GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0080]
[Docket No. 2024–0001; Sequence No. 4]

Submission for OMB Review; General Services Administration Acquisition Regulation; Release of Claims for Construction and Building Service Contracts

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection regarding release of claims for final payment under construction and building services contracts.

DATES: Submit comments on or before: September 3, 2024.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Mr. Bryon Boyer, Procurement Analyst, at *gsarpolicy@gsa.gov* or 817–850–5580.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration Acquisition Regulation (GSAR) requires construction and building services contractors to submit a release of claims before final payment is made to ensure contractors are paid in accordance with their contract requirements and for work performed. GSA Form 1142, Release of Claims is used to achieve uniformity and consistency in the release of claims process.

B. Annual Reporting Burden

Respondents: 1,427.
Responses per Respondent: 1.
Annual Responses: 1,427.
Hours per Response: 0.50.
Total Burden Hours: 714.

C. Public Comments

A 60-day notice was published in the **Federal Register** at 89 FR 42470 on May 15, 2024. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division (MVCB), at *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0080; Release of Claims for Construction and Building Service Contracts, in all correspondence.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2024–16981 Filed 7–31–24; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Blood-Based Tests for Multiple Cancer Screening: A Systematic Review

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

ACTION: Request for supplemental evidence and data submission.

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 *Blood-based Tests for Multiple Cancer Screening: A 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 September 3, 2024.

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: Kelly Carper, Telephone: 301–427–1656 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 *Blood-based Tests for Multiple Cancer Screening: A Systematic Review.* AHRQ is conducting this 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 *Blood-based Tests for Multiple Cancer Screening: A Systematic Review.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/cell-free-dna/protocol.*

This is to notify the public that the EPC Program would find the following information on *Blood-based Tests for Multiple Cancer Screening: A Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this topic. 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, if relevant: 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 topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, 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 topic 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 topics 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://effectivehealthcare.ahrq.gov/email-updates*.

The 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 (KQ)

KQ 1: What is the effectiveness of screening with blood-based multicancer screening tests (MCST) on cancer-specific mortality and all-cause mortality?

KQ 2a: What is the effectiveness of screening with MCSTs on the cumulative detection of cancer overall and by cancer type?

KQ 2b: What is the effectiveness of screening with MCSTs on the cumulative detection of late-stage cancer (*i.e.,* stage shift) overall and by cancer type?

KQ 3: What is the accuracy of MCSTs for detection of cancer and does accuracy vary by cancer type or stage?

KQ 4: What are the harms of screening with MCSTs?

KQ 5: What are the harms of the evaluation and additional testing following a positive MCST or with surveillance following a negative evaluation after a positive MCST?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

[Detailed inclusion and exclusion criteria for systematic review on blood-based tests for multiple cancer screening]

Inclusion criteria	Exclusion criteria
Population	
KQs 1, 2, 4, 5 ..... Asymptomatic people 18 years of age or older ..... *KQ 3:* People 18 years of age or older with either (1) biopsy-confirmed cancer or (2) who are asymptomatic without suspicion for cancer (*i.e.,* ''healthy'' individuals).	*All KQ:* People younger than 18 years of age; other than human populations (*e.g.,* animal or in vitro laboratory studies). *KQs 1, 2, 4, 5:* Adults with active cancer; adults undergoing evaluation for suspected cancer or cancer recurrence; adults with a history of invasive or hematologic cancer (other than nonmelanoma skin cancer) within the previous 3 years or a history of untreated cancer. *KQ 3:* Adults undergoing diagnostic evaluation for possible cancer or cancer recurrence.
Intervention	
KQs 1, 2, 3, 4 ..... • Blood tests used for the screening of at least 2 different types of cancer; tests using any analytes with any technology are eligible. • Tests that were designed for cancer prognosis or surveillance in those with cancer or who have completed cancer treatment (*i.e.,* evaluation for minimal residual disease) are eligible as long as they are being evaluated in an eligible population as defined above. • Blood tests used in combination with other tests such as imaging are eligible. • MCSTs used instead of or in addition to usual care screening are eligible. We define usual care screening as follows: mammography (breast), direct visualization such as colonoscopy or stool-based tests (colorectal), low-dose computed tomography (lung), cytology, human papilloma virus testing (cervical), and prostate specific antigen (prostate). *KQ 5:* Tests or procedures (imaging, tissue biopsy, blood, urine, or cerebrospinal fluid) to evaluate positive signal(s) resulting from an MCST or procedures used to surveil patients who have a negative evaluation after a positive MCST signal.	*KQs 1, 2, 3, 4:* Tests that are not blood based (*e.g.,* tissue, saliva, urine, or other bodily fluids). *KQ 5:* Tests or interventions not performed as a result of a positive MCST.
Comparator	
KQs 1, 2, 4 ..... • No screening test ..... • Usual care cancer screening as defined above ..... *KQ 3:* Tissue evaluation for confirmation of cancer; healthy asymptomatic status for controls. *KQ 5:* No comparator required	*KQs 1, 2, 4:* No comparator group. *KQ 3:* No reference standard for comparison. *KQ 5:* Studies without a comparator group will not be excluded.

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

[Detailed inclusion and exclusion criteria for systematic review on blood-based tests for multiple cancer screening]

Inclusion criteria	Exclusion criteria
Outcomes	
KQ 1: Cancer mortality overall and by cancer type, all-cause mortality, quality of life, functional status. *KQ 2a:* Cumulative detection of cancer overall and by cancer type ..... *KQ 2b:* Cumulative detection of late-stage cancer overall and by cancer type (*i.e.,* Stage III or IV or organ-specific definition of late stage); distribution of cancer stage at diagnosis (*i.e.,* stage shift). *KQ 3:* Accuracy (sensitivity, false negatives, specificity, false positives, predictive value) by cancer type and by cancer stage. *KQ 4:* Psychosocial and emotional distress including anxiety and worry, false reassurance resulting in decrease in receipt of usual care screening or change in health behaviors associated with cancer (alcohol, tobacco, drug use, diet, physical activity), overdiagnosis, out-of-pocket patient costs, patient financial toxicity, and impact on insurability. *KQ 5:* Radiation exposure from imaging, harms from invasive procedures, other adverse effects from evaluation that occur after a positive MCST, or out-of-pocket patient costs, patient financial toxicity, and impact on insurability.	Outcomes not specifically indicated as included. Composite measures composed of both included and excluded outcomes will be included but considered only in sensitivity analyses.
Timing	
KQ 1: At least 5 years of followup ..... *KQs 2, 4, 5:* any timing ..... *KQ 3:* At least 1 year of followup for prediagnostic performance designs.[a] For diagnostic performance designs, controls must be considered cancer free at the time of the sample.	*KQ 1:* Studies with less than 5 years of followup.
Setting	
• Recruitment from outpatient clinical settings, including primary care or specialty care, community-based or public health settings, electoral rolls, or other population-based registries. • Countries with a United Nations Human Development Index of *high* or *very high* (Appendix A).	• Acute care settings, inpatient care settings. • Countries with a United Nations Human Development Index of less than *high*.
Study Design	
KQs 1, 2, 4, 5: Randomized controlled trials; controlled trials ..... *KQs 1, 2:* Registered NRSIs with 1 or more eligible benefit outcomes listed on study registration[b]. *KQs 4, 5:* Unregistered NRSIs are also eligible ..... *KQ 3:* Studies that provide data related to test accuracy; both prediagnostic test performance and diagnostic test performance designs are eligible. However, only diagnostic performance designs conducted in external validation cohorts are eligible. Further, if results for multiple variations of the test are reported by authors, only results from the test version selected for future commercial use or for evaluation in future intervention studies will be eligible.	*For all KQ:* Modeling studies, case series, case reports, in vitro lab studies, studies designed to assess analytic validity, narrative reviews, systematic reviews (reviews will not be included but will be manually reviewed to identify primary research studies that the search may have missed). *KQs 1, 2:* Cohort studies that have not been registered or that report eligible outcomes that were not included in the study's registration[b] studies designed with a sample size that was not based on outcomes related to cancer detection or mortality. *KQ 3:* Accuracy results derived from discovery, development, internal validation, or split sample cohorts are not eligible because multiple analytes, technologies, or AI classifiers are being evaluated to develop the test and these results do not reflect the final state of the test that would be used in routine practice.
Language	
English	Languages other than English.

[a] KQ 3 prediagnostic accuracy performance studies that use disease-free longitudinal followup as a reference standard should have a minimum of 1-year followup.

[b] Refers to study registration in *ClinicalTrials.gov* database, or another study registry such as those included in the World Health Organization International Clinical Trials Registry Platform.

KQ = key question; MCST = multiple cancer screening test; NRSI = non-randomized study of interventions.

Dated: July 25, 2024.

Marquita Cullom,

Associate Director.

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