from the Performance Information section of SAM.

As stated in 2 CFR 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, the Federal awarding agency is required to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information, as appropriate.

The Federal awarding agency is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the FAPIIS), prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold (currently $250,000), defined in 41 U.S.C. 134, over the period of performance.

For non-federal entities (NFEs), if the total value of the NFEs currently active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of the Federal award, then the NFE must disclose semiannually, and maintain the currency of information reported to the SAM that is made available in the designated integrity and performance system (currently the FAPIIS) about civil, criminal, or administrative proceedings, as described in the award terms and conditions, for the most recent five year period.

B. Annual Reporting Burden

Proceedings Screening Question #1

Respondents: 13,683.
Respnoses per Respondent: 1.
Total annual responses: 13,683.
Hours per response: .1.
Total response burden hours: 1,368.

Proceedings Screening Question #2

Respondents: 1,663.
Responsed per Respondent: 1.
Total annual responses: 1,663.
Hours per response: .1.
Total response burden hours: 166.

Proceedings Details

Respondents: 24.
Responses per respondent: 2.
Total annual responses: 48.
Hours per response: .5.
Total response burden hours: 24.

C. Public Comments

Public comments are particularly invited on: Whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. Please cite OMB Control No. 3090–0293, Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements, in all correspondence.

Beth Anne Killoran,

Deputy Chief Information Officer.

[FR Doc. 2021–00867 Filed 1–14–21; 8:45 am]

BILLING CODE 6820–WY–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Interventional Treatments for Acute and Chronic Pain: Systematic Review

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 *Interventional Treatments for Acute and Chronic Pain: Systematic Review,* 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 February 16, 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 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 *Interventional Treatments for Acute and Chronic Pain: Systematic Review.* AHRQ is conducting this systematic review 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 *Interventional Treatments for Acute and Chronic Pain,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/interventional-treatments-pain/protocol.*

This is to notify the public that the EPC Program would find the following information on *Interventional Treatments for Acute and 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,* 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 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.

Key Questions (KQs)

KQ1: What are the effectiveness and harms of selected interventional procedures (vertebral augmentation procedures, piriformis injection, sphenopalatine block, occipital nerve stimulation, cooled or pulsed radiofrequency ablation, intradiscal and facet joint platelet rich plasma, intradiscal methylene blue, intradiscal ozone, and peripheral nerve stimulation) versus placebo, a sham procedure, or no interventional procedure for Medicare beneficiaries with pain?

a. How do the effectiveness and harms vary according to demographic (age, sex, race/ethnicity), clinical (type of pain, severity of pain, prior treatments, medical and psychiatric co-morbidities), and technical factors (variations in techniques, intensity, frequency, dose, and number of treatments)?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

PICOTS	Inclusion	Exclusion
Population	Adults with pain of any duration (pain conditions for each interventional procedure specified below); will highlight studies of populations applicable to Medicare, defined as persons enrolled in Medicare, age >55 years, or persons with disability (including end-stage renal disease [ESRD]), if available. Population subgroups of interest include those based on demographics (age, sex, race/ethnicity) and clinical factors (type of pain, severity of pain, prior treatments, medical and psychiatric co-morbidities, including presence of disability [including ESRD], prior substance use disorder, and psychological co-morbidities).	• Patients undergoing end-of-life care, terminally ill (e.g., hospice) patients; those under supervised palliative care; those with pain due to metastatic or advanced cancer. • Children.
Intervention	(1) Vertebral augmentation procedures (vertebroplasty and kyphoplasty) for pain due to vertebral compression fracture. (2) Piriformis injection (local anesthetic, corticosteroid, and/or botulinum toxin) for piriformis syndrome. (3) Sphenopalatine block for trigeminal neuralgia or headache. (4) Occipital stimulation for headache (5) Cooled radiofrequency denervation for degenerative back or hip pain and pulsed radiofrequency denervation for degenerative back pain. (6) Intradiscal and facet joint platelet rich plasma for presumed discogenic back pain. (7) Intradiscal stem cells for presumed discogenic back pain. (8) Intradiscal methylene blue for presumed discogenic back pain. (9) Intradiscal ozone for radicular low back pain or non-radicular, presumed discogenic back pain. (10) Peripheral nerve stimulation for ulnar, median, or radial neuropathy. Technical factors of interest as potential modifiers of treatment effect include variations in techniques, intensity, frequency, dose, or number of treatments.	• Minimally invasive surgical procedures • Orthopedic intra-articular and soft tissue injections • Local soft tissue injections • Other interventional procedures and conditions not listed as included
Comparator	Placebo, sham interventional procedure, or no interventional procedure. For cooled and pulsed radiofrequency denervation: standard (thermal, continuous) radiofrequency denervation.	Active treatments, other than standard radiofrequency denervation as a comparison for cooled radiofrequency denervation.
Outcome	• *Primary:* Pain, function • *Secondary:* HRQOL, emotional function (e.g., depression, anxiety), opioid use, surgery rates. • Global improvement • Harms (e.g., bleeding, infection, other complications), adverse events, unintended consequences.	*Patient-oriented outcomes:* • Non-validated instruments for outcomes (e.g., pain, function, HRQOL, depression, etc.). • Intermediate outcomes (e.g., range of motion, physical strength, etc.).

PICOTS	Inclusion	Exclusion
Timing	Duration of followup: ≥1 month; categorized as short term (1 to <6 months), intermediate term (≥6 to <12 months) and long term (≥12 months) following intervention.	<1 month.
Setting	Any	None.
Study design, publication type.	Randomized clinical trials and cohort studies if RCTs are not available..	• Case reports.
	Large (n > 500) case series for serious, rare harms	• Case series (other than large case series for serious, rare harms).
		• Case-control studies, cross-sectional studies.
		• Conference proceedings, editorials, letters, white papers, citations that have not been peer-reviewed.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–00800 Filed 1–14–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

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

ACTION: Notice of five AHRQ Subcommittee meetings.

SUMMARY: The subcommittees listed below are part of AHRQ's Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will be closed to the public.

DATES: See below for dates of meetings:

1. *Healthcare Safety and Quality Improvement Research (HSQR)*
   Date: February 3–4, 2021
2. *Healthcare Effectiveness and Outcomes Research (HEOR)*
   Date: February 10–11, 2021
3. *Health System and Value Research (HSVR)*
   Date: February 11–12, 2021
4. *Health Care Research and Training (HCRT)*
   Date: February 25–26, 2021 & March 1–2, 2021
5. *Healthcare Information Technology Research (HITR)*
   Date: February 25–26, 2021

ADDRESSES: Agency for Healthcare Research and Quality (Virtual Review), 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: (to obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Jenny Griffith, Committee Management Officer, Office of Extramural Research Education and Priority Populations, Agency for Healthcare Research and Quality (AHRQ), 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 427–1557.

SUPPLEMENTARY INFORMATION: In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the above-listed scientific peer review groups, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committee. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). 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.

Agenda items for these meetings are subject to change as priorities dictate.

Dated: January 12, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–00894 Filed 1–14–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2021–0003]

Notice of Availability of a Draft Policy Statement for the Biosafety of Large Animal Study-Related Activities With Brucella abortus and Brucella suis Using Outdoor Containment Spaces

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is opening a public docket to obtain comment on a draft *Brucella* policy statement. This draft policy statement, when finalized, will aid individuals and entities in the development of biosafety plans for outdoor large animal studies involving swine, elk, bison, and cattle to further brucellosis research in a manner that complies with the HHS and U.S. Department of Agriculture (USDA) select agent regulations. In a companion document published in this issue of the **Federal Register**, USDA has proposed the same policy for comment.

DATES: Submit written or electronic comments by March 16, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0003 by either of the methods listed below. Do not submit comments by email. CDC does not accept acomments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket No. CDC–2021–0003 for this rulemaking. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the draft policy statement, go to *http://www.regulations.gov.* Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and