

IP marketplace? How will they affect innovation and competition?

7. How does uncertainty regarding the validity and scope of patents affect the operation of the IP marketplace? Does the current system adequately fulfill the notice function of patents? How does uncertainty influence the operation of the IP marketplace? What are the sources of uncertainty that affect the value of patents and the operation of the IP marketplace? What could be done to address them?

8. How transparent is the current IP marketplace? Can it be made more transparent? Is that desirable?

9. During the past five years, what new learning has furthered the understanding of the patent system and the IP marketplace?

By direction of the Commission.

Donald S. Clark,
Secretary.

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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.

DATES: Comments on this notice must be received by (insert date 60 days after date of publication).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email 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 email at doris.lefkowitz@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

“Reducing Waste and Inefficiency through Process Redesign: Lean/Toyota Production System (TPS) Implementation” AHRQ, through its contractor, American Institutes for Research (AIR), proposes to investigate the contribution of Lean/TPS to reducing waste in health care delivery systems. Lean 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 sample 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. 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; 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

At least four research locations (i.e., hospitals or other health settings) will be selected to create eight case study reports. Four of the studies will employ a retrospective analytics perspective, while four will employ a prospective analytics perspective. At each 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. If there is more than one Lean/TPS project in the selected department, we will purposively select a project that appears to have the most information for others about the processes and outcomes of Lean/TPS implementation.

Qualitative data will be collected directly from the four locations selected for this study. The collection will be accomplished using interviews (telephone and in-person), collection of documentation, and digital diaries for the four prospective 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 total number of in-person interviews to be conducted across the four locations is 100; the total number of telephone interviews is 36. The in-person interviews will be conducted through a multi-day visit to each site. The number of digital diary submissions will depend on the number and duration of the Lean/TPS project within in each department.

Estimated Annual Respondent Burden

Exhibit I shows the estimated annualized burden hours. A total of 25 in-person interviews will be conducted with the administrative and clinical personnel from each of the four participating health care facilities. The estimated time per response is 1.0 hour for a total of 100 burden hours. Additionally, a total of 9 telephone interviews will be conducted with each facility. The estimated time per response is 30 minutes, for a total of 18 burden hours. The digital diaries will be completed once a month for eight months by two personnel from each facility, and will require about 30 minutes each per month for a total of 32 hours. Finally, 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. We anticipate this task will simply consist of forwarding emails and or photocopying and sending documents to the project team one time throughout the course of the project and will take about four hours per facility or 16 hours total. The total estimated burden is 166 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 total cost burden is about \$5,492.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
In-person interviews	4	25	1.0	100
Telephone interviews	4	9	30/60	18
Digital Diaries	4	16	30/60	32
Collection of documentation	4	1	4	16
Total	16			166

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
In-person interviews	4	100	\$35.07	\$3,507
Telephone interviews	4	18	35.07	631
Digital Diaries	4	32	35.07	1,122
Collection of documentation	4	16	14.53	232
Total	16			5,492

* 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 \$415,000, with an average annual cost of \$207,500. This figure includes the cost of data collection, data analysis, reporting, and government oversight of the contract.

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'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: November 6, 2008.

Carolyn M. Clancy,
Director.

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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: "Conducting Measurement Activities in Support of the AHRQ Health IT Initiative." 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 September 19th, 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 December 10, 2008.

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_submissionomb.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@ahrg.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Conducting Measurement Activities in Support of the AHRQ Health IT Initiative

AHRQ-supported research has helped to demonstrate the potential of health IT to enhance health care quality and patient safety. As the lead federal research agency on the quality, safety, efficiency, and effectiveness of health care in America, AHRQ plays a central role in efforts to increase the adoption of health IT.