



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS-10598 and CMS-10570]

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

**AGENCY:** Centers for Medicare & Medicaid 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 [INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**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' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

2. Call the Reports Clearance Office at (410) 786-1326.

**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-10598 Generic Clearance for Evaluation of Stakeholder Training—Health Insurance Marketplace and Market Stabilization Programs

## CMS-10570 Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services

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:* Extension of a currently approved information collection; *Title of Information Collection:* Generic Clearance for Evaluation of Stakeholder Training—Health Insurance Marketplace and Market Stabilization Programs; *Use:* CMS is strongly committed to providing appropriate education and technical outreach to States, issuers, self-insured group health plans and third-party administrators (TPA) participating in the Marketplace and/or market stabilization programs mandated by the ACA. CMS continues to engage with stakeholders in the Marketplace to obtain input through Satisfaction Surveys following Stakeholder Training events. The survey results will help to determine stakeholders' level of satisfaction with trainings, identify any issues with training and technical assistance delivery, clarify stakeholders' needs and preferences, and define best practices for training and technical assistance. CMS will continue to modify, enhance and develop forms for future years based on feedback from Stakeholders. *Form Number:* CMS-10598 (OMB control number: 0938-1331); *Frequency:*

Occasionally; *Affected Public*: Private Sector; *Number of Respondents*: 30,332; *Number of Responses*: 30,332; *Total Annual Hours*: 7,334. For questions regarding this collection contact Sonia Henderson at 301-492-4320.

2. *Type of Information Collection Request*: Reinstatement of a previously approved collection; *Title of Information Collection*: Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services; *Use*: Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, “Recognizing Appropriate Use Criteria for Certain Imaging Services,” which directs the Secretary to establish a program to promote the use of AUC. This program is codified at 42 CFR § 414.94. Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context. A provider-led entity (PLE) as defined in 42 CFR § 414.94(b) is a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside the organization, predominantly provide direct patient care. This program requires professionals ordering applicable imaging services as defined in § 414.94(b) to consult with specified applicable AUC, which are criteria developed, endorsed or modified by a qualified PLE.

The cornerstone of the PLE qualification process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. In the 2016 Physician Fee Schedule Final Rule with comment period (80 FR 70886, November 16, 2015; see pages 71102-71116 and pages 71380-71382) we established a qualification process and requirements for qualified PLEs in order to ensure that the AUC

development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B).

In order to become and remain a qualified PLE, we require PLEs to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. To ensure that these requirements are met, we require PLEs to submit information demonstrating their adherence to these requirements. CMS qualifies those PLEs that demonstrate adherence to the requirements for a period of five years. Qualified PLEs are also required, during the 5th year after their most recent approval date, to ensure adherence has been maintained and to account for any changes in the entities' processes. Qualified PLEs must reapply every five years and must submit the applications by January 1 of the 5th year after the PLE's most recent approval date. *Form Number*: CMS-10570 (OMB control number: 0938-1288); *Frequency*: Occasionally; *Affected Public*: Private: Business or other for-profit and Not for-profit institutions; *Number of Respondents*: 10; *Number of Responses*: 10; *Total Annual Hours*: 150. (For policy questions regarding this collection, contact Heather Hostetler at 410-786-4515.)

Dated: August 17, 2020.

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**William N. Parham, III,**

*Director,*

*Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**4120-01-U-P**