ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

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 existing OMB clearance regarding a notarized document submittal for System for Award Management (SAM) Registration.

DATES: Submit comments on or before December 9, 2021.

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: Nancy Goode, Integrated Award Environment, GSA, 703–605–2175, or via email at *nancy.goode@gsa.gov.*

SUPPLEMENTARY INFORMATION: The Federal Acquisition Regulation and Code of Federal Regulation prescribe the policies and procedures requiring registration in the System for Award Management database. Federal Acquisition Regulation (FAR) Subpart 4.11 prescribes policies and procedures for requiring registration in the System for Award Management (SAM) database to: (1) Increase visibility of vendor sources (including their geographical locations) for specific supplies and services; and (2) establish a common source of vendor data for the Government. The Code of Federal Regulations (CFR) at 2 CFR 25.200 prescribes policies and procedures for requiring recipient registration in the System for Award Management (SAM) database.

In the past, the GSA Office of Inspector General (OIG) conducted an investigation into fraudulent activities discovered within SAM. Certain bad actors have, through electronic means, used public information to impersonate legitimate entities and established new entity registrations for those entities in SAM. By establishing fraudulent entity registrations, bad actors submitted bids in certain U.S. Government procurement systems or shipped deficient or counterfeit goods to the U.S. Government.

GSA established an Information Collection Request (ICR) to collect additional information to support increased validation of entities registered in the System for Award Management (SAM). This additional information is contained in a notarized letter in which an officer or other signatory authority of the entity formally appoints the administrator for the entity when an administrator is not available to perform that function for that entity. The original, signed letter is submitted electronically to the Federal Service Desk (FSD) for SAM when an administrator needs to be appointed for an existing entity.

The new ICR expires December 31, 2021. GSA is actively pursuing technical alternatives to the collection of this information for all non-federal entities. GSA seeks to refine the requirement and adopt a risk-based approach. This notice for an extension of the ICR lays the groundwork for the authority to continue collection of the information provided GSA is still pursuing the technical alternative beyond the ICR expiration date. In the interim, the collection of the notarized letter information is essential to GSA's acquisition mission to meet the needs of all federal agencies, as well as the needs of the grant community. A key element of GSA's mission is to provide efficient and effective acquisition solutions across the Federal Government. SAM is essential to the accomplishment of that mission. In addition to federal contracts, federal assistance programs also rely upon the integrity and security of the information in SAM. Without assurances that the information in SAM is protected and is at minimal risk of compromise, GSA would risk losing the confidence of the federal acquisition and assistance communities which it serves. As a result, some entities may prefer not to do business with the Federal Government.

B. Annual Reporting Burden

Respondents: 686,400.
Responses per Respondent: 1.
Total Annual Responses: 686,400.
Hours per Response: 2.25.
Total Burden Hours: 1,544,400.

The information collection allows GSA to request the notarized letter and apply this approach to new registrants (an average of 7,200 per month) and to existing SAM registrants (an average of 50,000 re-register per month).

Entities registered and registering in SAM are provided the template for the requirements of the notarized letter. It is estimated that the Entity Administrator will take on average 0.5 hour to create the letter and 0.25 hour to submit an electronic copy of the letter to FSD. GSA proposes that an Entity Administrator equivalent to a GS–5, Step 5 Administrative Support person within the Government would perform these tasks. The estimated hourly rate of $24.70 (Base + Locality + Fringe) was used for the calculation.

Based on historical data of the ratio of small entities to other than small entities registering in SAM, GSA approximates 32,200 of the 57,200 new and existing entities (re-registrants) will have in-house resources to notarize documents. GSA proposes that the entities with in-house notaries will typically be large businesses where the projected salary of the executive or officer responsible for signing the notarized letter is on average approximately $150 per hour. The projected time for signature and notarizing the letter internally is 0.5 hour.

The other remaining 25,000 new and existing entities (re-registrants) per month are estimated to be small entities where the projected salary of the executive or officer responsible signing the notarized letter is on average approximately $100 per hour. These entities will more than likely have to obtain notary services from an outside source. The projected time for signature and notarizing the letter externally is 1 hour. The estimate includes a nominal fee ($5.00) usually charged by third-party notaries.

C. Public Comments

A notice was published in the **Federal Register** at 86 FR 47110 on August 23, 2021. No comments were received.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 3090–0317, Notarized Document Submittal for System for Award Management Registration, in all correspondence.

Beth Anne Killoran,

Deputy Chief Information Officer.

[FR Doc. 2021–24485 Filed 11–8–21; 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 Partial Breast Irradiation for Breast Cancer

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 *Partial Breast Irradiation for Breast Cancer,* 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 December 9, 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 *Partial Breast Irradiation for Breast Cancer.* 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 *Partial Breast Irradiation for Breast Cancer,* including those that describe adverse events. The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/accelerated-partial-breast-irradiation/protocol.*

This is to notify the public that the EPC Program would find the following information on *Partial Breast Irradiation for Breast Cancer* 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 (KQ)

KQ 1. In adult women with early stage breast cancer, what are the comparative effectiveness, adverse events, and cosmetic outcomes of partial breast irradiation compared to whole breast irradiation?

KQ1a. How does effectiveness of partial breast irradiation vary by clinical-pathologic characteristics?

KQ1b. How do the effectiveness, adverse events, and cosmetic outcomes of partial breast irradiation vary by target volumes, dose-fractionation schemes, motion management, and planning parameters?

KQ 2. In adult women with early stage breast cancer, what are the comparative effectiveness, adverse events, and cosmetic outcomes of different partial breast irradiation modalities (including multicatheter interstitial brachytherapy, single-entry catheter brachytherapy, 3-dimensional conformal external beam radiation therapy, intensity modulated radiation therapy, proton radiation therapy, and intraoperative radiotherapy)?

KQ 2a. When there are no eligible comparative studies to address KQ2 for a particular PBI modality, what are the rates of adverse events in noncomparative series of such modality?

KQ 2b. When there are no eligible comparative studies to address KQ2 for a particular PBI modality, what are the rates of long-term (>5 years) effectiveness outcomes and cosmesis in noncomparative series of such modality?

Contextual Question (CQ)

CQ 1. In adult women with early stage breast cancer, to what extent does financial toxicity differ between partial and whole breast irradiation?

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

PICOTS elements	Inclusion criteria	Exclusion criteria
Population	• Adult women (*i.e.,* 18 years and older) with early stage breast cancer (*i.e.,* a small tumor less than or equal to 3 cm that has minimal or no lymph node involvement (N0/1)).	• Animals. • Children (*i.e.,* age <18 years). • Men. • Recurrent breast cancer.
Interventions	For all KQs and CQ1, PBI includes the following modalities: • Multicatheter interstitial brachytherapy.	• Combination of PBI and WBI.

PICOTS elements	Inclusion criteria	Exclusion criteria
	• Single-entry catheter brachytherapy. • 3-dimensional conformal external beam radiation therapy. • Intensity modulated radiation therapy. • Proton radiation therapy. • Intraoperative radiotherapy.	
Comparators	KQ 1, CQ 1: WBI KQ 2: A different PBI modality. • Multicatheter interstitial brachytherapy. • Single-entry catheter brachytherapy. • 3-dimensional conformal external beam radiation therapy. • Intensity modulated radiation therapy. • Proton radiation therapy. • Intraoperative radiotherapy. KQ 2a and 2b: No comparator.	None.
Outcomes	KQ 1 and 2: • Ipsilateral breast cancer recurrence (*i.e.,* tumor bed ipsilateral breast cancer recurrence, elsewhere ipsilateral breast cancer recurrence). • Mastectomy-free survival. • Overall survival. • Cancer-free survival. • Contralateral breast cancer recurrence. • Distant breast cancer recurrence. • Regional breast cancer recurrence. • Any breast cancer recurrence. • Breast conservation. • Quality of life (*e.g.,* BCTOS, FACT–B, SF–36, Breast Q scale). • Patient-reported and physician-assessed cosmesis (*e.g.,* including Harvard Breast Cosmesis Scale, Global Cosmesis Scale, or the EORTC breast cancer cosmetic rating system). • Sexual health. • Adverse events, including scales measuring radiation toxicity: ○ RTOG/EORTC scores. ○ LENT–SOMA scales. ○ CTCAE scores. CQ 1: Contextual information about the construct of financial toxicity (*i.e.,* financial distress and hardship).	None.
Timing	At the following intervals: For effectiveness and cosmetic outcomes: • >=1 year to 5 years. • >5 years to 10 years. • >10 years. For adverse events: • <3 months. • >=3 months.	None.
Settings	Any	None.
Study design	KQ1: • RCTs. KQ 2: • RCTs. • Comparative observational studies. KQ 2a: • Single-arm observational studies (>=50 patients). KQ 2b: • Single-arm observational studies (>=50 patients and >=5 year followup). CQ 1: • RCTs. • Comparative observational studies. • Qualitative studies. • Cost-benefit analyses. • Surveys. All KQs and CQ 1: • Relevant systematic reviews or meta-analyses (used for identifying additional studies).	• In vitro studies. • Nonoriginal studies (*e.g.,* narrative reviews, editorials, letters, or erratum). • Cross-sectional (*i.e.,* non-longitudinal) studies.
Subgroup analysis	KQ 1 and 2: • Age. • Treatment schedule (*i.e.,* accelerated, nonaccelerated). • Race/ethnicity. • Socioeconomic status. • Area Deprivation Index. • DCIS vs. invasive disease. • Breast size. • BMI. • Cup size. • Breast implants.	None.

PICOTS elements	Inclusion criteria	Exclusion criteria
	• Mental health comorbidities. • Menopausal status. • Receipt of systemic therapy (*i.e.,* none, endocrine therapy, and/or chemotherapy, both). • Histologic subtype (*e.g.,* invasive ductal carcinoma, invasive lobular carcinoma, DCIS, other). • Nodal status (*i.e.,* N0, N1, NX, number of positive nodes). • Nodal assessment (*i.e.,* sentinel lymph node biopsy, axillary lymph node dissection, none). • Tumor grade. • Tumor size (*i.e.,* <1 cm, 1–2 cm, 2–3 cm, >3 cm). • Focality (unifocal vs multifocal). • Margin status (*i.e.,* positive, <2 mm, 2–3 mm, >3 mm). • Extensive intraductal component. • Ki-67 (<20% vs. >= 20%). • ASTRO or ESTRO risk category (*i.e.,* suitable, cautionary, unsuitable; low, intermediate, high). • Germline genetic mutation (*e.g., BRCA1, BRCA2, CHEK2, PALB2, ATM,* etc.). • Cancer-predisposing syndrome. • Estrogen receptor status. • Progesterone receptor status. • Hormone receptor status. • Lymphovascular invasion. • HER2 status. • Prior chemotherapy. • Monoelectron therapy. • Dermatologic Rheumatologic conditions (*i.e.,* lupus, scleroderma, rheumatoid arthritis). • Dose-fractionation schemes (*i.e.,* accelerated, nonaccelerated, daily vs every other day vs twice daily, total dose, EQD2). • Target volumes (*i.e.,* size of expansion on cavity, diameter of the inflated balloon, size of the planning target volume). • Motion management. • Planning parameters (*i.e.,* the diameter of the inflated balloon, the planning target volume, and the dose distribution organ-at-risk constraints and dose received [such as ipsilateral breast V50 and V100], number of beams, PTV coverage goals and constraints). • Number of treatment fields. • Image guidance (*i.e.,* MV imaging, kV imaging, cone beam CT, use of clips for localization). • Risk of bias (*i.e.,* low, moderate, high).	
Publications	• Studies published in English as peer reviewed full text. ..... • Published after Year 2000.	• Foreign language studies. • Conference abstracts.

Abbreviations: ASTRO = American Society for Radiation Oncology; *ATM* = ataxia telangiectasia mutated; BCTOS = Breast Cancer Treatment Outcomes Scale; BMI = body mass index; *BRCA1* = breast cancer 1; *BRCA2* = breast cancer 2; *CHEK2* = checkpoint kinase 2; cm = centimeter; CQ = contextual question; CT = computed tomography; CTCAE = Common Terminology Criteria for Adverse Events; DCIS = ductal carcinoma in situ; EORTC = European Organisation for Research and Treatment of Cancer; ESTRO = European Society for Radiotherapy and Oncology; FACT–B = Functional Assessment of Cancer Therapy-Breast; EQD2 = Equivalent Dose in 2 Gy fractions; HER2 = human epidermal growth factor receptor 2; KQ = key question; kV = kilovoltage; LENT–SOMA = Late Effects Normal Tissue Task Force- Subjective, Objective, Management, Analytic; mm = millimeter; MV = megavoltage; N0 = no involved lymph nodes; N1 = 1–3 involved lymph nodes; NX = lymph nodes not assessed; *PALB2* = partner and localizer Of *BRCA2;* PBI = partial breast irradiation; PICOTS = populations, interventions, comparators, outcomes, timing, and settings; PTV = planning target volume; RCT = randomized controlled trial; RTOG = Radiation Therapy Oncology Group; SF–36 = Short Form (36) Health Survey; V50 = volume (%) receiving >= 50% of the prescription dose; V100 = volume (%) receiving >= 100% of the prescription dose; WBI = whole breast irradiation.

Dated: November 2, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–24403 Filed 11–8–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10790]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of notice.

SUMMARY: This document corrects the information provided for [Document Identifier: CMS–10790] titled ''Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020.''

FOR FURTHER INFORMATION CONTACT: William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the October 22, 2021, issue of the **Federal Register** (86 FR 58664), we