

comment period closes Wednesday, October 26, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Substantive program information as well as summaries of meetings and a roster of committee members may be obtained from Marjorie S. Greenberg, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Room 2402, Hyattsville, Maryland 20782, telephone (301) 458-4245. Information also is available on the NCVHS home page of the HHS *Web site*: <http://www.ncvhs.hhs.gov/>, where further information including an agenda will be posted when available.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (301) 458-4EEO (4336) as soon as possible.

Dated: September 27, 2011.

**James Scanlon,**

*Deputy Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2011-25731 Filed 10-4-11; 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: "Evaluation of the Technical Assistance to ARRA Complex Patient Grantees Project." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on August 3rd, 2011, 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 November 4, 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](mailto: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](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

Evaluation of the Technical Assistance to ARRA Complex Patient Grantees Project Under the American Recovery and Reinvestment Act (ARRA) of 2009, the Agency for Healthcare Research and Quality (AHRQ) awarded \$473 million in grants and contracts to support patient-centered outcomes research. As part of this investment, AHRQ funded fourteen R21 (exploratory) grants and thirteen R24 (infrastructure development) grants to generate new knowledge on individuals with multiple chronic conditions. This work is critical to improve the understanding of how to prioritize evidence-based services for patients with multiple co-morbidities and to suggest appropriate adaptations to guidelines for their care.

In order to support the R21 and R24 complex patient grantees, AHRQ funded a Learning Network and Technical Assistance Center (LN&TAC) to encourage collaboration among the researchers and help them share research methods, definitions and products through in-person meetings, small workgroups and network facilitation. The LN&TAC will provide the grantees with technical assistance regarding research design, data collection, data analysis, public use dataset development, and dissemination.

Through the LN&TAC, AHRQ will support work to:

(1) Create and support a Learning Network of the complex patient grantees to facilitate advancement of infrastructure development, as well as to leverage developments and learning across the program. The Learning Network will give these grantees the opportunity to share information with and learn from other research teams, provide resources for data management and other research-related issues, and synthesize and disseminate findings that transcend individual projects.

(2) Provide both group and individual technical assistance to grantees as they

address issues of ARRA reporting, infrastructure development, data sharing, and creation of public use data sets.

(3) Disseminate results, including developing materials targeted to researchers and policy-makers to describe study results and facilitate future use of newly created datasets. This will include a marketing plan to advertise availability of datasets and promote their use.

(4) Develop and implement an evaluation of the above activities throughout the project.

The purpose of this Information Collection Request is to evaluate the effectiveness of the LN&TAC. The goals of the evaluation are to:

(1) Ascertain whether expected outcomes of the LN&TAC were achieved;

(2) Assess whether the LN&TAC met the needs and expectations of the grantees;

(3) Identify challenges and lessons learned, and determine the feasibility and advisability of developing similar project models in the future. This study is being conducted by AHRQ through its contractor, Abt Associates, pursuant to AHRQ's statutory authority to "conduct and support research, evaluations, and training, support demonstration projects, research networks and multidisciplinary centers, provide technical assistance, and disseminate information 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." 42 U.S.C. 299a(a)(1).

**Method of Collection**

To meet the goals of this evaluation the following data collections will be implemented:

(1) *LN Meeting Evaluation*—Grantees who attend the three annual in-person Learning Network meetings will be asked to complete the LN Meeting Evaluation to provide immediate feedback about their level of satisfaction with the meeting (including session topics and speakers) and make suggestions about how the meeting could be improved.

(2) *Group TA Evaluation*—Grantees who participate in group technical assistance activities, such as Webinars and the TA given at annual meetings, will be asked to complete the Group TA Evaluation to provide feedback about their level of satisfaction with the group TA (including session leader), how effective the TA was, and make suggestions about how the TA session could have been better.

(3) *Individual TA Evaluation*—Grantees who request individual technical assistance will be asked to complete the Individual TA Evaluation to provide feedback about their level of satisfaction with the TA (including session leader), how effective the TA was, and make suggestions about how the TA session could have been better.

(4) *Annual Survey*—All 27 Complex Patient grantees will be asked to complete the Annual Survey once a year. This survey is designed to measure whether, due to their participation in the project, grantees have experienced changes in knowledge, confidence or attitudes related to research activities and grant requirements, changes in their research itself (design, methods, and/or analyses), and/or if participation has increased collaboration (e.g., sharing methods, developing new coding, merging data sets) among the Complex Patient researchers, as well as satisfaction with the LN&TAC in general.

(5) *Annual Interview*—The Annual Interview will be administered with a small subset of 5 grantees per year, and will be used to augment the Annual Survey with more in-depth qualitative data. Therefore, similar questions will be asked in the Annual Interview as are asked in the Annual Survey, but the interview will allow for probing and clarification of answers. Different grantees will be asked to participate in the interview each year, such that no grantee participates in the Annual Interview more than once during the three-year contract.

These evaluation instruments are designed to capture a combination of quantitative and qualitative data. No claim is made that the results from this study will be generalizable in the statistical sense. Rather, this evaluation is aimed at determining the effectiveness of this particular program.

**Estimated Annual Respondent Burden**

Exhibit 1 shows the estimated annualized burden hours for the

grantees' time to participate in the surveys and interviews. The LN Meeting Evaluation will be completed by about 22 grantees and takes about 20 minutes to complete. The Group TA Evaluation will be completed by 8 grantees 4 times a year, although not necessarily the same 8 persons each time, and will take 5 minutes to complete. The Individual TA Evaluation will be completed by about 15 grantees annually and takes 5 minutes to complete. The Annual Survey will be completed by 22 grantees and will take about 10 minutes to complete. Annual Interviews will be conducted with 5 persons annually and will last 45 minutes. The total annualized burden hours are estimated to be 19 hours.

Exhibit 2 shows the estimated annualized cost burden for the grantees' time to provide the requested data. The estimated total cost burden is about \$774.

**EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
LN Meeting Evaluation .....	22	1	20/60	7
Group TA Evaluation .....	8	4	5/60	3
Individual TA Evaluation .....	15	1	5/60	1
Annual Survey .....	22	1	10/60	4
Annual Interview .....	5	1	45/60	4
<b>Total .....</b>	<b>72</b>	<b>na</b>	<b>na</b>	<b>19</b>

**EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN**

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost
LN Meeting Evaluation .....	22	7	\$40.75	\$285
Group TA Evaluation .....	8	3	40.75	122
Individual TA Evaluation .....	15	1	40.75	41
Annual Survey .....	22	4	40.75	163
Annual Interview .....	5	4	40.75	163
<b>Total .....</b>	<b>72</b>	<b>19</b>	<b>40.75</b>	<b>774</b>

\* Based upon the mean hourly wage rate for Medical Scientists, except Epidemiologists, from the National Compensation Survey: Occupational Wages in the United States May 2009, "U.S. Department of Labor, Bureau of Labor Statistics," accessed on April 26, 2011.

**Estimated Annual Costs to the Federal Government**

The total cost of this contract to the government is \$178,137 over the three

years of the project (September 27, 2010, to September 26, 2013). Therefore, the annualized cost to the government of the evaluation of the Complex Patient LN&TAC is \$59,379.

**EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST**

Cost component	Total cost	Annualized cost
Project Development .....	\$70,247	\$23,416
Data Collection Activities .....	54,636	18,212

## EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Data Processing and Analysis .....	31,220	10,406
Overhead .....	22,034	7,345
Total .....	178,137	59,379

**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 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: September 26, 2011.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 2011-25693 Filed 10-4-11; 8:45 am]

**BILLING CODE 4160-90-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0708]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Form 3728, Animal Generic Drug User Fee Act Cover Sheet

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain

information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection burden of the Animal Generic Drug User Fee Cover Sheet Form FDA 3728 that further implements certain provisions of the Animal Generic Drug User Fee Act of 2008 (AGDUFA).

**DATES:** Submit either electronic or written comments on the collection of information by December 5, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651,

[Juanmanuel.vilela@fda.hhs.gov](mailto:Juanmanuel.vilela@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

#### FDA Form 3728, Animal Generic Drug User Fee Act Cover Sheet—21 U.S.C. 379j-21 (OMB Control Number 0910-0632)—Extension

Section 741 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). Because the submission of user fees concurrent with applications is required, the review of an application cannot begin until the fee is submitted. FDA Form 3728 is the AGDUFA Cover Sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. FDA estimates the burden of this collection of information as follows: