DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10440]

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 *August 14, 2024.*

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.* 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, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each state a single, streamlined application form that may be used to apply for coverage through a Marketplace and for APTC/CSR, Medicaid, and CHIP (which we refer to collectively as insurance affordability programs). The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who may qualify for the programs by developing materials at appropriate literacy levels and ensuring accessibility.

Regulations at 45 CFR 155.405(a) provides more detail about the application that must be used by Marketplaces to determine eligibility and to collect information necessary for enrollment. Eligibility standards for the Marketplace are set forth in 45 CFR 155.305. The information will be required of each applicant upon initial application, with some subsequent information collections for the purposes of confirming accuracy of previous submissions and for changes in an applicant's circumstances. 42 CFR 435.907 and § 457.330 establish the standards for state Medicaid and CHIP agencies related to the use of the application. CMS has designed a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions in the FFM (please note SBM implementations may vary but the essence of the data collection must adhere to the same parameters). The paper version of the application will not be tailored in the same way but will require only the data necessary to determine eligibility.

Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (*i.e.,* Medicaid, CHIP, and APTC), and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. Additionally, this application provides consumers interested in voting resources. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 5,550,000; *Total Annual Responses:* 5,550,000; *Total Annual Hours:* 2,446,440. (For policy questions regarding this collection contact Erin Richardson at 202–619–0630.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2908]

Cellular and Gene Therapies Interactive Site Tours Program for Regulatory Project Managers and Reviewers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or the Agency) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) is announcing the Cellular and Gene Therapies Interactive Site Tours Program (the Interactive Site Tours Program). This program is