SUMMARY: The Department of Health and Human Services (HHS) is soliciting ideas and information relating to ways in which HHS could continue to improve its use of resources and authorities in encouraging the development and use of new medical technologies, consistent with the goals of (a) maintaining and improving the quality of care, (b) controlling overall healthcare costs, and (c) using timely and practical administrative procedures. This Request for Information is now available on the HHS Web site at *http://aspe.hhs.gov/sp/medtechinnovation/rfi*.

DATES: Responses should be submitted to the U.S. Department of Health and Human Services on or before 5 p.m., EDT, April 16, 2009.

ADDRESSES:

Instructions for Submitting Comments: Electronic responses are preferred and should be addressed to *medtechinnovation@hhs.gov*. Written responses should be addressed to the U.S. Department of Health and Human Services, Room 434E, 200 Independence Ave, SW., Washington, DC 20201. Attention: Medical Technology Innovation RFI. A copy of this RFI is available on the Web site of the Assistant Secretary for Planning and Evaluation at *http://aspe.hhs.gov/sp/medtechinnovation/rfi*.

The submission of comments in response to this notice should not exceed 25 pages, not including appendices and supplemental documents. Any information you submit will be made public. Consequently, please do not send any proprietary, commercial, financial, business confidential, trade secret, or personal information that you do not wish to be made public.

Public Access: Responses to this RFI will be available to the public in the Policy Information Center, 200 Independence Avenue, SW., Washington, DC, 20201. Please call (202) 690–6445 between 9 a.m. and 5 p.m. to arrange access.

FOR FURTHER INFORMATION CONTACT: Medical Technology Innovation Desk, Office of the Assistant Secretary for Planning and Evaluation, (202) 690–7858.

Dated: January 12, 2009.

Mary M. McGeein,

Principal Deputy Assistant Secretary for Planning and Evaluation.

[FR Doc. E9–807 Filed 1–14–09; 8:45 am]

BILLING CODE 4151–05–P

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 Flow and Reducing Emergency Department Crowding.'' 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 March 16, 2009.

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 Flow and Reducing Emergency Department Crowding''

AHRQ proposes to study implementation of strategies from the Urgent Matters (UM) Toolkit for improving patient flow in emergency departments (ED). UM, a Robert Wood Johnson Foundation (RWJF) funded initiative, began as a collaborative of 10 urban, safety net hospitals that experimented with a variety of strategies (now included in the ''UM Toolkit'') designed to relieve ED crowding. The first phase of this initiative demonstrated that reductions in ED crowding were achievable without investment of significant financial resources. However, implementation of these strategies has not been widespread, and questions remain about how readily the strategies could be implemented in a more diverse group of hospitals, and the associated costs and outcomes of implementation. This study is funded by a grant from RWJF to AHRQ.

Six diverse hospitals have been selected for this study of the implementation of strategies from the UM Toolkit for improving ED patient flow. This study poses a common outcome goal across all six sites of improving patient flow and reducing ED crowding, but requires each hospital to select strategies that fit its own needs amid context. This approach rests on innovation research showing that organizational innovations are more successful when they are aligned with features of the adopting hospital. Participating hospitals will select strategies from the UM Toolkit that they believe will work best to address the particular problems they face. The six hospitals have agreed to participate in a collaborative run by the UM National Program Office (NPO) over the course of this study to facilitate the sharing of data and experiences while the project is under way.

This study will document the experiences of a diverse set of hospital EDs as they identify and implement ED patient flow improvement strategies. The six case study hospitals were selected to reflect diversity of size, ownership, teaching status, safety net status, and types of challenges with ED crowding.

Research methods will include observational site visits, in-person and telephone interviews, and the analysis of cost data. AHRQ's contractor for this study, Health Research & Educational Trust (HRET), will perform analysis of secondary data on ED performance measures; this secondary data will be provided to HRET by the Urgent Matters NPO. These qualitative and quantitative methods will be used to:

- Study the processes through which hospitals decide upon and adopt patient flow improvement strategies;
- Identify facilitators and barriers to the implementation and maintenance of these strategies;
- Document changes in patient flow, patient satisfaction, and staff satisfaction associated with the implementation of strategies and processes;
- Generate estimates of the costs of adopting the strategies;
- Identify issues associated with the reporting of ED performance measures, and
- Develop lessons for hospitals considering the adoption of patient flow improvement strategies.

The study will not be used to answer questions about causality or degrees of effectiveness (e.g to what degree did a

given intervention cause an improvement in patient flow?). Rather, the study seeks to enhance understanding of factors affecting decision-making and adoption processes that facilitate or hinder implementation. Insights and lessons learned about organizational, technical and resource challenges arising from these improvement activities may be of interest or benefit to others seeking to identify and adopt strategies to address similar problems in their EDs.

This study 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

AHRQ seeks approval for the following data collection activities:

- In-person interviews will be conducted within two months of the implementation with up to 12 individuals at each of the 6 sites during two-day site visits to each of the hospitals.
- Telephone interviews will be conducted approximately 6 months after implementation with 12 individuals from each of the six hospitals (most or all of whom will be the same individuals interviewed in person).
- Each of the six hospitals will submit information on the costs associated with the planning, implementation, and maintenance of the patient flow improvement strategies on a monthly basis. One study team member at each site will record costs on an assessment instrument specifically designed for this purpose and tailored to each hospital's own organizational structure and patient flow strategies.

This assessment instrument will collect information on staff time devoted to the patient flow improvement initiatives as well as the costs of items or resources purchased to support the initiatives.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the hospitalst time to participate in this study. In-person interviews will be conducted within two months of implementation with 12 administrative and clinical personnel from each of the six participating hospitals and will require about one hour. Telephone interviews will be conducted approximately six months thereafter with 12 individuals (administrative and clinical) from each hospital and will take about 45 minutes. Monthly cost assessment data will be collected from each participating hospital each month and will require about one hour. The total estimated burden for participation in this study is 198 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents' time to provide the requested data. The total cost burden is approximately $6,536.

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	6	12	1	72
Telephone interviews	6	12	45/60	54
Cost Assessment	6	12	1	72
Total	18	na	na	198

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
In-person interviews	6	72	$35.07	$2,525
Telephone interviews	6	54	35.07	1,984
Cost Assessment	6	72	28.15	2,027
Total	18	198	na	6,536

*For the interviews, the hourly rate of $35.07 is an average of the administrative personnel hourly wage of $14.53, the physician rate of $62.52, and the registered nurse rate of $28.15. For cost assessment, the hourly rate of $28.15 is the hourly rate for 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

Exhibit 3 shows the total and annualized cost to the government for this eighteen-month study.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost	Annualized cost
Project Development	$52,446	$34,964
Data Collection Activities	90,298	60,199

EXHIBIT 3—ESTIMATED COST—Continued

Cost component	Total cost	Annualized cost
Data Processing and Analysis	70,569	47,046
Publication of Results	41,420	27,613
Project Management	68,908	45,939
Overhead	76,320	50,880
Total	399,961	266,641

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: December 30, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E9–537 Filed 1–14–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles

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 February 17, 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_submissions@OMB.eop.gov*. All comments should be identified with the OMB control number 0910–0575. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr.,Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Waiver of In Vivo Demonstration of Bioequivalence of Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles—21 CFR Part 514 (OMB Control Number 0910–0575)—Extension

The Center for Veterinary Medicine has written this guidance to address a perceived need for agency guidance in its work with the animal health industry. This guidance describes the procedures that the agency recommends for the review of requests for waiver of in vivo demonstration of bioequivalence for generic soluble powder oral dosage form products and Type A medicated articles.

The Generic Animal Drug and Patent Term Registration Act of 1988 permitted the generic drug manufacturers to copy those pioneer drug products that were no longer subject to patent or other marketing exclusivity protection. The approval for marketing these generic products is based, in part, upon a demonstration of bioequivalence between the generic product and the pioneer product. This guidance clarifies circumstances under which FDA believes the demonstration of bioequivalence required by the statute does not need to be established on the basis of in vivo studies for soluble powder oral dosage form products and Type A medicated articles. The data submitted in support of the waiver request are necessary to validate the waiver decision.

The requirement to establish bioequivalence through in vivo studies (blood level bioequivalence or clinical endpoint bioequivalence) may be waived for soluble powder oral dosage form products or Type A medicated articles in either of two alternative ways. A biowaiver may be granted if it can be shown that the generic soluble powder oral dosage form product or Type A medicated article contains the same active and inactive ingredient(s) and is produced using the same manufacturing processes as the approved comparator product or article. Alternatively, a biowaiver may be granted without direct comparison to the pioneer product's formulation and manufacturing process if it can be shown that the active pharmaceutical ingredient(s) (API) is the same as the pioneer product, is soluble, and that there are no ingredients in the formulation likely to cause adverse pharmacologic effects. For the purpose of evaluating soluble powder oral dosage form products and Type A medicated articles, solubility can be demonstrated in one of two ways: (1) ''USP definition'' approach or (2) ''Dosage adjusted'' approach.

In the **Federal Register** of October 29, 2008 (73 FR 64338), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows: