DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Presidential Commission for the Study of Bioethical Issues, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: The Presidential Commission for the Study of Bioethical Issues will conduct its fourteenth meeting on August 19–20, 2013. At this meeting, the Bioethics Commission will continue to discuss the ethical implications of incidental findings. The Bioethics Commission will also discuss the BRAIN Initiative and ongoing work in neuroscience.

DATES: The meeting will take place Monday and Tuesday, August 19–20, 2013.

ADDRESSES: Smilow Center for Translational Research, Perelman School of Medicine at the University of Pennsylvania, Smilow Center for Translational Research Commons, 3400 Civic Center Boulevard, Building 421, Philadelphia, PA 19104.

FOR FURTHER INFORMATION CONTACT: Hillary Wicai Viers, Communications Director, Presidential Commission for the Study of Bioethical Issues, 1425 New York Avenue NW., Suite C–100, Washington, DC 20005. Telephone: 202–233–3960. Email: *Hillary.Viers@bioethics.gov.* Additional information may be obtained at *www.bioethics.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act of 1972, Public Law 92–463, 5 U.S.C. app. 2, notice is hereby given of the fourteenth meeting of the Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission). The meeting will be held from 9 a.m. to approximately 5 p.m. on Monday, August 19, 2013, and from 9 a.m. to approximately 1 p.m. on Tuesday, August 20, 2013, in Philadelphia, PA. The meeting will be open to the public with attendance limited to space available. The meeting will also be webcast at *www.bioethics.gov.*

Under authority of Executive Order 13521, dated November 24, 2009, the President established the Bioethics Commission. The Bioethics Commission is an advisory panel of the nation's leaders in medicine, science, ethics, religion, law, and engineering. The Bioethics Commission advises the President on bioethical issues arising from advances in biomedicine and related areas of science and technology. The Bioethics Commission seeks to identify and promote policies and practices that ensure scientific research, health care delivery, and technological innovation are conducted in a socially and ethically responsible manner.

The main agenda item for the Bioethics Commission's fourteenth meeting is to discuss the ethical implications of incidental findings. The Bioethics Commission will also discuss the BRAIN Initiative and ongoing work in neuroscience.

The draft meeting agenda and other information about the Bioethics Commission, including information about access to the webcast, will be available at *www.bioethics.gov.*

The Bioethics Commission welcomes input from anyone wishing to provide public comment on any issue before it. Respectful debate of opposing views and active participation by citizens in public exchange of ideas enhances overall public understanding of the issues at hand and conclusions reached by the Bioethics Commission. The Bioethics Commission is particularly interested in receiving comments and questions during the meeting that are responsive to specific sessions. Written comments will be accepted at the registration desk and comment forms will be provided to members of the public in order to write down questions and comments for the Bioethics Commission as they arise. To accommodate as many individuals as possible, the time for each question or comment may be limited. If the number of individuals wishing to pose a question or make a comment is greater than can reasonably be accommodated during the scheduled meeting, the Bioethics Commission may make a random selection.

Written comments will also be accepted in advance of the meeting and are especially welcome. Please address written comments by email to *info@bioethics.gov,* or by mail to the following address: Public Commentary, Presidential Commission for the Study of Bioethical Issues, 1425 New York Ave. NW., Suite C–100, Washington, DC 20005. Comments will be publicly available, including any personally identifiable or confidential business information that they contain. Trade secrets should not be submitted.

Anyone planning to attend the meeting who needs special assistance, such as sign language interpretation or other reasonable accommodations, should notify Esther Yoo by telephone at (202) 233–3960, or email at *Esther.Yoo@bioethics.gov* in advance of the meeting. The Bioethics Commission will make every effort to accommodate persons who need special assistance.

Dated: July 10, 2013.

Lisa M. Lee,

Executive Director, Presidential Commission for the Study of Bioethical Issues.

[FR Doc. 2013–18157 Filed 7–30–13; 8:45 am]

BILLING CODE 4154–06–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 Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) Quality Demonstration Grant Program: Qualitative Data Collection.''* 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 30, 2013.

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

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

Section 401(a) of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA), Public Law 111–3, amended the Social Security Act (the Act) to enact section 1139A (42 U.S.C. 1320b–9a). AHRQ is

requesting approval from the Office of Management and Budget (OMB) for the collection of qualitative data through site visit interviews and focus groups to support a comprehensive, mixed-methods evaluation of the quality demonstration grants authorized under section 1139A(d) of the Act. AHRQ's mission of improving the quality and effectiveness of health care in the United States aligns with evaluating whether, and through what mechanism, projects funded by the CHIPRA demonstration grants improve the quality of care received by children in Medicaid and the Children's Health Insurance Program (CHIP).

CHIPRA included funding for five-year grants so that States can experiment with and evaluate several promising ideas related to improving the quality of children's health care in Medicaid and CHIP. In February 2010, the Centers for Medicare & Medicaid Services (CMS) announced the award of 10 demonstration grants to States that convincingly articulated an achievable vision of what they could accomplish by the end of the five-year grant period, described strategies they would use to achieve the objectives, and explained how the strategies would achieve the objectives. Applicants were encouraged by CMS to address multiple grant categories (described below) and to partner with other States in designing and implementing their projects.

Of the 10 grantee States selected, six 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 have implemented 51 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 pediatric quality measures, including those in the initial core set of children's health care quality measures (a group of measures developed for state Medicaid and CHIP agencies to report in a standardized fashion to CMS). Category B grantees are promoting health information technologies for improved care delivery and patient outcomes. Category C grantees are implementing the patient-centered medical home (PCMH) model of primary care, working with school-based health centers (SBHCs) to improve care, or using other provider-based service delivery models aimed at improving care quality. 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 phase of the project will use qualitative techniques such as in-depth interviews and focus groups.

The first round of interviews for the project was completed in an earlier phase of the project in August of 2012 under an information collection request approved by OMB on February 17th, 2012 (OMB Control No. 0935–0190). While the first round of interviews focused on demonstration goals and early strategies, the second round of interviews described in this information collection request will focus on demonstration outcomes and lessons learned. These interviews are designed to build on the information gathered in the first round to develop a complete picture of demonstration implementation.

AHRQ's goal in performing this evaluation of the CHIPRA Quality Demonstration Grant Program is to produce insights into how best to implement quality improvement programs as well as information on how successful programs can be replicated to improve children's health care quality in Medicaid and CHIP. The specific goals of this project are as follows:

1. Develop a deep, systematic understanding of how CHIPRA demonstration States carried out their grant-funded projects.
2. Understand why the CHIPRA demonstration States pursued certain strategies.
3. 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.
4. Identify CHIPRA State activities that measurably improve the nation's health care, especially as it pertains to children.

This study is being conducted by AHRQ through its contractor, Mathematica Policy Research Inc., and their subcontractors, the Urban Institute and AcademyHealth, 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 healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

To meet the project goals AHRQ will implement the following data collections:

1. Key Staff Interviews—Key staff members are staff directly involved in the design and oversight of grant-funded activities. 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. Semi-structured interviews will be conducted with up to 4 key staff members per state.

2. Implementation Staff Interviews—Other implementation staff are staff involved in the day-to-day implementation of grant-funded projects. 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. Semi-structured interviews will be conducted with up to 16 other implementation staff members per state.

3. Stakeholder Interviews—External stakeholders have a direct interest in children's care quality in Medicaid and CHIP. 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. Semi-structured interviews will be conducted with up to 8 external stakeholders per State.

4. Health Care Organization Staff Interviews—Depending on the projects a state is implementing, health care organizations participating in demonstration activities can include private practices, public clinics, federally qualified health centers, care management entities, or school based health centers. Interviews will capture information about project-related activities, staff perceptions of outcomes and impacts, and the organizations involvement in other quality-improvement initiatives. Semi-structured interviews will be conducted with up to 12 staff members per state.

5. Parent Focus Groups—We will hold in-person focus groups with parents, guardians, or other caregivers of children who are enrolled in Medicaid or CHIP and are served by the medical

practices involved in the CHIPRA demonstration. There will be four focus groups in four of the twelve states implementing patient-centered medical home demonstration projects. The number of participants per focus group will range from 8 to 10, resulting in a maximum of 160 adults participating. They will be conducted in English, and also in Spanish in states with high proportions of Hispanic individuals covered by Medicaid.

6. Adolescent Focus Groups—We will hold in-person focus groups with adolescents who are enrolled in Medicaid or CHIP and are served by school-based health centers involved in the CHIPRA demonstration. There will be four focus groups in one of the two states implementing school-based health center projects. The number of participants per focus group will range from 8 to 10, resulting in a maximum of 40 adolescents participating.

This evaluation is designed to develop a rich understanding of States' implementation activities (goal 1), document the rationale for the selection of particular strategies (goal 2), document provider and parent reported behavior change (goal 3), and assess the perceived impact of those changes on access, quality, and cost of care (goal 4).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation. Key staff interviews will be conducted with up to four persons from each of the 18 CHIPRA demonstration States (72 total) and will last for about 1½ hours. Implementation staff interviews will include up to 16 persons from each of the 18 CHIPRA demonstration States (288 total) and take an hour to complete. Stakeholder interviews will include up to 8 persons from each of the 18 CHIPRA demonstration States (144 total) and also take an hour to complete. Health care provider interviews will be conducted with up to 12 persons from each of the 18 CHIPRA demonstration States and will last 45 minutes (216 total). About 229 parents will be screened to get a maximum of 160 parents to participate in 16 focus groups across 4 States implementing PCMH-focused demonstration projects. The screener takes 25 minutes to complete and the focus group will last one and a half hours; the burden estimate of 2.5 hours includes one hour for travel time to and from the focus group site. About 57 adolescents will be screened to get up to 40 adolescents to participate in four focus groups completed in one State with SBHC demonstration projects. The screener takes 25 minutes to complete and the focus group will last one and a half hours (travel time does not apply because the focus groups will be held on school premises). The total burden for the qualitative evaluation is estimated to be 1,281 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents*	Number of responses per respondent	Hours per response	Total burden hours
Key Staff Interviews	72	1	1.5	108
Implementation Staff Interviews	288	1	1	288
Stakeholder Interviews	144	1	1	144
Health Care Provider Interviews	216	1	45/60	162
Parent Focus Group Screener	**229	1	25/60	95
Parent Focus Groups	160	1	2.5	400
Adolescent Focus Group Screener	**57	1	25/60	24
Adolescent Focus Groups	40	1	1.5	60
Total	1,206	na	na	1,281

*The number of respondents that will be interviewed in each state will vary depending on the number, scope, complexity, and nature of the projects implemented. This table reflects upper-bound estimates of total burden hours and the number of respondents per type per state.
**Based on an expected 70% screen-in rate

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this evaluation. The total cost burden for the interviews and focus groups is estimated to be $43,303.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Key Staff Interviews	72	108	[a] $55.22	$5,964
Implementation Staff Interviews	288	288	[b] 30.99	8,925
Stakeholder Interviews	144	144	[b] 30.99	4,463
Health Care Provider Interviews	216	162	[c] 80.59	13,056
Parent Focus Group Screener	229	95	[d] 22.01	2,091
Parent Focus Groups	160	400	[d] 22.01	8,804
Adolescent Focus Group Screener	57	24	[e] 0	0.00
Adolescent Focus Groups	40	60	[e] 0	0.00
Total	1,206	1,281	na	43,303

*National Compensation Survey: Occupational wages in the United States May 2012, ''U.S. Department of Labor, Bureau of Labor Statistics.''
[a] Based on the mean wages for general and operations manager (11–1021)
[b] Based on the mean wages for social and community service managers (11–9151)
[c] Based on the mean wages for general pediatricians (29–1065)
[d] Based on the mean wages for all occupations
[e] Wage rates for adolescents are assumed to be zero.

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: July 23, 2013.

Carolyn M. Clancy,

AHRQ Director.

[FR Doc. 2013–18378 Filed 7–30–13; 8:45 am]

BILLING CODE 4160–90–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: ''Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database.'' 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 16th, 2013 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 30, 2013.

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 email 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 email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Hospital Survey on Patient Safety Culture Comparative Database

Request for information collection approval. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Hospital Survey on Patient Safety Culture (Hospital SOPS) Comparative Database; OMB NO. 0935–0162, last approved on May 5th, 2010. The Hospital SOPS Comparative Database consists of data from the AHRQ Hospital Survey on Patient Safety Culture. Hospitals in the U.S. are asked to voluntarily submit data from the survey to AHRQ. The database was developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals in their efforts to improve patient safety.

Background on the Hospital SOPS. In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; *To Err is Human: Building a Safer Health System*). To respond to the need for tools to assess patient safety culture in health care, AHRQ developed and pilot tested the Hospital Survey on Patient Safety Culture with OMB approval (OMB NO. 0935–0115; Approved 2/4/2003). The survey was designed to enable hospitals to assess staff opinions about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 dimensions of patient safety culture. AHRQ released the survey to the public along with a Survey User's Guide and other toolkit materials in November 2004 on the AHRQ Web site. Since its release, the survey has been voluntarily used by hundreds of hospitals in the U.S.

Rationale for the information collection. The Hospital SOPS survey and the Hospital SOPS Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in hospital settings. The surveys, toolkit materials, and comparative database results are all made publicly available along with technical assistance, provided by AHRQ through its contractor at no charge to hospitals, to facilitate the use of these materials for hospital patient safety and quality improvement.

This study is being conducted by AHRQ through its contractor, Westat, 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; quality measurement and improvement; and database development. 42 U.S.C. 299a(a)(1), (2), and (a)(8).

Method of Collection

All information collection for the Hospital SOPS Comparative Database is done electronically, except the Data Use Agreement (DUA) that hospitals sign in hard copy and fax or mail back. Registration, submission of hospital information, and data upload is handled online through a secure Web site. Delivery of confidential hospital survey feedback reports is also done electronically by having submitters enter a username and password and downloading their reports from a secure Web site.

Survey data from the AHRQ Hospital Survey on Patient Safety Culture is used to produce three types of products: (1) An annual Hospital SOPS Comparative Database Report that is made publicly available in the public domain; (2) Individual Hospital Survey Feedback Reports that are confidential, customized reports produced for each hospital that submits data to the database; and (3) Research data sets of individual-level and hospital-level de-identified data to enable researchers to conduct analyses.