

PICOTS elements	Inclusion criteria	Exclusion criteria
Publications	<ul style="list-style-type: none"> • Mental health comorbidities. • Menopausal status. • Receipt of systemic therapy (<i>i.e.</i>, none, endocrine therapy, and/or chemotherapy, both). • Histologic subtype (<i>e.g.</i>, invasive ductal carcinoma, invasive lobular carcinoma, DCIS, other). • Nodal status (<i>i.e.</i>, N0, N1, NX, number of positive nodes). • Nodal assessment (<i>i.e.</i>, sentinel lymph node biopsy, axillary lymph node dissection, none). • Tumor grade. • Tumor size (<i>i.e.</i>, <1 cm, 1–2 cm, 2–3 cm, >3 cm). • Focality (unifocal vs multifocal). • Margin status (<i>i.e.</i>, positive, <2 mm, 2–3 mm, >3 mm). • Extensive intraductal component. • Ki-67 (<20% vs. ≥ 20%). • ASTRO or ESTRO risk category (<i>i.e.</i>, suitable, cautionary, unsuitable; low, intermediate, high). • Germline genetic mutation (<i>e.g.</i>, <i>BRCA1</i>, <i>BRCA2</i>, <i>CHEK2</i>, <i>PALB2</i>, <i>ATM</i>, 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>i.e.</i>, lupus, scleroderma, rheumatoid arthritis). • Dose-fractionation schemes (<i>i.e.</i>, accelerated, nonaccelerated, daily vs every other day vs twice daily, total dose, EQD2). • Target volumes (<i>i.e.</i>, size of expansion on cavity, diameter of the inflated balloon, size of the planning target volume). • Motion management. • Planning parameters (<i>i.e.</i>, 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>i.e.</i>, MV imaging, kV imaging, cone beam CT, use of clips for localization). • Risk of bias (<i>i.e.</i>, low, moderate, high). • Studies published in English as peer reviewed full text. • Published after Year 2000. 	<ul style="list-style-type: none"> • 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]

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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

published a Paperwork Reduction Act notice requesting a 60-day public comment period for the information collection request identified under CMS-10790, OMB control number 0938-New, and titled “Medicare-Funded GME Residency Positions in accordance with Section 126 of the Consolidated Appropriations Act, 2020 (Pub. L. 116-93).”

II. Explanation of Error

In the October 22, 2021, notice, the information provided in the middle of the middle column on page 58665, was published with incorrect information in the “Use” section. This notice corrects the language found in the “Use” section in the middle of the middle column on page 58665. All of the other information contained in the October 22, 2021, notice is correct. The related public comment period remains in effect and ends December 21, 2021.

III. Correction of Error

In FR Doc. 2021-23107 of October 22, 2021, (86 FR 58664), page 58665, the language in the middle of the middle column that begins with “Use.” and ends with “in early January 2022” is corrected to read as follows:

Use: The requirements in this rule were announced in CMS-1752-P (FY22 IPPS); however, the PRA package has been under development until now. The plan, approved by OMB and CM, is to have the 60-day **Federal Register** notice publish and then have CMS-1752-F3 serve as the required 30-day **Federal Register** notice, with the goal of approval in early January 2022. If this is not possible, CMS will publish a standalone 30-day **Federal Register** notice prior to submitting the information collection request (CMS-10790) to OMB.

Dated: November 3, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021-24418 Filed 11-8-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10792, CMS-10793, and CMS-367a-e]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 10, 2022.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS’ website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-10792 Patient-Reported Indicator Survey (PaRIS)

CMS-10793 Medicare Advantage and Prescription Drug Plan Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey Field Test

CMS-367a-e Medicaid Drug Rebate Program Labeler Reporting Format

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Patient-Reported Indicator Survey (PaRIS); *Use:* The Centers for Medicare and Medicaid Services (CMS) invites comments on a proposed new Information Collection Request (ICR) to conduct the International Survey of People Living with Chronic Conditions (hereafter referred to as the PaRIS Survey). This survey has been developed by a collaborative workgroup under the auspices of the Organization for Economic Cooperation and Development (OECD), an international organization that works with governments, policy makers, and citizens to shape policies that foster prosperity, equality, opportunity, and well-being for all.

The OECD launched the PaRIS initiative in 2017 to address gaps in health outcomes measures, particularly regarding user experiences with health care services. OECD member countries,