B. Purpose

FAR subpart 9.2 and the associated clause at FAR 52.209–1, implement the statutory requirements of 10 U.S.C. 2319 and 41 U.S.C. 3311, which allow an agency to establish a qualification requirement for testing or other quality assurance demonstration that must be completed by an offeror before award of a contract. Under the qualification requirements, an end item, or a component thereof, may be required to be prequalified.

The clause at FAR 52.209–1, Qualification Requirements, requires offerors who have met the qualification requirements to identify the offeror's name, the manufacturer's name, source's name, the item name, service identification, and test number (to the extent known). This eliminates the need for an offeror to provide new information when the offeror, manufacturer, source, product or service covered by qualification requirement has already met the standards specified by an agency in a solicitation.

The contracting officer uses the information to determine eligibility for award when the clause at 52.209–1 is included in the solicitation. Alternatively, items not yet listed may be considered for award upon the submission of evidence of qualification with the offer.

C. Annual Reporting Burden

Respondents: 7,998.

Responses per Respondent: 5.

Annual Responses: 39,990.

Hours per Response: 1.0.

Total Burden Hours: 39,990.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0083, Qualification Requirements, in all correspondence.

Dated: April 8, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–07268 Filed 4–11–19; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Skin Substitutes for Treating Chronic Wounds

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 *Skin Substitutes for Treating Chronic Wounds,* 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 May 13, 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 Benns, 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 *Skin Substitutes for Treating Chronic Wounds.* 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 *Skin Substitutes for Treating Chronic Wounds,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://www.ahrq.gov/research/findings/ta/index.html.*

This is to notify the public that the EPC Program would find the following information on Skin Substitutes for Treating Chronic Wounds 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 organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC 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 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