clinical trials that are intended to generate evidence of safety and effectiveness of therapies that in turn showcase the value of clinical trial innovations. CDER leads or co-leads several ongoing programs to advance innovation, and CDER recognizes that additional innovative areas would benefit from the enhanced interactions that are the staple of these programs.

CDER also recognizes that opportunities exist to further enhance the adoption of clinical trial innovations, including the amplification of lessons learned across CDER's robust clinical innovation programs. On October 17, 2023, CDER solicited public comments on the barriers and facilitators to incorporating successful or promising innovative clinical trial approaches in drug development programs. These public comments were discussed as part of a public workshop led by the Duke-Margolis Institute for Health Policy, under a cooperative agreement with FDA, on March 19 and 20, 2024. Topics addressed during the workshop included, but were not limited to, those listed below:

- Evolution of clinical research and the current state of trial innovation
- Regulatory and compliance considerations
- Patient-centric and recruitment considerations
- Infrastructure and organizational considerations
- Global regulatory collaboration on clinical trial innovation
- Collaborations across industry, academia, and FDA to leverage innovation
- Future directions on clinical trial innovation

As a result of these discussions and internal deliberation, FDA is establishing C3TI to further enhance clinical trial innovation for drug development and regulatory decision making. C3TI will serve as a central hub to (1) facilitate the sharing of lessons learned across CDER's existing clinical trial innovation programs, (2) communicate and collaborate with external parties about innovative clinical trials, and (3) manage a C3TI Demonstration Program that will expand opportunities for sponsors of innovative clinical trials in the areas described below that are under a pre-investigational new drug application (pre-IND) or IND to interact with CDER staff.

II. Goals of C3TI

Specifically, C3TI aims to:

- Assist stakeholders involved in clinical research in staying current with clinical trial innovations
- Improve the efficiency and effectiveness of clinical trials
- Help increase the participation of diverse populations in clinical trials
- Enhance the quality of clinical trial data
- Accelerate the development of safe and effective new drugs
- Serve as a central hub for knowledge management and coordinating lessons learned across CDER's clinical trial innovation programs
- Establish a C3TI Demonstration Program that will include case examples from ongoing development programs in the project areas described below to spur innovation across therapeutic areas

III. Activities of C3TI

C3TI provides a single CDER location to engage stakeholders and assist with non-product-specific questions on innovative clinical trial approaches. C3TI maintains a website at *fda.gov/C3TI* to centralize information on existing and new CDER clinical trial innovation efforts, including links to existing websites and resources. C3TI can be contacted at *CDERClinicalTrialInnovation@fda.hhs.gov.* Additionally, C3TI will coordinate and act as a liaison to facilitate information sharing with external stakeholders, as appropriate and permitted by law, when they engage CDER on general clinical trial innovation matters. It will also support knowledge sharing internally through various mechanisms, such as discussion forums and communications, and a centralized knowledge repository. This repository will curate knowledge about completed CDER clinical trial innovation activities and maintain a comprehensive portfolio of ongoing efforts and knowledge resources.

A critical component of C3TI is expanding the subject areas that could benefit from enhanced communication between CDER and sponsors and serve as case examples to spur further innovation. Therefore, C3TI will manage a demonstration program that includes three initial subject matter/project areas described below. The program is for selected sponsors of innovative clinical trials in certain initial project areas under a pre-IND or IND with CDER that are intended to support new drug product approvals or changes to approved drug product labeling and that will serve as case examples that can be shared both internally and externally to foster innovation across therapeutic areas. If selected, sponsors will have the opportunity for enhanced communication and interaction with CDER staff. Because the goal of selecting these case examples from clinical trials under a pre-IND or IND is to ultimately share lessons learned more broadly with the clinical trial community, participating sponsors and FDA will agree on aspects of the development program that FDA can disclose even before a drug is approved.

The three initial project areas under the C3TI Demonstration Program are (1) point-of-care or pragmatic trials, (2) Bayesian analyses, and (3) trials using selective safety data collection. More information about the C3TI Demonstration Program, including how to participate and how the program differs from existing clinical trial innovation programs, is available on the C3TI website: *fda.gov/C3TI.*

IV. Paperwork Reduction Act of 1995

For the C3TI Demonstration Program, FDA will request information from no more than nine sponsors. Initial statements of interest from sponsors interested in being evaluated for participation in the C3TI Demonstration Program are not ''information'' in accordance with 5 CFR 1320.3(h)(1). Thus, this notice contains no new collection of information.

This notice also refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collections of information relating to formal meetings between sponsors or applicants and FDA has been approved under OMB control number 0910–0001.

Dated: April 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07829 Filed 4–15–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0330]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork

Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services (HHS), is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 16, 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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV.* When submitting comments or requesting information, please include the document identifier 0990–0330–60D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Appellant Climate Survey.

Type of Collection: Revision.

OMB No. 0990–0330, HHS, OS, Office of Medicare Hearings and Appeals.

Abstract:

The Department of Health and Human Services under the Office of Medicare Hearings and Appeals is doing the annual OMHA Appellant Climate Survey. This is a survey of Medicare beneficiaries, providers, suppliers, or their representatives who participated in a hearing before an Administrative Law Judge (ALJ) from OMHA. Appellants dissatisfied with the outcome of their Level 2 Medicare appeal may request a hearing before an OMHA ALJ. The Appellant Climate Survey will be used to measure appellant satisfaction with their OMHA appeals experience, as opposed to their satisfaction with a specific ruling. OMHA was established by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (Pub. L. 108–173) and became operational on July 1, 2005. The MMA legislation also directed HHS to consider the feasibility of conducting hearings using telephone or video-teleconference (VTC) technologies. In carrying out this mandate, OMHA makes use of both telephone and VTC to provide appellants with a vast nationwide network of Field Offices for hearings. The first 3-year administration cycle of the OMHA survey began in fiscal year (FY) 2008, a second 3-year cycle began in FY 2011, a third 3-year cycle began in FY 2014, a fourth 3-year cycle began in FY 2018, and a fifth 3-year cycle began in FY 2021. The survey will continue to be conducted annually over a 3-year period with the next data collection cycle beginning in FY 2024.

The survey instrument includes several changes from the prior 3-year cycle: Added a new section, ''Request for Hearing.'' The section focuses on how customers requested a hearing, how satisfied they were with the method they used to request a hearing, and about the clarity of form OMHA–100 (Request for ALJ Hearing or Review of Dismissal).

Changed ''Hard Copy, internet and Phone Information'' section to ''Communications and Web Tools'' section.

Added a brief statement about when customers should have received the ''Notice of Nondiscrimination'' document.

Added two satisfaction questions for appellants who used the e-Appeal Portal—one about updates the portal provides on their appeal and another about using the portal for uploading documents electronically.

Changed ''Telephone Hearing'' section to ''Hearing.'' The appellant is asked what type of hearing they had (telephone or video) and satisfaction with using that method. If they attended a telephone hearing, appellants will be asked whether they were offered the option of a video hearing; if not, they will be asked if they would have participated in a video hearing if offered.

Data collection instruments and recruitment materials will be offered in English and Spanish. The estimated total number of respondents across all 3 years is 2,400 (800 respondents each FY for FY 2024, FY 2025, and FY2026). The estimated total annual burden hours expected across all years is 600 hours (200 hours each FY for FY 2024, FY 2025, and FY 2026).

The survey will be conducted annually, and survey respondents will consist of Medicare beneficiaries and non-beneficiaries (*i.e.,* providers, suppliers) who participated in a hearing before an OMHA ALJ. OMHA will draw a representative, nonredundant sample of appellants whose cases have been closed in the first 6 months of the surveyed fiscal year.

ESTIMATED ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
	Beneficiaries	400	1	15/60	100
	Non-Beneficiaries	400	1	15/60	100
Total		800	1	15/60	200

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

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