eligible for updates between July 2014 and June 2015, either by the registry owner's initiative, or when prompted by the automated RoPR reminder. This update process takes about 15 minutes. As the RoPR continues to grow and more patient registry records are added over time, this percentage represents a growing, cumulative number.

In February 2015, Quintiles conducted a knowledge transfer webinar for registry contacts learn how to enter new records into the RoPR. As a result of the knowledge gained during these processes, it is estimated that it takes users 45 minutes to manually enter a new RoPR record; 15 minutes to upload a new RoPR record (an average of 30 minutes using either method). It takes 15 minutes for a person to review and make updates to an existing RoPR record. The total respondent burden is estimated to be a maximum of 64 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
New RoPR Record (manually—entered or uploaded electronically method)	59	1	45/60	44.25
Review/update existing RoPR Record	79	1	15/60	19.75
Total	138			64.0

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden to respondents is estimated at an average of $1,799.60 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate †	Total cost burden
New RoPR Record (manually—entered or uploaded electronically method)	59	44.25	$36.54	$1,617
Review/update existing RoPR Record	79	19.75	36.54	721.67
Total	138	64		2,339

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational wages in the United States May 2014, ''U.S. Department of Labor, Bureau of Labor Statistics.'' Available at: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000*.

In order to highlight patient registry concerns about using the RoPR system and turning user feedback into future system maintenance and upgrade initiatives (increasing the usability of the RoPR and lowering the burden of entering patient registry information), plans for a voluntary user satisfaction survey are being considered for 2Q 2016. Its full nature and design is in the concept stage. Therefore, this survey is not part of the Estimated Annualized Respondent Hourly/Cost Burden noted in Exhibits 1 and 2.

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 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.

Sharon Arnold,

Deputy Director.

[FR Doc. 2015–31158 Filed 12–10–15; 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: *''Online Submission Form for Supplemental Evidence and Data for Systematic reviews for the Evidence-based Practice Center 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 September 21st, 2015 and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by January 11, 2016.

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).

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

This is a new activity of AHRQ's Evidence-based Practice Center Program.

Evidence-Based Practice Center Program

AHRQ's Evidence-based Practice Center (EPC) Program develops evidence reports and technology assessments on topics relevant to clinical and other health care organization and delivery issues—specifically those that are common, expensive, and/or significant for the Medicare and Medicaid populations. For example recent reviews have focused on clinical conditions, such as ''Treatment of Nonmetastatic Muscle-Invasive Bladder Cancer''; health delivery topics such as ''Management Strategies to Reduce Psychiatric Admissions''; and specific technologies such as ''Imaging Techniques for Treatment Evaluation for Metastatic Breast Cancer.'' These evidence reports include systematic reviews and technical briefs, and provide an essential foundation from which to understand what we know from existing research and what critical research gaps remain. These reports, reviews, and technology assessments are based on rigorous, comprehensive syntheses and analyses of the scientific literature on topics. EPC reports and assessments emphasize explicit and detailed documentation of methods, rationale, and assumptions. EPC reports are conducted in accordance with an established policy on financial and nonfinancial interests. These scientific syntheses may include meta-analyses and cost analyses.

The EPC Program supports AHRQ's mission by synthesizing and disseminating the available research as a ''science partner'' with private and public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care. The EPC Program is a trusted source of rigorous, comprehensive, and unbiased evidence reviews for stakeholders. The resulting evidence reports and technology assessments are used by Federal and State agencies, private-sector professional societies, health delivery systems, providers, payers, and others committed to evidence-based health care. These end users may use EPC Program evidence reports to inform policy decisions, clinical practice guidelines, and other health care decisions.

EPC research has the following goals:

○ Use research methods to gather knowledge on the effectiveness of certain treatments for specific medical conditions, both published and unpublished, to evaluate the quality of research studies and the evidence from these studies.

○ Promote the use of evidence in health care decision making to improve health care and health.

○ Identify research gaps to inform future research investments.

The Institute of Medicine standards for quality systematic reviews include an assessment of publication bias through the identification of unpublished studies. This is an important source for bias which could affect the nature and direction of research findings. Identifying and including the results of these additional unpublished studies may provide a more complete and accurate assessment of an intervention's effect on outcomes. An important way to identify unpublished studies is through requests to medical device manufacturers, pharmaceutical companies, and other intervention developers.

The proposed project involves sending a request letter to relevant medical device manufacturers, pharmaceutical companies and other intervention developers to invite them to submit unpublished studies or other scientific information to the EPC Program Web site, with one request per systematic review topic. Because research on each topic must be completed in a timely manner in order for it to be useful, the collections are never ongoing—there is one request and collection per topic. Investigators in the EPC Program will review the information and assess potential risk of bias from both published and unpublished studies and its impact on the EPC Program's findings. AHRQ believes the display of these assessments in the systematic review's evidence tables will improve the response and submission rates of industry stakeholders by informing the health care community of the impact of potential bias on the research conclusions, and for health care decision making.

This activity is being conducted by AHRQ's EPC Program through its contractor, the Scientific Resource Center (SRC), pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care and to disseminate government-funded research relevant to comparative clinical effectiveness research. 42 U.S.C. 299a(a); 42 U.S.C. 299b–37(a).

Method of Collection

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

• Online Submission Form Instrument. This information is collected for the purposes of providing supplemental evidence and data for systematic reviews (SEADS). The online submission form (OSF) collects data from respondents on their organization name, their product's name, and whether they are providing all information on requested studies characteristic of the review in progress. This happens following receipt of a request letter from the SRC. These requests will be sent to relevant sponsors of preventive and treatment interventions (*e.g.,* medical device manufacturers, pharmaceuticals, and other intervention and health care system developers), with one request per topic. For the purposes of meta-analyses, trial summary data from missing and unidentified studies are sought. For the purposes of constructing evidence tables and quality ratings (*e.g.* on public reporting of cost measures or health information exchange), data can vary (*e.g.,* URLs, study designs, and consumer-mediated exchange forms). Information on both completed and ongoing studies are requested.

The EPC Program, through the SRC, currently uses a **Federal Register** notice and broad-based email announcement to stakeholders to allow the public to know about each topic, and the opportunity to submit scientific information. In 2014, the Program sent 517 notifications to 336 industry stakeholders. Of those 517 announcements sent, 14.1% received a response; 56.2% of the responses (or 7.9% of all requests) contained submissions of information on the results of interventions. This experience has prompted this proposed project.

The additional use of direct requests to relevant organizations would improve the Program's ability to obtain this information. Contacting intervention sponsors for missing and potentially unidentified studies could improve the impact of research efforts and downstream dissemination efforts and could positively impact the health of individuals, burdened by poor health along with their supporting communities. Including information about response data to these requests to more accurately characterize the

completeness of the evidence in the systematic reviews may also address this issue.

The proposed project does not duplicate other available sources of this information. Available study registries and databases may not be complete to sufficiently inform the Program's research.

The purpose of SEADS requests is not to collect generalizable data, but to supplement the published and grey literature searches EPC investigators are conducting. Furthermore, considering the evidence and data included in responses collected from industry stakeholders, an assessment pertaining to the completeness of the evidence-base will be produced. This, AHRQ believes, will increase the value of AHRQ's research reviews to end users and potentially provide stakeholders a better understanding of how their submissions are used.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on pilot testing of materials and what can reasonably be requested of respondents. The number of respondents listed in ''Number of respondents per SEADS request'' of Exhibit 1 reflects a projected 80% response rate.

Online Submission Form: A form for submitting scientific evidence and data related to medical interventions sponsored by organizations and individuals such as pharmaceutical companies and independent researchers. The form has three required fields: The organization's name, the intervention in question, and whether the information they provide is all the information they know to exist. They may upload documents and they are also provided a data entry form if they wish to offer greater details on their studies.

An Optional Data Entry Form is available as an alternative to the Online Submission form. The time requirements for response would be same as the Online Submission Form.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents per SEADS request	Number of responses per respondent	Hours per response	Total burden hours per SEADS
Online Submission Form (OSF)	70	1	15/60	17.5
Total	70	1	15/60	17.5

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of SEADS requests	Total burden hours per SEADS	Average hourly wage rate *	Total cost burden
OSF	70	17.5	[a] $55.48	$970.90
Total	70	17.5	55.48	970.90

* Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.*

[a] Based on the mean wages for *Public Relations and Fundraising Managers, 11–2031,* the occupational group most likely tasked with completing the OSF.

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.

Sharon Arnold,

Deputy Director.

[FR Doc. 2015–31159 Filed 12–10–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–16–0950]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of