

developed based on the Consolidated Framework for Implementation Research framework will be used to conduct the interviews, together with a corresponding consent form.

Estimated Annual Respondent Burden

Exhibit 1 shows only the estimated annualized burden hours for the

respondents' time to participate in updates to the information collection of the SPPC–II Demonstration Project.

One-hour qualitative interviews will be conducted with a total of 8 AIM Team Leads and 30-minute qualitative interviews with 32 frontline staff in 8 hospitals. We will also conduct 8 one-

hour focus group discussions with a total of 40 AIM Team Leads and frontline staff in the same hospitals.

The total burden hours resulting from the proposed updates to the SPPC–II data collection is 64 hours. The total annual burden hours are estimated to be 54,693 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Qualitative semi-structured interviews with AIM Team Leads	8	1	1.00	8
Qualitative semi-structured interviews with frontline staff	32	1	0.50	16
Focus group discussions with AIM Team Leads and frontline staff	40	1	1	40
Total	80	NA	NA	64

Exhibit 2 shows only the hours and cost of updates to the collection. The total cost burden of the updated

collection is estimated to be \$1,421,576.68 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Qualitative semi-structured interviews with AIM Team Leads	8	8	\$49.83	\$398.64
Qualitative semi-structured interviews with frontline staff	32	16	49.83	797.28
Focus group discussions with AIM Team Leads and frontline staff	40	40	49.83	1,993.20
Total	80	64	3,189.12

* National Compensation Survey: Occupational wages in the United States May 2017 “U.S. Department of Labor, Bureau of Labor Statistics.” Weighted mean hourly wage for obstetrician-gynecologists (\$113.10; occupation code 29–1064; 30%); nurse-midwives (\$49.83; occupation code 29–1161; 30%); registered nurses (\$35.36; occupation code 29–1161; 20%); and nurse practitioners (\$51.86; occupation code 29–1171; 20%).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, 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.

Dated: May 21, 2021.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Evaluation of Mental Health Applications

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

Evaluation of Mental Health Applications, 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 June 28, 2021.

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 *Evaluation of Mental Health Applications*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 *Evaluation of Mental Health Applications*, specifically the following:

- Characteristics and minimal standards in terms of appropriateness and effectiveness of available behavioral health applications including adverse events.
- Behavioral health applications assessment frameworks for evaluation/scoring tools.
- The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/mental-health-apps/protocol>.

This is to notify the public that the EPC Program would find the following information on *Evaluation of Mental Health Applications* 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*, 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 organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The technical brief will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Guiding Key Questions (KQs)

1. What characteristics and minimal standards of available behavioral health mobile applications need to be analyzed in existing tools to assess the appropriateness (to various stakeholders) and effectiveness of available apps to include, but not limited to:

- Accessibility including ease of use, health literacy, 508 compliance, digital equity, cost
- App background including funding source, purpose
- Security features and privacy policy such as data ownership/usage
- Clinical foundation and linkage to current evidence-base
- Usability, including interoperability across platforms, stability
- Therapeutic goals, linkage to the provider, crisis warning notification/alert system

2. Identify or develop an assessment framework for evaluation/scoring tools (e.g., websites) and apply the framework to help consumers, family members and peer supports, providers and health systems select behavioral health mobile applications. The framework will take into account current FDA status on the use and classification of risks of apps in healthcare.

Dated: May 21, 2021.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0514]

Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act." The existing postmarket surveillance guidance was issued in May 2016 to address certain postmarket surveillance requirements. This draft guidance is intended to update the 2016 guidance to increase transparency to stakeholders on FDA's approach to the issuance and tracking of these postmarket surveillance orders, and expectations for timely study completion. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by July 26, 2021 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third-party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note