individuals with infectious illnesses. The Ethics Subcommittee will also discuss a draft charge that clearly articulates the ethical foundation for focusing on health protection activities and examining the social determinants of health. The National Biosurveillance Advisory Subcommittee will seek approval on recommendations for latitude to share specific points with key members of the new administration. The Budget Workgroup will provide recommendations around principles for change, in terms of the budget and the budget structure and process for the CDC.

Agenda items are subject to change as priorities dictate.

Supplementary Information: This conference call is scheduled to begin at 3 p.m. Eastern Standard Time. To participate in the teleconference, please dial 1 (888) 323–9787 and enter conference code 4735949.

Contact Person for More Information: Brad Perkins, M.D., M.B.A., Executive Officer, ACD, CDC, 1600 Clifton Road, NE., M/S D–14, Atlanta, Georgia 30333. *Telephone:* (404) 639–7000.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. E9–2805 Filed 2–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Assessing the Accuracy of Self-Report of HIV Testing Behavior, Program Announcement Number (PA) 09–002

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting.

Time and Date: 8 a.m.–5 p.m., March 20, 2009 (Closed).

Place: Sheraton Gateway Hotel, Atlanta Airport, 1900 Sullivan Road, Atlanta, GA 30337, Telephone (770) 997–1100.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of ''Assessing the Accuracy of Self-Report of HIV Testing Behavior, Program Announcement Number (PA) 09–002.''

Contact Person for More Information: Gregory Anderson, M.P.H., M.S., Scientific Review Administrator, Strategic Science and Program Unit, Office of the Director, Coordinating Center for Infectious Diseases, CDC, 1600 Clifton Road, Mailstop E–60, Atlanta, GA 30333, *Telephone:* (404) 498–2275.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: February 3, 2009.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E9–2803 Filed 2–9–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0339]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 12, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–NEW and title ''Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices

In the **Federal Register** of June 12, 2008 (73 FR 33438), FDA announced the availability of a draft guidance for