

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	300	1	5/60	25
Hospital Information Form	300	1	5/60	25
Data Use Agreement	300	1	3/60	15
Data Files Submission	2	150	1	300
Total	902	NA	NA	365

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete one

submission process. The cost burden is estimated to be \$16,722 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	300	25	53.69 ^a	\$1,342
Hospital Information Form	300	25	^a 53.69	1,342
Data Use Agreement	300	15	^b 94.25	1,414
Data Files Submission	2	300	^c 42.08	12,624
Total	902	365	NA	16,722

* National Compensation Survey: Occupational wages in the United States May 2017, "U.S. Department of Labor, Bureau of Labor Statistics."

(a) Based on the mean hourly wage for Medical and Health Services Managers (11-9111).

(b) Based on the mean hourly wage for Chief Executives (11-1011).

(c) Based on the mean hourly wages for Computer Programmer (15-1131).

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.

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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 "Consumer Assessment of Healthcare Providers and Systems (CAHPS) Home and Community Based Services (HCBS) Survey Database."

DATES: Comments on this notice must be received by May 20, 2019.

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 emails at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home and Community Based Services (HCBS) Survey 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. The CAHPS Home and Community-Based Services Survey is the first cross-disability survey of home and community-based service beneficiaries' experience receiving long-term services and supports. It is designed to facilitate comparisons across state Medicaid HCBS programs throughout the country that target adults with disabilities, e.g., including frail elderly, individuals with physical disabilities, persons with developmental or intellectual disabilities, those with acquired brain injury and persons with severe mental illness.

The HCBS CAHPS Survey was developed by the Centers for Medicare & Medicaid Services (CMS) for

voluntary use by state Medicaid programs, including both fee-for-service HCBS programs as well as managed long-term services and supports (MLTSS) programs. States with adequate sample sizes may consider using survey metrics in value-based purchasing initiatives.

The HCBS-CAHPS Database will serve as a primary source of data available to states, agency programs and researchers to help answer important questions related to beneficiary experiences. AHRQ, through its contractor, will collect and make available de-identified survey data, enabling HCBS programs to identify areas where quality can be improved.

Rationale for the information collection. Aggregated HCBS-CAHPS Database results will be made publicly available on AHRQ’s CAHPS website. Technical assistance will be provided by AHRQ, through its contractor, at no charge to programs to facilitate the access and use of these materials for quality improvement and research. Technical assistance will also be provided to support HCBS-CAHPS data submission.

The HCBS-CAHPS Database will support AHRQ’s goals of promoting improvements in the quality and patient-centeredness of health care in home or community-based care settings. This research has the following goals:

1. Improve care provided by individual providers and state programs.
2. Offer several products and services, including providing survey results presented through an Online Reporting System, summary chartbooks, custom analyses, private reports and data for research purposes.
3. Provide information to help identify strengths and areas with potential for improvement in patient care.

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

Method of Collection

The development and operation of the HCBS-CAHPS Database will include the following major components undertaken by AHRQ through its contractor. To achieve the goals of this project, the following activities and data collections that constitute information collection under the Paperwork Reduction Act (PRA) will be implemented:

- Registration with the site to obtain an account with a secure username and password: The point-of-contact (POC) completes an online registration form, providing contact and organizational information required to initiate the registration process.
- Submission of signed Data Use Agreements (DUAs) and survey questionnaires: The data use agreement completed by the participating organization provides confidentiality assurances and states how the data submitted will be used.
- Submission of program information form: The POC completes an online information form to describe organizational characteristics of the program.
- Submission of de-identified survey data files: POCs upload data files in the format specified in the data file specifications to ensure data submitted is standardized and consistently named and coded.
- Follow-up with submitters in the event of a rejected file, to assist in

making corrections and resubmitting the file.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondents to participate in the database. The 51 POCs in Exhibit 1 represent the 51 states or agencies that will administer the Adult HCBS survey. An estimated 13 survey vendors will assist them.

Each state or agency will register online for submission. The online Registration form will require about 5 minutes to complete. Each submitter will also complete a program information form of information about each program such as the name of the program, program size, state, etc. The online program information form takes on average 5 minutes to complete. The data use agreement will be completed by each of the 51 participating States. Survey vendors do not sign or submit DUAs. The DUA requires about 3 minutes to sign and return by fax or mail. Each submitter, which in most cases will be the survey vendor performing the data collection, will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provided by the HCBS-CAHPS Database. Since the unit of analysis is at the program level, submitters will upload one data file per program. Once a data file is uploaded the file will be automatically checked to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to correct any errors in their data file and resubmit if necessary. It will take about one hour to submit the data for each program. The total burden is estimated to be 63 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form	51	1	5/60	4.25
Program Information Form	51	1	5/60	4.25
Data Use Agreement	51	1	3/60	2.5
Data Files Submission	13	4	1	52
Total	166	NA	NA	63

Exhibit 2 shows the estimated annualized cost burden based on the

respondents’ time to complete one

submission process. The cost burden is estimated to be \$2,880 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Registration Form	51	4.25	^a 53.69	\$228
Program Information Form	51	4.25	^a 53.69	228
Data Use Agreement	51	2.5	^b 94.25	236
Data Files Submission	13	52	^c 42.08	2,188
Total	** 166	63	NA	2,880

* National Compensation Survey: Occupational wages in the United States May 2017, "U.S. Department of Labor, Bureau of Labor Statistics."

^a Based on the mean hourly wage for Medical and Health Services Managers (11–9111).

^b Based on the mean hourly wage for Chief Executives (11–1011).

^c Based on the mean hourly wages for Computer Programmer (15–1131).

** The 51 POCs listed for the registration form, program information form and the data use agreement are the estimated POCs from the estimated participating programs.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Noninvasive Nonpharmacologic Treatment for Chronic Pain

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Noninvasive Nonpharmacologic Treatment for Chronic Pain*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before April 18, 2019.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Jenae Bennis, Telephone: 301–427–1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Noninvasive Nonpharmacologic Treatment for Chronic Pain*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we

are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Noninvasive Nonpharmacologic Treatment for Chronic Pain*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/topics/noninvasive-nonpharm-pain-update/protocol>.

This is to notify the public that the EPC Program would find the following information on Noninvasive Nonpharmacologic Treatment for Chronic Pain helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your