



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10570 and CMS-10437]

#### Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to

[www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain) . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

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 Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *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.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to extend the approval of the generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. The information collected will be used to create a streamlined and proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences.

The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies

and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in a form that can help them make the most of their benefits and options

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for us to communicate more effectively with our audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. *Form Number:* CMS-10437 (OMB control number: 0938-1247); *Frequency:* Yearly; *Affected Public:* Individuals; *Number of Respondents:* 7,732;

*Number of Responses: 61,992; Total Annual Hours: 26,588.* (For policy questions regarding this collection contact Sabreet Kang Rajeev at 410-786-5616.)

**Dated:** October 23, 2020.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

4120-01-U-P

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