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 Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) Quality Demonstration Grant Program.'' 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. One comment was 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 7, 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

Evaluation of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) Quality Demonstration Grant Program

AHRQ is requesting approval from the Office of Management and Budget (OMB) for data collection to support a national evaluation of the quality demonstration grants authorized and appropriated funding under subsection (d) of Sec. 401(a) of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Attachment A). Evaluating whether the CHIPRA demonstration grants improve the quality of care received by children in Medicaid and CHIP aligns with AHRQ's mission of improving the quality and effectiveness of health care in the United States.

CHIPRA included funding for five-year grants so that states can demonstrate effective, replicable strategies for improving the quality of children's health care in Medicaid and CHIP. In February 2010, the U.S. Department of Health and Human Services announced the award of 10 demonstration grants. Six of the grantee states are partnering with other states, for a total of 18 demonstration states. The demonstration states are: Colorado (partnering with New Mexico); Florida (with Illinois); Maine (with Vermont); Maryland (with Wyoming and Georgia); Massachusetts; North Carolina; Oregon (with Alaska and West Virginia); Pennsylvania; South Carolina; and Utah (with Idaho).

These demonstration states are implementing 48 distinct projects in at least one of five possible grant categories, A to E. Category A grantees are experimenting with and/or evaluating the use of new pediatric quality measures. Category B grantees are promoting health information technology (HIT) for improved care delivery and patient outcomes. Category C grantees are expanding person-centered medical homes or other provider-based levels of service delivery. Category D grantees will evaluate the impact of a model pediatric electronic health record. Category E grantees are testing other state-designed approaches to quality improvement in Medicaid and CHIP.

This research has the following goals:

(1) To identify CHIPRA state activities that measurably improve the nation's health care, especially as it pertains to children.

(2) To develop a deep, systematic understanding of how CHIPRA demonstration states carried out their grant-funded projects.

(3) To understand why the CHIPRA demonstration states pursued certain strategies.

(4) To understand whether and how the CHIPRA demonstration states' efforts affected outcomes related to knowledge and behavior change in targeted providers and/or consumers of health care.

This study is being conducted by AHRQ through its contractor, Mathematica Policy Research, and two subcontractors, 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 and with respect to quality measurement and improvement, 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To achieve the goals of this project the following data collections will be implemented:

(1) Key Staff Interviews—two rounds of semi-structured interviews with key staff directly involved in the design and oversight of grant-funded activities in each of the 18 demonstration states. Key staff includes the project director, project manager, and principal investigator and/or medical director. The purpose of these interviews is to gain insight into the implementation of demonstration projects, to understand contextual factors, and to identify lessons and implications for the broad application and sustainability of projects. Because key staff have the most knowledge of project design and implementation, they will be interviewed annually. This request for OMB approval covers the first two annual interviews with key staff.

(2) Implementation Staff Interviews—semi-structured interviews with staff involved in the day-to-day implementation of grant-funded projects in each of the 18 demonstration states. These staff members include state agency employees, provider trainers or coaches, health IT vendors, and/or project consultants. The purpose of these interviews is to gain insight into the opportunities and challenges related to key technical aspects of project implementation.

(3) Stakeholder Interviews—semi-structured interviews with external stakeholders that have a direct interest in children's care quality in Medicaid and CHIP in each of the 18 demonstration states. Stakeholders include representatives of managed care organizations, state chapters of the American Academy of Pediatrics, advocacy organizations for children and families, and social service agencies. These stakeholders will be familiar with the CHIPRA projects and may serve on advisory panels or workgroups related to one or more projects. The interviews will gather insight into the opportunities and challenges related to project implementation, stakeholder satisfaction with their project involvement, and contextual factors.

(4) Health Care Provider Interviews—semi-structured interviews with health care providers who are, or are not,

participating in demonstration grant activities (participating and comparison providers, respectively) in each of the 18 demonstration states. Providers can include clinicians from private practices, public clinics, Federally qualified health centers, care management entities, or school based health centers. The interviews with participating providers will capture information about project-related activities, providers' perceptions of the likelihood of achieving intended outcomes, and providers' involvement in other quality-improvement initiatives. The interviews with comparison providers will ask about the providers' experiences providing care to children in Medicaid and CHIP, coordinating with other providers, use of HIT, and provision of patient-centered care.

(5) Non-demonstration States Interviews—semi-structured interviews with knowledgeable Medicaid or CHIP personnel including the Medicaid/CHIP director, the Medicaid health-IT coordinator, and/or project directors for state medical home initiatives in 9 non-demonstration states. The purpose of these interviews is to enrich AHRQ's understanding of how the CHIPRA quality grants contribute to improved care quality above and beyond other quality-related initiatives happening at the same time. Examples of other quality-related initiatives include those funded by the HITECH Act, the Pediatric Quality Measures Program, and various medical home initiatives.

The information collected through the semi-structured interviews will be a key source of evidence for the national evaluation of the demonstration. Collecting high-quality, timely interview data from a wide range of knowledgeable respondents directly serves AHRQ's goal of understanding project implementation and the selection and execution of strategies, and of identifying the particular activities and resources that contributed most to any observed improvement in children's care quality. The products that will result from this project include practice profiles, replication guides, case studies, and peer-reviewed journal articles.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in this evaluation. Key Staff Interviews will be conducted twice with 4 persons from each of the 18 CHIPRA demonstration States and will last for about 1½ hours. Implementation Staff Interviews will include 16 persons from each of the 18 CHIPRA demonstration States and take an hour to complete. Stakeholder Interviews will include 8 persons from each of the 18 CHIPRA demonstration States and also take an hour to complete. Health Care Provider Interviews will be conducted with 12 persons from each of the 18 CHIPRA demonstration States and will last 45 minutes. Non-demonstration States Interviews will be conducted with 5 persons from 9 non-demonstration States and will take about 1 hour to complete. The total burden for this evaluation is estimated to be 855 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this evaluation. The total cost burden is estimated to be $32,914.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of States	Number of responses per respondent	Hours per response	Total burden hours
Key Staff Interviews	4	18	2	1.5	216
Implementation Staff Interviews	16	18	1	1	288
Stakeholder Interviews	8	18	1	1	144
Health Care Provider Interviews	12	18	1	45/60	162
Non-demonstration States Interviews	5	9	1	1	45
Total	45	na	na	na	855

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Number of States	Total burden hours	Average hourly wage*	Total cost burden
Key Staff Interviews	4	18	216	$36.35	$7,852
Implementation Staff Interviews	16	18	288	34.67	9,985
Stakeholder Interviews	8	18	144	18.68	2,690
Health Care Provider Interviews	12	18	162	62.50	10,125
Non-demonstration States Interviews	5	9	45	50.26	2,262
Total	45	na	855	na	32,914

*Based upon the mean of the average wages, National Compensation Survey: Occupational wages in the United States May 2009, ''U.S. Department of Labor, Bureau of Labor Statistics.'' Key project staff are state government workers who are general managers. Other implementation personnel are state workers who are managers of social and community services. External stakeholders are civilian workers who are in community and social services occupations. Participant providers are civilian pediatric physicians. Medicaid/CHIP personnel are Federal employees in a medical and health service management role.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost for this evaluation. The total cost to the government of the entire evaluation contract is $8,258,311 (including a base period and four option periods); the annualized cost is $1,651,662 per year (Exhibit 3). These costs will be incurred from 2010 to 2012.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUAL COST

Cost component	Total cost	Annual cost
Administration	$571,422	$114,284

EXHIBIT 3—ESTIMATED TOTAL AND ANNUAL COST—Continued

Cost component	Total cost	Annual cost
Coordination	38,003	7,601
Stakeholder Feedback	201,637	40,327
Technical Expert Panel	359,276	71,855
Evaluation Design & Implementation	3,981,390	796,278
Technical Assistance Plan	934,440	186,888
Data Collection Instruments	138,997	27,799
OMB Clearance	35,617	17,808
Section 508 Compliance	13,883	2,777
Data and Analysis Reports	735,426	147,085
Interim Evaluation Reports	408,803	81,761
Dissemination	736,149	184,037
Final Report	103,269	103,269
Total	8,258,311	1,651,662

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: September 26, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–25691 Filed 10–6–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–11–0576]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Possession, Use, and Transfer of Select Agents and Toxins (OMB) Control No. (0920–0576) Exp. 12/31/2011—Revision—Office of Public Health Preparedness and Response (OPHPR), Division of Select Agents and Toxins (DSAT), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The *Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107–188 (42 U.S.C. 262a),* requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins (*i.e.,* select agents and toxins) that could pose a severe threat to public health and safety. The *Agricultural Bioterrorism Protection Act of 2002, Subtitle B of Public Law 107–188 (7 U.S.C. 8401),* requires the United States Department of Agriculture (USDA) to regulate the possession, use, and transfer of biological agents or toxins (*i.e.,* select agents and toxins) that could pose a severe threat to animal or plant health, or animal or plant products. In accordance with these Acts, HHS and USDA promulgated regulations requiring entities to register with the CDC or the Animal and Plant Health Inspection Service (APHIS) if they possess, use, or transfer a select agent or toxin (42 CFR part 73, 7 CFR part 331, and 9 CFR part 121).

CDC is requesting continued OMB approval to collect this information through the use of five forms: (1) Application for Registration, (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin, and (5) Request for Exemption. Revision will be made to (2) Request to Transfer Select Agent or Toxin, (3) Report of Theft, Loss, or Release of Select Agent and Toxin, (4) Report of Identification of Select Agent or Toxin. There will be no revisions made to the Application for Registration and Request for Exemption The total estimated annualized burden for all data collection is 8,878 hours. Information will be collected via fax, e-mail and mail from respondents of the 320 entities registered with the Select Agent Program. Annualized burden hours were calculated by multiplying the average number of hours used to complete the: (1) Application for Registration; (2) Request to Transfer Select Agent or Toxin; (3) Report of Theft, Loss, or Release of Select Agent or Toxin; (4) Report of Identification of Select Agent or Toxin; and (5) Request for Exemption. The estimated annualized burden for the 2008 Possession, Use, and Transfer of Select Agents and Toxins submission was 9,656.5 hours. The 2011 estimated annualized burden hours are 8,878. Burden has been reduced by 778.5 hours due to the removal of similar questions on the Request to Transfer Select Agent or Toxin (Form 2), Report of Theft, Loss, or Release of Select Agent or Toxin (Form 3) and the Report of Identification of Select Agent or Toxin (Form 4). Therefore respondents are not required to answer as many questions as requested in the previous data collection tool.

The Request to Transfer Select Agent or Toxin form (42 CFR 73.16) will be used by entities requesting transfer of a select agent or toxin to their facility. CDC in conjunction with APHIS has revised the Request to Transfer Select Agent or Toxin form by requiring the recipient to submit the initial request, be notified by the sender of the expected shipment date, and verify if the shipment did not occur. Estimated average time to complete this form is 1 hour, 30 minutes. Based on data regarding the transfer requests received since the last submission, CDC estimates 1 transfer requests submitted per registered entity on an annual basis.

The Report of Theft, Loss, or Release of Select Agent and Toxin form (42 CFR 73.19(a)(b)) must be completed by entities whenever there is theft, loss, or release of a select agent or toxin. Estimated average time to complete this form is 1 hour. Based on data regarding the reports received since the last submission, CDC estimates that 1 report