

EXHIBIT A.2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
b. Structural Assessments—Cohort 4 (baseline and endline) .....	167	67	<sup>a</sup> 98.83	6,622
2. Team Antibiotic Review Form (Cohorts 1, 2, and 3) .....	337	7,583	<sup>a</sup> 98.83	749,428
3. AHRQ Patient Safety Culture Surveys:				
a. HSOPS, NHSOPS, MOSOPS (Cohort 1) .....	83	83	<sup>b</sup> 27.87	2,313
b. HSOPS (Cohort 2) .....	4,167	4,167	<sup>b</sup> 27.87	116,134
c. NHSOPS (Cohort 3) .....	4,167	4,167	<sup>b</sup> 27.87	116,134
d. MOSOPS (Cohort 4) .....	4,167	4,167	<sup>b</sup> 27.87	116,134
4. Semi-structured qualitative interviews (Cohort 1):				
a. Physicians .....	30	60	<sup>a</sup> 98.83	5,930
b. Other Health Practitioners .....	60	120	<sup>b</sup> 27.87	3,344
5. EHR data (Cohorts 1, 2, and 3) .....	334	4,008	<sup>b</sup> 27.87	111,703
6. EHR data (Cohort 4) .....	167	2,505	<sup>b</sup> 27.87	69,814
<b>Total</b> .....	<b>14,022</b>	<b>27,064</b>	.....	<b>1,311,096</b>

\* National Compensation Survey: Occupational wages in the United States May 2016 “U.S. Department of Labor, Bureau of Labor Statistics:” [http://www.bls.gov/oes/current/oes\\_stru.htm](http://www.bls.gov/oes/current/oes_stru.htm).

<sup>a</sup> Based on the mean wages for 29–1069 Physicians and Surgeons, All Other.

<sup>b</sup> Based on the mean wages for 29–9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other.

**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.

**Gopal Khanna,**

*Director.*

[FR Doc. 2019–06193 Filed 3–29–19; 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.*”

**DATES:** Comments on this notice must be received by May 31, 2019.

**ADDRESSES:** Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at [doris.lefkowitz@AHRQ.hhs.gov](mailto: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](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*

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. 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 health care 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 health care decision making to improve health care 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 health care 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**

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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.

**Gopal Khanna,**

*Director.*

[FR Doc. 2019-06192 Filed 3-29-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE19-004, Etiologic and Effectiveness Research To Address Polysubstance Impaired Driving; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CE19-004, Etiologic and Effectiveness Research to Address Polysubstance Impaired Driving; May 7-8, 2019; 8:30 a.m.–5:30 p.m., (EDT) which was published in the **Federal Register** on February 15, 2019, Volume 84, Number 32, page/s/4446-4447.

The meeting is being amended to change the meeting location to The W Buckhead, 3377 Peachtree Road, NE, Atlanta, GA 30326. The meeting is closed to the public.

**FOR FURTHER INFORMATION CONTACT:** Mikel L. Walters, M.A., Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F-63, Atlanta, Georgia 30341, (404) 639-0913; [mwalters@cdc.gov](mailto:mwalters@cdc.gov).

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Sherri Berger,**

*Chief Operating Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2019-06146 Filed 3-29-19; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1725-N]

#### Medicare Program; Meeting Announcement for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the next public meeting dates for the Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) on Monday, July 22, 2019 and Tuesday, July 23, 2019. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services on issues related to clinical diagnostic laboratory tests.

**DATES: Meeting Dates:** The meeting of the Panel is scheduled for Monday, July 22, 2019 from 8:00 a.m. to 4:30 p.m., Eastern Daylight Time (E.D.T.) and Tuesday, July 23, 2019, from 8:00 a.m. to 4:30 p.m., E.D.T. The Panel is also expected to participate in the Clinical Laboratory Fee Schedule (CLFS) Annual Public Meeting for Calendar Year (CY) 2020 on June 24, 2019 in order to gather information and ask questions to presenters. Notice of the CLFS Annual Public Meeting for CY 2020 is published elsewhere in this issue of the **Federal Register**.

**Deadline for Registration:** The public may attend the Panel meeting in person, view via webcast or listen via teleconference. Beginning Monday, April 8, 2019 and ending Monday, July 1, 2019 at 5:00 p.m. E.D.T., registration to attend the Panel meeting in person may be completed online at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. On this web page, under "Panel Meetings," click the "Register for July 22 through 23, 2019 Panel Meeting" link and enter the required information. We refer readers to Section IV. of this notice for additional details related to meeting registration.

**Webinar, Webcast, and Teleconference Information:** Teleconference dial-in instructions, and related webcast and webinar details will be posted on the meeting agenda, which will be available on the CMS website approximately 2 weeks prior to the meeting at <https://www.cms.gov/>

[Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html](https://www.cms.gov/Regulations-and-Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html). A preliminary agenda is described in Section II. of this notice.

**ADDRESSES:** The Panel meeting will be held in the auditorium of the Centers for Medicare & Medicaid Services (CMS), Central Building, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**FOR FURTHER INFORMATION CONTACT:** Rasheeda Arthur, Ph.D., (410) 786-3434, email [CDLTPanel@cms.hhs.gov](mailto:CDLTPanel@cms.hhs.gov). Press inquiries are handled through the CMS Press Office at (202) 690-6145. For additional information on the Panel, refer to the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Medicare Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) is authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m-1), as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113-93), enacted on April 1, 2014. The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (the Secretary) to consult with an expert outside advisory panel established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests. Such individuals may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator of the Centers for Medicare & Medicaid Services (CMS) on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use "crosswalking" or "gapfilling" processes to determine payment for a specific new test.