deadline for submitting this request is listed in the **DATES** section of this notice.

VIII. Copies of the Charter

The Secretary's Charter for the Medicare Advisory Panel on CDLT's is available on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/clfs-advisory-panel* or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

IX. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–08008 Filed 4–15–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Public Comment Request; Prevention and Public Health Fund Evidence-Based Falls Prevention Program Information Collection; OMB Control Number 0985–0039

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the proposed extension of this ACL Prevention and Public Health Fund Evidence-Based Falls Prevention Program Information Collection.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. ET or postmarked. May 16, 2024.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. By mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attention: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Donna Bethge, Administration for Community Living. Washington, DC 20201, or *Donna.Bethge@acl.hhs.gov,* (202) 795–7659.

SUPPLEMENTARY INFORMATION: In compliance with the Paperwork Reduction Act (44 U.S.C. 3506), the Administration for Community Living (ACL) has submitted the following proposed collection of information to OMB for review and clearance. The Evidence-Based Falls Prevention Grant Program is financed through the Prevention and Public Health Fund (PPHF). The statutory authority for cooperative agreements under the most recent program announcement (FY 2023) is contained in the Older Americans Act, title IV; and the Patient Protection and Affordable Care Act, (Prevention and Public Health Fund). The Falls Prevention Grant Program awards competitive grants to implement and promote the sustainability of evidence-based Falls Prevention programs that have been proven to provide older adults and adults with disabilities with education and tools to help them reduce falls and/or risk of falls and fall-related injuries and supports a National Falls Prevention Resource Center that provides technical assistance, education, and resources for the national Falls Prevention network of partners. OMB approval of the existing set of Falls Prevention data collection tools (OMB Control Number, 0985–0039) expires on 04/30/2024. This data collection continues to be necessary for the monitoring of program operations and outcomes. ACL currently uses and proposes to continue to use the following tools to collect information for each program:

(1) a Program Information Cover Sheet and an Attendance Log, completed by the program leaders, to record the location of agencies that sponsor programs and will allow mapping of the delivery infrastructure; and

(2) a Participant Information Form and a Participant Post Program Survey to be completed by participants.

ACL intends to continue using an online data entry system for the program and participant survey data.

This IC collects demographic data from grantees receiving programs and services funded by HHS. ACL will adhere to best practices for collection of all demographic information when this information is collected for the programs listed in accordance with OMB guidance.

This includes, but is not limited to, guidance specific to the collection of sexual orientation and gender identity (SOGI) items that align with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, and Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation. Understanding these disparities can and should lead to improved service delivery for ACL's programs and populations served.

Comments in Response to the 60-day Federal Register Notice (FRN)

ACL published a 60-day FRN on December 14, 2023, at 88 FR 86657. ACL received fifty-four comments from the public, feedback from four focus groups (that included a subset of current and past falls prevention grantees and program administrators) and input from subject matter experts during the 60-day public comment period. A public comment summary table and ACL response is provided below.

PARTICIPANT INFORMATION FORM AND PARTICIPANT POST PROGRAM SURVEY

Comment	Response
Several comments suggested incorporating inclusive sexual orientation and gender identity question(s).	HHS and ACL, as an operating division of HHS, recognize the importance of collecting Sexual Orientation and Gender Identity (SOGI) data to better assess diversity and equity in evidence-based program scaling and participation. ACL has incorporated more inclusive questions and responses.
Several comments suggested adding a question to ask if the participant was a caregiver.	ACL has adopted this suggestion.
Suggestions were received to edit the question regarding chronic conditions: • Include additional conditions (*e.g.,* Hearing Loss and Vision Impairment among others). • Increase possible responses (including length of diagnosis, don't remember or not sure).	ACL reviewed the chronic condition question and: • Adopted suggestions of certain conditions that most aligned to fall risk and the growing prevalence of these conditions in the aging population. • Additional responses were not adopted at this time.
Several comments received suggested revising the social isolation and loneliness question as it combines two different conditions.	ACL has adopted the suggestion to separate the single question into two questions in efforts to better analyze and report the information collected.
Multiple comments made suggestions for the existing question 11 regarding falls: • Change formatting for clarification • Change Primary Care Physician to Health Care Provider • Edit and reorder answers for 11 b and c. Add 'urgent care' and 'blank response'. • Distinguish the difference between telling family/friend verse telling a healthcare provider.	ACL adopted the following suggestions: • Corrected formatting. • Changed language from Primary Care Physician to Health Care Provider. • Combined question b and c to reduce burden and added Urgent Care Center as a response option.
Some comments suggested changing language in the existing question 13: • Make language consistent with existing question 11, changing "During the last 4 weeks" to "In the past 3 months". • Remove "to what extent" • Provide an example such as "avoiding a friend's home that has steps to enter", "avoiding areas with uneven ground," etc.".	ACL adopted these suggestions by adjusting language: • Changed "During the last 4 weeks" to "In the Past 3 months" for consistency across the collection. • Removed "to what extent" for language simplification. • Added clarifying example of "avoiding situations with stairs or uneven ground".
There were several comments surrounding existing question 14: • Rephrase language to clarify the question and produce more useful feedback. • Replace existing question 14 with a validated outcome measure using activities of daily living (ADLs) to rate confidence. • A physical function question would be a better fit to define level of independence more clearly.	ACL adopted the suggestions by replacing the existing question 12 and 14 with questions that rate falls confidence level surrounding activities of daily living (ADLs).
Many comments received made suggestions for existing question 15: • Change language to lower reading level • Include descriptions for certain terms • Define 'vigorously' and 'moderately' more clearly and include examples in laymen's terms.	ACL adopted some modifications to the question: • Modified language to replicate wording from the Physical Activity Guidelines. • Added examples of activity from the Physical Activity Guidelines.
Several comments suggested adding the following questions to the forms: • Reason for taking the class • Collect name, date of birth, and insurance information • How did you hear about this class? Use of a mobility aid to include cane, walker, wheelchair, crutches, prosthesis, orthosis, others.	ACL did not adopt these suggestions. These questions can be added as an optional question by grantees when appropriate.
For Participant Post Program Survey only Many comments suggested changes to the existing question 8 and 9 • Remove the redundancy of question 8 and 9 • Adjust questions to action-oriented responses rather than feelings or intent • Suggest "I increased my activity level" rather than "I feel more comfortable increasing my activity level.". • Suggest moving some questions under a different heading • Recategorize "recommend program to friend" • Remove questions that are not relevant to falls prevention programs that have a different focus area.	ACL adopted the suggestions by: • Reviewing and removing the redundancy of question 8 and 9. • Combining the questions to reduce burden. • Removing any questions that were not core questions that spanned all program areas. Removed questions like "I have made safety modifications in my home . . .". These can be optional questions added by grantees when appropriate. • Language was adjusted to be action oriented.

FALL PREVENTION COVERSHEET

Comment	Response
A few comments suggested that program leaders do not know the funding source	ACL added language to clarify that the form should be adapted by the grantee to only include applicable funding sources.
Several comments suggested adding questions to capture: • Mode of delivery • Program setting • Whether facilitators are paid staff, volunteers or other • Whether the program is an adaptation	ACL has adopted 2 of the suggestions: • A question was added to indicate mode of delivery. • A question was added clarifying if facilitators are paid staff, volunteers or other. ACL did not adopt adding a question about adaptation.

FALL PREVENTION ATTENDANCE LOG

Comment	Response
A suggestion was submitted to add a column for the total number of classes attended and a check box if the participant was considered a completer.	ACL adopted the suggestion add a column for the total number of classes attended. ACL did not adopt adding a box to check if a participant was a completer due to the variability of definition of a completer across programs.
A suggestion was submitted to add space for the date of each session and names of leaders/coaches.	ACL did not adopt this suggestion. The form can be modified by the grantee.
Some comments suggested that for ease of data entry, the participant identification number is too long.	ACL acknowledges these comments.

COMMENTS RELEVANT TO ALL FORMS

Comment	Response
Some commenters suggested changes to the collection of data, *i.e.,* prefilled forms and positive remarks to prevent falls.	ACL will provide the documents in Word format. If resources allow, we will provide fillable PDFs for grantee use.
One respondent commented that the burden of data entry falls on the program coordinators taking hours to enter different forms.	ACL acknowledges the comment.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Program leaders (Program Information Cover Sheet, Attendance Log).	480 leaders	Twice a year (one set per program).	.50	480
Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey, Participant Post Program Survey).	48 data entry staff	Once per program × 938 programs.	.50	469
Program participants (Participant Information Survey)	12,265	1	.10	1,226
Program participants (Participant Post Program Survey)	7,359	1	.10	735
Total Burden Hours				2,910

Dated: April 10, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2024–08009 Filed 4–15–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1336]

Center for Drug Evaluation and Research Center for Clinical Trial Innovation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing this notice to announce the establishment of the Center for Drug Evaluation and Research (CDER) Center for Clinical Trial Innovation (C3TI). C3TI aims to be a central hub within CDER that supports innovative approaches to clinical trials that are designed to improve the quality and efficiency of drug development and regulatory decision making. C3TI's mission is to promote existing and future CDER clinical trial innovation activities through enhanced communication and collaboration. Existing CDER clinical development innovation programs will continue to operate according to their established processes with C3TI serving to synthesize lessons learned across those programs. C3TI will also be providing additional opportunities for sponsors of innovative clinical trials in the project areas described below to interact with CDER staff with the goal of fostering knowledge sharing both internally and externally.

DATES: The applicable date of this notice is April 15, 2024.

FOR FURTHER INFORMATION CONTACT: Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–2302, *Kevin.Bugin@fda.hhs.gov* or *CDERClinicalTrialInnovation@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDER guides and fosters drug development by providing scientific and regulatory advice and direction. Evolving understanding of disease biology and molecular pharmacology, advancements in drug discovery, and growth in novel therapeutics have the potential to transform the development of promising new therapies. These changes in the drug development landscape can be further facilitated by novel clinical trial designs, innovative strategies for trial execution, and the expanding range of drug development tools. Similarly, later stages of development, including in the postmarketing setting, can benefit from innovative approaches to study design and analysis. These innovative approaches can include adoption of new statistical approaches, incorporation of pragmatic trial elements, the implementation of point-of-care trials, and wider adoption of selective safety data collection.

With this changing landscape in mind, CDER has many ongoing efforts to advance innovation in clinical trial design and conduct. These CDER efforts have led to improvements in more efficiently designing and conducting