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

The Key Questions

1. *What skin substitutes currently used to treat chronic wounds are being regulated by the U.S. Food and Drug Administration (FDA) under the following pathways: Premarket Approval (PMA), Premarket Notification (510[k]), Section 361 of the Public Health Service Act (21 CFR 1270 and 1271)?*

2. *What classification systems have been developed to categorize skin substitutes?*

a. What are important skin substitute parameters and active components currently being used when classifying skin substitutes?

3. *What are the study design characteristics (such as those listed below) in each included investigation for each chronic wound type?*

a. Comparator to skin substitute
b. Inclusion/exclusion criteria of patients including at least age, gender, and general health requirements (*e.g.,* status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal)
c. Inclusion/exclusion criteria of wounds including at least wound type, wound size/depth/duration/severity, vascular status, infection status, and prior treatment requirements (*e.g.,* no treatment with growth factors or negative pressure wound therapy)
d. Patient characteristics of enrollees including at least age, gender, general health (*e.g.,* status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal), and prior and concurrent wound treatments
e. Wound characteristics of enrollees including at least wound type, wound size/depth/duration/severity, vascular status, and infection status
f. Basic study design and conduct information including at least method of patient enrollment, care setting, and use of run-in period
g. Definition of wound characteristics: definition of ''failure to heal'', and definition of a successfully healed wound
h. Method of applying skin substitutes including provider, frequency of application, definition of standard of care, and handling of infections
i. Measurement and assessment methods including method of assessment(s); frequency and time points for assessment(s); and blinding of assessors
j. Statistical methods including power calculations, intent-to-treat analysis for studies designed to test superiority, and handling of drop-outs

4. *What are the outcomes of treatment strategies including skin substitutes alone and/or in addition to other wound care modalities compared to other wound care modalities in patients with different types of chronic wounds, for patient oriented outcomes such as the following? Consider at least:*

a. Number/percentage of completely closed/healed wounds (skin closure with complete re-epithelialization without drainage or dressing requirements versus failure to heal)
b. Time to complete wound closure
c. Wound reoccurrence (include time when initial wound healing was measured, and follow-up to assess durability of healed wounds)
d. Wound infection
e. Need for amputation
f. Need for hospitalization (frequency and duration)
g. Return to baseline activities of daily living and function
h. Pain reduction
i. Exudate and odor reduction
j. Adverse effects (besides those above)

5. *What skin substitutes are currently being investigated in ongoing trials?*

6. *What best practices in study design could be used to produce high quality evidence on skin substitutes?*

Gopal Khanna,

Director.

[FR Doc. 2019–07302 Filed 4–11–19; 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 ''*Evaluating and Implementing the Six Building Blocks Team Approach to Improve Opioid Management in Primary Care.*''

DATES: Comments on this notice must be received by June 11, 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

Evaluating and Implementing the Six Building Blocks Team Approach To Improve Opioid Management in Primary Care

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 project ''Evaluating and Implementing the Six Building Blocks Team Approach to Improve Opioid Management in Primary Care'' fully supports AHRQ's mission. The ultimate aim of this project is to further validate and expand the Six Building Blocks to Safer Opioid Management (6BBs) intervention and its associated resources and guidance to support primary care providers in safer opioid prescribing.

Opioid overdose deaths have increased dramatically since 1999, and despite recent decreases in the national opioid prescribing rate, prescribing rates remain high in many U.S. counties. Primary care providers (PCPs) are responsible for about half of all dispensed opioid pain relievers. To address the emerging opioid epidemic, the Six Building Blocks to Safer Opioid Management (6BBs) Toolkit has been developed to support primary care providers in safer opioid prescribing, largely concordant with the Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain. The 6BBs is a structured, systems-based approach for improving management of patients on long-term opioid therapy that targets six work areas a primary care practice needs to redesign in order to improve their clinic's management of patients on long-term opioid therapy.

Building upon previous work supported by AHRQ to address the opioid epidemic, this research has the following goals:

1. To improve the guidance for the 6BBs Toolkit,

2. To further implement the 6BBs in primary care practices, and

3. To understand the facilitators and barriers to implementing the Six Building Blocks to Safer Opioid Management.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., 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 and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

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

(1) *Clinical Staff Survey.* A brief survey will be administered electronically to all clinical staff, including primary care physicians, nurse practitioners, physician assistants, social workers, medical assistants, registered nurses, pharmacists and behavioral health workers, toward the beginning of 6BBs Toolkit implementation and approximately 12 months later. A quality improvement (QI) point person will provide email addresses for the staff who will be invited to complete the survey from each participating organization. These email addresses will be used to send clinical staff the surveys at both time points. The survey will collect information about staff's self-reported use of evidence-based opioid prescribing practices; procedures in place around opioid prescribing management; self efficacy regarding safe opioid prescribing; knowledge, beliefs and attitudes regarding opioid prescribing; adaptive reserve; self-reported burnout; and reported implementation experiences. The survey will also collect information about staffs' background (*e.g.,* clinic role and tenure). The survey will consist largely of closed-ended questions (*e.g.,* scale or Likert response options) with several open-ended questions.

(2) *Staff Interviews.* Interviews will be conducted with 5 staff at each of the 12 participating health care organizations. AHRQ will conduct 2 rounds of interviews, with the first round occurring within several months after the How-To-Guide is distributed to the organization and the second round occurring 12 months later. The evaluation team will conduct in-depth interviews with:

a. The quality improvement (QI) lead and

b. Four additional staff who are involved in 6BBs implementation at each organization, that might include a clinician, information technology analyst, social worker, behavioral health specialist, and/or care coordinator.

Staff interviewees will be selected by the QI lead at each organization, who will be asked to nominate a range of staff from those who embraced changes to those who were less willing to implement changes. Interviews will capture qualitative data regarding the organization's history with efforts to curb opioid prescribing, experiences using the How-To-Guide, implementation of the 6BB intervention and associated opioid management interventions, and lessons learned that can be shared with other health care organizations.

(3) *Virtual Launch Meeting.* A virtual launch meeting will be held for organization liaisons and quality improvement leaders participating health care organizations to launch 6BBs Toolkit implementation. The meeting will be conducted by web-conference, and will last up to 2 hours.

(4) *Quarterly Check-In Calls.* A project team member will hold a quarterly check-in call with organization liaisons and quality improvement leaders to assess the progress of implementation of the 6BBs intervention and improvement initiatives at each organization. Check-in calls will occur quarterly for up to 12 months. Each call will be up to 60 minutes in duration, and notes will be taken by an evaluation team member during each call.

(5) *QI Measures.* Each health care organization will be asked to report quarterly on the number of patients on long-term opioid therapy and the proportion of those who are on greater than 90 morphine milligram equivalents, co-prescribed a benzodiazepine, and had the prescription drug monitoring program checked and a urine drug screen. Organizations may also select other outcome measures aligned to their own goals.

(6) *Other outcome and output data from administrative records, electronic medical records, and organizational documents (Secondary Data).* Health care organizations may also report their progress on implementing the 6BB intervention and associated changes in care processes through completion of worksheets contained in or associated with the How-To-Guide. Since these data collections involve simply submitting worksheets they complete for their own benefit while working through the How-To-Guide, they pose only minimal data collection burden to the health care organization, specifically the person who completes the worksheets (*i.e.,* QI lead). The project team will also obtain relevant organizational documents (*e.g.,* opioid prescribing policies, quality improvement plans, sample patient agreements, relevant practice workflows, screen shots of data dashboards).

The purpose of the proposed data collection effort is to obtain information needed to modify and enhance the 6BB How-To-Guide and to provide information to health care organizations considering using the How-To-Guide to improve their opioid prescribing practices and relevant outcomes. Since this is only a study conducted in 12 organizations, outcomes or impacts will not be generalizable.

The data collected will help the project team: (1) Understand the facilitators and barriers of using the 6BB Toolkit and recommended improvements to processes of care and opioid prescribing practices, and (2) assess the effectiveness of using the 6BB Toolkit to improve processes of care and opioid prescribing practices. The data collection effort may also provide insights that could guide dissemination of the Toolkit. For example, if it was found that a specific type of organization included in this pilot study (*e.g.,* small, stand-alone clinic in a rural area) particularly benefitted from using the Toolkit, then AHRQ could tailor and target its dissemination of the Toolkit to similar organizations. Once revisions are made based on results of this evaluation, the How-To-Guide corresponding to the Toolkit will be published on AHRQ's website. A manuscript describing the pilot study and its results will also be produced for publication in a peer-reviewed journal.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences and what can reasonably be requested of participating health care organizations. The number of respondents listed in column A, Exhibit 1 reflects a projected 75% response rate for data collection efforts 2a and 2b below.

1. *Clinical Staff Survey.* A brief survey will be emailed to all clinicians both toward the beginning of 6BBs Toolkit implementation and approximately 12 months later. We assumed 20 clinical staff per clinical site, and approximately 33 clinical sites overall (with a range from 1 clinic to 17 per organization), for a total of 660 staff across all 12 organizations. We assumed 495 clinical

staff will complete the survey based on a 75% response rate. It is expected to take up to 15 minutes to complete.

2. *Staff Interviews.* In-depth interviews will occur with 5 staff at each health care organization, for a total of up to 60 individuals. The evaluation team will conduct these interviews, each lasting up to 1 hour, at 2 points in time with:

a. One QI lead per organization (toward the start of and at the end of the project).

b. Four additional staff (*e.g.,* clinician, information technology analyst, social worker) per organization (midway through and at the end of the project).

3. *Virtual Launch Meeting.* The meeting will occur with the quality improvement (QI) leads at participating health care organizations to launch 6BBs Toolkit implementation. The meeting will be conducted by web-conference, and will last up to 2 hours.

4. *Quarterly Check-In Calls.* Calls will occur with QI leads, clinical champions, and other relevant staff the QI lead identifies, for a total of no more than 5 individuals per organization. These calls will assess progress with the organization's use of the Toolkit and implementation of associated practice changes, and will occur quarterly over 15 months, for a total of 5 quarterly check-in calls. Each call will take up to 60 minutes.

5. *QI Measures.* Aggregate reports of the specified quality measures will be provided on a quarterly basis over the course of an 18-month period by a data analyst at each organization, for a total of 12 individuals across all 12 organizations. We assume 40 hours total (10 hours per quarter) for each data analyst to collect and provide these data.

6. *Other outcome and output data from administrative records and organizational documents (Secondary Data).* These secondary data will be provided by the QI lead at each organization, for a total of 12 individuals across all 12 organizations. We assume 4 hours per month for 12 months for a total of 48 hours for each QI lead to collect and provide these data.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	Number of respondents A.	Number of responses per respondent B.	Hours per response C.	Total burden hours D.
1. Clinical Staff Survey *	495	2	15/60	248
2a. Staff Interview—QI Lead	12	2	1	24
2b. Staff Interview—Additional Staff	48	2	1	96
3. Virtual Launch Meeting	12	1	2	24
4. Quarterly Check-In Calls	60	5	1	300
5. QI Measures	12	4	10	480
6. Secondary data	12	12	4	576
Total	651	na	Na	1,748

* Number of respondents (Column A) reflects a sample size assuming a 75% response rate for this data collection effort.

Exhibit 2, below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated to be about $70,779.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
1. Clinical Staff Survey	495	248	$48.45	$12,016
2a. Staff Interview—QI Lead	12	24	53.69	1,289
2b. Staff Interview—Additional Staff	48	96	38.83	3,728
3. Virtual Launch Meeting	12	24	53.69	1,289
4. Quarterly Check-In Calls	60	300	38.83	11,649
5. QI Measures	12	480	20.59	9,883
6. Secondary data	12	576	53.69	30,925
Total	.....	.....	.....	70,779

The average hourly rate of $48.45 for the clinical staff survey was calculated based on the 2017 mean hourly wage rate for health diagnosing and treating practitioners, $48.45 (occupation code 29–1000).

The average hourly rate of $53.69 for QI lead interviews was calculated based on the 2017 mean hourly wage rate for medical and health services managers, $53.69 (occupation code 11–9111).

The average hourly rate of $38.83 for staff interviews was calculated based on the 2017 mean hourly wage rate for health care practitioners and technical occupations, $38.83 (occupation code 29–0000).

The average hourly rate of $53.69 for the virtual launch meeting was calculated based on the 2017 mean hourly wage rate for medical and health services managers, $53.69 (occupation code 11–9111).

The average hourly wage rate of $38.83 for quarterly check-in calls was calculated based on the 2017 mean hourly wage rate for health care practitioners and technical occupations, $38.83 (occupation code 29–0000).

The average hourly rate of $20.59 for QI measures was calculated based on the 2017 mean hourly wage rate for medical records and health information

technicians, $20.59 (occupation code 29–2071).

The average hourly rate of $53.69 for secondary data was calculated based on the 2017 mean hourly wage rate for medical and health services managers, $53.69 (occupation code 11–9111).

Mean hourly wage rates for these groups of occupations were obtained from the Bureau of Labor & Statistics on ''Occupational Employment and Wages, May 2017'' found at the following URL: *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.htm.*

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. 2019–07303 Filed 4–11–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—RFA–CE–19–006, Grants to Support New Investigators in Addressing Cross-Cutting Violence Prevention and Opioid Overdose Prevention.

Date: June 11, 2019.

Time: 11:00 a.m.–5:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Kimberly Leeks, Ph.D., M.P.H., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (770)488–6562, *KLeeks@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. 2019–07266 Filed 4–11–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—CK19–002, Quantifying Contact Rates and Mixing Patterns in Workers in Non-healthcare Work Settings in the United States; CK19–004, Study To Assess the Risk of Blood Borne Transmission of Classic Forms of Creutzfeldt-Jakob Disease (CJD); and CK17–005SUPP, Vector-Borne Disease Regional Centers of Excellence

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); CK19–002, Quantifying Contact Rates and Mixing Patterns in Workers in Non-healthcare Work Settings in the United States; CK19–004, Study To Assess the Risk of Blood Borne Transmission of Classic Forms of Creutzfeldt-Jakob Disease (CJD); and CK17–005SUPP, Vector-Borne Disease Regional Centers of Excellence; May 7, 2019; 10:00 a.m.—5:00 p.m., (EDT) which was published in the **Federal Register** on March 15, 2019, Volume 84, Number 51, pages 9523.

The meeting is being amended to remove CK17–005SUPP, Vector-Borne Disease Regional Centers of Excellence. The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT: Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30329, (404) 718–8833, *gca5@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. 2019–07265 Filed 4–11–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Communities Opioid Response Program Performance Measures, OMB No. 0906–xxxx, New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.