



**BILLING CODE 4160-90-M**

**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, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the *Federal Register* on April 1, 2019 and allowed 60 days for public comment. AHRQ received no 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**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](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 email at [doris.lefkowitz@AHRQ.hhs.gov](mailto:doris.lefkowitz@AHRQ.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

*Proposed Project*

*Online Submission Form for Supplemental Evidence and Data for Systematic Reviews for the Evidence-based Practice Center Program*

The AHRQ Evidence-based Practice Center (EPC) Program develops evidence reports and technology assessments that summarize evidence for federal and other partners 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. Better understanding and use of evidence in practice, policy, and delivery of care improves the quality of health care.

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.

This research has the following goals:

- Use research methods to gather knowledge on the effectiveness or comparative effectiveness of treatments, screening, diagnostic, management or healthcare delivery strategies 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 healthcare decision making to improve healthcare and health.
- Identify research gaps to inform future research investments.

The 2011 Institute of Medicine report “Finding What Works in Health Care: Standards for Systematic Review” includes 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 notification via an email listserv and via Federal Register notice as needed of the opportunity to submit information on unpublished studies or other scientific information to the EPC Program website, 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. This study is being conducted by AHRQ, 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. 42 U.S.C 299a(a)(1).

### **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 purpose of SEADS requests is not to collect generalizable data, but to supplement the published and grey literature searches EPC investigators are conducting. The online submission form (OSF) collects data from respondents on their name and the information packet. This happens following notification of opportunity to submit via email listserv and/or *Federal Register* notice as needed, 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). Submitters are informed of the types of information that would be most helpful to include in the information packet, which includes a list of all sponsored but unpublished studies (both completed and ongoing), as well as comment on the completeness of information provided.

The EPC Program currently uses a broad-based email announcement via email listserv and a Federal Register notice, as needed, to publicize the opportunity to submit scientific information about each topic. The proposed project does not duplicate other available sources of this information. Available study registries and databases may not sufficiently inform the Program's research. The EPC Program does not anticipate more than 15 topics per year with SEADS requests.

### **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 33% response rate with approximately 1-2 responses per request and assumes about 15 SEADS requests per year.

**Exhibit 1. Estimated annualized burden hours**

Form Name	Number of SEADS requests	Number of SEADS request that receive response	Number of responses per SEADS request	Annual number of SEADS responses	Hours per response	Total burden hours per annum
Online Submission Form (OSF)	15	5	1.5	7.5	15/60	1.87

**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	15	1.87	\$61.39 <sup>a</sup>	\$ 115.10

\*Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics.

[https://www.bls.gov/oes/current/oes\\_nat.htm#11-0000](https://www.bls.gov/oes/current/oes_nat.htm#11-0000)

<sup>a</sup>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's 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.

**Virginia L. Mackay-Smith,**

*Associate Director.*

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