

domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*. Pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of such determination, on October 1, 2008, former Secretary of Health and Human Services, Michael O. Leavitt, declared an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a).¹

Pursuant to section 564(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b), and on the basis of Secretary Chertoff's September 23, 2008 determination, I hereby renew former Secretary Leavitt's October 1, 2008 declaration of an emergency justifying the authorization of the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a) and amend the declaration to justify the authorization of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a). I previously renewed the declaration on October 1, 2009 and October 1, 2010.² I am issuing this notice in accordance with section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Dated: July 20, 2011.

Kathleen Sebelius,
Secretary.

[FR Doc. 2011-18937 Filed 7-26-11; 8:45 am]

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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: "Pre-test of an Assisted Living Consensus Instrument." 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 May 11, 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 August 26, 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 (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

Pre-Test of an Assisted Living Consensus Instrument

Using a consensus-based process and in partnership with the Center for Excellence in Assisted Living (CEAL), AHRQ has developed a data collection tool that will collect uniform information about individual assisted living facilities (ALFs) in the United States to increase the value of healthcare for consumers by helping them make informed choices when selecting an ALF. Included in the development process were a voluntary committee of

national representatives of Assisted Living Facilities, consumers, and researchers.

Assisted living (AL) is a relatively new long-term care option that currently serves approximately one million older and dependent Americans. Unlike skilled nursing facilities which are federally regulated and relatively uniform from state to state, ALFs vary from state to state, as well as within each state, reflecting various core values that embrace consumer choice and provider diversity.

Most states mandate a set of basic services that an ALF must offer, such as meals and housekeeping. The upper limits of allowable services are also often prescribed. However, within the range of services required and allowed, ALFs in most states are given some latitude as to who they choose to serve and what services they choose to provide. Further, the choice of services is not always confined by geography; that is, given the widespread dispersion of families, potential AL residents may be looking to choose among assisted living properties in different states, thereby widening the choices available.

While some ALFs are equipped to serve a wide range of resident needs, it is more common that an assisted living property will address a particular "market niche." There are many ways in which ALFs offer diversity — in the religious or cultural affiliations of its target market; in the house rules that influence expectations about dress and behavior in the dining room; in the admission and discharge criteria in place; as well as in the range of services provided. Major variation is found in the extent to which a particular ALF is able and willing to serve those with dementia. While most ALFs admit and retain residents with mild cognitive impairment, those without a specialized dementia program may have difficulty serving residents with common symptoms such as a lack of safety awareness, wandering, sleep disturbances and agitation.

To some extent, admission and discharge criteria are dictated by the laws and regulations of the state in which a particular ALP operates. Beyond this, ALFs have considerable latitude in assessing individuals whom they will admit and retain in their facilities.

In addition to the assessment of needed services in relation to the services that are available, the ability to pay for AL services is a critical factor for both the consumer and ALF decision-making about whether and when an individual moves into and out of a particular ALF. Approximately ten

¹ Pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, notice of the determination by the Secretary of Homeland Security and the declaration by the Secretary of Health and Human Services was provided at 73 FR 58242 (October 6, 2008).

² Pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, notices of the renewal of the declaration of the Secretary of Health and Human Services were provided at 74 FR 51,279 (Oct. 6, 2009) and 75 FR 61,489 (Oct. 5, 2010).

percent of AL residents receive subsidies through State Medicaid Waiver or State Plan programs, and fewer than three percent are covered by long-term care insurance. Thus, a substantial percentage of AL consumers use savings and other assets, including proceeds from the sale of their homes, to pay for their stay in an ALF. In choosing an ALF, consumers need to consider whether a particular facility is able to accept Medicaid or other third party payments, both now and in the future, should their assets become depleted.

This research has the following goals:

(1) Refine the data collection tool through pre-testing with a sample of ALFs; and

(2) Make the data collection tool publically available through the AHRQ website.

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. 42 U.S.C. 299a(a)(1).

Method of Collection

To achieve the goals of this project the following data collection will be undertaken:

(1) Telephone verification. The purpose of the telephone verification is to ensure that the most current mailing address of each ALF is utilized for the survey pre-test, and to obtain the name of the Administrator or Executive Director of the ALF so the mailed pre-test survey can be addressed directly to that person; and

(2) Pre-test of the Assisted Living Provider Information Tool for Consumer Education. The data collection will include information on several topics of interest to consumers including services available in ALFs and costs of those services, criteria for moving into and out of an ALF, resident's rights, house rules, life safety features, staffing within the ALF, and the availability of dementia care services within the ALF. The purpose of the pre-test is to assess the

utility of the data collection tool as well as the feasibility for its implementation.

The data that will be collected through this effort will be used to make final refinements to the Assisted Living Provider Information Tool for Consumer Education and to make adjustments to the recommended processes for implementing a similar data collection effort on a broader basis.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden for the respondents' time to participate in this project. The telephone verification will be completed by 285 AL providers and will take approximately one minute to complete. The pre-test of the Assisted Living Provider Information Tool for Consumer Education will be completed by 191 ALFs and will require approximately 25 minutes to complete. The total annual burden is estimated to be 85 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this project. The total annualized cost burden is estimated to be \$3,576.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Telephone verification	285	1	1/60	5
Pre-test	191	1	25/60	80
Total	476	na	na	85

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Telephone verification	285	5	\$15.37	\$77
Pre-test	191	80	43.74	3,499
Total	476	85	na	3,576

* Based upon the mean of the average wages reflected in the National Compensation Survey (May 2009), US. Department of Labor, Bureau of Labor Statistics. Wage categories used: Phone verification—office and administrative support workers; pre-test—medical and health services managers in the United States.

Estimated Annual Costs to the Federal Government

The total cost of this contract to the government is \$424,000. The project

extends over four years, but this request is for a one-year OMB clearance. Exhibit 3 shows a breakdown of the total cost as well as the annualized cost.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	\$125,000	\$31,250
Data Collection Activities	90,000	22,500
Data Processing and Analysis	30,000	7,500
Reporting of results	30,000	7,500

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST—Continued

Cost component	Total cost	Annualized cost
Project Management	164,552	41,138
Total Costs	439,552	109,888

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 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: July 13, 2011.

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: "Evaluation of ARRA Comparative Effectiveness Research Dissemination Contractor Efforts." In accordance with

the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by September 26, 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

Evaluation of ARRA Comparative Effectiveness Research Dissemination Contractor Efforts

Today, both patients and their health care providers have many options when deciding on a treatment plan. Information available to patients and their health care providers offers great opportunities for informed decision making. However, the volume of information that needs to be reviewed and synthesized can be daunting. To complicate matters, studies may offer conflicting information or have a conflict of interest (e.g., research sponsored by pharmaceutical companies that make drugs). Sorting through conflicting information requires a background in research that most patients do not have, and physicians have limited time to conduct these reviews. Having a neutral third party review research, draw conclusions, and disseminate findings is necessary to ensure effective health care delivery and consumption of quality care.

AHRQ recognizes the need to fill this gap and has taken a lead role in developing mechanisms for reviewing and disseminating Comparative Effectiveness Research (CER) and findings to clinicians, health care decision makers, purchasers/business decision makers, and consumers through its Effective Healthcare Program

(EHCP). CER directly compares the benefits, potential risks, and costs of two or more health care interventions. These direct comparisons allow assessments of how well a health care treatment or intervention works under real-world conditions. AHRQ has paid careful attention not only to how studies are conducted but also to how results are communicated to its audiences.

To augment AHRQ's existing CER dissemination efforts performed by the Eisenberg Center and other initiatives, AHRQ is conducting four one-time projects to test other ways to disseminate CER results. These four related projects will test new approaches to CER dissemination and promote awareness of the EHCP. Collectively, dissemination efforts will reach AHRQ's priority audiences of: clinical decision makers, health care system decision makers, purchasers/business decision makers, public policy decision makers, and consumers/patients.

Through these four projects AHRQ aims to: (1) Educate professional and consumer audiences about CER; (2) inform professional and consumer audiences about AHRQ's EHCP; (3) and inform a wide range of audiences about new EHCP research findings.

This project will evaluate the effectiveness of these four new dissemination efforts. The evaluation has four main goals:

1. Assess the effectiveness of the four dissemination strategies in creating awareness of CER, specific CER topics, and the EHCP.

2. Assess the effectiveness of the four dissemination strategies in fostering knowledge and understanding of CER finding, specific CER topics, and the EHCP.

3. Assess the effectiveness of the four dissemination strategies in promoting utilization, including use of the EHCP materials by consumers and by clinicians in patient care and if usage by clinicians is increasing across time.

4. Assess the effectiveness of the four dissemination strategies in supporting the benefits of using CER, and specific CER topics, for both patients and health care providers.

This study is being conducted by AHRQ through its contractor, IMPAQ